DEPARTMENTS OF LABOR AND HEALTH, EDUCATION, AND WELFARE APPROPRIATIONS FOR 1979

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS HOUSE OF REPRESENTATIVES

NINETY-FIFTH CONGRESS

SECOND SESSION

SUBCOMMITTEE ON THE DEPARTMENTS OF LABOR AND HEALTH, EDUCATION, AND WELFARE

DANIEL J. FLOOD, Pennsylvania, *Chairman*

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NEAL SMITH, Iowa
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PART 2

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Testimony of the Secretary
Special and Investigative Reports

Printed for the use of the Committee on Appropriations

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DEPARTMENTS OF LABOR AND HEALTH, EDUCATION AND WELFARE APPROPRIATIONS FOR 1979

TUESDAY, FEBRUARY 21, 1978.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

WITNESSES

JOSEPH A. CALIFANO, JR., SECRETARY
CHARLES MILLER, ACTING ASSISTANT SECRETARY FOR MANAGEMENT AND BUDGET
RICHARD D. WARDEN, ASSISTANT SECRETARY FOR LEGISLATION
RICHARD I. BEATTIE, DEPUTY GENERAL COUNSEL

Mr. FLOOD. We now have the Department of Health, Education, and Welfare. The presentation will be made by Joseph A. Califano, the Secretary.

I suppose you want us to meet the people you have with you here today.

Secretary CALIFANO. Yes, Mr. Chairman. I have on my far right Richard Warden, who is the Assistant Secretary of Health, Education, and Welfare for Legislation; Charles Miller, on my immediate right, who is the Acting Assistant Secretary for Management and Budget; and, on my left Richard Beattie, the Deputy General Counsel of the Dep artment.

Mr. FLOOD. I see you have a prepared statement, Mr. Secretary. How do you wish to proceed with this?

Secretary CALIFANO. I would like to submit the statement for the record. I can highlight the budget through the charts, I think.

Mr. FLOOD. Without objection, we will do that.

[The information referred to follows:]

JOSEPH A. CALIFANO, JR.

Secretary of Health, Education, and Welfare

Mr. Califano was born in Brooklyn, New York, on May 15, 1931. He attended St. Gregory's Elementary School and Brooklyn Preparatory School in Brooklyn, New York.

Mr. Califano received his Bachelor of Arts degree from Holy Cross College in Worcester, Massachusetts in 1952 and his LL.B., *magna cum laude*, from Harvard Law School in 1955. In Law School, he was an editor of the Harvard Law Review.

In 1955, Mr. Califano enlisted in the Navy as an officer candidate. He was commissioned an ensign in November 1955; served three years in the Office of the Judge Advocate General in Washington, D.C., and was released to inactive duty in October 1958 as a lieutenant. In October 1958, he associated with the law firm of Dewey, Ballantine, Bushby, Palmer & Wood in New York City until April 1961.

In April 1961, Mr. Califano became Special Assistant to the General Counsel of the Department of Defense. In July 1962, he was appointed Special Assistant to the Secretary of the Army. On July 1, 1963, he was appointed General Counsel of the Department of the Army. While General Counsel of the Army, he also served as Special Assistant to the Secretary of the Army for Civil Functions, supervising the Corps of Engineers' $1 billion Civil Works Program. As such, he served as a member of the President's Appalachian Regional Commission.

In early 1964, Mr. Califano was selected to serve as the principal legal advisor to the United States Delegation Investigating Committee of the Organization of American States on the Panama riots of January 1964. Subsequently, he was also selected to present the United States case before the International Commission of Jurists during hearings held in Panama dealing with those riots.

In recognition of his work as General Counsel of the Department of the Army, Mr. Califano was awarded the Distinguished Civilian Service Medal, the highest civilian award of the Army.

On April 1, 1964, Mr. Califano was appointed Special Assistant to the Secretary and Deputy Secretary of Defense. He had special responsibilities for Department of Defense liaison with the Office of the President of the United States. He also acted as Executive Secretary of the President's Advisory Committee on Supersonic Transport, as the Department of Defense representative on the President's Committee on the Economic Impact of Defense and Disarmament and as a member of the Federal Radiation Council.

In recognition of his work as the Special Assistant to the Secretary and Deputy Secretary of Defense, Mr. Califano was awarded the Distinguished Service Medal of the Department of Defense.

Mr. Califano was appointed Special Assistant to President Lyndon B. Johnson on July 26, 1965. In this position, Mr. Califano was charged with developing the President's legislative program and coordinating its preparation and presentation to the Congress, as well as helping coordinate economic policies. He also worked on a variety of domestic problems, including the Northeast power failure, the water drought in the Northeast, labor-management relations, balance of payments and urban issues. He served in this position until January 20, 1969.

In early 1969, Mr. Califano traveled around the world on a study of the "student-youth-and-establishment" problem under a Ford Foundation grant. Mr. Califano wrote about those travels in his book, entitled *The Student Revolution: A Global Confrontation,* published by W. W. Norton in November 1969. His second book, *A Presidential Nation,* was published by W. W. Norton in September 1975. His third book, *The Media and the Law,* was published by Praeger Special Studies early in 1976 and was co-authored and co-edited with Mr. Howard Simons, managing editor of The Washington Post. Mr. Califano has also written articles for The New York Times, The Washington Post, New Republic and other publications.

Mr. Califano was a member of the Washington law firm of Arnold and Porter from March 1969 until May 1971. He had been a member of the Washington law firm of Williams, Connolly & Califano from June 1971 until he became Secretary.

Mr. Califano is admitted to practice before the Supreme Court of the United States and is a member of the Bars of the State of New York and the District of Columbia. He is a member of the American Bar Association, the Federal Bar Association, the Bar Association of the city of New York and the American Judicature Society.

Mr. Califano is a Democrat and served from 1969 to 1971 as Co-Chairman of the Committee on National Priorities of the Democratic Policy Council, from March 1971 until August 1972 as General Counsel to the Democratic National Committee and from 1972 to 1974 as a member of the Democratic Party's National Charter Commission.

Mr. Califano is married to the former Trudy Zawacki of Taunton, Massachusetts. Mr. and Mrs. Califano have two sons, Mark Gerard, 14, and Joseph A., III, 13, and a daughter, Claudia Frances, 6.

January 1977

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

IT IS A PLEASURE TO BE HERE TODAY TO DISCUSS THE HEW PORTION OF THE PRESIDENT'S FISCAL YEAR 1979 BUDGET. THIS IS THE FIRST COMPLETE BUDGET PREPARED BY THE CARTER ADMINISTRATION. IT BLENDS AN AWARENESS THAT VITAL HUMAN SERVICES ARE STILL NOT REACHING MANY NEEDY AMERICANS WITH A DEEP COMMITMENT TO MANAGE THE DEPARTMENT'S RESOURCES PRUDENTLY. THIS BUDGET DEMONSTRATES THAT GOVERNMENT CAN BE BOTH COMPASSIONATE AND EFFICIENT.

THE HEW BUDGET PROPOSES $181.5 BILLION IN 1979 OUTLAYS, UP $16.9 BILLION FROM OUR CURRENT ESTIMATE OF $164.6 BILLION FOR 1978. FOR THE ITEMS CONSIDERED BY THE LABOR-HEW APPROPRIATIONS SUBCOMMITTEES, WE ARE REQUESTING APPROPRIATIONS OF $59.5 BILLION FOR 1979, $5.6 BILLION MORE THAN 1978. THE 1978 ESTIMATE INCLUDES $635 MILLION IN REQUESTED SUPPLEMENTAL APPROPRIATIONS.

A NUMBER OF OUR PROPOSED BUDGET INITIATIVES DEPEND ON THE ENACTMENT OF NEW LEGISLATION. ALTHOUGH THIS SUBCOMMITTEE CANNOT TAKE ACTION UNTIL THE AUTHORIZING PROCESS HAS BEEN COMPLETED, I WOULD LIKE TO DISCUSS THE KEY LEGISLATIVE ITEMS AS WELL AS FUNDING LEVELS FOR EXISTING PROGRAMS BECAUSE THEY ARE AN ESSENTIAL PART OF OUR OVERALL BUDGET STRATEGY, AND THE REQUEST FOR APPROPRIATIONS TO CARRY OUT THESE LEGISLATIVE INITIATIVES WILL BE BEFORE YOU DURING THIS SESSION OF CONGRESS.

THE PRESIDENT'S HEW BUDGET AND LEGISLATIVE PROGRAM REFLECTS TWO MAJOR THEMES:

-- IMPROVED SERVICES FOR CHILDREN AND YOUTH. THIS IS AN INVESTMENT THAT WILL RETURN SUBSTANTIAL DIVIDENDS IN THE FUTURE.

-- EXPANDED EFFORTS TO INCREASE EFFICIENCY AND REDUCE UNNECESSARY PROGRAM COSTS. DOING AN EFFECTIVE JOB OF MANAGING OUR RESOURCES MEANS THAT WE CAN GET MORE FOR OUR DOLLARS NOW AND MAKES IT MORE LIKELY THAT WE CAN PROPOSE NEW INITIATIVES IN FUTURE BUDGETS.

CHILDREN AND YOUTH

OUR EFFORTS TO IMPROVE SERVICES FOR CHILDREN AND YOUTH CUT ACROSS ALL PARTS OF THE DEPARTMENT AND COVER EARLY CHILDHOOD THROUGH COLLEGE EDUCATION. FOR EDUCATION PROGRAMS, OUR BUDGET IS $2.4 BILLION HIGHER THAN THE 1978 APPROPRIATION. THIS IS NEARLY $5.2 BILLION HIGHER THAN THE LAST FORD BUDGET. THE MAJOR INITIATIVES ARE:

-- A 15 PERCENT INCREASE IN FUNDING FOR ELEMENTARY AND SECONDARY EDUCATION PROGRAMS. THIS $895 MILLION INCREASE IS THE LARGEST SOUGHT BY A PRESIDENT

SINCE THE ELEMENTARY AND SECONDARY EDUCATION ACT WAS FIRST PROPOSED MORE THAN A DECADE AGO. IF APPROVED, IT REPRESENTS A $2.2 BILLION TOTAL INCREASE IN APPROPRIATIONS FOR ELEMENTARY AND SECONDARY EDUCATION OVER THE $4.7 BILLION REQUESTED BY PRESIDENT FORD IN HIS FISCAL 1978 BUDGET. THE MAJOR INCREASES INCLUDE:

- $644 MILLION FOR COMPENSATORY EDUCATION UNDER TITLE I OF THE ELEMENTARY AND SECONDARY EDUCATION ACT. THIS ADMINISTRATION IS COMMITTED TO THIS PROGRAM BECAUSE IT HAS SHOWN ITS EFFECTIVENESS IN HELPING DISADVANTAGED CHILDREN IMPROVE THEIR SCHOOL PERFORMANCE. IN 1979, WE ARE ASKING THAT JUST UNDER $3 BILLION BE ALLOCATED UNDER THE EXISTING TITLE I FORMULA, AN INCREASE OF $244 MILLION OVER THE 1978 APPROPRIATION.

IN ADDITION, WE ARE ASKING CONGRESS TO ADD A NEW PROVISION TO TITLE I WHICH WILL PERMIT US TO CONCENTRATE A GREATER PORTION OF TITLE I FUNDING ON URBAN AND RURAL SCHOOL DISTRICTS WHICH SERVE PARTICULARLY HIGH CONCENTRATIONS OF DISADVANTAGED CHILDREN. WE PLAN TO REQUEST $400 MILLION FOR THIS NEW CONCENTRATION PROVISION WHICH WOULD BRING SERVICES TO 900,000 ADDITIONAL DISADVANTAGED CHILDREN, BRINGING THE TOTAL SERVED BY TITLE I TO 7.4 MILLION.

- ALMOST $1 BILLION FOR EDUCATION OF THE HANDICAPPED. FUNDING FOR STATE GRANTS WILL BE $804 MILLION, $279 MILLION MORE THAN 1978. THIS WILL FINANCE 12 PERCENT OF THE EXCESS COSTS OF EDUCATING

THE ESTIMATED 4 MILLION CHILDREN WHO ARE EXPECTED TO RECEIVE SERVICES DURING THE SCHOOL YEAR COVERED BY THE 1979 APPROPRIATION. IN 1978, THE FEDERAL APPROPRIATION PROVIDES 9 PERCENT OF EXCESS COSTS FOR 3.8 MILLION CHILDREN. THE BUDGET ALSO INCLUDES $168 MILLION FOR PROJECT GRANTS, AN INCREASE OF $19 MILLION. THE ADDITIONAL FUNDS WILL BE USED MAINLY FOR IN-SERVICE TRAINING OF CLASSROOM TEACHERS.

- A REQUEST OF $150 MILLION FOR BILINGUAL EDUCATION, $15 MILLION MORE THAN 1978. THE BUDGET INCREASE WILL BE USED FOR RESEARCH TO DEVELOP IMPROVED METHODS OF TEACHING BILINGUAL CHILDREN AND TRAINING TEACHERS AND ADMINISTRATORS.

-- AN INCREASE OF $1.46 BILLION IN STUDENT AID PROGRAMS TO ENSURE THAT STUDENTS FROM POOR AND MIDDLE-INCOME FAMILIES WILL BE ABLE TO ATTEND POST-SECONDARY SCHOOLS. THE STUDENT AID PROGRAMS PASSED BY THE CONGRESS AND ADMINISTERED BY HEW WERE ENACTED TO ENSURE ACCESS TO A POST-SECONDARY EDUCATION FOR CHILDREN FROM THE POOREST FAMILIES IN OUR SOCIETY. THIS GOAL IS STILL A TOP PRIORITY OF STUDENT FINANCIAL ASSISTANCE.

THE PARTICIPATION RATE OF THE POOR IN POST-SECONDARY EDUCATION HAS RISEN DRAMATICALLY AND IS FAST APPROACHING THAT OF MIDDLE-INCOME FAMILIES. WE MUST CONTINUE AND EXPAND THIS COMMITMENT TO STUDENTS FROM POOR FAMILIES. BUT THE TIME HAS ALSO COME TO PROVIDE ASSISTANCE TO FAMILIES WHO DO NOT NOW RECEIVE BENEFITS BUT WHO ALSO NEED THEM.

THE RAPIDLY RISING COST OF HIGHER EDUCATION (UP 77% BETWEEN 1967 AND 1976) IS MAKING IT INCREASINGLY DIFFICULT FOR MIDDLE-INCOME FAMILIES TO CONTINUE TO GIVE THEIR CHILDREN THE OPPORTUNITY TO GO TO COLLEGE. TO SOLVE THIS PROBLEM, THE PRESIDENT IS PROPOSING A 1979 STUDENT AID BUDGET WHICH WILL PROVIDE 7 MILLION GRANTS AND LOANS TO 5 MILLION STUDENTS, MORE THAN DOUBLE THE 1978 LEVEL. MOST OF THE INCREASE WILL BE FOR STUDENTS FROM MIDDLE-INCOME FAMILIES. THE MAJOR ELEMENTS OF THE PRESIDENT'S PROPOSAL ARE:

- AN INCREASE OF $990 MILLION IN BASIC EDUCATIONAL OPPORTUNITY GRANTS TO GUARANTEE A $250 GRANT TO STUDENTS FROM FAMILIES WITH INCOMES UP TO $25,000. IT WOULD ALSO INCREASE THE AVERAGE GRANT BY $200 FOR

STUDENTS IN FAMILIES WITH INCOMES BETWEEN $8,000 AND $16,000, AND INCREASE THE MAXIMUM GRANT FOR STUDENTS FROM LOW-INCOME FAMILIES FROM $1600 TO $1800. BEOGS GRANTS WILL GO TO 5.3 MILLION STUDENTS, UP 3.1 MILLION FROM 1978.

- AN INCREASE OF $165 MILLION FOR COLLEGE WORK-STUDY TO PROVIDE SALARY SUBSIDIES FOR 280,000 ADDITIONAL JOBS, BRINGING THE TOTAL TO MORE THAN ONE MILLION. THE INCREASE IS MOSTLY FOR STUDENTS FROM FAMILIES WITH INCOMES ABOVE $16,000.

- AN INCREASE OF $297 MILLION FOR THE GUARANTEED STUDENT LOAN PROGRAM TO CONTINUE THE 1978 LEVEL OF OBLIGATIONS AND PROVIDE 260,000 MORE LOANS TO STUDENTS WITH FAMILY

INCOMES ABOVE $16,000. TO MAKE MORE LOAN CAPITAL AVAILABLE, WE ARE ASKING CONGRESS TO RAISE THE SPECIAL ALLOWANCE PAID TO BANKS, THEREBY INCREASING THEIR RATE OF RETURN. WE ARE PROPOSING THAT SUBSIDIES BE PROVIDED FOR STUDENTS FROM FAMILIES WITH INCOMES UP TO $45,000. THE CURRENT LIMIT IS $30,000.

-- AN $8 MILLION REQUEST, MORE THAN DOUBLE THE 1978 LEVEL, FOR THE NEW PROGRAM TO HELP MINORITIES ACHIEVE ADVANCED PROFESSIONAL TRAINING. WITH THE 1978 APPROPRIATION OF $3.2 MILLION WE ARE PLANNING TO MAKE AWARDS TO 350 MINORITY CANDIDATES FOR PROFESSIONAL DEGREES. WE WILL ADD 500 MORE PARTICIPANTS WITH THE 1979 REQUEST.

-- A $142 MILLION INCREASE FOR PROGRAMS WHICH PROVIDE HEALTH AND RELATED SERVICES TO ADOLESCENTS, WITH SPECIAL EMPHASIS ON AVOIDING UNWANTED PREGNANCIES. EACH YEAR ABOUT 1 MILLION TEENAGE GIRLS (1 IN 10) BECOME PREGNANT AND ALMOST 600,000 DECIDE TO HAVE THEIR BABIES AND 90 PERCENT KEEP THEM. SUCH PREGNANCIES ARE LIKELY TO HAVE ADVERSE HEALTH, SOCIAL, AND ECONOMIC CONSEQUENCES. ADOLESCENT MOTHERS RUN TWICE THE RISK OF HAVING LOW BIRTH-WEIGHT INFANTS AS OLDER WOMEN, WITH HIGHER RISKS OF DEATH AND DEVELOPMENTAL DEFECTS. IN ADDITION, WITHOUT PREVENTIVE SERVICES, 44 PERCENT OF ADOLESCENTS WILL BE PREGNANT AGAIN WITHIN ONE YEAR AFTER HAVING THEIR FIRST CHILD. THE DEPARTMENT PROPOSES TO DEAL WITH THE PROBLEM THROUGH A COORDINATED EFFORT EXPANDING EXISTING PROGRAMS SUCH AS FAMILY PLANNING, COMMUNITY HEALTH CENTERS, HEALTH EDUCATION, AND RESEARCH, PLUS A NEW LEGISLATIVE AUTHORITY WHICH WILL HELP STATES AND

COMMUNITIES INTEGRATE AND SUPPLEMENT EXISTING ADOLESCENT HEALTH AND PREGNANCY PREVENTION PROGRAMS. THE PROGRAM WILL NOT ONLY AIM AT HELPING PREVENT PREGNANCIES FOR THOSE WHO DO NOT WANT TO HAVE CHILDREN BUT WILL ALSO FOCUS ON TEACHING NECESSARY CHILD CARE AND PARENTING SKILLS TO THOSE WHO BECOME PREGNANT AND KEEP THEIR CHILDREN. OF THE $33 MILLION INCREASE FOR THE NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT, $21 MILLION WILL BE USED FOR STUDIES OF REPRODUCTIVE BIOLOGY AND HEALTHY CHILD DEVELOPMENT RELATED TO THIS INITIATIVE.

-- FUNDING FOR IMMUNIZATIONS TO ENSURE THAT 90 PERCENT OF THE NATION'S CHILDREN UNDER 15 WILL BE IMMUNIZED BY OCTOBER 1979. THE BUDGET REQUESTS $35 MILLION FOR

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IMMUNIZATION GRANTS, AN INCREASE OF $12 MILLION. IMMUNIZATION FOR SUCH CHILDHOOD DISEASES AS MEASLES, POLIO, DIPHTHERIA, AND MUMPS HAS FALLEN TO AN OVERALL LEVEL OF ABOUT 50 PERCENT. BY EXPANDING HEW'S NATIONAL CHILDHOOD IMMUNIZATION PROJECT, STARTED LAST YEAR, WE WILL BE ABLE TO IMMUNIZE 16.6 MILLION CHILDREN CURRENTLY INCOMPLETELY PROTECTED AND TO CREATE SUSTAINED COMMUNITY EFFORTS TO PROVIDE APPROPRIATE IMMUNIZATIONS FOR NEARLY ALL NEW-BORN CHILDREN. OUR EFFORTS TO DATE HAVE ALREADY PRODUCED SOME RESULTS:

- DURING CALENDAR YEAR 1977, SOME 4.5 MILLION CHILDREN WERE VACCINATED AGAINST MEASLES -- AN INCREASE OF 1.6 MILLION CHILDREN -- MORE THAN ONE AND ONE-HALF TIMES THE NUMBER VACCINATED IN 1976.

o MOST NOTABLY, BY JANUARY 1978, THE INCIDENCE OF CHILDHOOD DISEASES DROPPED FROM THE LEVEL FOR THE SAME PERIOD IN 1977: CASES OF MEASLES WERE DOWN ALMOST 75 PERCENT; THE INCIDENCE OF MUMPS WAS DOWN 35 PERCENT; THE INCIDENCE OF RUBELLA WAS DOWN 26 PERCENT.

o FOR POLIO, DIPHTHERIA, TETANUS AND PERTUSSIS, THE SMALL NUMBER OF REPORTED CASES DO NOT PERMIT US TO MAKE A MEANINGFUL COMPARISON WITH EARLIER DATA ON THE BASIS OF THE QUARTERLY FIGURES NOW AVAILABLE.

-- AN INCREASE OF $9.5 MILLION FOR THE DEPARTMENT'S RECENTLY ANNOUNCED PROGRAM TO REDUCE SMOKING, BRINGING THE OVERALL 1979 EFFORT TO $30 MILLION. CIGARETTE

SMOKING IS THE GREATEST PREVENTABLE CAUSE OF PREMATURE DEATH AND DISABILITY IN THE UNITED STATES. CIGARETTE SMOKING IS THE CHIEF CULPRIT IN THOUSANDS UPON THOUSANDS OF CASES OF LUNG CANCER, HEART DISEASE, EMPHYSEMA, AND OTHER RESPIRATORY KILLERS. SEVENTY-SIX PERCENT OF THE PEOPLE WHO BEGIN TO SMOKE AND ACQUIRE THE ADDICTIVE HABIT DO SO BEFORE THEY ARE 21 YEARS OF AGE. THE INCREASED COST IN HUMAN SUFFERING IS ACCOMPANIED BY A VERY REAL DOLLAR COST TO THIS BUDGET AND TO HEALTH CARE IN THE UNITED STATES. TO COMBAT THIS PROBLEM, THE BUDGET PROPOSES A BALANCED PROGRAM OF RESEARCH AND EDUCATION ACTIVITIES TO INFORM PEOPLE OF THE DANGERS OF SMOKING, ASSIST SMOKERS WHO

DECIDE TO STOP, AND MOST IMPORTANTLY, DISCOURAGE YOUNG PEOPLE FROM STARTING TO SMOKE. IT IS TO CHILDREN AND TEENAGERS THAT OUR PROGRAM IS PRIMARILY DIRECTED.

-- AUTHORIZATION OF THE CHILD HEALTH ASSESSMENT PROGRAM AT A 1979 COST OF $263 MILLION. THIS INITIATIVE WILL IMPROVE THE DELIVERY OF PREVENTIVE AND PRIMARY HEALTH CARE TO POOR CHILDREN. THIS PROPOSED LEGISLATION WAS FIRST SUBMITTED TO THE LAST SESSION OF CONGRESS. UNDER THE REVISED PROPOSAL SUBMITTED WITH THE 1979 BUDGET, ALL POOR CHILDREN UP TO AGE 21 WOULD BE ELIGIBLE FOR SERVICES.

-- NEW LEGISLATION MAKING ALL LOW-INCOME PREGNANT WOMEN ELIGIBLE FOR MEDICAID (1979 COSTS: $118 MILLION). PROVIDING ADEQUATE PRE- AND POST-NATAL MEDICAL CARE FOR ALL LOW-INCOME PREGNANT WOMEN WILL PREVENT FURTHER EXPENSIVE HEALTH PROBLEMS AND WELFARE DEPENDENCY.

-- EXPANSION OF THE HEAD START PROGRAM TO SERVE 430,000 CHILDREN, 30,000 MORE THAN IN 1978. RECENT STUDIES HAVE SHOWN THAT HEAD START PRODUCES LASTING GAINS FOR THE CHILDREN WHO PARTICIPATE IN THESE PROJECTS. TOGETHER WITH THE INCREASE APPROVED FOR FISCAL YEAR 1978, SERVICES WILL BE PROVIDED TO 100,000 MORE CHILDREN THAN WERE SERVED IN 1977. THE PRESIDENT'S BUDGET PROVIDES FOR AN INCREASE OF $205 MILLION OVER THE 1977 APPROPRIATION -- ALMOST 30 PERCENT MORE FOR THIS PROGRAM IN THE FIRST TWO YEARS OF THE CARTER ADMINISTRATION.

-- LEGISLATION REFORMING THE CHILD WELFARE SERVICES PROGRAM SO THAT IT PROVIDES INCENTIVES FOR PLACING CHILDREN IN PERMANENT HOMES. THE LEGISLATION THE DEPARTMENT IS SUPPORTING WOULD ENCOURAGE STATES TO RELY LESS ON FOSTER CARE AND MAKE GREATER EFFORTS TO REUNITE CHILDREN WITH THEIR RELATIVES OR ARRANGE FOR ADOPTIONS. UNDER CURRENT LAW WE ARE REQUESTING $57 MILLION FOR CHILD WELFARE SERVICES, THE SAME AS THE 1978 APPROPRIATION. WHEN THE NEW LEGISLATION IS ENACTED, WE WILL ASK FOR AN ADDITIONAL $84 MILLION, BRINGING THE TOTAL PROGRAM LEVEL TO $141 MILLION.

IMPROVED EFFICIENCY

THE DEPARTMENT'S PROPOSALS TO IMPROVE EFFICIENCY INVOLVE EFFORTS TO HOLD DOWN COSTS WHERE WE BELIEVE THEY ARE GROWING TOO RAPIDLY AND TO REALLOCATE RESOURCES TO MEET CRITICAL PRIORITIES. OUR MAJOR PROPOSALS ARE:

-- Hospital Cost Containment legislation which would save $2 billion nationally in 1979 and reduce Medicare and Medicaid outlays by $739 million. Over the long haul, if our proposals are effective by July 1, 1978, the Nation could save $57 billion through 1983. Although this proposal does not require Appropriations Committee action, it clearly has a direct impact on budgetary resources available for other programs which are of major concern to you.

-- A new Medicaid quality control effort which could save $399 million in 1979 outlays. This initiative involves activities under current law as well as some new legislative authority. We are asking Congress to give the Department clear statutory authority to withhold Federal Medicaid matching payments from States which fail to achieve quality control targets. In anticipation of acquiring this authority, we are seeking

125 NEW POSITIONS IN THE 1978 SUPPLEMENTAL SO THAT A MORE STATISTICALLY RELIABLE QUALITY CONTROL SAMPLE CAN BE PREPARED AS A BASIS FOR MEASURING FUTURE PROGRESS. CURRENTLY, WE ESTIMATE THAT 8.6 PERCENT OF MEDICAID FUNDS ARE BEING SPENT FOR SERVICES TO INELIGIBLE PEOPLE. IN 1977, FEDERAL, STATE AND LOCAL GOVERNMENTS LOST $1.2 BILLION BECAUSE OF ERRONEOUS PAYMENTS. IT IS IMPERATIVE TO BRING THIS PROBLEM UNDER CONTROL AS QUICKLY AS POSSIBLE.

-- MAKING PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS MORE EFFECTIVE. THE DEPARTMENT IS PROCEEDING TO MAKE ALL PSRO'S FULLY OPERATIONAL IN FISCAL YEAR 1979. HOWEVER, RATHER THAN CONTINUING THE CURRENT PRACTICE OF HAVING PSRO'S REVIEW ALL HOSPITAL ADMISSIONS UNDER MEDICARE AND MEDICAID, WE WILL REQUIRE THEM TO REVIEW A SELECTION OF ADMISSIONS BASED ON A PROFILE OF CASES

MOST LIKELY TO LEAD TO EXCESSIVE STAYS OR OVERUTILIZATION OF SERVICES. IN THIS WAY, WE BELIEVE THAT THE EFFECTIVENESS OF THE PSRO SYSTEM CAN BE IMPROVED AT A LOWER OVERALL COST THAN WOULD OTHERWISE BE REQUIRED.

-- CONTINUED IMPLEMENTATION OF THE NETWORK OF HEALTH PLANNING AGENCIES. IN 1979, NEARLY ALL OF THE 213 HEALTH SYSTEMS AGENCIES AND 57 STATE AGENCIES WILL BE DEVELOPING HEALTH SYSTEMS PLANS AIMED AT ASSURING ACCESS TO HEALTH CARE AT REASONABLE COSTS. EVIDENCE FROM SEVERAL STATES INDICATES THAT HEALTH PLANNING AGENCIES ARE EFFECTIVE IN AVOIDING UNNECESSARY NEW FACILITIES AND SERVICES. WE ARE PROPOSING TO INCREASE THE HEALTH PLANNING BUDGET BY $9 MILLION, BRINGING THE TOTAL TO $152 MILLION.

-- A FURTHER EFFORT TO REDUCE LONG-RANGE HEALTH CARE COSTS BY ACCELERATING THE HMO PROGRAM. WE ARE PROPOSING FUNDING FOR 70 NEW HMO FEASIBILITY GRANTS WHICH, TOGETHER WITH EFFORTS NOW UNDERWAY, WOULD PROVIDE FEDERAL ASSISTANCE FOR 172 HEALTH MAINTENANCE ORGANIZATIONS TO BE IN OPERATION BY 1982. HMO'S HAVE SHOWN THAT THEY CAN DELIVER HIGH-QUALITY HEALTH CARE AT A LOWER OVERALL COST THAN THE FEE-FOR-SERVICE SYSTEM AND THEIR DEVELOPMENT SHOULD BE ENCOURAGED.

-- HELP OVERCOME MALDISTRIBUTION OF HEALTH SERVICES BY ESTABLISHING 131 NEW COMMUNITY HEALTH CENTERS AND RECRUITING 300 MORE NATIONAL HEALTH SERVICE CORPS PERSONNEL TO WORK IN UNDERSERVED AREAS. THIS WILL BRING THE TOTAL NUMBER OF HEALTH CENTERS TO 705 AND THE NATIONAL HEALTH SERVICE CORPS TO AN OVERALL STRENGTH OF 1,725. THESE TWO METHODS OF ATTRACTING

RESOURCES TO UNDERSERVED AREAS HAVE PROVEN THEIR EFFECTIVENESS AND DESERVE EXPANDED FEDERAL SUPPORT.

-- REDIRECTION OF FEDERAL ASSISTANCE FOR MEDICAL EDUCATION AS PART OF THE EFFORT TO OVERCOME PROBLEMS OF MALDISTRIBUTION OF RESOURCES. WE ARE PROPOSING TO REDUCE ACROSS-THE-BOARD SUBSIDIES (CAPITATION PAYMENTS) BUT WE WILL MAINTAIN PROJECTS AIMED AT OVERCOMING RECOGNIZED SHORTAGES OR MAKING HEALTH MANPOWER MORE RESPONSIVE TO CURRENT NEEDS SUCH AS ENCOURAGING FAMILY PRACTICE OR THE USE OF PARAPROFESSIONALS. IF THIS POLICY RESULTS IN HIGHER TUITION FOR HEALTH PROFESSIONS SCHOOLS, WE HOPE THAT MORE STUDENTS WILL TAKE ADVANTAGE OF THE NATIONAL HEALTH SERVICE CORPS SCHOLARSHIPS AND THE HEALTH PROFESSIONS GUARANTEED LOAN PROGRAM WHICH ENCOURAGE GRADUATES TO SERVE IN SHORTAGE AREAS.

-- A COMPREHENSIVE NEW LOOK AT THE PUBLIC HEALTH SERVICE HOSPITAL SYSTEM. I HAVE ESTABLISHED A SPECIAL PHS HOSPITAL STUDY GROUP, WHICH HELD ITS FIRST MEETING ON JANUARY 27. VISITS WILL BE MADE TO EACH OF THE EIGHT CITIES WHERE A PHS HOSPITAL IS NOW OPERATING. THEY WILL REPORT THEIR FINDINGS AND RECOMMENDATIONS TO ME BY JUNE 30. IN THE INTERIM, WE ARE ASKING THAT YOU HOLD RESOURCES FOR THE PUBLIC HEALTH SERVICE HOSPITALS TO THE MINIMUM NEEDED TO CARRY OUT CURRENT STATUTORY REQUIREMENTS.

-- CONTINUED PROGRESS ON OUR PLANS TO UPGRADE THE QUALITY OF CARE OF ST. ELIZABETHS HOSPITAL. WE ARE ASKING CONGRESS TO APPROPRIATE $55.3 MILLION IN THE 1978 SUPPLEMENTAL TO PERMIT US TO CONSTRUCT AND RENOVATE FACILITIES SO THAT THE HOSPITAL CAN REGAIN ITS ACCREDITATION. WE ARE ALSO PLANNING TO MOVE 400 PATIENTS OUT OF ST. ELIZABETHS TO MORE APPROPRIATE

FACILITIES. ABOUT 250 OF THESE PATIENTS WILL BE CARED FOR IN THE J.B. JOHNSON NURSING HOME IN NORTHWEST WASHINGTON, A FACILITY RECENTLY ACQUIRED BY THE DEPARTMENT. AS SOON AS ADMINISTRATIVE AND FINANCING ARRANGEMENTS CAN BE WORKED OUT, WE WILL TRANSFER THE J.B. JOHNSON FACILITY TO THE DISTRICT OF COLUMBIA.

-- A GRADUAL REFORM OF IMPACTED AREA AID. THIS HAS BEEN AN ITEM OF CONTROVERSY BETWEEN THE EXECUTIVE AND LEGISLATIVE BRANCHES SINCE THE 1950'S. WE ARE PROPOSING A MODERATE REFORM THAT AIMS AT MORE GRADUAL AND LIMITED CHANGES THAN THE EXECUTIVE BRANCH HAS REQUESTED IN THE PAST. WE ARE PROPOSING LEGISLATION WHICH WILL REQUIRE SCHOOL DISTRICTS TO ABSORB A MINIMUM THRESHOLD OF FEDERALLY-CONNECTED STUDENTS AND ELIMINATE PAYMENTS FOR CHILDREN WHOSE PARENTS WORK ON FEDERAL PROPERTY OUTSIDE THE COUNTY WHERE THE SCHOOL DISTRICT IS LOCATED. WE WILL ALSO SUGGEST

REFORMS IN THE METHOD OF CALCULATING THE LOCAL CONTRIBUTION RATE. THESE REFORMS WOULD BE ACHIEVED OVER A PERIOD OF THREE YEARS. PENDING ENACTMENT OF LEGISLATIVE REVISIONS, WE ARE PROPOSING A FUNDING LEVEL OF $811 MILLION UNDER CURRENT LAW, WHICH WOULD MAINTAIN THE SAME PROGRAM AS THE 1978 APPROPRIATION. IF OUR LEGISLATIVE REFORMS ARE ADOPTED BEFORE OCTOBER 1, WE WOULD ONLY NEED TO SPEND $735 MILLION ON IMPACT AID, $76 MILLION LESS THAN THE CURRENT PROGRAM WOULD REQUIRE.

-- REVISIONS IN THE LEGISLATION AUTHORIZING DISCRETIONARY EDUCATION PROGRAMS. CURRENTLY, THE SPECIAL PROJECTS ACT PRESCRIBES RIGID FUNDING ALLOCATIONS FOR VARIOUS PROGRAM ACTIVITIES. WE WOULD LIKE TO MAKE THE FUNDING ALLOCATIONS MORE FLEXIBLE SO THAT WE COULD DO A BETTER JOB OF IMPROVING THE

QUALITY OF EDUCATION, ESPECIALLY BASIC SKILLS. WHEN THE NEW LEGISLATION IS ENACTED, WE WILL ASK FOR $11 MILLION MORE THAN THE $50 MILLION WE ARE REQUESTING FOR THE EXISTING SPECIAL PROJECTS ACT.

-- ADVANCE FUNDING FOR STATE FORMULA GRANT PROGRAMS. CURRENTLY, MOST EDUCATION PROGRAMS ARE FUNDED ONE YEAR IN ADVANCE, BUT THIS IS NOT THE CASE FOR HEALTH AND SOCIAL SERVICES. WE ARE ASKING THAT YOU APPROPRIATE $2.5 BILLION FOR THE FY 1980 PROGRAM ACTIVITIES FOR VOCATIONAL REHABILITATION, AGING, MATERNAL AND CHILD HEALTH, COMPREHENSIVE HEALTH SERVICES, AND IMPACTED AREA AID, THE ONLY EDUCATION FORMULA GRANT NOT ALREADY ADVANCE-FUNDED. WE BELIEVE THAT STATES AND LOCALITIES CAN USE FEDERAL FUNDS MORE EFFECTIVELY IF THEY HAVE MORE LEAD TIME. IN ADDITION, IT WILL GIVE STATE LEGISLATURES DEFINITE

KNOWLEDGE OF FEDERAL FUNDING LEVELS SO THAT THEY CAN DETERMINE HOW MUCH IN STATE MATCHING IS NEEDED TO TAKE FULL ADVANTAGE OF FEDERAL APPROPRIATIONS.

-- EXPANSION OF OUR EFFORTS TO CURB FRAUD AND ABUSE IN ALL OF THE DEPARTMENT'S PROGRAMS, PARTICULARLY THE MAJOR ENTITLEMENT PROGRAMS, WHICH MAKE UP 90 PERCENT OF HEW SPENDING. WE ARE ASKING FOR 160 ADDITIONAL STAFF FOR THE INSPECTOR GENERAL TO EXPAND PROJECT INTEGRITY, PROJECT MATCH AND OTHER FRAUD PREVENTION ACTIVITIES, INCLUDING MAJOR AUDITS OF PROGRAMS WHICH ARE PRONE TO HIGH RATES OF ERROR. WE ARE ALSO REQUESTING STAFF FOR THE HEALTH CARE FINANCING ADMINISTRATION AND THE SOCIAL SECURITY ADMINISTRATION TO IMPROVE PROGRAM MANAGEMENT AND QUALITY CONTROL. WE BELIEVE THAT THE EFFORTS NOW UNDERWAY OR FOR WHICH WE ARE REQUESTING AUTHORITY IN 1979 WILL SAVE THE DEPARTMENT $2.5 BILLION BY 1981.

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BESIDES THE TWO MAJOR THEMES OF CHILDREN AND YOUTH AND IMPROVED EFFICIENCY, I WOULD LIKE TO CALL THE COMMITTEE'S ATTENTION TO SOME OTHER SIGNIFICANT ITEMS IN THE BUDGET. THESE BUDGET INITIATIVES ARE RELATED TO OUR EFFORTS IN CIVIL RIGHTS AND BASIC RESEARCH.

Civil Rights Enforcement

WE ARE PROPOSING A MAJOR EXPANSION OF THE OFFICE FOR CIVIL RIGHTS TO ENSURE THAT ALL COMPLAINTS ARE INVESTIGATED AND THAT CIVIL RIGHTS LAWS ARE FULLY ENFORCED. THIS INCLUDES LAWS BARRING DISCRIMINATION BASED ON RACE, SEX, AND HANDICAPPING CONDITIONS. WE ARE ASKING FOR 898 NEW POSITIONS IN THE 1978 SUPPLEMENTAL TO ELIMINATE ALL COMPLAINT BACKLOGS PURSUANT TO COURT ORDER AND TO HELP GRANTEES COMPLY WITH THE REGULATIONS IMPLEMENTING THE LAW PROHIBITING DISCRIMINATION AGAINST THE HANDICAPPED.

FURTHER ASSISTANCE FOR CIVIL RIGHTS COMPLIANCE WILL BE PROVIDED THROUGH TWO BUDGET REQUESTS FOR THE OFFICE OF EDUCATION:

-- $50 MILLION IN CONSTRUCTION GRANTS TO AID POST-SECONDARY SCHOOLS TO REMOVE STRUCTURAL BARRIERS TO THE HANDICAPPED. IN ADDITION, IN FY 1978, WE ARE ASKING YOU TO PERMIT $30 MILLION IN UNOBLIGATED BALANCES IN THE HIGHER EDUCATION FACILITIES LOAN FUND TO BE USED FOR THE SAME PURPOSE.

-- $333 MILLION, $23 MILLION MORE THAN 1978, FOR AID TO DESEGREGATING SCHOOL DISTRICTS. THESE FUNDS WILL BE USED TO IMPLEMENT SCHOOL DESEGREGATION PLANS AND ENCOURAGE VOLUNTARY COMPLIANCE WITH CIVIL RIGHTS LAWS.

IN ADDITION TO REQUESTING INCREASED FUNDS AND STAFFING FOR CIVIL RIGHTS PROGRAMS, WE ARE ASKING CONGRESS TO REMOVE A PROVISION CONTAINED IN THE 1978 APPROPRIATION ACT WHICH IMPEDES OUR EFFORTS TO ACHIEVE DESEGREGATION OF ELEMENTARY AND SECONDARY SCHOOLS. SECTION 208 OF THE 1978 APPROPRIATION BILL RESTRICTS THE DEPARTMENT'S

AUTHORITY TO REMEDY UNCONSTITUTIONAL SCHOOL SEGREGATION WHERE STUDENT TRANSPORTATION IS INVOLVED. UNDER THE PROVISION, WHEN A TITLE VI VIOLATION IS FOUND TO EXIST, HEW IS PRECLUDED FROM: (1) REQUIRING THE TRANSPORTATION OF A STUDENT BEYOND HIS OR HER NEAREST SCHOOL; AND (2) RECOMMENDING DESEGREGATION PLANS WHICH INVOLVE SUCH TRADITIONAL MEASURES AS GRADE REORGANIZATION, PAIRING, AND CLUSTERING, IF THE EFFECT IS TO TRANSPORT ANY STUDENT BEYOND THE NEAREST SCHOOL WHICH OFFERED THE APPROPRIATE GRADE LEVEL PRIOR TO IMPLEMENTING THE PLAN. IF ALLOWED TO STAND, THE AMENDMENT WOULD CONTINUE TO UNDERCUT OUR EFFORTS TO CARRY OUT A VIGOROUS CIVIL RIGHTS COMPLIANCE PROGRAM.

RESEARCH

CONSISTENT WITH THE PRESIDENT'S PRIORITY ON BASIC RESEARCH, HIS BUDGET PROPOSES A NUMBER OF SIGNIFICANT INCREASES IN RESEARCH PROGRAMS.

-- AN INCREASE OF $77 MILLION FOR THE BIOMEDICAL RESEARCH PROGRAMS OF THE NATIONAL INSTITUTES OF HEALTH. ALTHOUGH THE TOTAL RESEARCH BUDGET FOR NIH IS UP ONLY 3 PERCENT, FUNDING FOR BASIC RESEARCH WILL GROW BY 13 PERCENT.

ABOUT HALF OF THIS INCREASE -- $32.6 MILLION -- IS FOR THE NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT. NICHHD WILL INCREASE ITS RESEARCH ON BASIC REPRODUCTIVE BIOLOGY BY $16.3 MILLION, WITH EMPHASIS ON REDUCTION OF UNPLANNED PREGNANCIES THROUGH STUDIES OF ADOLESCENT PREGNANCY, CONTRACEPTIVE SAFETY, AND NEW CONTRACEPTIVES FOR BOTH MEN AND WOMEN. THERE WILL ALSO BE AN INCREASE OF $16.3 MILLION FOR RESEARCH ON MOTHERS AND CHILDREN WITH EMPHASIS ON (1) ASSURANCE OF HEALTHY BABIES THROUGH PREVENTION OF PREMATURITY AND LOW BIRTH

WEIGHT, (2) ADVANCES IN FETAL MEDICINE, (3) PROMOTION OF NUTRITION AS A MEANS OF ACHIEVING GOOD HEALTH, AND (4) PREVENTION OF PREMATURE DEATH AND DISABILITY BY CONCENTRATION ON PROBLEMS IN CHILDHOOD THAT LEAD TO LATER POOR HEALTH. UP TO $4 MILLION OF THIS INCREASE WILL BE USED FOR THE SMOKING PREVENTION INITIATIVE. THIS RESEARCH WILL EXAMINE THOSE EARLY SOCIAL AND BEHAVIORAL FACTORS THAT ARE ANTECEDENTS TO SMOKING.

-- AN INCREASE OF $40 MILLION IN MENTAL HEALTH RESEARCH INCLUDING DRUG ABUSE AND ALCOHOLISM. THIS IS A 25 PERCENT INCREASE OVER 1978 AND CARRIES OUT THE PRELIMINARY RECOMMENDATIONS OF THE PRESIDENT'S COMMISSION ON MENTAL HEALTH.

-- An increase of $10 million for the National Institute of Education, bringing the total budget for NIE to $100 million. The funding increase will be used for such studies as why some students cannot acquire such basic skills as reading, writing, and mathematics and for development of bias-free achievement tests. This increase reflects the President's desire to emphasize basic skill achievement in the 1979 budget and in the Elementary and Secondary Education Act reauthorization.

Conclusion

The HEW portion of the President's budget is the largest in the Federal Government. HEW is the principal arena for testing whether we can have both a compassionate and efficient government; whether we can provide needed government services without fraud and abuse; and whether we can have a government as good as the American people.

THESE ARE ENORMOUS RESPONSIBILITIES. IN THE FIRST YEAR OF THE CARTER ADMINISTRATION, I THINK THAT WE HAVE TAKEN SIGNIFICANT STRIDES TOWARD MEETING THESE GOALS. WE STILL HAVE A LONG WAY TO GO. WITH THIS BUDGET, OUR NEW LEGISLATIVE INITIATIVES AND YOUR HELP, I KNOW WE WILL BE SUCCESSFUL.

1979 BUDGET THEMES

Children and Youth

- Largest Budget Increase in More Than a Decade for Elementary and Secondary Education with Special Emphasis on Compensatory Education and the Handicapped
- Better Health Care for Children and Adolescents.
  Major Initiatives: Child Health Assessment, Adolescent Health and Pregnancy Prevention, Medicaid for All Low-Income Pregnant Women, Immunization, and Anti-Smoking Campaign
- Improved Social Services through Headstart and Child Welfare Programs
- Help for Middle-Income Families to Send Children to College: Greatly Expanded BEOG Program, Plus Increased Funds for Work-Study and Liberalized Guaranteed Student Loan Program

Improved Efficiency and Cost Containment

- Hospital Cost Containment Bill and New Medicaid Quality Control Effort
- More Efficient Use of Health Resources by Encouraging HMO Development and Attracting Resources to Underserved Areas
- Impact Aid Reform
- Continued Emphasis on Curbing Fraud and Abuse

HEW BUDGET BY AGENCY

($ in Billions)

	1977	1978	1979
Public Health Service BA	$ 6.4	$ 7.1	$ 7.2
Outlays	6.4	6.8	7.1
Health Care Financing BA	33.0	38.3	43.8
Outlays	31.5	36.5	41.5
Education Division BA	8.9	10.5	12.9
Outlays	7.8	8.9	10.4
Social Security BA	93.3	101.0	113.9
Outlays	96.6	106.9	116.6
Human Development Services BA	5.0	5.1	5.6
Outlays	4.8	5.1	5.5
Other HEW BA	.2	.3	.3
Outlays	.4	.4	.4
Total, HEW BA	$146.8	$162.3	$183.7 1/
Outlays	147.5	164.6	181.5

1/ Excludes $2.5 Billion One-time Advance Funding Re...

FUNDS REQUESTED IN LABOR — HEW APPROPRIATIONS BILL

(Budget Authority in Millions)

	1978		1979
	Appropriation to Date	Revised HEW Request	Appropriation Request
Public Health Service	$ 6,203	$ 6,310	$ 6,308
Health Care Financing	18,032	18,037	19,849
Education Division	10,135	10,390	12,834
Social Security Administration	13,806	13,806	14,466
Human Development Services	5,083	5,095	5,866
Special Institutions	163	163	179
Departmental Management:			
Civil Rights	31	53	72
Inspector General	25	29	36
WCF Financing Change	20	20	40
Other Departmental Management	110	116	116
Total, HEW	53,320	53,919	59,516
Reconciliation to Subcommittee's Table:			
Advance Funding for 1980 Under Current Law	—	—	+1,730
Proposed New Legislation	—	—	— 607
Subcommittee Table	53,320	53,919	60,639

TRENDS IN THE BUDGET

(Outlays in Billions)

	1964	1969	1974	1979	15-Yr. Change
HEW:					
Health	$ 2.3	$11.7	$21.6	$ 48.6	$ +46.3
Education	.7	3.4	5.4	10.6	+9.9
Social Services	.2	1.0	2.9	5.6	+5.4
Social Security Benefits	16.6	26.2	55.9	103.1	+86.5
Other Income Assistance	2.4	4.3	7.9	13.6	+11.2
Total, HEW	$22.2	$46.6	$93.7	$181.5	$+159.3
% of Federal Budget	18%	25%	35%	36%	+18%
Total Federal Outlays	$120.3	$184.6	$268.4	$500.2	$+379.7

TRENDS IN THE BUDGET
IN CONSTANT 1979 DOLLARS
(Outlays in Billions)

	1964	1969	1974	1979	15 Yr. Change
HEW	$ 7.0	$27.5	$ 38.2	$ 48.6	$+ 41.6
Health	1.6	6.7	7.8	10.6	+ 9.0
Education	.4	1.9	4.0	5.6	+ 5.2
Social Services	36.4	48.7	77.2	103.1	+ 66.7
Social Security Benefits	5.3	8.0	10.9	13.6	+ 8.3
Other Income Assistance					
Total HEW	$50.7	$92.8	$138.1	$181.5	$+130.8
% of Federal Budget	18%	25%	35%	36%	+ 18%
Total Federal Outlays	$282.2	$366.0	$392.1	$500.2	$217.8

COMPOSITION OF THE BUDGET

(Outlays in Billions)

Entitlements:	1977		1978		1979	
Social Security Benefits	$ 83.9	57%	$ 93.1	57%	$103.1	57%
Medicare	21.5	14%	25.6	15%	29.4	16%
Medicaid	9.9	7%	10.8	7%	12.0	7%
AFDC, SSI and Other Welfare	12.8	9%	13.8	8%	13.3	7%
Title XX Social Services	2.4	2%	2.6	2%	2.6	1%
Interest Payments and Other	.2	–	.8	–	.8	1%
Subtotal	$130.7		$146.7		$161.2	
% of Total	88.6%	+12.2%	89.1%	+9.9%	88.8%	
Discretionary Funds:						
Health Programs	$ 6.4	4%	$ 6.8	4%	$ 7.1	4%
Elementary, Higher and Other Education	7.8	5%	8.4	5%	9.9	5%
Human Development Services	2.4	2%	2.6	2%	3.1	2%
Other	.2	–	.1	–	.2	–
Subtotal	$ 16.8		$ 17.9		$ 20.3	
% of Total	11.4%	+6.5%	10.9%	+13.4%	11.2%	
Total HEW Outlays	$147.5	100%	$164.6	100%	$181.5	100%

1979 BUDGET HIGHLIGHTS
(Budget Authority)

Education: Total for Education up $ 2.4 billion

Elementary and Secondary

- Largest Increase Proposed by a President in More than a Decade: $686 Million
- $3.4 Billion for Title I ESEA, Up $644 Million:
  - $244 Million for the Currently Authorized Title I Program
  - $400 Million for New Concentration Provision
- $972 Million for Handicapped Children — up $279 Million
- New Legislation to Reform Impact Aid, Reducing Costs by $76 Million
- $150 Million for Bilingual Education — up $15 Million for Teacher Training, and Research
- Increase in Per-pupil Spending for Indian Education — from $117 to $143
- Expended Funding of $14 Million, Coupled with Legislative Changes, for the Special Projects Act to Improve Quality of Elementary and Secondary Education — Total $61 Million
- $333 Million Increase to Assist Desegregating School Districts — up $23 Million

EDUCATION HIGHLIGHTS (CONT'D)

(Budget Authority in Millions)

Higher Education	1978	1979	Change
Student Aid:			
Basic Grants	$2,160	$3,167	$+1,007
Supplemental Grants	270	270	—
Work Study	435	600	+165
Direct Loans	326	304	−22
Incentive Grants for State Scholarships	64	77	+13
Guaranteed Student Loan Programs	530	827	+297
Total	$3,785	$5,245	$+1,460

- Budget Provides 7 Million Federal Student Assistance Awards, More than double 3.2 Million in 1978
- Expansion is Mostly for Students from Middle-income families who will:
  - Get at least a $250 BEOG (Maximum grant for poor raised to $ 1,800)
  - Have greater access to Work-Study and Guaranteed Loans

Other Higher Education

- $50 Million to Aid Higher Education Institutions Eliminate Structural Barriers to the Handicapped
- $5 Million Increase for a Total of $8 Million in Graduate Professional Opportunities to Permit More Minority Students to Enter Professions where they are Underrepresented

1979 BUDGET HIGHLIGHTS

(Budget Authority)

Health

- Medicaid Eligibility for Low-Income Pregnant Women to Provide Pre-natal Care and Related Services — $118 Million.

- Expanded Child Health Assessment Program — New Legislation to Improve Health Screening and Follow-up Treatment for Low-Income Children Up to Age 21 — $263 Million.

- Fifty Percent Increase in Funds to Raise Immunization Levels from 60 Percent of the Nation's Children to 90 Percent — $+12 Million for a Total of $35 Million

- $9.5 Million Additional for New Education, Research and Demonstration Activities Directed Toward Smoking and Health — for a Total of $30 Million

- $142 Million Expansion in Health and Related Services to Aid Adolescents and Avoid Unwanted Pregnancies — $338 Million

ADOLESCENT HEALTH, SERVICES, AND PREGNANCY PREVENTION

(BA in Millions)

	1978			
	Ford	Carter	1979	Change
New Legislation:				
Adolescent Health, Services, and Pregnancy Prevention Act	$ –	$ –	$ 60	$ + 60
Expanded Medicaid Coverage for Low-Income Pregnant Adolescents	–	–	18	+ 18
Current Law:				
Family Planning Project Grants	35	50	66	+ 16
Family Planning Reimbursement Through:				
Medicaid	26	26	26	–
Title XX Social Services	7	7	7	–
Community Health Centers	25	45	60	+ 15
Maternal and Child Health	40	45	52	+ 7
Health Education	–	1	3	+ 2
Research and Training	13	22	44	+ 22
TOTAL	$146	$196	$326	$ + 130

Total Program Coordinated by Special Project Manager

SMOKING AND HEALTH

	1978		
	Ford	Carter	1979
NIH			
Cancer	$ 7.9	$ 8.4	$ 8.4
Heart and Lung	6.9	7.4	7.5
Environmental Health	1.1	1.1	1.1
Child Health	—	—	4.0
Total, NIH	15.9	16.9	20.0
CDC/Asst. Sec. for Health	1.2	2.1	7.3
ADAMHA	.1	1.3	1.5
Total	$17.2	$20.3	$29.8

HEALTH HIGHLIGHTS (CONT'D)

— $44 Million Expansion of Health Services in Medically Underserved Areas — 131 New Community Health Centers, 300 More National Health Service Corps Personnel

— $5.3 Million for 70 New HMO Feasibility Grants — 172 Operating HMO's by 1982

— 25 Percent Expansion in Mental Health Research — Carries Out Preliminary Recommendations of the President's Commission — $202 Million Total

— Hospital Cost Containment Legislation — 1979 Total Savings Estimated at $2 Billion; Medicare/Medicaid — $730 Million Outlay Savings. Total Savings over 6 Year Period: $57 Billion

— $34 Million More for PSRO's — Review of Hospital Admissions Financed by Medicare/Medicaid Increased from 43 Percent in 1978 to 70 Percent in 1979 through Sampling Techniques — $174 Million Program Level

— Continued Support of Health Professions Education Programs Targeted at Shortages of Primary Care Health Professionals and at Underserved Areas — Phase Down of Capitation Grants to all Health Institutions

1979 BUDGET HIGHLIGHTS
(Budget Authority)

Human Development Services

- —Head Start Expansion from $625 to $680 Million — Serving 430,000 Children — 30,000 More than 1978
- —$141 Million to Fund Child Welfare Services Legislation Providing Adoption Subsidies and Foster Care Reforms Up from $57 Million
- —Continuation of $200 Million 100% Federally Funded Day Care Program Under Title XX
- —$543 Million (in Treasury Department Budget) to Settle Old Social Services Claims
- —Transfer of Aging Nutrition Food Commodities Program — $37 Million — from Department of Agriculture. Funds will go as Grants to State Aging Agencies Rather than as Commodities

BETTER MANAGEMENT

Attack on Fraud and Abuse

- 160 New Staff Over Two-Year Period for the Inspector General for Project Integrity, Project Match and Other Fraud Prevention Activities
- 150 Staff Increase for Strengthened Quality Controls and Program Assessments Under Medicaid
- 100 New Jobs in AFDC to Strengthen Quality Control

Vigorous Civil Rights Enforcement

- 900 New Staff in 1978 in the Office for Civil Rights to Eliminate Complaint Backlog by End of 1979

Greater Efficiencies

- $30 Million to Upgrade Social Security Automated Claims Processing
- Reduction of 150 Regional Office Positions by the End of FY 1980

ADVANCE APPROPRIATIONS
(Budget Authority)

Money Covering Two Years, 1979 and 1980, is Requested in the 1979 Budget for Several State Formula Grants

Funds for These Programs Will then be Appropriated One Year in Advance, Giving States Added Lead-time to Fit Programs in their Budget Cycles

Programs Included:	1980 Request (In Millions)
	$ 785
1. Vocational Rehabilitation	499
2. Aging Programs (Title III, V, and VII)	345
3. Maternal and Child Health	101
4. Comprehensive Health	752
5. Impact Aid	
Total	$ 2,482

Note: Already on an Advance Basis are th . Education Formula Grants to States, E.G., Title I ESEA, Vocational Education, and Handicapped Education

NEW EMPLOYMENT

Full-time, Permanent Positions:	1977	1978	1979
Social Security Administration	79,514	79,586	79,851
Public Health Service	49,112	51,347	51,768
Health Care Financing Administration	4,209	4,425	4,540
Education Division	4,171	4,164	4,222
Human Development Services	1,977	1,985	1,976
Office for Civil Rights	1,064	2,000	2,000
Office of the Inspector General	1,157	1,257	1,317
Departmental Management	4,179	4,216	4,216
Total Positions	145,373	149,980	149,891
Employment Ceiling:			
Full-time Permanent	141,450	144,256	145,059
Part-time, Temporary and Other	12,000	12,000	13,500
Total Ceiling	153,450	156,256	158,559

STATEMENT OF THE SECRETARY

Secretary CALIFANO. Mr. Chairman, and members of the committee, these charts will just give a quick highlight of the budget, and, I think, in a more condensed form than the lengthy statement.

FOCUS OF THE HEW FY 1979 BUDGET

The focus of the budget of HEW this year is in the area of elementary and secondary education, health care—again directed at children—Headstart and child welfare programs, and a new program for middle income families and the problems related to higher education costs.

To achieve improved efficiency and cost containment, we are preparing hospital cost containment legislation and a major new Medicaid effort in quality control; we have funds to encourage the development of health maintenance organizations, a gentle scalpel-type reform of the impact aid program instead of the meat axe we used last year and continued emphasis on curbing fraud and abuse.

By agency, this next chart gives you a snapshot of the HEW budget and in gross terms you can see we are moving from $162.3 billion in FY 1978 to $183.7 billion in FY 1979. That number does not include $2.5 billion of one-time advance funding for several programs which I will list in a moment.

In terms of the HEW appropriations bill, that portion that is before this subcommittee, our revised request for FY 1978 is up only $600 million from $53.3 billion to $53.9 billion. Our request for fiscal 1979 is at $59.5 billion. This just reconciles those numbers to the tables that the subcommittee members have before them.

In terms of trends in the budget, Mr. Chairman, I thought it would be interesting for you and the committee just to notice what is happening to the Federal budget in the context of what has been happening to the HEW budget. In 1964, the HEW budget was $22 billion. It was 18 percent of the Federal budget. Fifteen years later, in 1979, the HEW budget is now $181.5 billion. It is 36 percent of the Federal budget. This represents a tremendous increase in the investment of this country in social programs, but the biggest increase as you will notice, is in the area of Social Security.

In constant dollars, it is also a very substantial investment, an increase, as you can see, roughly from $50 billion in 1964 to $181 billion in 1979.

In this chart, Mr. Chairman, I have divided the HEW budget into entitlement programs, such as Social Security, Medicare, Medicaid, AFDC, and so forth, and discretionary funds, elementary and secondary education funds and health programs; and I would ask you to note one important element in this chart. The entitlement programs went up 12.12 percent from 1977 to 1978. From 1978 to 1979, they are going up only 9.9 percent.

As we project, there are a couple of reasons for that. One is the cost containment program related to hospitals, which begins to come into play, but more important are a host of changes tightening some of the entitlement programs, for example quality control and fraud programs and AFDC and Medicaid and what-have-you. Whereas the dis-

cretionary programs, where there is greater ability for this committe or the Administration to target funds, went up only 6.5 percent fro 1977 to 1978, they will rise by 13.4 percent from 1978 to 1979, a muc more substantial increase.

In terms of the three sectors of HEW, Mr. Chairman, briefly, ou total education budget is up $2.4 billion. As far as elementary ar secondary education is concerned, it is the largest increase proposed b a President in more than a decade. Elementary and secondary educ tion, the Title I Program, is up by $644 million. $244 million of that simply an increase in existing Title I programs, and $400 million for a provision to concentrate Title I programs into areas of high ru poverty or into urban areas with high poverty populations. There is increase of $279 million in the handicapped children program. Th takes the percentage of the additional cost of States to comply w the Handicapped Education Act from roughly nine percent to roug 12 percent. The statutory objective was to take it to 20 percent, though that is not mandated because there are provisions in the stat for distribution when we are below 20 percent. It would require a li more than another $400 million to get it to the 20 percent.

IMPACT AID REFORM

We have a very gentle reform in the impact aid program wh would reduce cost by about $76 million, but the budget does not ass that legislation is passed. The estimates are based on the law a exists, unlike what we did last year. There is $150 million for bilin education, an increase of $15 million. Eleven million dollars is research and $4 million is for training teachers. We increased our pupil spending for Indian education from $117 million to $143 mil We will be proposing legislation in the area of quality and impro and enhancing basic skills. That will provide for integrating existing programs and for an increase of about $14 million.

There is an increase of $23 million, for a total $333 million, in ai desegregating school districts.

STUDENT FINANCIAL ASSISTANCE

The student aid program does include the additional funds th President identified out of the contingency fund the week befor when he proposed his middle income program; so it is basically a billion increase in student aid programs. The focus is on the I program, which we think is the best administered of the progra the evidence we have to date. Supplemental grants we leave work study we increase by $165 million. We will increase the n of students eligible for work study programs.

I might go back to BEOGs for a second. What we basically d that is increase the minimum grant level of $1,600 to $1,800; would be eligible for that up to incomes of about $8,600 a year. income range of roughly $8,600 to $16,000, we would have a down to a $250 grant. Families in the $16,000 to $25,000 range be eligible for a minimum $250 BEOG grant. They would eligible for an expanded guaranteed student loan program.

would provide loans to them and to any family with an adjusted gross income of $45,000 or less.

We do not provide for any increase in the direct student loan program; indeed, there is a decrease. There are several reasons for this, but the overriding reason in my own mind is that we now have $600 million of defaulted loans in that program. It is the worst administered loan program in HEW, and it will take some time to put that back in shape. It is a campus-administered program, although HEW has clearly not done its job in this area.

The Congress passed, for example, legislation in 1972, providing a system whereby the government was able to take over loans from schools as long as the loans were in default, but no guidelines of any kind were issued under that legislation, and, for the most part, bills have not been sent to the students. We have about 700,000 students in default and $600 million in principal outstanding under that program.

Work study eligibility would increase to families with higher incomes than is currently the case. Basically we would provide 7 million student assistance awards in 1979, as compared with 3.2 million in 1978. That would go to about 5 million students, since more than one award often goes to the same student.

COMPLIANCE WITH SECTION 504 OF THE VOCATIONAL REHABILITATION ACT

The other elements of higher education worth mentioning are: a request for $50 million in construction funds to provide assistance to colleges and universities to comply with the 504 regulations involving discrimination against the handicapped: an increase from $3 million to $8 million for a program we are starting this year for graduate professional opportunities for disadvantaged and minority students, trying essentially to identify excellence and then providing the funds necessary to get a good education.

HEALTH BUDGET

In the health area, there are proposals to increase Medicaid eligibility for low income pregnant women at an additional cost of $118 million. These proposals basically would make eligible for Medicaid two classes of women that are largely not now eligible, women having their first child who are not eligible because the categorical eligibilty is AFDC and, secondly, women who are married in States that do not have an Unemployed Fathers program. We think that prenatal care is so important over the long run that we believe the law should be changed, and we have recommended it.

Last year, when the child health assessment bill began working its way through Congress, we proposed to cover children from age zero to six. Now we have moved it up to age 21 with $263 million and a new formula and more aggresive program. It has cost us about $80 million more to go from age six to age 21.

We propose a 50 percent increase in funding for immunization, from roughly $23 million to $35 million. That is to meet our objective of immunizing 90 percent of the children against basic childhood diseases

by October 1, 1979. We are well on the way toward doing tha
believed we have increased from roughly 3 million to 4.5 million
number of children who have been inoculated over this past fall sea
and we are moving pretty well, particularly in the measles and rul
area. We don't have information yet to know how well we are d
with polio.

There is $9.5 million additional for new education research
demonstration activities included in the total $30 million for the s
ing program. There is a $142 million expansion in health and re
services for adolescents. Part of this includes the teenage pregn
program I will mention later. The total amount we will be inve
in teenage pregnancy is $338 milion.

Let me briefly explain the $142 million being added in this prog
Let me preface it, incidentally, by a brief statement of the pro

TEENAGE PREGNANCY

One million teenagers became pregnant in the past year, we est
That is one out of every 10 teenagers. With family planning and
most of that year—abortion services readily available, 600,000 d
to have the child and to carry it to term. Of that 600,000, 85 p
decided to keep the child themselves. Forty-five percent of the
agers who had a first baby will be pregnant again within a yea
80 percent of the teenagers who had a first baby will be pre
again within two years, so it is a very serious problem. These fun
planned to deal with two parts of it: One, a family planning
we would target that family planning effort on teenagers and
the repeat problems, since there is such a high incidence of repe
Secondly, an effort to provide parenting education and par
counseling for those teenagers who decide to have their child, w
a large group needing help.

In the smoking and health area, the President proposes a $30
program. The bulk of the program, as you can see, is in areas
to research, cancer research, heart and lung research, environ
health and child health. In the child health area we also would
ing behavioral research as well as research on the physical asp
smoking to try and determine why children smoke.

We will have a substantial education plan largely directed
agers and subteens. The reason is that: 75 percent of the smo
the United States begin to smoke and acquire the habit befo
are 21. We now have 100,000 regular smokers who are under 1
of age. Every day in this country 4,000 more children become s
The program is targeted there, and we hope that we will hav
impact there.

I would stress that the program is voluntary; it is designed
vide information; it is designed to let individuals make up th
mind.

As for other health areas: There is a $44 million expansion o
services in medically underserved areas, with some new com
health centers and 300 more national health service corps pe
who will be focused in inner cities and in rural areas. We ha

million for new HMO (Health Maintenance Organization) feasibility grants. We would like to have 172 HMO's operating by 1982.

There is a 25 percent expansion in mental health research, to carry out the preliminary recommendations of the President's Commission on Mental Retardation. The hospital cost containment legislation would, if enacted on our time schedule, save $2 billion in 1979 for $730 million in outlay savings. The total savings over a 6-year period—that is, both what is in the Federal budget and what is in the private sector—is estimated at $57 billion. Of that $57 billion, about $21 billion would be a reduction in the Federal budget for Medicare and Medicaid.

PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

We have put some more money in the PSRO programs, although as far as the Administration is concerned, that program is in some jeopardy. We hope to demonstrate that PSRO's can work by focusing on the best of them and by focusing on certain types of hospital procedures to see whether or not there is potential for improving quality and saving money.

The support for the health professions education programs will undoubtedly raise some questions before this committee. We phased down many capitation grants, cut out much of the nursing money, and tried to focus our attention on primary care physicians.

In the human development area, in Headstart, we increase from $625 million to $680 million. That will bring us to serving about 430,000 children, 30,000 more than last year. It is still substantially less than half the eligible population.

We are doing an assessment of the Headstart program, which, as we learn more about it, may result in increased requests in future years. We are trying to determine exactly what kind of services should be delivered to different aged children in these programs.

There is a total of $141 million to fund child welfare services legislation, up from $57 million. We have recommended two changes in the child welfare legislation statute: One, where a family that is not eligible for AFDC has a foster child, they get AFDC funds while that child is a foster child. However, if they love the child enough to adopt him or her, at that point they now lose those AFDC payments. We would like them to continue to receive payments in cases of adoption; second, we would like to provide some money for States to set up better adoption tracking systems so there is a better sense of what is happening to these children.

We again request $200 million in title XX for a 100 percent federally-funded day care program. There is $543 million in the Treasury Department budget to settle the couple of billion dollars in old social services claims that had been pending for a few years, and there is $37 million previously distributed as food commodities which is now cash in our budget to provide food for older Americans.

In terms of better management, I just note a couple of things. We ask for 160 new staff over a 2-year period for the Inspector General for project integrity, a project focused on Medicare and Medicaid, doctors and pharmacists, and for Project Match, focused on AFDC welfare recipients and other fraud prevention activities. We are re-

questing a staff increase of 150 for quality control under Medicaid a 100 in AFDC for quality control. Both of those operations have b weak, and I think all of these staffs will more than pay for themsel

In the civil rights area we ask for 900 new spaces to eliminat complaint backlog by the end of 1979 and to comply with various co orders.

IMPROVED EFFICIENCY

In terms of greater efficiency, I note briefly we are upgrading Social Security automated claims processing, and we will reduce regional office positions by the end of 1980: 100 in 1979 and 50 in 1

Here is just a snapshot of the programs we have requested adv funding for that were not previously advance funded: Vocational habilitation, titles III, V and VII of the Aging Programs, Mat and Child Health and Impact Aid. We are already advance fun the title I programs, Vocational Education and Handicapped cation. We believe this makes more sense in the concept of State local planning.

Lastly, the HEW employment situation: In terms of full-time manent positions the Congress has authorized 148,980 for FY In FY 1979, the level would be 149,891. In terms of employment ing proposed by OMB, we now have 145,059 full-time perm employees, and 13,500 part-time temporary and others, for wh estimate to be about 158,500 for 1979, as compared with 156,2 1978.

"GRAYING" OF THE HEW BUDGET

The last point, Mr. Chairman, I would like to make deals wi extent to which the HEW budget is now a budget directed at citizens and the dramatic change in the last 10 years.

This is not on your charts, but I thought it was an important to mention. In 1969, Social Security payments were $24.7 bill 1979, they will be $90.1 billion. Federal Medicare hospital costs were $4.8 billion. In 1979, they will be $21 billion. HEW fund Medicare doctors' bills in 1969 was $1.8 billion. In 1979, it will billion. Medicaid for the aged—and we believe this is a low nu was $.9 billion in 1969.

In 1979, Federal Medicaid funding for older Americans is $ lion. We are approaching 50 percent of the Medicaid budget fo term care in this country. Supplemental security income estin the Federal budget were $1.2 billion in 1969. In 1979, they billion. The Administration on Aging was a $23 million pro 1969. It is a $549 million program in 1979.

In total, what that means is that in fiscal 1969 about $33 b HEW's budget was devoted to senior citizens of this country how the HEW budget has grayed over the years, in 1979, $1 lion out of a $180-plus billion HEW budget is directed at se zens. It is something that is also reflected, I might note, in Federal budget in which $39.7 billion was for senior citizen country in fiscal 1969. $152.7 billion of President Carter's $500 billion budget is for senior citizens. As a percent of total outlays in the last 10 years, the money for the graying of Am grown from 21.5 percent of the Federal budget in 1969 to 30.

of the Federal budget in 1979, and if that increase continues at that same rate—showing another 50 percent increase—you would have 45 percent of the Federal budget directed at senior citizens in 1989.

REDISTRIBUTION OF INCOME

I mention this only because we all tend, myself included, to think in terms of redistributing resources through the HEW budget to people who are poor, or people who are black, or people who are in the inner city or in pockets of rural poverty, but the largest redistribution in the history of this country is currently going on, and it is generational, not from one economic class to another.

That is it, Mr. Chairman.

Mr. FLOOD. Mr. Secretary, that is a good way to start; we appreciate these new perspectives.

NUMBER OF PROGRAMS

Mr. Secretary, as you know, this subcommittee has the formidable task in the months ahead of reviewing this enormous budget of yours and deciding how much to recommend for each program that is funded. Can you tell us how many separate and distinct programs are now administered by HEW?

Secretary CALIFANO. Mr. Chairman, we say that there are 372 legislative programs. There probably are hundreds more individual programs, if you take childhood immunization, for example, a spinoff of the general immunization program. I have tried to do some consolidating, but the number is large.

NEED FOR FISCAL RESTRAINT

Mr. FLOOD. Just about everyone, of course, agrees that the Federal Government is spending too much in the aggregate, but when you ask people, and we do, to tell you which programs to cut, they generally become very vague about that, right away.

Most of the people who talk to the subcommittee are advocates—of health, education, Headstart, aging, you name it. And every year they try to recommend more money for highly meritorious programs. But if you added up all the requests for HEW programs, just for HEW programs, you probably would exceed the total Federal budget. We rarely hear from anyone who suggests cutting the budget for any specific program.

As a result, Congress generally adds more money to the President's budget request for HEW.

Is there any reason why we should try harder to hold the line in your budget this year?

Secretary CALIFANO. Mr. Chairman, I think this is a good budget, with substantial increases in the education area and in other areas, far more substantial than have been proposed in recent years. And I believe those increases are more than adequate, or adequate to meet the needs out there in the context of the whole Federal budget that the entire Appropriations Committee has to act on.

Mr. FLOOD. Well, last year, you recall, you assured us that we don't need to worry about the President's vetoing the Labor–HEW bill anymore. Will you say the same thing this year?

Secretary CALIFANO. Well, Mr. Chairman, I find it difficult to l
lieve that the Congress and the President will not be able to come
an agreement on this appropriations bill, particularly because I thi
it is, by comparison with last year's, a much more substantial budg

REDUCTION IN HEALTH BUDGET

Mr. FLOOD. How can we defend a budget which proposes a decre
for the Public Health Service and a $2.5 billion increase for
Education Division?

Secretary CALIFANO. Mr. Chairman, there are many increases
the Public Health Service. The increases are in adolescent hea
community health centers, the national health service corps, mate
and child health grants, family planning, immunization, health
cation, child health research, a modest increase in NIH research,
abuse and alcohol research, community health centers, and HM
There are decreases——

Mr. FLOOD. The Public Health Service goes from $6,310 to $
in 1979, a slight cut there. In education you go from $10,398 to $12
How do you defend that?

Secretary CALIFANO. There are decreases, Mr. Chairman.

Mr. FLOOD. I mentioned the Public Health Service program.

Secretary CALIFANO. And those decreases come in the manp
area, certain capitation grants, in nursing, in Public Health Se
hospital operations.

Mr. FLOOD. On the Public Health Service, Mr. Secretary, the
budget seems to consciously hold down spending for discreti
health programs in comparison to other controllable activiti
HEW, such as the one I just mentioned, education.

Why is this the case? Have you found your health programs
unproductive? What role does the new zero-based budgeting s
play in arriving at that health budget estimate?

Secretary CALIFANO. It played a role across-the-board at HE
isolating decision packages, forcing us to rank them packa
package. I think it also played a role, in personal terms, of pro
me and the Under Secretary and others with a monumental
course in hundreds of programs that we otherwise would no
had a chance to review.

If you are asking me whether or not I can point to a specific d
that would or would not have been made one way or the o
think I would find it difficult to do that, not having gone throu
budget under any other system.

With respect to your earlier question, what we tried to do
Public Health Service budget was to provide funds where we t
we would encourage changes in the system that are very imp
whether it is to provide health service for poor people in th
areas, to create more HMO's, to try to build competition in the
or to deal with preventive measures. I should also mention th
is a lot of money in Medicaid related to preventive health.

In terms of significant increases, it seems to us that since
in the midst of putting together major recommendations in
tion with some kind of national health plan, that the substa
creases should come when we have completed our studies in t

and there will be recommendations for substantial changes as the President unfolds his program.

MEDICAL MANPOWER ESTIMATES

Mr. FLOOD. Mr. Califano, you have been quoted as saying that the nation is producing too many doctors and too many specialists, and you obviously believe this to be true. Your 1979 budget eliminates capitation grants for nursing schools, and it reduces capitation grants for medical, dental, osteopathic schools.

What hard data do you have in your department to support your statement and those budget cuts, specifically the ones I just mentioned?

Secretary CALIFANO. Mr. Chairman, the graduates of medical and osteopathic schools have grown from 7,421 in the 1960–1961 academic year to 14,270 in 1976. If we continue the way we are going, we will graduate more than 17,000 new physicians in 1980 and 20,000 in 1990.

The ratio shows, as you can see, a dramatic increase between 1960 and 1990. In 1960, there were 143.6 active physicians per 100,000 people in the population. In 1975, there were 177.3. By 1990, there will be 242.4. We feel that we don't need that number of physicians. We do need physicians in underserved areas—rural areas, inner city areas—where we have shortages, and to get them there, we have recommended an expansion of the national health service corps program from 1,435 to 1,735.

As far as nurses are concerned——

Mr. FLOOD. Keep in mind. "Never turn your back on a nurse." Be careful with this one.

Secretary CALIFANO. I understand that, Mr. Chairman. It is actually because we don't want to do that, that we have recommended trimming back those programs.

Last year, in this country, there were 200,000 teachers who graduated from schools of education and about 70,000 of them did not get jobs. We are going to reach a point in this country where we will build a capacity in nursing schools that will be like that of the teaching schools, and we will have a terrific glut on the market.

In 1960, there were 458,000 nurses. By 1977, there were 845,000; by 1990, at the rate we are going, we will have 1.3 million. We don't believe we need that many nurses.

We have left money in programs to increase the number of physician extender-type nurses, if you will, and we have left money in programs to improve the curriculum to direct it in that way, and the Congress, at our urging, did pass legislation last year to provide for direct reimbursement of physician extender-type nurses in rural areas and as a demonstration program, in inner city areas.

CAPITATION GRANTS

Mr. FLOOD. We are talking about the capitation grants. These grants are eliminated entirely for veterinarian, optometry, pharmacy, and podiatry schools. Medical and osteopathic and dental schools were all cut by 33 percent.

Now, to us, at least, it would seem logical that in order for someone to decide that we have an excess of health manpower, we would

have to have in mind a specific ratio of doctors to population. What ratio do you have in mind? Have we reached a desired ratio, do you think?

NUMBERS OF MEDICAL SPECIALISTS

Secretary CALIFANO. Mr. Chairman, I cannot give you a precise ratio. What I can tell you is that we think in some areas, in some specialties, we have more than we need, and I will submit for the record a list of those. We think in primary care physicians we do not have enough. We don't have the control. We can't order people to become primary care physicians. We can take our Federal investment in medical schools and direct it down that road to the extent we have authority to do that under the law.

Mr. FLOOD. You said you would submit a list of certain classifications for the record. Will you submit to the committee the studies, whatever studies have led you to conclude that we have a surplus of health professionals?

Secretary CALIFANO. Yes, I will, Mr. Chairman.

[The information referred to follows:]

SURPLUS PHYSICIANS IN NATIONS

Several recent studies have raised concerns about a possible over supply of physicians in the nation. Two of these studies are:

Study of Surgical Services in the United States, Department of Health, Education, and Welfare Publication, 1975. This study raised concerns about excess surgery in the nation and indicated that there may be too many surgeons in the United States. On the basis of the study's finding, many surgeons were performing below a level determined as their full-time capacity.

Progress and Problems in Medical and Dental Education, Council on Policy Studies in Higher Education, 1976. This study expresses concern about possible over supply of physicians and suggests State and Federal action to prevent establishment of additional medical schools in the nation.

SUPPLY OF NURSES AND OTHER HEALTH PROFESSIONALS

Several recent studies have indicated that the supply of nurses and other health professionals in the nation has increased substantially since the 1 Some of these studies have indicated that the nation currently has or may have a surplus of nurses and other health professionals. Some of these st are:

"United States Health Manpower Policy—Will The Benefits Justify the C J. Morrow and A. Edwards, JMED, October 1976. As a result of subst increases in practicing professionals, the authors expected that the port GNP connected with health services would increase to 12 percent over th 25 years. The authors expressed concern that despite substantially inc expenditures for health resources only marginal improvements in services result.

First Annual Report For The Health Professions. This report is nov prepared by the Department and will be sent to Congress as soon as it pleted. The report provides detailed information on the increasing su health professionals.

Source Book on Nursing Personnel. Department of Health, Educati Welfare Publication, Health Resources Administration 75-43, Decemb This study indicated that by 1980 the supply and requirements for r nurses would be approximately equal.

First Annual Report for Nursing. This report was sent to Congres vember 1977. It provides detailed information on the increasing supply ing professionals.

Second Annual Report for Nursing. This report is now being prepared by the Department and will be sent to Congress as soon as it is completed. The report will provide detailed information on the supply and requirements for nurses.

HEALTH MANPOWER MALDISTRIBUTION

Mr. FLOOD. Now, this budget before us places a very heavy emphasis on solving the health manpower maldistribution problems, and, of course, we agree maldistribution is by all means a problem. The major programs that are proposed in the budget for doing this seem to be National Health Service scholarships and the National Health Service Corps. Is it realistic to assume that these two programs can solve the problem?

Secretary CALIFANO. Mr. Chairman, I don't think they alone can solve the problem, and they are not the only tool we have. We do think that the National Health Service Corps, based on the limited evidence we have so far, holds great promise of being one of the major developments in the future in terms of distributing physician resources around the country. We propose increases in community health centers, which we believe is another important element in distributing health resources properly, and we propose a substantial increase in HMO's, which we believe indirectly will have a significant impact on the distribution of health resources.

NATIONAL HEALTH SERVICE CORPS GROWTH

Mr. FLOOD. How many people will be supported under the scholarship and the corps program five years from now, and how much is the cost?

Secretary CALIFANO. I can't answer the question five years from now. In 1979, it will be 1,735, roughly, an increase of 300 over the prior year, in terms of new scholarships. I will have to submit it for the record.

Mr. FLOOD. Do that, then.

Secretary CALIFANO. Yes, sir.

[The information referred to follows:]

NATIONAL HEALTH SERVICE CORPS

Estimating the size of the National Health Service Corps Scholarship program and the field strength of the National Health Service five years in advance is a complex process requiring assumptions about a number of factors, including personnel decisions and Congressional actions, over which the Department may have only limited influence. Therefore, the estimates which follow should be considered tentative, although they are based as much as possible on past program experience.

NHSC SCHOLARSHIP PROGRAM

In 1983, the scholarship program is expected to support approximately 4,600 students. This assumes an appropriation level of $60 million and an average cost per award of about $13,000 compared to $11,000 in FY 1979.

NATIONAL HEALTH SERVICE CORPS

The field strength of the Corps in 1983 is estimated to be within the range of 4,000 to 4,700 at a program cost of between $170 million and $200 million. This compares with the FY 1979 budget request of $63 million to support 1,725 field assignees. The main factor accounting for the increase is the large number of

NHSC scholarship recipients who will be available for service between now and the early 1980s. The lower end of the range for program level in FY 1983 assumes no recruitment of volunteers for service in the Corps, while the higher program estimate assumes volunteer recruitment at a rate of about 300 health professionals per year.

FUNDING FOR BIOMEDICAL RESEARCH

Mr. FLOOD. You are proposing an increase of $74 million, 2.7 percent, for NIH Research Institutes. $32 million of the increase is for just one institute, the National Institute for Child Care and Human Development.

For all the other institutes, the increase you are recommending is $42 million, or 1.6 percent. That means, of course, a reduction in real dollars. Why are you proposing a reduction in support for research on cancer, heart disease, arthritis, neurology, eye disease, aging, allergies, and so on?

Secretary CALIFANO. Mr. Chairman, let me deal with all pieces of your question.

As far as cancer is concerned, it is our belief that the National Cancer Institute is well funded. It has increased tremendously in the last several years.

As far as NIH generally is concerned, since 1969 appropriations there have increased by 264 percent, a very substantial increase. We did focus very much on one area, as the Chairman noted, the National Institute for Child Health and Human Development.

Of the $33 million increase we recommended there, $29 million is to fund an intensive program of research related to reproduction and family planning. You know, we spend more money in this country on the reproductive processes of cows, to make them produce better steak and better hamburger, than we do on the reproductive processes of human beings, where we are dealing with the need to produce healthy children. We must see whether or not there are ways we can learn more about the fetus so we can treat the fetus while it is in the mother's womb, and also to see whether or not we can find safe ways of family planning, and ways of family planning that would be acceptable to anybody, regardless of personal belief.

We have spent a good part of this past year talking to experts in this field who hold a variety of views as to the propriety of contraception, and we have put together research programs that all people dicate constitutes a legitimate and fair search for the facts. We t there is no higher payoff potential than there is in that area.

The other $4 million of the $33 million increase for that Institute is directed at the research on children's smoking and child he much of it in the behavioral area.

As for the rest of NIH, we had to make judgments about the amount of funds that should be put in the budget. We had to make judgments vis-a-vis other demands on the budget, and OMB had to make judgments.

FUNDS FOR BASIC RESEARCH

I would note there is one other shift in the budget that doesn't up in the numbers per se, which I should bring to the attention Chair and the committee. This is that our budget has about a 1

cent increase in it for basic research in NIH, which means there will be a shifting of funds into the basic research area and out of the more applied research areas.

Mr. FLOOD. The President's budget message, page 20, talks about an increase of 10.9 percent over 1978 for basic research. We cannot find any such increase in all your budget. Where is it?

Secretary CALIFANO. Mr. Chairman, it involves targeting of funds from NIH into the basic research area. On a governmentwide basis, the President is talking about a $3.7 billion program for basic research in 1979, versus $3.3 billion in 1978. For HEW department-wide, we go, from $864 million in 1978 to $973 million in 1979 for basic research. NIH will go from $763 million in basic research to $856 million, up $93 million. ADAMHA will go from $64 million to $78 million in basic research, up $14 million. The National Institute of Education goes from $16 million in 1978 to $20 million in 1979, up $4 million. Other basic research activities go from $21 million to $19 million, down $2 million.

Mr. FLOOD. If there is an increase in basic research in your NIH budget there must be a big cutback in other kinds of research.

Secretary CALIFANO. That is correct, Mr. Chairman; there is a decrease in other kinds of research.

RURAL HEALTH CARE DELIVERY

Mr. FLOOD. Last year, you placed considerable emphasis on the improved delivery of rural health services. What progress has your department made to date in this area, and what does your 1979 budget request include for the rural health service program?

I also may as well point out that if we ever have a National Health Service program, the rural communities are not going to benefit unless they have access to health care.

Secretary CALIFANO. That is right, Mr. Chairman.

Mr. FLOOD. What about that?

Secretary CALIFANO. Mr. Chairman, overall in fiscal 1978 we believe we served 5,217,000 individuals at a cost of $188.3 million. In fiscal 1979, we are requesting $217.3 million, which we believe will provide service to 6,074,000 individuals. The increases are in community health centers, migrant programs, family planning, and the National Health Service Corps; but perhaps the most significant thing in the rural health area, from our point of view, may be the fact that we can now provide direct reimbursement for physician extenders under legislation passed by the Congress. We hope this will provide a significant increase in the number of people served and the access of individuals in rural areas to health care.

But, I am not prepared to say that we have done enough.

Mr. FLOOD. Mr. Michel.

Mr. MICHEL. Thank you, Mr. Chairman.

Mr. Secretary, you know we spend months in this hearing room in going over these different line items and trying to arrive at figures, then have a markup and go to the floor and have extensive debate, but then I look at the paper the next day after we have debated a bill of

$63 billion or $64 billion of direct appropriations and $189 billion or $190 billion in total, as you outline here, and there isn't anything said about the figures at all. It is either about abortion or busing, or something like that.

So I am inclined to think maybe the figures don't mean two hoots, and I ought not spend any time on the figures and go to those issues which apparently the people want to read about.

But I have to ask you a couple.

SUPPORT OF THE PRESIDENT'S BUDGET

I guess I have to follow up on the Chairman's question. You know, last year I tried my darnedest on some of these items to hold to the President's budget and support him, and I didn't get much help from downtown—either from your department, from OMB, or from the President, himself; and so, you know, after you go to the well and try and take their chestnuts out of the fire once in a while and you get no help, you think what is the use.

I have to ask you, are you really ready to defend this budget, no holds barred, when this runaway Congress piles on one increase after another on items in your bill?

Secretary CALIFANO. Mr. Michel, yes, I am prepared to defend it I hope better prepared than we were last year when we only had abou 30 days to get into it.

Mr. MICHEL. I understand that, but this is different.

Secretary CALIFANO. I also think, for whatever it is worth, that w made the best accommodation we could last year in terms of holdir down the HEW budget in the House and in the Senate.

I think we fought pretty hard to hold that budget, and we held to an increase of only a billion dollars or so more than we had reco mended, which after the bruises of last year, I considered no sn achievement.

EVALUATION STUDIES

Mr. MICHEL. Now, do you know how much your department spe in evaluation studies over all?

Secretary CALIFANO. Overall I can't answer that.

Mr. MICHEL. Supply it for the record.

Secretary CALIFANO. Yes.

[The information referred to follows:]

COST OF EVALUATION STUDIES IN HEW

[Obligations in Millions of Dollars]

Program area	1977 actual	197
Health	$19.7	
Education	18.0	
Social services	12.7	
Total	$50.4	

Mr. MICHEL. You know I have to ask the question, do you eve any attention to the findings of such evaluations? I must confes

in the Congress the tendency is to ignore any evaluation findings which may conflict with preconceived notions, and, you know, when we are called upon then to fund considerable sums of money for evaluation of programs, and you alluded to it several times in the course of your dissertation with the large cards, then I have to ask the question: What are we going to do after we evaluate them all? Are we going to ignore them? Last year, the evaluation of the bilingual program showed it has not helped to improve reading or vocabulary skills and over two-thirds of the students enrolled in federally-financed bilingual classrooms were of regular English-speaking ability and thus presumably not in special need of bilingual help.

But you pride yourself in showing a significant increase in bilingual education, so I have to ask the question: why? On what ground?

BILINGUAL EDUCATION

Secretary CALIFANO. Let me try the various pieces. On the bilingual education program, I think it is a relatively modest increase. I am not happy with that program.

Mr. MICHEL. And may I take the opportunity here to applaud you for some of those areas where I sense you are not altogether wedded with programs of 20 years ago just because they have a popular name or handle but that were in need of a whole lot of changes. I would have to applaud you for that. This doesn't happen to be one of those members who takes the position that because we provided money up here 20 years ago, and 15, and 10, we have to continue to do so or we are not performing our job.

Secretary CALIFANO. In the bilingual program, the increase is $15 million. $11 million of it is directed towards research. It is really directed at the fact that we are not satisfied that we know how to teach children effectively who need to learn English and need to be taught in their primary language for a year or two or three while learning English. We don't know how to do that well enough.

I do not believe the program should be used in a way you described it being used in the report you are referring to. There is some dispute over that report. But I think we will also be making some legislative recommendations to the Congress within the next two weeks for bilingual education which will sharpen its focus some.

PLANNING AND EVALUATION OFFICES IN HEW

I guess I would like to make a couple of general points. One, I now have underway a study of all the planning and evaluation offices in HEW. They are sprinkled around HEW like holy water in the church, and we are trying to do an analysis of them to see how they ought to be organized and what they should do.

EVALUATING HEAD START

Secondly, I mentioned Head Start. We have selected about nine social service programs, and I have the Office of the Inspector General trying to devise ways of measuring their effectiveness. To use Head Start as an example, we are devising a series of questions about Head

Start programs. Does it teach digital skills, letters, color recognition, words, addition, number recognition, maybe ten or eleven or twelve things. We will use progress against such indicators as a way of evaluating program performance and effectiveness. So when I come up here and say we are serving 430,000 children in Head Start, I will be able to tell you what we are doing. We are providing everything ranging from a babysitting operation to pretty sophisticated and attractive and exciting programs. We are running similar evaluations on home health care, senior center programs, and about six others.

I don't know what I will have next year, but I will have a much better sense with respect to some of these programs than we now have.

ABORTION REGULATIONS

Mr. MICHEL. I will have a number of questions in the education field, but let me turn now if I might to abortion.

Were there ever consultations with President Carter regarding the drafting of regulations covering the payment of Medicaid funds for abortion?

Secretary CALIFANO. No. I did not——

Mr. MICHEL. Did the White House have anything to do at all with the final regulations you issued?

Secretary CALIFANO. No, Mr. Michel, nothing.

Mr. MICHEL. The Attorney General in his letter to you stated that you have "broad discretion in formulating regulations consistent with the intent of Congress." He also said the intent in this case is not very clear and added that "Congress intended to leave many matters of interpretation concerning section 101 to the sound discretion of the Secretary rather than attempt a more detailed statutory scheme."

One of the reasons we were able to achieve adoption of compromise language in the House was a belief that, because the President had strongly committed himself in opposition to Medicaid funding for abortion, his administration would develop tight regulations with the flexible framework our legislative language provided. You know I get the general feeling that I was absolutely wrong in, well, in believing the President when he was campaigning around the country and maybe even believing some of the earlier statements you were making on the subject——

Secretary CALIFANO. Mr. Michel——

Mr. MICHEL.——as I balance those statements with what I read in those regulations when they come out, and I have to assume with your full approval.

Secretary CALIFANO. Mr. Michel, I welcome the opportunity to comment on this.

Let me just state clearly and flatly, the President does not believe that Federal funds should be used for purposes of abortion, as he indicated during the campaign; I do not believe that Federal funds should be used to finance abortions.

I personally read the 267 pages of legislative history before I put those regulations out. We have copies of the legislative history which each member might want to have. We went through that; there was lots of difficulty, language not clear, lots of contradictory elements in the debate itself. For example, one of the issues with respect to the

regulations we have issued was whether or not medical procedures included abortions. The Senate was absolutely clear on that point. In our judgment, while the House was not as clear as the Senate, it, too, was pretty clear on that point.

MEANING OF "PROMPT"

Another issue was how the word "promptly" should be interpreted. In that connection——

Mr. MICHEL. I did not get the word, what do we mean——

Secretary CALIFANO. By the word "promptly."

You, yourself, Mr. Michel, on the word "promptly" said that prompt, and I quote from the debate, "Prompt leaves itself open to a number of days. Let us face it, pregnancy is a fact which cannot obviously be known until the rape victim has missed her first period." So sometimes that prompt covers a period that is at least in the 30-day range and treatment and reporting within 30 days would still be acceptable as "prompt." Much of the Senate debate said it should be a 90-day period. We ended up with a 60-day period.

Mr. MICHEL. I was going to ask you how you arrived at 60 days, because nowhere in our deliberations were we talking in those terms at all.

HOUSE VS. SENATE INTERPRETATION

You know I go through one item after another, and the House position was not—there is no place where the House position was taken at all in the regulations; it was a complete capitulation to the Senate's position. Even after enactment of the bill I wrote to you as author of the amendment finally adopted setting forth my interpretation of some of the terms used as defined in the debate on the House floor.

I know Senators Brooke and Magnuson wrote you likewise with differing views. Of course, in virtually every instance you accepted the Senate interpretation over that of the House. I would like to think, you know, I just had the feeling that what you were saying earlier and what you again reaffirmed today as your position and the President's position, would have led you just a little closer to supporting the House position when the legislative history was unclear. Since you didn't do so, I get the feeling it just could not have been a very strong commitment on your part or the part of the Administration.

Secretary CALIFANO. Mr. Michel, many people wrote to us. You wrote to us, many other members of the House wrote to us, many members of the Senate wrote to us after the debate. Those communications are not relevant in the context of interpreting legislative history. Indeed, in many cases the history was not clear.

For example, in your letter you indicated that you did not think that the term "medical procedures" included abortions. In the debate which I quoted from, you indicated that it would be at least 30 days. Well, I think it is generally recognized that after about 7 to 10 days what is involved is an abortion. So there was that kind of discussion.

The reason I wanted to submit that legislative history for the record is because I think anyone who takes the time to plow through that will come out about where we came out.

On the issue of "promptly," why did we come up with 60 days? It was clear that both Houses wanted to give the woman an opportunity to make sure she was pregnant; they recognized that reporting a rape or an incest is not an easy thing to do.

Mr. MICHEL. Yes——

Secretary CALIFANO. Often a young woman misses one period and then has her second period. In a situation where she missed one period and then had her second period, it seemed clear that the Congress did not intend that she be subjected to this reporting procedure. So if you give her 60 days, she will at least be sure she is pregnant before she gets into this.

As far as the other element, which is who must report, whether it is the individual victim or someone else who has to report in an exchange on the floor between you and Mr. Volkmer regarding the language of the statute, Mr. Volkmer says:

> The language says only reported; it does not say by whom.
>
> Mr. MICHEL. No, it does not.
>
> Mr. VOLKMER. It could be anyone.
>
> Mr. MICHEL. The Department of HEW may want to tie this down by rules, that could be done.
>
> Mr. VOLKMER. What is the gentleman's intention in that regard?
>
> Mr. MICHEL. I would not be one to force that particular victim as an individual to report.

Our reporting regulations allow either the victim or someone else to make the report; we narrowly defined Public Health Service, Public Health Office; we narrowly defined law enforcement agency; we required that the reports be made in writing by the individual reporting and that the certifications contain the name and address of the individual reporting, the name and the address of the victim, we require each of the documents——

Mr. MICHEL. I do not think you required that.

Mr. CONTE. The address is not required.

Mr. MICHEL. You do not require the address. That is one of the things I was going to ask. Why do you not ask for the address?

Secretary CALIFANO. We do require the address. It is not required in the regulation but it is required in the instruction that went out on February 13 from HCFA.

Mr. MICHEL. I am glad to have that clarification, because obviously, if I was not going to ask it, Mr. Conte was.

Mr. CONTE. Could we have a copy of that, Mr. Secretary?

Secretary CALIFANO. We will send up a copy of those instructions for the record.

[The document follows:]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
HEALTH CARE FINANCING ADMINISTRATION
WASHINGTON, D. C. 20201

REGULATION

ACTION TRANSMITTAL
HCFA-AT-78-10 (MMB)
February 3, 1978

TO: STATE ADMINISTRATORS AND OTHER INTERESTED AGENCIES AND ORGANIZATIONS

SUBJECT: Federal Financial Participation in State Claims for Abortions

REGULATION REFERENCES: 42 CFR 449.100 through 449.109

ATTACHMENTS:
1. Final regulations published in the Federal Register on February 3, 1978, setting forth rules governing Federal financial participation in expenditures for abortions funded through various HEW programs. The regulations are necessary as a result of enactment of Public Law 95-205.
2. Summary of provisions of these regulations.

EFFECTIVE: The regulations are effective on February 15, 1978 (12 days after publication).

ACTION REQUIRED: States must establish procedures to assure that the documentation, reporting, and public information requirements specified in the attached summary are met (Section II, items 1 - 6).

COMMENT PERIOD: Even though the regulations are effective on February 15, the Department will consider written comments or suggestions received by March 20, with a view to revising the regulations. The comments and suggestions received will be responded to by further publication in the Federal Register no later than 90 days after the date of publication of the regulations. Address comments relating to abortions funded under title XIX (Medicaid) to: Administrator, Health Care Financing Administration, Department of Health, Education, and Welfare, P.O. Box 2366, Washington, D.C. 20013.

INQUIRIES TO: Acting Regional Medicaid Directors. Should additional instructional material be required, it will be provided in subsequent transmittals.

Administrator

Attachment

HCFA-AT-78-10
2/6/78

SUMMARY OF REGULATIONS LIMITING
FEDERAL FUNDING OF ABORTIONS

Section 101 of Public Law 95-205 sets strict limitations on the Federal funding of abortions and requires the Department to "promptly issue regulations and establish procedures to ensure that the provisions of this section are rigorously enforced." Set forth below is a summary of those regulations governing Medicaid funding of abortions, which will be rigorously monitored and enforced by HCFA and the Inspector General, DHEW.

I. FEDERAL FINANCIAL PARTICIPATION

Federal funding of abortions will not be available except in the following three circumstances:

(1) when a physician has found, and so certified in writing to the applicable State agency, that on the basis of his/her professional judgment, the life of the mother would be endangered if the fetus were carried to term;

(2) when two physicians have found, and so certified in writing to the applicable State agency, that on the basis of their professional judgment, severe and long-lasting physical health damage to the mother would result if the pregnancy were carried to term; and

(3) for medical procedures, including abortions, performed upon a victim of rape or incest if the State agency has received signed documentation from a law enforcement agency or public health service stating that: (a) the person upon whom the medical procedure was performed was reported, within 60 days of the incident, to have been the victim of an incident of rape or incest; and (b) the report included the name, address and signature of the person who reported the rape or incest.

II. DOCUMENTATION REQUIREMENTS

To ensure that Federal funds are used to pay only for those abortions specified in the Act, States must satisfy each of the following documentation requirements:

(1) States must have the documentation and certifications described above in hand prior to paying the provider for the abortion;

(2) States must maintain copies of the documentation and certifications for three years pursuant to requirements at 45 CFR 74.20, et seq;

(3) all documentation and certifications must be in writing;

(4) States must safeguard against improper disclosure of the information contained in the documentation and certifications;

(5) States will report to the HCFA Regional Medicaid Director, at the close of each quarter, the number of abortions reimbursed in each of the above three categories; and

(6) States are responsible for providing appropriate information and clarifying materials to beneficiaries, provider groups and other affected organizations.

The regulations do not specify the form which the documentation and certifications must take in order to satisfy the requirements for Federal funding. However, the following are examples of the types of certifications and documentation which will satisfy these requirements.

(1) Life of the mother.

I, Dr. John Smith, certify that on the basis of my professional judgment, the life of Jane Doe of (address) would be endangered if the fetus were carried to term.

/S/
John Smith, M.D.

(2) Severe and long-lasting damage to physical health.

I, Dr. John Smith, certify that on the basis of my professional judgment, severe and long-lasting physical health damage to Jane Doe of (address) would result if the pregnancy were carried to term.

/S/
John Smith, M.D.

It should be reemphasized that two physicians must certify that a woman would suffer severe and long-lasting physical health damage if the pregnancy were carried to term for an abortion to qualify for Federal funding under this exception. Both physicians may sign the same certification or they may submit separate certifications.

(3) Victim of Rape or Incest.

(a) I, John Smith, of the Greenleaf Public Health Service (or Greenleaf Police Department), received a signed report from Mr. Roe of (address) that Jane Doe of (address) was the victim of an incident of rape (or incest). The report was made within 60 days of the reported date of the occurrence of the incident and included the name, address, and signature of the person making the report.

/S/
John Smith, M.D.

(b) I, John Smith, of the Greenleaf Public Health Service (or Greenleaf Police Department), received a signed report from Mary Doe on January 29, 1978, stating that Mary Doe of (address) was a victim of a rape (or an incident of incest) which occurred on January 15,1978. The report included Mary Doe's name and address and was signed by her.

/S/
John Smith, M.D.

CERTIFICATIONS REQUIRED FOR PAYMENT

I might note, if I may, that we have provided samples of model certifications required before payment can be made for an abortion under the three exceptions. We require the name and address of the physician certifying that the life of the mother is at stake, and we require a signed certification by the physician. Where two physicians have to certify that the mother would suffer from severe and long-lasting health damage if pregnancy were carried to term, we require the name and address and all the relevant information.

For law enforcement purposes we require what is indicated, the name of the victim and the other individuals, both their addresses, the date of the occurrence, the signature of the person making the report.

AUDIT OF MEDICAID ABORTIONS

I also would like to announce that around the 10th or so of May, we will begin an audit by the Inspector General of a sufficient number of States to cover what we estimate to be roughly 75 percent of the abortions likely to be performed under these regulations. It will be a very intensive audit, more intensive than in other parts of the Medicaid program. So we will keep track of this as best we can.

Mr. MICHEL. I had made that point sometime during the course of our debate, that I would hope that we would have some real sound figures upon which to base some future judgments, because there were all kinds of figures being thrown around and you know the issue is not dead and it is not going to go away.

ABORTION LEGISLATION

Let me ask you, since we really ought not to be dealing with that subject as a rider on this bill—is there any plan on the part of the administration to go the legislative route in that area at all?

Secretary CALIFANO. Not that——

Mr. MICHEL. By a legislative proposal before whatever committee, judiciary, whatever it is?

Secretary CALIFANO. No. I have been told Senator Magnuson said during our Appropriations Committee hearings on the Senate side that he intended to introduce a variety of abortion bills into the Senate to get them into the substantive committees.

I know from just reading the newspapers that both the Speaker and others in the leadership think that the Appropriations Committee is not the appropriate place to consider these issues, but I think——

Mr. O'BRIEN. If the gentleman will yield, that may well be true, Mr. Secretary, but if you do not get a bill to come out of the proper committee to deal with the issue of, say, the constitutional amendment that many of us feel is a significant national issue, you have no other way to go.

Secretary CALIFANO. It is a point Congressman Brademas made vis-a-vis the Vietnam war when there was no chance to vote on it; the only chance to vote on it was through the Department of Defense appropriations statute.

Mr. MICHEL. I personally happen to be one of those individuals who does not like to see our Constitution cluttered up with amendments

for busing, for abortion, for booze, or anything else of that nature. But by glory, you know, it is hard for us to sustain that position when there is a significant number of people who think there ought to be at least a shot at some legislative remedy.

Mr. Chairman, I understand——

PHYSICIAN ACCOUNTABILITY FOR ABORTIONS

Mr. CONTE. Will you yield so we can get the record clear?

Mr. NATCHER. Go right ahead, Mr. Conte.

Mr. CONTE. Mr. Secretary, do these new regulations or instructions that you are going to submit for the record have any provisions for accountability on the part of the physician who performed the abortion so that we can prevent any widespread abuse or fraud by the physician?

Secretary CALIFANO. We rely on the physician's judgment on whether or not the mother's life would be in danger if the fetus were carried to term. We do require, as the law requires, that we get two signed certifications that there will be severe and long-lasting physical health damage to the mother. We are also developing regulations to go out shortly which will prohibit either of those physicians from having a financial interest in the performance of the medical procedure, in this case the abortion.

We will not pay the physician in cases involving report of rape or incest to a law enforcement or public health authority unless the papers of certification are submitted with the form, something we do not ordinarily require under Medicaid, which will give us a better opportunity to audit.

I should not minimize the audit difficulties in this area. We can do some spot checks, and, obviously, where we find egregious cases, the audit will not be too difficult. But the issues involved in questioning individuals about their personal life, in getting into questions of women who claim they were subjected to incest, and the privacy considerations in those areas, are not easy problems. This is a very difficult thing to deal with.

Mr. MICHEL. Mr. Chairman, I understand you wanted to move along.

LACK OF PRESIDENTIAL LEADERSHIP ON ABORTION ISSUE

Mr. O'BRIEN. Would you yield for one more question?

Mr. NATCHER. Go right ahead, Mr. O'Brien.

Mr. O'BRIEN. I think it was reported in the New York Times not long ago that when an agency drafts regulations to implement the law, policy as well as legal procedures are discussed. I think the comment made by the paper was that there was literally no discussion of policy.

Following what I understand to be your personal position and that of the President, it was my conviction that during that 6 months' debate, Mr. Secretary, any leadership by the President was conspicuous by its absence. May I put the question directly to you as his representative:

Do you anticipate that he will take a more vigorous stance in trying to resolve the controversy if we get into it again——

Secretary CALIFANO. Let me make a couple of comments.

The article to which you refer in the New York Times had twelve factual errors in it. It was an article of the "News of the Week in Review," by Shabecoff. It was riddled with factual errors, so I do not consider that it furnishes a basis for making a judgment on what happened.

My responsibility in drafting these regulations was to try and reflect accurately the law that Congress passed. My personal views and the President's personal views were not relevant to performance of that legal duty. It was the Secretary who was directed to issue regulations and to enforce them vigorously. I have established all these certification requirements, I have set up procedures for the coming audits by the Inspector General to comply with the rigorous enforcement portion of that statute, something we found no precedent for in any other statute ever passed by the Congress.

The President's views on the subject of Federal funding of abortion are abundantly clear. I know them very clearly, he and I have discussed them on many occasions. My views are abundantly clear as to what the public policy of this country should be. Those views were absolutely irrelevant in drafting this legislation. The only thing that counted was for me to do the best I could and to divest myself of my own person views and to try to do the best I could in going through those documents.

I daresay there are few people in this country who have read every page of that 267 pages of legislative history. I read it. I spent hours with the lawyers on this subject, trying to figure out what the Congress intended—not what I thought was right or what I thought was wrong or what I thought was good public policy or what I thought was bad public policy, but what I thought Congress intended. I did the best I could.

Mr. O'BRIEN. I understand that, only the bottom line I had was, I find that the President does not hesitate to inquire of me my views with regard to the B–1 bomber, he urged me to vote a certain way because he thinks that his view there is very important, he takes a leadership stand. I regard this issue as a very important one and I do not think he took a leadership stand on it the last time.

My inquiry is, do you expect he will continue——

Secretary CALIFANO. Let me say, I suggest you talk to Chairman Mahon. I talked to Chairman Mahon several times during the course of the debate in the House. If there had been anything that we could have done fruitfully, I think we would have been happy to do it. I think the problem is, as the Speaker himself noted, this is an issue on which men and women in the Congress are voting their conscience and the ability to twist an arm, if you will, to use the jargon of the legislative-executive relationships, in some respects, or to change a mind or to deal with some peripheral matter that may also help get a vote on this, that ability does not exist in this area.

I have probably discussed this subject with 70 or 80 members of the House and 40 senators, and I have not changed anybody's mind on this subject, and they have not changed my mind.

I think what you all went through during the course of that conference is an indication of how difficult it is to do that. If the Presi-

dent thought or if I thought that our injection in a more active way into the conference between the House and the Senate would have produced something, we would not have hesitated to come in, but it was clear that it would not. I mean, I think I could spend all the time in the world sitting down with Senator Magnuson and Senator Brooke and Senator Bayh, and I would not change their mind one iota.

So I do not think there was anything else we could have done. We repeatedly make our views known. I made my views and the President's views known again this morning.

BUDGET FOR GRANTS AND CONTRACTS

Mr. NATCHER. Mr. Secretary, we want to thank you for appearing before our committee at this time in behalf of your budget request for the fiscal year 1979.

Now according to the figures you presented, Mr. Secretary, you propose to spend some $181 billion. This would make your department the largest Federal department as far as spending is concerned; that is correct, is it not?

Secretary CALIFANO. Yes, sir, Mr. Chairman.

Mr. NATCHER. How much of your budget is for grants and contracts?

Secretary CALIFANO. About $8 billion.

Mr. NATCHER. $8 billion, grants and contracts——

Secretary CALIFANO. I am sorry, I was thinking about grants and contracts in a negotiated or competitive way.

Mr. NATCHER. Yes. In fact, Mr. Secretary, I believe that about 93 or 94 percent of your entire budget request is for grants and contracts, is that not right?

Secretary CALIFANO. That is about right, Mr. Chairman.

I am sorry, I misunderstood.

Mr. NATCHER. Yes. Can you tell us approximately how many grants and contracts that you have? If not, you can submit that for the record.

Secretary CALIFANO. I will submit that for the record.

[The information referred to follows:]

Grant and contract awards, fiscal year 1977

	Amount (millions)
58,455 grants	$29,015
12,624 contracts	1,538
71,079 total	$30,553

Grant awards shown above are exclusive of amounts such as (1) payments to individuals (Basic Educational Opportunity Grants, Special benefits for Disabled Coal Miners, etc.), (2) appropriations to the Special Institutions, (3) interest subsidies for the Guaranteed Student Loan and Health Teaching Facilities programs and (4) benefit payments under the AFDC program.

AUDIT OF GRANTS AND CONTRACTS

Mr. NATCHER. After a grant has been approved, Mr. Secretary, what do you do to make sure that the money is being expended according to the requirements at the time the grant was approved.

The reason I say that to you, a number of years ago, Mr. Secretary, we had an individual in this country who had received a number of grants from HEW. He proceeded to write letters to the newspapers and to most members of the subcommittee, calling for more money to be appropriated in certain categories. We did a little checking on him, Mr. Secretary, just to find out who he was and what he was doing.

We found out that he was under investigation in Federal court. Now that is a part of the hearings 7 or 8 years ago. What do you do now as far as the issuance of the grants to see that this money is properly expended?

Secretary CALIFANO. Mr. Natcher, we have substantially enhanced our audit capability and I think the institution of the Office of Inspector General, which the Congress created just before I became Secretary, has been a tremendous help.

To give you a sense of that, and a sense of the increase in our auditing and investigatory operation, in March of 1977 we had about 345 cases in our Inspector General's Office, 264 of which were under active investigation. These are auditing of grants and contracts, what have you. At the end of 1977, on December 31, we had 721 cases, 646 of which were under active investigation.

We have also requested more quality control people in the Medicaid area and in the AFDC program. In AFDC we are doing a lot. We have a whole host of programs and had meetings in New York City just a couple of weeks ago to try and make sure that the States and cities are running those programs in a much better way.

Mr. NATCHER. Pardon me if I interrupt you.

Do you feel generally that as far as grants are concerned that the system now in use is better than during the past several years as far as following the grant to see that the money is being used according to the requirements at the time the grant was issued and approved?

Secretary CALIFANO. I think it is better, but I think there are lots of other things we can do. Just very quickly, we need more sophisticated sampling techniques. On the $8 billion which I mentioned of grants and contracts made largely to individuals and organizations, we had no certified contracting officers, not a single certified contracting officer in HEW. In three years everybody will be certified under our new program. As a result, many of those contracts were so loosely written that they are unenforceable in any lawyer-like sense of telling people what they ought to be doing. We gave them such fuzzy tasks that there is no way to deal with it.

I may want to submit additional things for the record that I think we should be doing. I do not know how fast we could get them in place, with respect to the States and cities that are getting the large grants.

Mr. NATCHER. Thank you, Mr. Secretary.

ANTISMOKING INITIATIVE

Mr. Secretary, on January 11 of this year you announced a vigorous new program to discourage smoking. You went on to say that you are establishing an Office of Smoking and Health in the immediate Office

of the Surgeon General. The new Office of Smoking and Health would, according to your statement, be established within current position levels under the authority contained in Public Law 94-317, the National Consumer Health Information and Health Promotion Act of 1976.

Mr. Secretary, you may find that any attempt on your part to control the personal habits of the people in this country will be a right difficult task and I say that to you frankly. We have too much control now and people continue to object to more controls promulgated at the Federal level and promulgated daily.

As I understand, in your speech on January 11 you stated that you were determined to permit the American citizens to make a genuinely free choice about smoking and their own health; that is correct, is it not?

Secretary CALIFANO. That is correct, Mr. Natcher.

Mr. NATCHER. Further, Mr. Secretary, I believe that you have stated this morning to the committee that as far as this program is concerned it would be a voluntary program and you would let the individuals make up their own mind, is that correct?

Secretary CALIFANO. That is correct, Mr. Natcher.

REPROGRAMMING FOR ANTISMOKING CAMPAIGN

Mr. NATCHER. Further, in this speech on January 11 you said that certain moneys would have to be reprogramed. Have you made a request to the committee now to reprogram any money?

Secretary CALIFANO. Mr. Natcher, that was a loose use of the word "reprogramming." There was an exchange of correspondence, a letter from the chairman on February 1, and my response on February 8. There is no need to reprogram any money in fiscal 1978. The money will be used within the same line items that it would otherwise have been used in.

Most of the money is for research, as you know; some of it, a small amount in 1978, is for health education, and it is in the same line item, but you are right that I used the word in a speech, and the word was a mistake. I do not have it with me, but I would like to submit for the record my testimony before the Health Subcommittee.

Mr. NATCHER. You might submit that to the staff, Mr. Secretary.

Secretary CALIFANO. To the staff if I may.

[The information is available in the Subcommittee files.]

Mr. NATCHER. As far as the use of the word "reprogramming," there is, as one member of the subcommittee I would agree, on $500,000 of unearmarked funds added by the Congress to the National Cancer Institute, that that would not require a reprogramming.

I further would agree with you, Mr. Secretary, on $500,000 from unearmarked funds by the Congress to the National Heart Institute. I would agree that those two $500,000 items would not have to be reprogrammed and no reprogramming request would be necessary.

When it comes to my turn again, Mr. Secretary, to question you before you leave today, I will go into detail with you about the item of $1.2 million for the research budget of the National Institute of Mental Health.

Under the rules of this committee, Mr. Secretary, and under the rules of the full Committee on Appropriations, I believe that is a request that you have to come up and ask be reprogrammed. In addition to that, $1.1 million to expand the smoking and health education efforts under the leadership of a new Office of Smoking and Health, that would have to be reprogrammed, Mr. Secretary.

Before the day is over, when it comes my turn again, I will go into detail with you again on those items that I believe that portion of the $3 million-plus that must be under a reprogramming request.

RELOCATION OF NATIONAL CLEARINGHOUSE ON SMOKING & HEALTH

Now, Mr. Secretary, in your speech and in the press conference that you held during the month of June, you said that you were bringing the National Clearing House and Smoking and Health section back to Washington where it had been exiled in Atlanta, Georgia. Did you mean that, Mr. Secretary?

Secretary CALIFANO. Yes, Mr. Natcher.

Mr. NATCHER. Tell us what you mean by being exiled in the home State of the President. Go into right much detail about that for me, Mr. Secretary, please.

Secretary CALIFANO. Mr. Chairman, that office had been in Washington, D.C., and I think in the Sunday New York Times there is a story which details how pressure from the tobacco industry during the Nixon administration was brought to move the office out of Washington to Atlanta. Their budget was sharply reduced to $900,000. I would like to submit the article for the record. I do not have it with me.

[Clerk's note: The article appeared in the Feb. 19, 1978, New York Times and is also available in the Subcommittee files.]

Secretary CALIFANO. The most devastating killer in this country is smoking, and it begins with children. It is the single most damaging preventable act that human beings can perform on a continuing basis. It seemed utterly inappropriate to me to have an activity designed to disseminate information to the American people about the dangers of smoking and then to bury that activity out in the field where it will get no attention. That is why we are moving it back to Washington where it was. It is a major initiative in the area of preventive health that I think we must undertake because the evidence is so overwhelming; it costs $5 to $7 billion a year in terms of health care, $12 to $18 billion in terms of lost work productivity, what have you.

It deserves an investment and kind of attention at the national level adequate to educate people to the dangers, so they can make a genuinely free choice. I do not believe at the present time that there is enough information going out to our young people. We have 100,000 children under 13 as regular smokers, and 75 percent of the people who smoke get the habit before they are 21.

Mr. O'BRIEN. If the gentleman would yield.

Mr. NATCHER. Not at this point if you do not mind.

Go right ahead, Mr. Secretary.

Secretary CALIFANO. I just make those points. That is why I brought that office up, and that is why I have gone into this campaign.

STATISTICS ON SMOKING AND HEART DISEASE

Mr. NATCHER. On January 11 you said smoking was a major factor in 220,000 deaths from heart disease. On February 15 you said smoking was a major contributor to 175,000 deaths from heart disease. Which figure do you rely upon, Mr. Secretary, 220,000 or 175,000?

Secretary CALIFANO. I think the larger figure is all heart disease and the second, smaller figure is the cases of heart disease which smoking was the cause of. I will have to give you those numbers this afternoon. I thought I had them with me.

Mr. NATCHER. You might, the next time we go around you probably would have that figure and we will come back to it.

ROLE OF THE SECRETARY

Mr. Secretary, in going back under the authority of the law that you are now operating under, this same section of the law calls for this Office of Health Information to coordinate all such activities within Health, Education, and Welfare. It seems, Mr. Secretary, that you are reaching out beyond the department. You are stimulating the Treasury Department to raise cigarette excise taxes, the Federal Trade Commission to revise the warning label, the CAB to ban smoking on aircraft, the FCC to provide more free time for antismoking messages.

Where do you get your authority, Mr. Secretary, for this expansion of power, outside of HEW, that is?

Secretary CALIFANO. Mr. Natcher, I have an obligation to protect the public health under the law, and the Surgeon General has the same obligation. As far as the Treasury Department is concerned, we are simply working with them to see whether or not an increase in the excise tax on cigarettes would be appropriate. There is evidence in this country and abroad that an increase of 10 to 15 percent in the price of a pack of cigarettes will reduce the number of people who are smoking cigarettes.

The agencies you mentioned need no stimulation from me in the smoking area. They are, if anything, much more aggressive than HEW in their pursuit of both the issues relating to false advertising and also in their pursuit of data that the cigarette companies have about the behavioral research they have done to influence children to smoke, data which I hope they would give to our National Institute of Child Health and Human Development, data which the FTC has been trying to get from them.

As far as the Civil Aeronautics Board is concerned, Dr. Cooper, who was the last Assistant Secretary for Health in the prior administration, had already written to the FAA asking that smoking be prohibited in airplanes.

I simply am filing with the CAB in an ongoing proceeding so that they will have a record of our view that smoking should be prohibited in aircraft because it is a closed space. I think all of those things are well within the authority of the Secretary of Health, Education and Welfare.

Mr. NATCHER. Mr. Secretary, you mentioned Dr. Cooper. Dr. Cooper, to me, is one of the ablest men in this country. This afternoon when it comes my turn I want you to listen to one or two statements he has made along the same line that you have discussed with me during this colloquy that we have held this morning.

CHEMICAL EFFECTS OF TOBACCO

One other matter that I want to point out to you, Mr. Secretary: I was here in 1964 when the smoking and health report was issued by Dr. Terry. The Committee on Agriculture immediately set up a hearing and had Dr. Terry appear before the committee: During that hearing a question was asked as to whether or not if you burn spinach and tobacco, you get exactly the same chemical after-effect; whether it is inhaled, chewed, consumed as a liquid, that you get exactly the same effect.

Last year, Mr. Secretary, Dr. Rauscher, the Director of the National Cancer Institute, another able man, one that I think is one of the ablest men in this country—the hearings show last year upon being questioned that he was asked: "Dr. Rauscher, is it not true?" He said "It is true." All you have to do is look in the hearings, Mr. Secretary. He said it is true.

Let me say this to you: They point out to us from time to time, as far as cancer is concerned, Mr. Secretary, that we have thousands of things that cause cancer. We have over 100 kinds of cancer.

TOBACCO RESEARCH

You know, in the State of Kentucky, Mr. Secretary, in 1958, before the smoking and health report was issued, we started to do something about it. We said in Kentucky if tobacco is harmful to the health of the people in this country, something ought to be done about it. The State of Kentucky built a building, Mr. Secretary, that is now being used for research, with State funds, not Federal money, State funds. We put a small amount in the agricultural appropriation bill to start a research program at the University of Kentucky.

The people in the State of Kentucky since that time have voted additional tax upon themselves of about $4 million that goes into this research facility to investigate as to whether or not tobacco is harmful to the health of the people. Mr. Secretary, that is the way my people feel about it in the State of Kentucky.

We have 120 counties in Kentucky, 118 of them produce tobacco, 160,000 farm families, a $10 billion industry, paying into the Federal Government, as you and I know, a little over $6 billion a year in taxes. So, Mr. Secretary, a little later on when it comes my turn again today we will go into a little more detail about this matter.

Thank you, Mr. Chairman.

Mr. FLOOD. Mr. Patten?

HEALTH RISK OF ALCOHOL

Mr. PATTEN. I was glad to see that you added $5 million toward alcohol research. You have been trying very hard.

In my life experiences, far and away the champ, the enemy of health, the enemy of my families is booze. If you want to know the economic loss to this country. I have figures many times the figures you cited on tobacco. At Rutgers we have the only real center on alcohol for the whole United States. It used to be up at Yale. It was transferred to Rutgers, so I am glad somebody in the department is aware. I know in my local hospital, the few dollars we get from the Federal Government do a world of good. Everybody says it is a wonderful program. We can talk about so much in your programs. I am going to forego it because obviously everybody is loaded for bear here this morning.

When they moved that institute down there to Atlanta, it made me think of Gone With the Wind. But here it is back again.

So it is good to see you, Mr. Secretary.

Secretary CALIFANO. Thank you, Mr. Patten.

Mr. PATTEN. I am going to yield.

Secretary CALIFANO. I would note, as I said earlier, that we spend about $174 million on alcohol problems, and we are proposing to spend only $30 million on cigarette problems.

Mr. PATTEN. What we collect in taxes, do you want to make a comparison? Do you know what we get from booze in the United States? We collect over $10 billion in taxes in the United States. It is number one on the hit parade.

Mr. FLOOD. Mr. Conte.

ABORTION STATISTICS

Mr. CONTE. Mr. Secretary, how much did we spend on Medicaid abortions last year with the amendment we had?

Secretary CALIFANO. Mr. Conte, I do not know. The unfortunate thing about abortion numbers is that we do not have accurate figures. Most of the figures are pulled out of the air, the so-called 300,000 people who will not be able to get abortions, nobody knows whether that figure is accurate or not. We now have in place, I hope, a system which will give this subcommittee some better data next year, but we simply do not know, we do not have computers programmed in the right way and we do not have data collected in the right way.

Mr. CONTE. With the data reports, will you be able to present us with those figures next year?

Secretary CALIFANO. I hope so. We put an annual report out which I can submit for the record, that CDC puts out generally on the subject of abortion but they are even concerned about the soundness of those figures.

(Clerk's note: the report which covers data for 1975 only is available in the Committee files.)

Mr. CONTE. In other words, data on Medicaid payments does not breakout information on abortions.

Secretary CALIFANO. We do not have a breakout in Medicaid payments that is worth anything.

ADMINISTRATION'S RECOMMENDATIONS REGARDING ABORTION LANGUAGE

Mr. CONTE. I do not mean to put you on the spot, but I only ask for information. Do you have any recommendations for this committee?

Certainly we are going to be facing this issue once again, as sure as night follows day.

Do you have any recommendations to us on what language should be in there?

Secretary CALIFANO. Our recommendation would be to go back to the things that the President supported during the campaign, namely, no Federal funding for abortions except where the life of the mother is at stake, treatment for rape and incest. That would be our recommendation. Whether that is possible or not I do not know. It is an incredibly difficult problem.

I do not wish anybody the task of reading the material that I read, but I think the difficulty of dealing with this issue on the floor of the Congress is apparent from reading that.

Regardless of anyone's view on the subject, one of the things that was helpful during the course of the time that the Hyde amendment was in effect was that States and municipalities were forced to debate this issue face-to-face and learn that there are people of good will, extremely good will on both sides of this issue. We pushed it down into the grass roots.

One of the problems—it is not just with this issue but there is a host of others, with Federal funding of health care generally—is that it creates instant national issues of a whole host of problems. All the problems relating to fetal research, psychosurgery, life extension equipment.

We are now dealing with the question, when does somebody begin living? The Congress in no time is going to have to deal with the issue, when does somebody die?

My own instinct, based on my personal experience over the last year, is that we would be better off as a country if somehow or other these issues could get more thoroughly debated town-by-town, city-by-city, and State-by-State before they flash onto the national scene in Washington.

[The following letter was subsequently received:]

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D. C. 20201

February 21, 1978

The Honorable Daniel J. Flood
Chairman
Subcommittee on Labor, Health,
Education & Welfare
Committee on Appropriations
U. S. House of Representatives
Washington, D.C. 20215

Dear Mr. Chairman:

At the hearings today on the HEW Appropriations Bill for fiscal year 1979, your committee requested that I put in writing the Administration's views with respect to Federal funding of abortions.

As I stated during the hearings, we believe that, as a matter of public policy, Federal funding of abortions should be restricted to two situations: first, where a doctor certifies that in his or her opinion the life of the mother would be endangered if the fetus were carried to term; and second, for the victims of rape or incest, where such rape or incest has been reported promptly to a law enforcement agency or a health facility which is an agency of the Federal, State, or local government. In the case of rape or incest, we believe that present law requires the 60 days specified in the regulation as the period Congress intended for prompt reporting. In order to reduce the potential for fraud and abuse, it may be advisable to reduce that period to a shorter period of time. (As I indicated before the subcommittee, to comply with the rigorous enforcement requirement contained in the statute, we have issued detailed instructions and will conduct meticulous audits.)

As provided under the current law and under the 1977 law, Federal funding should be permitted for drugs or devices to prevent implantation of the fertilized ovum and for medical procedures necessary to terminate an ectopic pregnancy.

Sincerely,

Joseph A. Califano, Jr.

cc: Subcommittee Members

EMPHASIS ON CHILD HEALTH

Mr. CONTE. Mr. Secretary, I am in favor of the emphasis placed on improved services for children and youth. I note that your proposal in this area included a request for a $142 million increase to provide health and related services to adolescents, with special emphasis on avoiding unwanted pregnancies, introduction of new legislation making all low-income pregnant women eligible for Medicaid, and new legislative reforms for child welfare services.

Are these new programs designed to provide poor women and others improved prenatal and postnatal care as alternatives to abortion?

Secretary CALIFANO. Both, Mr. Conte.

I think the increased dangers to the life of an individual whose mother does not receive proper care in the prenatal period, whose mother does not have the proper diet in the prenatal period, all of those things are problems that I think affect the poor people in the country more than other people, and problems which we think increased Federal coverage for health care will help take care of.

CONTRACEPTIVE SAFETY

Mr. CONTE. What is the process of testing birth control devices before the safety of that device is decided? It seems odd that after such a device is placed on the market, supposedly as an effective product, that statistical data and consumer reports indicate that these devices must be recalled and restudied.

Are we doing enough in this field?

Secretary CALIFANO. We have asked for an increase in the personnel in the Food and Drug device area to enhance our capability there. We have only been in that area for a relatively short period of time. That is the device part, the IUD part of this.

As products are found to be dangerous, they are taken off the market. On the pill, as we have indicated, if you smoke, do not take the pill, and if you take the pill, do not smoke. There are dramatic increases in the danger of death due to heart attack for women who both smoke and take the pill.

As Commissioner Kennedy indicated, if he were advising his own daughters he would advise them not to take the pill. Part of the problem in that area is why with all the testing you do with a drug before you clear it, you learn a lot when it goes out into hundreds and hundreds of thousands of people and you get much, much higher samples, much better indications. There is no way to do some of that before.

Part of your concern is also why we have suggested such a substantial increase in research for the National Institute of Child Health and Human Development, to look into this whole area.

TEENAGE PREGNANCY

Mr. CONTE. Have you studied data from the teenage pregnancy clinic in Boston? The data indicates that many teenage girls become pregnant because they want to become pregnant. They feel unwanted in the family and in society, and this is one way of gaining security

and a sense of responsibility. They have children and then go on welfare when they become unable to support their children after the father has left. The staff of the Boston clinic talks to the girl, gives her psychiatric treatment, helps her along her pregnancy stage, et cetera. This counseling has a positive ripple effect because its clients often bring in a friend for company; and hearing these conversations, the friend realizes it is not the best thing in the world to go out and become pregnant.

I wonder if you are familiar with that.

Secretary CALIFANO. I have not personally been up there, but my staff has, the task force that worked on the Teenage Pregnancy Program, there and at Johns Hopkins, and other places and formed the basis for the proposed legislation we will submit for the Adolescent Health, Services and Teenage Pregnancy Act. They provide something a large number of family planning clinics do not provide, which is the kind of personal counseling needed in these situations. That is also why we have an increase in the budget here.

NURSING EDUCATION CUTS

Mr. CONTE. My time is just about up, but in closing I want to say to you that, though I have given you plaudits, I agree with the chairman that the nurses have been done in here.

You look at the figures—Capitation Grants, minus $30 million; advanced nurse training, minus $12 million; special projects, $7.5 million. You have a total cut of $47 million in loans, scholarships, training, loan repayment, fellowships; programs that some of us on this committee have worked long and hard for through the years.

I happen to have a close association with nurses, having married one. I do not know how you could do a thing like this.

Secretary CALIFANO. Mr. Conte, I am, in all candor, surer of our judgment with respect to doctors and the excessive number of doctors in specialties than I am of our numbers with respect to nurses.

I do think we—I gave the numbers to the chairman—I will put the other data we have in the record—of studies that we think justify the action we took with respect to the capitation support for nursing.

[The information referred to follows:]

SUPPLY AND REQUIREMENTS FOR NURSE PROFESSIONALS

Source Book on Nursing Personnel, Department of Health, Education, and Welfare Publication, Health Resources Administration 75-43, December 1975. This study indicated that by 1980 the supply and requirements for registered nurses would be approximately equal.

First Annual Report for Nursing. This report was sent to Congress in November 1977. It provides detailed information on the increasing supply of nursing professionals.

Second Annual Report for Nursing. This report is now being prepared by the Department and will be sent to Congress as soon as it is completed. This report will provide detailed information on the supply and requirements for nurses.

Mr. CONTE. How about the other supports I mentioned. You cut just about every program on nurses. With a new health bill, which will come out of the Congress either late this year or next year, there is going to be an increased demand for nurses to work in the health fields, and they will not be there if you cut them out now.

Secretary CALIFANO. In terms of student assistance, there is money available for nurses under the basic educational opportunity grant program, the BEOGS program. That is need-based through $1800 if our proposal is adopted. They can also get loans under the guaranteed student loan program.

I think we do propose continued support of $13 million for training for about 850 nurse practitioners of the kind I indicated we would like to see more of, and $7.5 million for special projects to help promote improvements in the curriculum.

Mr. CONTE. That is advanced training, Mr. Secretary——

Secretary CALIFANO. That is correct.

Mr. CONTE [continuing]. Not the basic training.

Secretary CALIFANO. That is correct.

Mr. O'BRIEN. Will the gentleman yield?

Mr. CONTE. Did you make these requests of OMB or did OMB cut you down in all these categories?

Could you supply me with what you asked OMB for the nurses program?

Secretary CALIFANO. Yes; I will give you all that.

[The information referred to follows:]

DEPARTMENT REQUEST TO OMB FOR NURSING

The Department asked OMB for $35.5 million for nursing programs in 1979. This would have continued the Nurse Practitioner and Special Projects programs at $13 and $15 million respectively. The request included $7.5 million for nursing scholarships which would have been a reduction of $1.5 million from the 1978 level.

Mr. O'BRIEN. On that point of nurses, this is a personal experience, I am not sure it is totally relevant, but just recently my mother had a bad hip fall, terrible fracture; my wife went back to help her over a period of time. She must have spent a whole day calling around trying to get nurses, private nurses. Maybe that is different, but it seems to me they just were not in such great supply as we needed in that circumstance.

I kind of share Mr. Conte's view that I would take a hard look at that situation before I go back.

Mr. FLOOD. We will adjourn now till 2:00 o'clock.

[The hearing resumed as scheduled.]

Mr. FLOOD. The witness is Mr. Obey's.

Mr. OBEY. Thank you, Mr. Chairman.

Mr. Secretary, before I ask any questions I had in mind, I wanted to say two things. First of all, I want to say I personally am glad to see you are in the seat you are in, because I think you have shown two things: Number one, that it is possible to be for programs and still be concerned how effectively they are administered, and, secondly, you have been able to show that it is possible to concern yourself with administration of a program without gutting the program, itself, and I think both of those are important qualifications for anybody in your position.

REPROGRAMMING

I also want to take up on something Mr. Natcher was mentioning earlier. Let me just say I think your initiative on cigarette smoking is correct. I don't know what makes people quit smoking. The only thing

that made me quit was my wife said she wouldn't marry me if I didn't. That worked for me, but I don't know that it would work for everyone.

I think it is important that you do what you are trying to do. I do agree with Mr. Natcher, however, on the process by which it is being suggested that it be done.

If I can give a speech for a minute, what is really involved here is, I think, the nature of this committee and the nature of Congress, as an institution, because there is really very little that any individual Member of Congress can do to affect the society in which he lives or to affect, if you please, the work product of Congress as an institution.

It becomes terribly frustrating, and I think institutionally very troublesome, if we are told that even though the committee votes a very large sum of money under a series of conditions spelled out in a report that that can be changed without going through a process which gives us an opportunity to make a judgment as to whether that is a sensible change or not. And I would like to tell you the same thing I told the President when I talked to him about this issue, not about the cigarette issue, but about another issue, and that is it is very frustrating when we realize that a whole year of our work can be wiped out almost anonymously without an opportunity for us to vote on whether it should be or not.

What concerns me, for instance, if I can speak very selfishly, is that if this initiative goes through—for instance, if I understand it correctly, there is $1.2 million which would affect NIMH funds. There were a number of add-ons made by the Congress in that area. One of them was one which I had in this committee relating to research on pharmaceuticals, to research the side effects of drugs like Thorazine and Lithium as applied to medical patients, and it just seems to me that if those funds are in danger of being wiped out because they happen to be in the same line item, that there really isn't much point in my doing the work I do in this committee, because that work can always be wiped out whether it is by a stroke of the President's pen in regard to personnel ceilings or by an initiative of this nature.

So I would just urge you to send up your programs and reprograming requests, and if the committee is convinced that the items that are being reduced are acceptable items, I think you can win them in this subcommittee, and I urge you to do that.

Secretary CALIFANO. Mr. Obey, let me first say the amount we plan to re-target, if you will, is not a large amount. Secondly, none of the money is earmarked money of the kind you are mentioning for the project you are mentioning. That will all be retained. The procedure makes no difference to me. I have no problem with it, and obviously this committee is the ultimate arbiter of what is reprograming and not reprograming.

Up until this point in time, it had always been assumed money spent within the same line-item was not reprograming. If this committee wants me to submit a letter with respect to those items, even though they are in the same line item because they involve the smoking issue, I am happy to do it. I have no problem with that.

I understand your point of view very well, and we weren't as successful as I thought we would be, but I tried this year for the first time at HEW to take all those things that were listed as questions or studies or programs in the committee's report, which really is as in-

formative as the appropriation, itself, and make assignments and set deadlines for people to report back here so we could report to the Congress.

I think we got about 70 percent of it done. That is nowhere near 100 percent, but it was more than the 20 percent or so done in the past. So I have no problem with that at all.

Mr. OBEY. That is good.

DEPARTMENT OF EDUCATION

Let me ask you a series of questions about education.

The President has suggested or asked for a separate Department of Education. I frankly have great misgivings about that because I think the education community would be trading power for visibility, and I am not sure I would like to make that trade were I in their position.

While one would presume that the Department of Education would take all of the Office of Education, would it not be logical that educational efforts in other departments would be consolidated in the new department as well? What other functions would you see as being moved into this new Department of Education?

Secretary CALIFANO. Mr. Obey, when the President spoke to that he said, and I quote from his most considered statement during the campaign: "I am in favor of creating a separate cabinet level Department of Education. Generally I am opposed to the proliferation of Federal agencies, now numbering some 1,900, which I believe should be reduced to 200. But the Department of Education would consolidate the grant programs, job training, early childhood education, literacy training and many other functions currently scattered throughout the government. The result would be a stronger voice for education at the Federal level."

I believe now being looked at are all the veterans programs for education, the Labor Department job training programs, the National Science Foundation, the Arts and Humanities, the Indian school programs in the Interior Department, the Defense Department schools in the Department of Defense, the school nutrition programs in the Agriculture Department, which are part of the Ribicoff bill, the Head-start program, the day care programs, the college housing loans from the Department of Housing and Urban Development, some programs out of the Community Services Administration, the institutional training programs out of CETA Title II, and I am sure some others.

There are 14 student assistance programs outside HEW, and until the latest proposed increase in BEOGs, the biggest student assistance program in the government was in the V.A. So all of those are candidates for inclusion within the Department of Education.

As he said during the campaign, the President indicated that he would reach wide and consolidate many of those programs.

ALTERNATIVES TO EDUCATION DEPARTMENTS

Mr. OBEY. Let me ask you this: I know you are in a position where you have to defend the President's proposal, and I would expect you to, but if that should fail, and I frankly hope it does, if it should fail.

is there any means by which educational programs could get greater prominence and visibility without requiring legislative action?

Secretary CALIFANO. Without any legislative action at all in terms of the administrative powers that I have, with a few exceptions, I think that I and the Commissioner of Education have gone as far as we can go in reorganizing the Education Division. I believe that short of a Department of Education, the best thing to do would be to have some kind of a reorganization plan.

There are a couple of problems. One is the problem of the two-headedness of the Education Division, an Assistant Secretary, on the one hand, sitting at the head of the Education Division, and a Commissioner of Education with virtually all the funds going to the Education Division appropriated directly to him.

Secondly, I think some elevation of position is appropriate, particularly in terms of an evolutionary step. I think one evolutionary way to go would be to make the current Under Secretary of HEW Deputy Secretary—since the Defense Department has one, and State has one, and that is appropriate for the kind of budget we have—and then create an Under Secretary of Education.

I think that when you look at HEW five or 10 years out, it is going to evolve that way, or something similar to that way.

Within the Education Division, I think the research and statistical programs should be put in one place. There should be some kind of an organizational entity within the Division to consolidate the teacher programs, if you will, the teacher training, the teacher corps, the teacher center kinds of programs new scattered. There should be some bureau for students, if you will, a little broader than the Bureau of Student Financial Assistance, and then a reorientation of some of the existing bureaus.

But I think the way the legislation is now going, you would need a reorganization plan to do that.

JOB-CREATING PROGRAMS

Mr. OBEY. Thank you.

Thirdly, last week, the Labor Department testified their prime sponsors are paying such high salaries under CETA that the average cost per job is nearly $9,200. We have supported CETA, at least I have on this committee in the past, partly because we were told it was the least expensive way of creating new jobs.

But I learned last week that in the community action program you create a lot of jobs for considerably less than the cost of a job under CETA. I can't believe that there are not areas in your budget where you couldn't do the same thing.

Let me ask, for instance, is there room for personnel expansion under Head Start without wasting money and create jobs for less than $9,200 that we have to pay for CETA jobs?

Secretary CALIFANO. In Head Start, yes, some of that money, a significant amount of it, goes to pay for the people that operate the Head Start centers, and many of them may be paid less than $9,200.

I think a more likely candidate, and one we propose in the welfare

reform program, is the day care program. We put $200 million into day care, which provides more of a sophisticated babysitting facility and does not require the imparting of a lot of teaching skills. I don't think many, if any, of these jobs pay $9,200 a year. They pay much less.

There are also jobs that may be particularly appropriate for women who are on welfare as a way of working their way back into the main job stream, satisfying work in the first instance and also a way to move up.

Mr. OBEY. I wonder if you could have the department work up for the record all of the places in HEW programs where we might increase job opportunities for useful work at a per unit cost of less than $9,200, and, if you could have them list the number of jobs in each area, and an estimate of the total cost per job.

I don't really know what the possibilities are, but somebody who knows a helluva lot more about it than I do should look at it.

Secretary CALIFANO. That is a very difficult thing to do, but let us do the best we can.

[The information referred to could not be submitted in time to be included in the printed record.]

MONITORING OF CONTRACTS

Mr. OBEY. Let me ask you a question in the health area. As you know, yesterday my office released the contents of a GAO report on the Eppley contract with NCI, and that report indicated a significant departure from established procedures took place in the awarding and monitoring of one of the largest contracts at the Cancer Institute, the Epply contract. According to GAO, those include failure to justify the sole source nature of the contract, failure to use charter advisory committees, and informal, inadequate and ineffective monitoring of the contract by the institute once the contract was awarded.

What are you doing now to ensure that funding in the future will be monitored in a more effective manner?

Secretary CALIFANO. Let me note, Mr. Obey, partly as a result of your question to me about NCI last year, and also as a result of Dr. Upton and my looking at NCI a little, on July 20 of last year I asked the Inspector General to conduct a review of the contracting procedures at NCI, with emphasis on compliance with statutory requirements, regulation policies and good business practices. That study is underway and continuing.

Two months ago, because we kept in close touch with the GAO as they were doing the report for you, Dr. Upton asked for an audit of the NCI-Eppley relationship. Yesterday, when I read the story in the Washington Post and talked to Dr. Upton, I asked the Inspector General to do a very detailed study of NCI and Eppley. This is the one-paragraph memo I sent today to formalize it.

Memorandum for Thomas D. Morris, Inspector General. This will confirm my request yesterday to Deputy Inspector General Ruff that you undertake a top-to-bottom, complete and penetrating investigation of Dr. Phillippe Shubik and the Eppley Institute for Research in Cancer and Allied Diseases and their relationship to the National Cancer Institute and any other HEW components. I realize you have been conducting an audit at the request of the National Cancer Institute for the past several weeks. The investigation I am requesting should

include not only that detailed audit, but a thorough review and analysis of Dr. Shubik's and the Eppley Institute's relationship with the National Cancer Institute, its employees, other federal officials, and other contractors and consultants to the National Cancer Institute and other HEW components.

So we have done that. I haven't seen the final report of the GAO, but in the draft report which they circulated to us for comment we are in essential agreement with the corrections they think have to be made, and we are in the process of trying to put them in place.

But I would like to submit this for the record, Mr. Chairman.

Mr. FLOOD. Without objection.

[The information referred to follows:]

REVISION OF NCI CONTRACTING PROCEDURES

The National Cancer Institute (NCI) generally concurs with the comments made by the General Accounting Office (GAO) in its study of the administration of the Eppley contract.

Many of the problems cited in the GAO report have been corrected over the past several years through changes in review policies and improvement in management controls. New procedures have been initiated by NCI and Eppley to correct other problems uncovered by the review. For example, three Institute scientists have been designated as project officers, accounting practices have been modified, and a DHEW audit review of the contract is underway.

Although minor disagreements remain on some points raised in the GAO report, we expect these matters will be resolved shortly through discussions with GAO and DHEW auditors, contracts management specialists, and Eppley Institute officials. The goal of these adjustments is to achieve more efficient contract management without imposing unduly strict monitoring of the scientific investigations, since flexibility is essential to biomedical research.

Mr. OBEY. I think that is fine. Let me ask you a specific question. It is my understanding that right now we are looking primarily at Eppley. It is my understanding also that another GAO operation is looking at TRACOR–JITCO, one of the other major contractors in that division of NCI.

My question is, will you also be looking at, for instance, the Litton contract, because that is a large contract and in some circles it is very controversial as well, and I think it is important that not just one institute be singled out but that all of the major contractors be reviewed.

Secretary CALIFANO. I will certainly look at those two contractors you mentioned.

Let me note the July memo, which was July of last year, was directed at an audit of all procedures, contracting procedures and what-have-you, at NCI, something that Dr. Upton and I thought was necessary and something the Inspector General has now been working on for the last several months. I think that there is no question that their contracting procedures need improvement as they do throughout HEW. We will look at those contracts specifically.

I have also, as a general proposition, asked for and set in motion an analysis of our major contractors and their relationships with the department through the Assistant Secretary for Management and Budget and I have put in place a whole new set of procedures designed at increasing competition and ending sole source procurement of two types, one of which occurred in the department in the Eppley situation. One is just a sole source action from the outset. The other is a situation where the initial contract is let on a competitive bid with tremendous add-ons that are in effect sole source contracts, where there may be reason to believe that if you had thought through the contract

at the beginning, you would have been able to have a much broader competition and not have so much sole source work going on.

Mr. OBEY. Let me just say I applaud what the department is doing in regard to Eppley, and I hope that you will follow through very thoroughly, and I just want to make it clear that I selected NCI for the subject of that GAO report simply because, among other reasons, in addition to some of the comments that were being made around the country on the problems in contracting, that budget had simply grown so fast it appeared there would be more problems there than maybe in other institutes, but I would think just given the nature of contracting, you have some of those problems in some of the other institutes as well, and I don't want it to be interpreted that I am only interested in the contracting problems at NCI because am concerned about all of them.

SPECIAL STATUS OF NATIONAL CANCER INSTITUTE

Let me just ask you one other question, and I don't want to get into personalities on this one, but given the GAO findings, do you feel, and you may not know the answer to this, but do you feel that the fact that the White House appoints the Director of NCI and the members of the National Cancer Advisory Board, that that increases the potential for politicization of NCI?

As you know, all the other institutes are wholly contained in HEW. NCI is the only one that is not.

Secretary CALIFANO. Let me answer it this way: I think that the country would be better off if NCI were treated like any other institute out at NIH, and was folded within the NIH and HEW family more solidly than it now is.

I think in terms of how appointments are made to those institutes, my own experience in the last few months has been that it hasn't made much difference whether I have had the final appointing authority, or delegated it to the Director of the National Institutes of Health, or the President has had it. I think there have been very few changes in the initial recommendations. Most of the changes that I have made have been to open it up, not to have the same people in there all the time, and to get more women and more minorities and not to have everybody either from the West Coast or the East Coast on these high-powered advisory committees.

I don't know what happened in cases in the past. I do know that some of those nominees were not nominees that were sent forward by NCI. I was informed of that this morning when I checked on it.

I would add one other thing. Another issue on the Senate side is whether or not some of those individuals, or at least the chairman, whether or not more of them should be confirmed by the Senate.

POSITIONS AT HEW

Mr. OBEY. Let me ask you if you would, for the record, provide the department breakdown of all appropriated position levels for each line item in the appropriation bill and the respective OMB ceilings.

Secretary CALIFANO. We will do that.

[The information referred to follows:]

Employment, FY 1978

The authorized positions in the following table are based on the guidance in the Conference Report on the 1978 Appropriation Bill. All positions authorized by Congress have been allocated to the appropriate organizational unit.

Employment ceiling is a limit placed by the President on the number of employees which can be on duty at the end of the fiscal year. A single ceiling is placed on the Department by the President and OMB. For fiscal year 1978, the ceiling on full-time, permanent employment for the Department is 144,256. Allocations by the Secretary are made to the Department's operating components and the operating components subdivide it among their own agencies; the allocations may be revised without clearance with OMB as long as the Department stays within the overall total. The ceiling allocations are revised during the year based on actual employment trends and changing program priorities. The following table shows how the Department's operating components have distributed employment ceiling among programs covered by the Labor-HEW Appropriations Bill:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Labor - HEW Appropriation Bill
Employment, FY 1978

	Authorized Positions	Employment Ceiling
HSA:		
Community Health Services	2,247	2,190
Health Care Services and Systems	6,047	6,047
Program management	193	188
- Computer Operations	172	168
Other (Reimbursements and Allocations)	265	248
Sub-total, Health Services	8,924	8,541
CDC:		
Disease Control	2,732	2,665
Occupational safety and health	904	881
Program management	129	126
Other (Reimbursements and Trust Fund)	151	147
Sub-total, CDC	3,916	3,819
NIH:		
National Cancer Institute	2,042	1,987
National Heart, Lung and Blood Institute	774	752
National Institute of Dental Research	284	277
National Institute of Arthritis, Metabolism, and Digestive Diseases	622	603
National Institute of Neurological and Communicative Disorders and Stroke	552	538
National Institute of Allergy and Infectious Diseases	636	620
National Institute of General Medical Science	170	165
National Institute of Child Health and Human Development	386	375
National Institute on Aging	223	215
National Eye Institute	171	167
National Institute of Environmental Health Sciences	366	354
Research Resources	78	76
J.E. Fogarty International Center for Advanced Study in the Health Sciences	51	50
National Library of Medicine	495	483
Office of the Director	549	535
Management Fund	3,365	3,294
Service and Supply Fund	781	765
Sub-total, NIH	11,545	11,256

	FY 1978 Authorized Position	FY 1978 Employment Ceiling
ADAMHA:		
General Mental Health:		
- Research	373	366
- Management and information	668	653
Drug Abuse:		
- Research	102	102
- Management and information	314	314
Alcohol Abuse:		
- Research	37	37
- Management and information	157	157
Program Management	215	215
Sub-total, Alcohol, Drug Abuse and Mental Health	1,866	1,844
Saint Elizabeths Hospital	4,297	4,165
Sub-total, ADAMHA	6,163	6,009
HRA:		
Health Planning and Resources Development	374	365
Health Professions Education	603	588
Program Management	258	253
Reimbursable Operation	25	24
Sub-total, HRA	1,260	1,230
Assistant Secretary for Health:		
Program Operations:		
- Health statistics	578	565
- Health services research	226	220
- Health maintenance Organizations	134	134
- Special health programs	63	62
Public Health Service Management:		
- Regional management	130	127
- Program direction and support services	425	414
Reimbursable operations	75	73
Service and Supply	298	291
Sub-total, ASH	1,929	1,886
Total, Public Health Service	33,737	33,041 1/
HCFA:		
Quality Care Management, Research and Admin.		
- Administrative costs	4,247	4,071 2/
(Medicare)	(1,748)	
(Medicaid)	(708)	
(Program Integrity)	(384)	
(Health Standards and Quality)	(788)	
(Other)	(619)	
Total, Health Care Financing Administration	4,247	4,071

1/ Public Health Service was assigned a ceiling of 48,860 by the Secretary for its operating agencies, including Food and Drug Admin. and Indian Health Service which are not covered in the Labor-HEW bill. The distribution by Public Health Service totals 50,065. This includes an overallocation of 1,205. The overallocation is based on PHS' assumption that their agencies will not actually recruit above PHS' total ceiling and on OS' belief that, if PHS exceeds its total ceiling, the excess can be absorbed within the Department's total ceiling.

2/ Employment ceiling has not been distributed by HCFA to the program levels.

	FY 1978 Authorized Positions	FY 1978 Employment Ceiling
Office of Education:		
Salaries and Expenses		
- Advisory Committees	34	34
- Planning and Evaluation	48	46
- Program Administration:	3,438	3,240
(Education for the Handicapped)	(184)	(181)
(Elementary and Secondary Education)	(410)	(378)
(Higher and Continuing Education)	(244)	(240)
(Occupational and Adult Education)	(184)	(184)
(Student Financial Assistance)	(500)	(439)
(Educational Programs, Regions)	(1,020)	(929)
(Other, including Administration)	(896)	(889)
Sub-total, S & E	3,520	3,320
National Institute of Education:		
- Program direction and administration	340	310
Office of the Assistant Secretary for Education:		
Salaries and Expenses:		
- National Center for Educational Statistics	178	161
- Program direction and support services	69	62
Total, Education Division	4,107	3,853
Social Security Administration:		
Special Benefits for Disabled Coal Miners:		
- Administration	443	443
Supplemental Security Income Program:		
- Payments to the trust funds for administrative costs	19,000	18,749
Assistance Payments Programs:		
- Program administration	909	909
Refugee Assistance:		
- Federal administrative expenses	21	21
Limitation on Administrative Expenses:		
- Old-age and survivors insurance and Disability insurance	58,679	57,919
- Reimbursable operations	534	534
Total, Social Security Administration	79,586	78,575

	FY 1978 Authorized Employment Positions	Ceiling
Human Development Services:		
Administration for children, youth and families	420	376
Administration on Aging	253	234
Administration for Handicapped Individuals	461	435
Administration for Public Services	388	371
Administration for Native Americans	35	35
White House Conference on Families	15	14
Assistant Secretary and other	413	384
Total, Human Development Services	1,985	1,849
Departmental Management:		
General Departmental Management:		
Departmental Direction		
- Executive Direction	392	377
- Public Affairs	46	46
- Management and Budget	521	513
- Personnel Administration	198	198
- Field Management	274	228
- General Counsel	288	283
Sub-total	1,719	1,645
Departmental Operations		
- Facilities Engineering	345	326
- Administrative Services	108	108
- Grants Payment System	46	56
- Regional Services	1,116	1,054
- Employee systems center	262	241
- Legal services	287	281
Sub-Total	2,164	2,066
Sub-total, Gen. Departmental Management	3,883	3,711
Office of the Inspector General:		
Immediate Office	10	10
Health care and systems review	40	40
Audit agency	993	993
Office of investigations	114	114
Sub-total, Office of Inspector General	1,157	1,157
Office for Civil Rights	1,102	1,102
Policy Research	10	10
Working Capital Fund	162	157
Total, Departmental Management	6,314	6,137
Total, HEW (in Labor-HEW Appropriations Bill)	129,976	127,386

HOSPITAL COST CONTAINMENT

Mr. OBEY. Just a couple more questions. Where do you get the figure on page 12 of your charts about the $57 billion cost-saving from hospital cost containment legislation?

Secretary CALIFANO. That we project out year-by-year. I can submit for the record the data on which it is based. That $57 billion is the total cost, both Federal and non-Federal. What it does is to assume that we will have levels of hospital cost increases that would come in under our cap as distinguished from levels that would otherwise prevail.

I can give it to you year-by-year if you want it for the record.

Mr. OBEY. I think it would be helpful.

Secretary CALIFANO. And I can give you the basis on which it is put together. The Federal dollars involved are about $21 billion savings through 1983.

[The information referred to follows:]

SAVINGS FROM HOSPITAL COST CONTAINMENT PROPOSAL

[In millions of dollars]

	Fiscal year—					
	1978	1979	1980	1981	1982	1983
Medicare	40	630	1,765	3,270	5,225	7,440
Medicaid	5	100	265	490	770	1,095
Subtotal	45	730	2,030	3,760	5,995	8,535
Total all payers	140	2,030	5,570	10,280	16,170	22,885

EFFECTIVENESS OF TITLE I ESEA FUNDS

Mr. OBEY. Just two other questions. We always get these assertions made about Title I, at least we used to, of ESEA, that it hasn't proven out, or accomplished much. What is your best judgment? Does Title I really work? Does it do what it is supposed to be doing?

Secretary CALIFANO. I think we have studies now that demonstrate that Title I is effective to a degree, not as much as we would like, but it is effective in terms of transmitting compensatory education in reading and arithmetic, which it is supposed to do.

There are two areas in which there can be improvements. One is largely administrative. On the whole, we have not enforced the rights that the Congress wrote into that statute for private school children entitled to Title I benefits to get those benefits as effectively as we should have. We are beginning to do that now.

We have some investigations going in Missouri and Virginia and also in your own State of Wisconsin, eleven or twelve districts out there. Congress wrote in authority for us to bypass the school district if they did not provide those services to private school children. We have bypassed four districts in Missouri and will do more. We have bypassed four districts in Virginia and will be awarding a contract in March and investigating districts there. The second area is one in which I think we will be proposing legislative change, and that

is, we need to concentrate more of the Title I money in districts where there are high concentrations of poor children, both in rural areas and inner cities, and we are working on a formula now to do that. That is where $400 million of the $644 million increase will go.

Mr. OBEY. I think it would be helpful to have inserted in the record examples that you or NIE can point to, to show the actual benefit which has accrued because of Title I expenditures over the last 10 years.

Secretary CALIFANO. I will, and I will also make sure that the Director of NIE is prepared to speak to that subject when she testifies here.

[The information referred to follows:]

]Benefits from Title I of the Elementary and Secondary Education Act[

Recent evaluations indicate that children participating in Title I programs make achievement gains during the school year, and that these gains are greater than would be expected for these children without Title I programs.

In the National Institute of Education's Congressionally mandated study of Title I instruction, achievement-test results were gathered for a sample of 400 classrooms. While not a random sample, these classrooms included a range of income levels and ethnic composition; they were in urban, rural, and metropolitan districts in both the North and the South. What distinguished them from other classrooms was that their Title I programs were especially stable and well implemented. Achievement in reading and mathematics was tested in the fall and spring for first and third graders. Results included the following:

—"First graders made an average gain of 12 months in reading and 11 months in mathematics during the 7-month period between fall and spring testing and improved their percentile ranks in the two subjects by 12 and 15 points, respectively."

—"Third graders gained 8 months in reading and 12 in mathematics. Their percentile gains in the two subjects were 7 and 15 points, respectively.' (National Institute of Education, "The Effects of Services on Student Development," September 30, 1977, p. 19.)

A study of compensatory reading programs sponsored by the Office of Education and carried out by the Educational Testing Service and RMC Research Corporation gathered data on the reading achievement of children in grades 2, 4, and 6 who were served by Title I, another compensatory program, or the regular school program. Six analytic techniques were employed. Five of them indicated that compensatory students tend to catch up with noncompensatory students between fall and spring. That is, compared with the test scores of unassisted students, the compensatory students' reading scores had risen over the course of the school year. The sixth analytic technique (of residual gain scores) did not support the conclusion that compensatory students catch up with their peers, but this analysis did show that they gain in achievement to about the same extent as other students.

The Stanford Research Institute recently collected and analyzed 283 State-level reports on Title I produced during the years 1969-74. From pre-test and post-test data over the school year, students' average monthly gains were calculated. The data found that "The averages of the reported monthly gains are consistently near 1.1 month gain for each month in Title I....In terms of the unofficial standard of success, which is a month's gain for a month in the program, Title I must be judged a significant success."

Findings on the achievement of Title I participants must be interpreted in light of the achievement gains that would be expected for these children. A study of Title I participation conducted by Decima Research shows that "the group of students with the greatest proportion selected for Title I and other CE (compensatory education) is the economically and educationally disadvantaged....The group with the next highest selection rates includes the educationally but not economically disadvantaged." (pp. iv-v)

The Office of Education sponsored ETS-RMC study of compensatory reading programs found that "In schools that offer compensatory instruction in reading the most educationally needy students, as indexed by their depressed reading test scores, are the ones who receive compensatory assistance, with students in Title I supported projects being more needy than students in compensatory reading projects funded from other sources." (Executive Summary, p. 3)

Information on participating students is important because students whose achievement is significantly below average would not ordinarily have the same rate of achievement growth as their peers. Nationwide data in the Coleman report showed in 1966 that disadvantaged students fell increasingly farther behind their more advantaged peers in reading and mathematics.

A more recent study of the Emergency School Aid Act program indicated that children in minority isolated schools scored at decreasing percentile levels in reading in grades 3, 4, and 5. (Ozenne, et al., 1974)

Other researchers have examined the achievement of non-Follow Through children-those not selected to participate in that program--and found a percentile decline over the years. They also found this decline to be most pronounced for poor, central city, minority students. (Kaskowitz and Norwood)

As part of the Stanford Research Institute study of Title I reading achievement the researchers calculated expected rates of growth for Title I students. For each month of the school year, they concluded that Title I students would be expected to gain less than one month in achievement (between 0.7 and 0.9 months).

Against this background, it is clear that results from Title I programs are better than the gains that would be expected for participating children in the absence of such programs. If the children at least keep pace with their peers in terms of percentiles, or make gains of more than one month for each month of the school year, then Title I is apparently having a beneficial effect

While these findings are encouraging, there is some reason for concern about the long-term gains of children whom Title I serves. The ETS-RMC compensatory reading study found that compensatory students tend to rank at about the same percentile in the fall of grades 2, 4, and 6--that is, students selected for Title I were apparently no closer in achievement to their peers as they reached later grades.

The meaning of this finding is somewhat equivocal because the study was cross-sectional, not longitudinal. Rather than following the same children over the years, it measured the achievement for each year's group of children. Thus, the low achievement of sixth-graders could indicate either that children whom Title I serves do not make significant relative gains over the years, or that a new group of children selected in the sixth grade is a group with low achievement, or both.

Considerable research indicates, however, that low-achieving children tend to have a drop in achievement during the summer. Therefore, even if a Title I program results in fairly good gains during the school year, summer loss could leave the children at least as far behind as they were initially.

While cautioning that their analysis is somewhat speculative, Stanford Research Institute researchers present findings from Statewide testing programs in California, Michigan, and New York, all suggesting that Title I gains are not sustained as sutdents move through the grades.

Less clearly focused on Title I, but relevant to consideration of the program's impact, is the evidence from recent trends in nationwide test scores. Such evidence has importance because Title I has been such a broadly based program, operating in 14,000 of the country's 16,000 school districts, and now serving nearly 6 million children annually. Since the majority of Title I services go to the early grades, evidence from those grades is most relevant.

The National Assessment of Educational Progress reports an improvement in the reading skills of 9-year-olds in 1971. Metropolitan Reading Test scores have risen for first graders and the California Testing Bureau reports that national norming data show a rise in grades 2, 3, and 4.

Test scores at higher grades, on the other hand, have been declining. The best known example of this phenomenon occurs in the case of the Scholastic Aptitude Test. The decline is largely explained by changes in the population going to college, but the deline is at least partially due to changes in school and society as well. Again, one implication of this decline is that there is a problem among older children.

It is worth noting that societal explanations advanced for the decline in test scores--changes in family structure, television, social upheaval--might reasonably be expected to depress achievement in the early grades as well as aptitude in later grades. The fact that they have apparently not done so provides another possible piece of evidence that Title I is having positive effects.

USEFULNESS OF HMO'S

Mr. OBEY. On HMO's, what is your conclusion on their usefulness in terms of delivery of health care at lower cost?

Secretary CALIFANO. We have studies which indicate that HMO's can provide about 30 percent lower health care costs and anywhere from 40 to 60 percent lower hospitalization costs.

We finally folded in the Kaiser group, which is the largest federally-qualified HMO. I have a conference on March 10th, I think it is, of a large number of industrial corporations whom we are trying to interest in HMO's. We are also trying to change the whole regulatory apparatus. It is too cumbersome. The average length of an HMO application is 1,000 pages and to try to get three young doctors to set up an HMO when they have to start from there is preposterous; so we are also reorganizing that whole area, and putting all HMO activities in one place.

TAX CREDITS FOR TUITION COSTS

Mr. OBEY. One last question: Again, would you state to the committee why you feel that the administration position on student aid, the BEOG's approach, for instance, is preferable to a tax credit?

Secretary CALIFANO. The package we put together is BEOGs, plus loans, plus some work study money.

One, we think it provides more flexibility. If you write a tax credit into the tax laws, you can't change that amount of money and can't change the family contribution schedules the way you can under the authority in the BEOGs programs.

Two, a $250 or $500 tax credit will not solve the problem in private schools where the average tuition is now about $4,800 a year, and in many public universities where the tuition is now at about $2,500 a year and can run as high as $7,500 to $8,000 a year. We think a much increased loan program will do that, spread over higher income levels.

We also have a sense that the education policy should be held within one committee of the Congress, or should be coherently developed by the Congress. You could split this and put maybe the biggest money in education in the country in the Finance Committee and the Ways and Means Committee in the House rather than in the Education Committees of the House and the Senate.

At the elementary and secondary level, the problem is somewhat different, and the $500 tax credit in the Packwood-Moynihan bill presents a serious problem, I think, of basic Federal educational policy. We now provide $128 per pupil, to public school students in Federal education money. We now provide somewhere between $55 and $75 per pupil to children in private schools at the elementary and secondary level. If you put in a $500 tax credit for private schools, we will be providing $555, at least, per pupil to private school children, plus the tax deduction for contributions to the church. So we will be providing three or four times the amount of money per private school pupil from the Federal Government at the elementary and secondary level that we provide for the public school pupil, and that sets current Federal education policy on its head.

Another reason is obviously that the tax credit proposal takes out of the whole appropriations and authorization process the ability of

the Congress to look at the effectiveness of programs and to look at how well money is targeted. I think we are better off going through both those processes on the whole and going with programs that we think will work.

Mr. OBEY. How do you answer, coming at you from the other direction, some of the criticism I heard, for instance, from some people on the Budget Committee that 250 bucks really isn't much of an impact for somebody in the income group that you are helping, and so rather than spending that 250 bucks, we would be better off dumping it all in student loans?

Secretary CALIFANO. We thought that some combination of relief was appropriate. I have a simple chart here which explains the reason we held it to $250.

If you look at that chart, the dotted line on the left is the current program and the relief that we are providing. You will notice that we provide a basic maximum grant of about $1,600 to students and families making up to $7,400, and it drops down to $250 at around $14,000. Our proposal would fund, for the poorest children, from the poorest families, up to $1,800 out to incomes of about $8,650, coming down, then, to about $15,100, or so, gradually, and going out to $250 in the $25,000 income range.

Now the reason we went out at $250 was because it is obvious in the future that the maximum grant for the poorest children will have to be increased and the expense of increasing it, if you just have a minimum of $250, is about $100 million. The expense of increasing it $100 at the maximum level if you draw that line like that, and go gradually down, providing more cash at the other levels, becomes $500 million per one hundred dollars, and we thought that that would really inhibit helping the poorest kids.

We would fill in that gradual line and provide additional help to those people with loans. We think they should get some cash and some loans.

Unlike the tax credit, we think this proposal does not help the middle class at the expense of poor people. The tax credit would, in effect, do that, because you wouldn't provide the increase for the poorest students in these maximum grants.

But I think you are right to the extent that you say those people in that $15 to $25 thousand range, actually on up to $45,000, need loans. They do need loans, and we have provided substantial kick in the guaranteed student loan program where we have some control. We did not provide any increase in the direct student loan program, because it needs so many administrative changes. With $600 million in default, 700,000 students in default, campus-based, we thought we should get that program cleaned up before coming here for additional funds for it.

Let me say, I am not condemning the campuses. Although they have some fault, HEW bears plenty of fault, and the fact is that virtually no bills have been sent out since the program started, and most people do not pay bills they don't receive.

Mr. OBEY. Thank you, Mr. Chairman.

Mr. NATCHER [presiding]. Mr. Smith.

Mr. SMITH. You don't expect this proposal to be passed before we mark up this bill, do you?

Secretary CALIFANO. I certainly expect this proposal to be through the House before you mark up this bill. I think they are scheduled to mark up on February 28, and they are on a fast track to bring it to the floor.

Mr. SMITH. How much of this can you do without legislation? You can increase the BEOG's from 1,600 to 1,800 couldn't you?

Secretary CALIFANO. Yes, we can increase BEOG's from 1,600 to 1,800 without legislation. The $250 minimum out to $25,000 we cannot do. The work study program we take right up to the authorization of $600 million with our proposal. There are changes in the guaranteed student loan program we need legislation for to make it more attractive to banks, to give them another half percent, and to change those eligible for loans to kick it up to $45,000 adjusted gross income.

But I think the current plans of the House are to move that legislation very fast.

Mr. SMITH. Well, I wouldn't put too much confidence in the passage in its present form. I think there are a lot of inadequacies. I don't know who drew it all up, but I think it misses the mark in many respects.

To start with on the $250 amount, everybody in that category would rather have a tax credit than to have their child go through all the paperwork, and so forth, and get a $250 grant. So you haven't made any points there at all. If that were up to, say, $400 or $500, you might make some points, but from what I hear around here, nobody is buying that part of the package.

Secretary CALIFANO. Let me say, I am not saying this proposal precisely as it is drafted is going to pass. What I am saying is the House Education and Labor Committee is going to pass a proposal in this area that would accomplish the same objectives as the Administration's proposal.

Secondly, whatever the minimum amount turns out to be in terms of a BEOG's grant, we are proposing that there be a short form of one page in effect, which you would fill out in order to get it.

I would like to make one other comment about the tax credit proposal. As you know, there is a substantial problem at the universities and with students in the context of having to fill out and comply with a whole set of regulations put out by the V.A. for their student assistance programs. If there were a tax credit, the Treasury Department, would have to put out a whole new set of regulations with their definitions of what a full-time student was, what a part-time student was, who was entitled to a tax credit, what the income arrangements would be with respect to that.

ASSET LIMITATIONS

Mr. SMITH. You haven't, on this chart, said anything about assets. Are you making any changes in assets limitations?

Secretary CALIFANO. There are changes in our BEOGs proposal for assets limitations, yes. I would like to submit it for the record, but,

to the best of my recollection, we are changing the treatment of assets for non-farm and non-business families, so that these families will again get 50% of the offset of farm and business families.

[The information referred to follows:]

We propose to increase the asset offset for families from $17,000 in 1978 to $25,000 in 1979. This is commensurate with the 1978 increase in the asset offset for farmers and small businessmen from $25,000 to $50,000.

GRANTS VS. LOANS

Mr. SMITH. That helps, but the fact of the matter is after working with this for several years, we still have self-employed people below the poverty level who can't qualify for BEOG's, and so to rely on BEOG's and reduce direct loans it just seems to me, I don't understand where you come with that idea.

Secretary CALIFANO. Well, we are not reducing direct loans. We are increasing the guaranteed student loan program.

Mr. SMITH. But you know a lot of them can't get a guaranteed loan. You go to the banker, and if your father doesn't have a bank account there, you don't get a loan. So the poorest students are excluded from your package when you reduce the direct loans and rely more on guaranteed loans.

Secretary CALIFANO. There is still $260 million or $270 million in the direct loan program. Let me make a few points about that program. It is running at a 20 percent default rate today.

Mr. SMITH. Let me ask you this: How much of this BEOG's money have you gotten back to use a second time?

Secretary CALIFANO. It is a grants program.

Mr. SMITH. That is right; 80 percent of the other has come back to be used the second time, and none of BEOG's. How can you compare that and say BEOG's is better?

Secretary CALIFANO. There is presently a 20 percent default rate, but 80 percent hasn't come back. In terms of carrying out the law of the Congress, as passed, it was the worst administered student program in HEW, by far. There was no attempt frequently to recover any of that money. We are now putting in a system whereby if universities and colleges do not collect that money at a certain level, we will drop them out of the program.

Mr. SMITH. How do you compare that with BEOG's where they don't have to have repayment? Anybody can hand out money, but, of course, it is harder to administer something where you get the money back to use for something else.

Secretary CALIFANO. The BEOG's program we estimate is running at about a 5 to 7 percent fraud level. We lost about $165 million a year in BEOG's. We instituted a program with respect to that, too. There have been no checks of the BEOG's applications. As you know, a GAO report last year criticized that aspect of the BEOG's program.

Mr. SMITH. Any way you look at it, it seems to me to say you reduce direct loans and increase BEOG's on the basis that some of them haven't repaid the direct loans: there may be administrative problems, but with BEOG's you are not getting any money back. It is gone forever once you put it out there. We can't use it the second and third

and fourth time. What we should do is change the repayment so it isn't so rigid.

Some of these kids don't have an income for a few years so they can't repay. We should have flexible repayment of a percentage of income, or something like that, and then you wouldn't have as many defaults.

INCREASED REPAYMENTS

Secretary CALIFANO. There are a lot of reasons for the defaults, Mr. Smith. One of them is the reason you mentioned. But I would note that as we have begun to act, we get tremendous repayment percentages. In HEW, when we acted on the 317 HEW employees who were in default, upon being contacted, 184 either paid completely or went on payment schedules, 33 were dead or disabled or bankrupt, 62 were not located, and 38 are in contest. There are lots of contests over the proprietary schools in which students argue they are not entitled to be paid; they never got an education. Also, we turned 1,500 cases over to the Justice Department in the last four months, and more than 900 are in payment upon being sued.

Mr. SMITH. So that part of the problem is solvable, that repayment part?

Secretary CALIFANO. In the guaranteed student loan program. We recommend an increase in that program.

Mr. SMITH. Guaranteed student loan?

Secretary CALIFANO. Yes, we do. We recommend an increase of $297 million.

Mr. SMITH. I am talking about direct loans; you recommend a reduction.

Secretary CALIFANO. It is a revolving fund. The quickest way to increase the direct loan program is for the universities to start collecting and for us to start collecting.

Mr. SMITH. When we get more for our money out of that program than any other loan program or grant program, I don't know why we should reduce. That is where we are getting the money back, using for the second time, and some of it now for the third time. An original dollar appropriated there is going further; after you have reduced the amount that wasn't paid back, it is still going a lot further than any other program we have. The interest rate is lower than it is on direct loans; it is reaching poorer students, and that is the other thing about the package is you don't reach the poorer students.

What good is it to somebody to get $1,800 instead of $1,600 if it still isn't enough to go to school?

Secretary CALIFANO. As you know, Mr. Smith, that is not the only money available to those students.

Mr. SMITH. I know, but you add up all that is available and they still don't have enough. Take $1,800, add to it even if they are in a course where they can work and not all of them can, but even under work study, they don't have enough money.

Secretary CALIFANO. There is the supplemental grant program through which needy students can and do get funds, and I think you will find that although we didn't recommend an increase in that pro-

gram, there will be a recommended increase in the legislation coming out of the House Education and Labor Committee.

Mr. SMITH. These finance officers tell me they get students that if you put all this together you are not going to have enough money if you don't have a substantial amount of loan money. It is the poorest students that need direct loans. They cannot go to the bank and get loans. It is okay for one who can.

NURSING EDUCATION PROGRAMS

The other thing about this that I am wondering, in your proposal for a new Department of Education, are you proposing to include nurses, professional student loans and capitation grants?

Secretary CALIFANO. OMB is working on that proposal. I think presently the health professions student assistance legislation and similar programs would move out of HEW, but I don't know where they ultimately are going to come out.

Mr. SMITH. The reason I asked that, I notice year after year there is a reduction in the money for nursing loans and nursing assistance, capitation grants, which is sort of understandable in the way your budget is made up. At every pass that the process goes through, there is a medical doctor standing there looking over the options and, of course, they don't prefer nurses if they have a shortage of money, so in the end we get these up here every year; you reduce nurses, everything for nursing.

I think it would be a good thing if you got it in your Department of Education, and then you would have educators looking at nurses' needs.

Secretary CALIFANO. I have a feeling doctors would find their way in.

Mr. SMITH. Let them find their way in, that is okay, but they shouldn't be cutting out the nurses year after year after year. How do you justify this cut in nursing assistance? You want to cut it down to $20.5 million from $122 million.

SUPPLY OF NURSES

Secretary CALIFANO. As far as nursing is concerned, the supply of registered nurses from 1970 to 1977 has increased by 40 percent and is expected to increase again by 40 percent from 1977 to 1990, which would give us 1.5 million nurses at that point in time.

Mr. SMITH. Which still are not enough.

Secretary CALIFANO. As I indicated before, we think that is too many. I am not as certain about the judgment with respect to nurses as I am with respect to doctors, particularly specialists. We do provide support for 850 new nurse practitioners, who we think are very important, particularly in rural areas, where we are now authorized to reimburse them directly under Medicare and Medicaid. There is $13 million in the budget.

Mr. SMITH. But that is the same amount that was in a year ago. That is not even an increase to take care of the cost-of-living increase.

Secretary CALIFANO. We think they will produce 850 nurse practitioners, and we think that is about right. We also have $7.5 million,

although, as the Chairman pointed out, it is for the support of nurses studying at the graduate level.

Mr. SMITH. You know, you can't take nurse practitioner training until you become a nurse.

Secretary CALIFANO. The thing that worries us, Mr. Smith, as I mentioned before, there are 200,000 people graduated from education schools, largely spurred on by investments that the Federal Government made to produce more teachers. Seventy thousand of them couldn't find work.

Mr. SMITH. You are not talking about nurses now?

Secretary CALIFANO. I am talking about teachers, but we believe we are headed for the same thing. If we keep on the same track, we will be producing thousands and thousands of nurses who cannot find work. They are also, I would note, eligible for these loan programs to help finance their education, and they are eligible for the BEOG's program. Having said all that——

Mr. SMITH. I hate to see you get sold on that. I know for several years people in the department have gotten sold on the idea there are too many nurses. But I used to reorganize school districts, and every time we would have an argument that there are too many rooms in the area anyway, they counted all the rooms in the one-room schoolhouses, which were not available.

With nurses, you have, and always will have, a lot of nurses who are out of work and don't want to work for a few years while they are raising a family, or else it is part-time work while children are in high school. You can't just take numbers. What really counts is you go to hospitals and find out they don't have enough nurses.

Secretary CALIFANO. At the same time, Mr. Smith, in Germany, which has as fine a system as this country has, the staff ratio there is one staff to one patient. In the U.S., the staff ratio today is 3.6 staff to 1 patient and growing rapidly, headed for four probably by next year.

Mr. SMITH. What does that have to do with nurses?

Secretary CALIFANO. Nurses are a large part of that staff and a lot of these hospitals are overstaffed.

Mr. SMITH. When I have been in the hospital, I see very few nurses, and I know sick people have told me they see less nurses than any other people running down the halls.

Secretary CALIFANO. That is a function of the hospital administrator.

In terms of your concern, let me say, as I indicated before, I am quite comfortable and believe our judgment is quite correct as far as the medical profession is concerned, as far as doctors are concerned, specialists versus primary care; I am not as certain that the judgment was made about nurses is as correct. I am not as clear on those numbers as we are on the doctors' numbers.

STUDENT AID CONCERNS

Mr. SMITH. I really have great concerns about your student aid package. I happen to be, myself, for a separate Department of Education, but I think you should get health professions in it, too, and if you don't, it seems to me you have not—well, all the arguments you make

for a number of these other programs apply also to the health profession; otherwise, I don't know how you can justify it.

Generally speaking, I think you are doing a good job, but I think you have a package here that is not salable and shouldn't be sold without some major revisions on student aid.

Mr. FLOOD [presiding]. Mr. O'Brien.

INTENT OF ABORTION LEGISLATION

Mr. O'BRIEN. Thank you, Mr. Chairman.

Mr. Secretary, for a moment I would like to go back to the early morning discussion touching on abortion and the matter of legislative intent. I understand your position and that of the President with regard to legislative intent. That is outside of your personal notion, but if you look at the laws and you refer to certain things that came up in the Senate and came up in the House, let me tell you where I think you were wrong.

For example, medical procedures were interpreted to include abortions, although that wasn't the way it was interpreted when the language first came into the report language the previous year.

Second, promptly reported, the word promptly didn't come from Senator Metzenbaum or Senator Magnuson, but from Senator Helms, and that Senator said with reference to it, "placing the word promptly before the word reported eliminates the possibility that two or three months after the fact the supposed victim would claim to be raped, when, as a matter of fact, she had not."

The other Senators disagreed with that, but the intent of the man who picked the word up and put it in was clear.

Finally, when you take all that in context with the closing language of using the words rigorously enforced. I think my interpretation of the impact of that phrase and the whole business of legislative intent would bring me down on the more restrictive side rather than the permissive side, and I think you have gone the wrong way in it.

That is not a question, but I feel strongly about it.

Secretary CALIFANO. As far as the first point, whether the term medical procedures in terms of the statutory language includes abortion, in the regulation we indicated that the statute that was passed last year specified that, and I quote, "None of the funds provided in this paragraph shall be used to perform abortions, except"—and among the exceptions was "for such medical procedures necessary for the victims of rape or incest." The structure of the rest of the statute we felt supported that conclusion. The placement of "medical procedures" as the second phrase in a series of three exceptions to the ban on the use of appropriated funds for abortions stands in contrast to the sentence which follows the paragraph describing those exceptions.

Now, had Congress, as we looked at that statute, intended that medical procedures for victims of rape or incest not include abortions but solely something different, the logic would have required the placement of that reference somewhere else, not in a list of exceptions, and I would contrast what you did the year before.

In section 209 of the 1977 Labor Appropriations Act, you said, and I quote,

It is the intent of the conferees to limit the financing of abortions under the Medicaid programs to instances where the performance of an abortion is deemed by a physician to be a medical necessity and to prohibit payment for abortions as a method of family planning or for emotional or social convenience

and I skip—

nor is it the intent of the conferees to prohibit medical procedures necessary for the termination of an ectopic pregnancy or treatment of incest victims.

When we interpreted that language, the Attorney General contrasted the first two sentences, where the conferees talked about precluding payment for abortions and permitting payments for abortions, with the third sentence, saying that the first two sentences used the word abortion, describing generally those which may be funded and those which may be not, with the last sentence in which the word abortion nowhere appeared, and, based on this juxtaposition, and based on the conference committee's rejection of a proposal to include rape and incest among the exceptions, the Attorney General concluded in his opinion of July 27 that Congress did not intend that medical procedures for victims of rape or incest would include abortions.

With that opinion on the public record, instead of writing it the way you wrote it in the Conference Report last year, you wrote it right into the statute among the list of exceptions. We did the best we could with that.

As far as "promptly" is concerned, I cited the language on the House side, indicating at least 30 days, the language on the Senate side, indicating 90 days or more, and noted that in the context of that we came out for 60 days. We did this to take into account the skipping of a period, if you will, for the younger girl. That is our best reading.

NEED FOR TIGHTER ABORTION LANGUAGE

If you are asking me what the law should be in that area, as far as I am concerned, as far as the Administration is concerned, our position would be that you should tighten up on the law, that if you want to make it a shorter period of time, you should indicate you want to make it a shorter period of time. It will not be easy to enforce this law. We put out the tightest regulations we felt were consistent with Congressional intent, but we would prefer a much tighter law. We would prefer a provision, as I indicated this morning, which provided an exception for abortion where the life of the mother was at stake and a very tightly drawn exception in cases of rape or incest, and that is where we would stop.

Mr. CONTE. Will you yield?

Mr. O'BRIEN. I would add one comment. I think you are stretching a bit when you push promptly up to 60 days in case of the Helms' origination of the term and also in the face of what is determined to be the House side of the interpretation of the term.

I yield to Mr. Conte.

Mr. CONTE. Mr. Secretary, when you say you would go along with exceptions on rape and incest, do you mean in the medical procedure?

Secretary CALIFANO. We would go along with a termination of pregnancy in connection with rape or incest by a medical procedure or by an abortion but with a much tighter reporting situation. It would

be much easier to administer and much less prone to abuse and fraud if you had a very tight reporting period, a report within a number of days from the time of the incident, a relatively small number of days. I think we would prefer something that tight in terms of Federal funding.

STATISTICS ON ABORTIONS

Mr. CONTE. If I recall correctly, when we were laboring over this decision, I brought out some statistics that there are very, very few cases of abortions where there is a rape involved because a woman is treated medically, in 99 percent of the cases, in the hospital right after the rape incident.

Secretary CALIFANO. I remember those figures in debate. We don't know enough about that. You have cases in which a woman comes in immediately, within a day, or goes to the police, but there may well be other women out there who do not report or come in for one reason or another, through embarrassment or what-have-you. We don't know when they do come in, whether they are coming in for treatment or abortion at a subsequent time because they have been raped. Some don't indicate they have been raped, I am sure, or that they have been subjected to an incestuous relationship.

Mr. CONTE. Is it likely that your statistics will include better data on abortions next year?

Secretary CALIFANO. To the best of our ability to get them. Indeed it might be wise for us to review the procedures we are putting in place with you and anyone else on the subcommittee and the staff.

LEGISLATIVE INTENT VS HEW REGULATIONS

Mr. O'BRIEN. Mr. Secretary, touching on legislative intents, and then I will leave it alone, it seemed to me it was quite clear that the legislative intent with the Senate was quite permissive. The legislative intent in the House was quite restrictive, and in that context, it seems to me you came down on the side of the Senate and not on the side of the House.

Just as a general premise, it seems to me your interpretations have always in these regulations leaned with the Senate and not with the House, and we deem our legislative intent to be just as valid as theirs as a representation of what congressional intent really is. I don't want to argue the point with you, but I think that is a serious weakness in your position.

Secretary CALIFANO. Mr. O'Brien, if I may, I tried not to come down on the side of either the Senate or the House. I think with respect to every interpretation we made, there is support in the debates of both the House and the Senate for it. In a sense, neither the House nor the Senate said 60 days. It is not easy to read the legislative history because different people get on the floor of the House or the Senate and say different words and mean different things.

Mr. MICHEL. Except that the timing of that issue is not like cutting up compromising figures as we do. So one House has 40 and another has 20 and we are going to compromise at 30. That issue there and the timing, so much hangs on that.

Secretary CALIFANO. Mr. Michel, I understand that. I would go back to note again that, during the debate on December 6, you, as a strong opponent of free Federal funding for abortion, and a Ranking Member of this subcommittee, on the issue of the word "prompt," said, and I quote,

> The prompt leaves itself open to a number of days, but let us face it, pregnancy is a fact which cannot obviously be known until the rape victim has missed her first period.

Mr. MICHEL. At that time, when we were arguing that with the Senate, in the conference, we were not making headway, and I was trying to break a little ground, feeling if I gave the impression I was giving something, we were going to maybe get some kind of movement here, but, at the outside, I said all right, let's be that amenable to time and extend to 30 days, but that was the outside limit, because I gather, as we have gone over it before, the positions you had enunciated before, and the President, that, by glory, you were going to be a strong leader in telling the bureaucrats that this is the way we wanted this thing to come out. And I get the general impression that the bureaucracy went the same old way it has always gone, and you didn't have that imprint.

Secretary CALIFANO. Let me just continue, with all due respect. You said,

> It seems to me that prompt embraces a period that is at least in the 30-day range and still would be acceptable as prompt treatment and prompt reporting.

In that exchange in which you discussed "promptly," which was the main discussion of the word on the House floor, there was no suggestion of an outer range. There were Senate proposals that suggested going well beyond the 90 days, out as far as the Supreme Court would permit you to go.

The lawyers who worked on these regulations were largely lawyers that I brought into the department, and I, myself, spent an enormous amount of time trying to define as best I could the intent of the Congress. I don't agree with that provision in the law.

If I were starting from scratch, I wouldn't write the regulations that way; I wouldn't write legislation that way; but that was irrelevant in the context of what I was charged to do under the law and the Constitution, which was to do my best to figure out what the Congress intended by the words they wrote. I did the best I could.

Mr. O'BRIEN. Mr. Chairman, the clock is getting away from me again, and I have a few questions on other topics. Maybe the Secretary would like me to change topics anyway.

SUPPORT FOR A DEPARTMENT OF EDUCATION

With regard to the Department of Education, Mr. Secretary, the President has indicated his support for that, and you spoke to the issue. The arguments in touching upon it range from "Education has been lost in the burgeoning DHEW" to "Education should not be tied to the abortion issue."

It doesn't seem to me these hold much water, considering how much is given to education in the new budget, and it is unlikely that education would be separated from the abortion controversy any more than labor is.

NIH BUDGET

Mr. O'BRIEN. With regard to the National Institutes of Health, in 1978 Congress appropriated $2.776 million for the NIH biomedical research, an increase of $300 million, or 12 percent. This year, it is an increase of about 3 percent, and if we take out an 8 to 10 percent rate of inflation in research costs, it seems to me we are reducing the level of biomedical research, and if we have been lobbied on anything in this area, very eminent authorities have been urging us to stress that particular feature.

I would like for the record, a table showing the history in both real and constant dollars.

National Institutes of Health
Biomedical Research
($ in millions)

I. Budget in Current Dollars

	1970	1975	1977	1978	1979	Increase 1979 Over 1970
NCI.....	$ 175	$ 693	$ 814	$ 872	$ 879	402%
% increase over previous column..	---	296%	17%	7%	1%	---
NHLBI.....	151	324	396	448	454	200%
% increase over previous column..	---	115%	22%	13%	1%	---
Other Research a/.	739	1,025	1,212	1,400	1,462	98%
% increase over previous column..	---	39%	18%	16%	4%	---
Total, NIH.....	$1,095	$2,089	$2,542	$2,842	$2,885	164%
% increase over previous column..	---	91%	22%	12%	2%	---

II. Budget in Constant Dollars b/

NCI.....	$ 143	$ 402	$ 403	$ 405	$ 383	168%
% increase over previous column..	---	181%	---	---	- 5%	---
NHLBI.....	127	189	196	208	198	56%
% increase over previous column..	---	49%	4%	6%	- 5%	---
Other Research a/.	543	593	597	650	637	17%
% increase over previous column..	---	9%	1%	9%	- 2%	---
Total, NIH.....	$ 865	$1,214	$1,275	$1,320	$1,257	45%
% increase over previous column..	---	40%	5%	4%	- 5%	---

a/ Excludes Office of Director, National Library of Medicine, Buildings and Facilities.

b/ 1965 = 100

In the last several years, NIH has received significant increases in resources available for biomedical research. Since 1970, the appropriations have increased by 164 percent. Even considering inflation, since 1970, the total research budget has increased by 45 percent.

In general, the fiscal year 1979 budget provides adequate resources to pursue the most promising research opportunities. However, a 20 percent budget increase has been proposed for the National Institute and Child Health and Human Development.

These funds will support new initiatives in Adolescent Health and Smoking Prevention.

HMO INITIATIVE

Finally, what do you plan to do to encourage HMO's, and do you intend to take any real steps to reduce the complicated application process? As I recall, the Kaiser application weighed 600 pounds.

Secretary CALIFANO. On the HMO point, I have already changed some of the application procedures in new proposed regulations I issued about three weeks ago. We will further change them. We are putting the whole HMO operation in one place in HEW now. It has been scattered in two separate places. I brought in Howard Viet to head the HMO office. I wrote to the Fortune 500 to try to interest them in HMO's and got such a tremendous response from them and other corporations that we had to change the date of the conference to get a larger room, and they are coming in on March 10 for a one-day conference to encourage them to try out HMO's.

I am also bringing Leo Beebe on as a consultant, who put together the National Alliance for Businessmen during the last year of the Johnson Administration and who has worked with businessmen, to be a liaison with the business community, because I think they are so pressed with health costs now. They are interested, and some of those companies are doing superb things in that area.

R. J. Reynolds and Ford Motor are looking into HMO's as possibilities for their health care plans. I hope we can push them, and we also are shortening the applications.

Mr. O'BRIEN. A couple more questions, Mr. Secretary.

COST FACTORS IN HOSPITAL OPERATIONS

One on hospital cost containment: I know you have taken a lot of things into consideration, but I question some. The effect of the minimum wage on hospitals: In one Illinois hospital alone, it has been estimated to be $351,000. Extensive renovation might be required to implement section 504 of the Rehabilitation Act.

In Illinois, in late 1974, the State enacted a certificate-of-need provision. Construction dropped from $578 million to $219 million and maintained a level in 1977 of $239 million. All were approved as necessary by State and local agencies. The projected Illinois allocation under the act would be $129 million, and I think that is unrealistic when you take one Chicago hospital, Providence, which plans to replace its facility at $144 million, and that is $68 million over the projected amount for the entire City of Chicago.

Is it your judgment that every facility contains waste; that there is utterly no competition. I worry about that particular feature.

Secretary CALIFANO. Not every facility contains waste. Roughly 20 to 25 percent of the hospitals in this country, in every part of this country, in every type of hospital, already are holding their costs to an increase of 9 percent or less. The number you read of 119 million or 129 million seems to me, if I recall it correctly, to be just taking the $2.5 billion cap on capital construction that is proposed and dividing it by population by State, which is what we do for the first 18 months. But there are a number of exceptions to that cap which permit it to grow, as I recall, by at least another billion dollars. I think you will find there is ample room for construction that is necessary.

The same agencies, the HSA's that are making the determinations you are talking about, would make the determinations under the proposed Hospital Cost Containment Act.

All I can do is keep bringing to the attention of this body, and the American people, the staggering increase in hospital costs. They have been uncontrolled since 1974, when they asked to be decontrolled under the Nixon wage and price program, and they have risen at an average rate of 14.1 percent a year since then.

Hospital charges were up 16.1 percent in December 1977, over December 1976, which is another acceleration. Massachusetts, the State Mr. Conte is from, has one of the hospital rate commissions on which we modeled the Federal proposal. They have been rising at 9 percent and less per year, and they have the finest hospitals in the country. So there is no question in my mind it can be done. Maryland is doing the same thing. That legislation really grew out of what was being done by States that were successfully dealing with this problem, and there will also be exceptions for them.

As far as the minimum wage is concerned, there are provisions related to the general issue of labor costs that pass through in that statute. I would have to submit for the record exactly how they deal with it.

Mr. O'Brien. Thank you, Mr. Secretary.

[The additional information follows:]

LOW-WAGE HOSPITAL WORKERS

Under the Administration's bill as introduced, hospitals would be permitted an adjustment of the revenue limit based on actual increases in pay they granted to non-supervisory employees. Specifically, a separate calculation would be made for the increases in wages of non-supervisory employees. That increase would be applied to the portion of hospital costs attributable to wages and added to the amount by which the remainder of the hospital's costs are allowed to increase under the revenue limit. Thus, the bill would provide for a direct pass-through of wage increases for hospitals requesting it in order to avoid an inequitable impact on the earnings of low-wage hospital workers.

Mr. Flood. Mr. Roybal.

Mr. Obey. Would you yield?

Mr. Roybal. Yes.

DIFFICULTY OF DETERMINING LEGISLATIVE INTENT ON ABORTION

Mr. Obey. Mr. Secretary, I just want to say, if you can determine what congressional intent was on abortion, you are a whale of a lot smarter man than I am, because I find it is very difficult, given the conflicting statements on the floor of both Houses, to determine what the actual intent was.

Each of us has the luxury, I suppose, of being able to interpret that language as we so choose, but you are the only guy who has to put it right there on the dotted line, and I don't envy you, because, in addition to being a touchy political and moral question, it is also very difficult to determine what 535 people with their conflicting values and judgments really meant to say when we passed that inexact language.

I think you have done a superb job in trying to determine what that intent was, even though I don't think any Member of the Congress can,

in fact, determine what our intent was. I think you have 16 different views on this committee, much as we might try to agree.

HISPANIC EMPLOYMENT

Mr. ROYBAL. Mr. Califano, my figures indicate over 10 percent of this country's low income families are Hispanic. After a year, what has been the overall percentage increase of Hispanics employed by HEW?

Secretary CALIFANO. In September of 1977, which is the last point for which I have numbers, we had 3,917. In August of 1976, we had 3,845, which is an increase of 72 individuals.

Mr. ROYBAL. Your figures as of September of 1977 indicate that there were 3,917 employees with Spanish surnames for a total percentage of 2.8; is that correct?

Secretary CALIFANO. That is right.

Mr. ROYBAL. That is 2.8, while the national level, as bad as it is, was 3.4, which is a lot better than HEW. But that figure is correct, is it not, 2.8?

Secretary CALIFANO. That is correct, Mr. Roybal.

Mr. ROYBAL. We have been told Hispanics are placed in minority designated positions, such as Spanish-speaking coordinators, equal employment opportunity positions, so forth. Of the total number of Hispanic employees at GS Level 12 and above, how many are in program and policymaking positions?

Secretary CALIFANO. I will have to submit that for the record, but let me make one point at least. Although they were not chosen because they were Hispanic surnamed, in terms of my own appointments, Arabella Martinez, the Assistant Secretary for Human Development——

Mr. ROYBAL. That is an excellent appointment.

Secretary CALIFANO [continuing]. Who oversees the social service programs and the Title XX programs, and Bambi Cardenas, head of the Headstart program and the administration on children, youth and families, another presidential appointee. Those are not jobs that are locked in for Spanish surnamed individuals.

[The following additional data was supplied for the record:]

HISPANIC-AMERICAN EMPLOYEES

The Department currently has 540 employees at GS-12 through GS-18 who are identified as Hispanic-American. Of the above number, 155 employees are in program or policy-making positions as managers or supervisors.

Mr. ROYBAL. I think we can stipulate to the fact that you made some meaningful appointments, but the truth of the matter is that the percentage as of September of 1977 is still 2.8 percent, and that is very little increase, if any, for the same survey that was made a year previous to that.

Secretary CALIFANO. That is true.

SPANISH-SURNAMED EMPLOYEES IN HEW

Mr. ROYBAL. Now, in the health resource administration and the adult drug abuse, mental health programs, we find that less than one percent of the employees have Spanish surnames. However, I think we

must compliment you for the fact that you have done well insofar as other minorities are concerned.

Now, in the health resource administration, less than one-tenth of one percent have Spanish surnames, while the black employment in that department is 19 percent. In the alcohol drug abuse mental health administration, Spanish surnames, according to my figures, are four-tenths of one percent, while the black employment is 48 percent. In the Office of the Secretary, it is 3.5 percent for Hispanics, while black employment is 28 percent.

I compliment you for the fact that you have made opportunities available to black employees, but I see that HEW has a long way to go when it comes to Hispanic employees.

Now, have you devised any plan whereby a better break can be given to the Spanish-speaking employees insofar as HEW is concerned?

Secretary CALIFANO. I hope to be able to do better in this area next year. I suppose the most important thing we are doing, although we haven't yet directed it specifically at the Spanish surnamed employees, but it will help there, we have just about completed a study of how to organize the equal employment opportunity offices in HEW. They have not been doing well. They have indeed been ghettos, as you well know. I don't know whether they have briefed you on this or not, but I urged them to solicit your views and other views, and I hope if we can revitalize that function, we can revitalize some of our efforts to get more minorities into HEW.

The second thing is that for a good part of this year I have been subjected to a freeze on hiring, and when the freeze was lifted, for the most part, we were required to absorb the vacancies that were in place, so that my ability to hire people is much more limited than the Congressional numbers that you have would indicate, as illustrated in the last chart I submitted. I have very restrictive ceilings under which I am operating.

Mr. ROYBAL. Mr. Secretary, I realize you have been in your present position for about a year.

Secretary CALIFANO. But we can do better. I am not saying we can't do better.

Mr. ROYBAL. That is exactly my point, that just because the record has been so poor in the past, there is no reason why it cannot be improved, and I think you agree with me that improvement is something that is needed at the moment?

Secretary CALIFANO. Yes, it is.

IMPROVED DATA COLLECTION BY FEDERAL AGENCIES

Mr. ROYBAL. Let's go into still another area, and this is P.L. 94–311. Too often I hear the programs don't reach our Spanish community because officials don't even know that the problem does exist.

This legislation is directed toward that purpose, that is, calling for the improvement on data collection by different Federal agencies, including HEW. Does that include HEW?

Secretary CALIFANO. Mr. Roybal, I am not personally familiar with that law. I would have to check and submit answers to that question for the record.

Mr. ROYBAL. I may be mistaken that it does include HEW, but will you find out if it does?

Secretary CALIFANO. Yes, and what we are doing to comply with it.

[The information referred to follows:]

DATA ON HISPANIC-AMERICANS

PL 94-311, among other things, mandates that the Department of Health, Education and Welfare along with the Departments of Commerce, Labor and Agriculture shall each collect, and publish regularly, statistics which indicate the social, health, and economic conditions of Americans of Spanish origin or descent. In order to determine its compliance with this law, HEW recently conducted a Department-wide survey of data collection activities as they relate to Hispanic-Americans, particularly in light of PL 94-311. Our preliminary review of this survey indicates that the Department is collecting Hispanic-American data through several of its collection activities and breaking out some of the data by sub-groups which reflect Mexican, Puerto Rican and Cuban backgrounds. This survey's preliminary findings indicate that the Department has initiated the data collection activities required to implement this law. Additionally, we are considering the need for actions to accelerate full implementation.

BILINGUAL EDUCATION

Mr. ROYBAL. An increase of $50 million is requested in 1979, earmarked for teacher training research. Will research include activities on how bilingual funds are being spent by school district?

Secretary CALIFANO. I should make a couple of points. The research we are after there is largely research on how to teach English to students whose primary language is other than English, on how to do it fast and effectively, and what the differences are at different grade levels. We don't have a good sense of that. That is the bulk of that research.

We are trying to take a hard look at the bilingual education program, I indicated earlier we are really not satisfied with the way it works. It has become an incredibly complex program. I think we teach about 90 languages now through that program, and we tend to think of it as a Spanish-speaking program or, with the increase in cities like New York, a French bilingual program. But when we settled the civil rights issue with the City of Chicago, the issues relating to bilingual education, the thing that surprised me during those negotiations was that they were required to have 20 different bilingual programs in the city. So it has become a very complicated program.

Mr. ROYBAL. We were talking about the legislative intent a little while ago. I think the legislative intent with regard to this legislation should be carefully studied. I believe it was the intent of Congress that the language of the home be used for the teaching of English. Now, there have been a lot of complaints made with regard to Title VII and the way the funds are being used. Actually, questions are asked of me concerning the misuse of Title VII funds.

Have you looked into the allegation that these funds have been misused?

Secretary CALIFANO. We are looking at that, Mr. Roybal, both in terms of inept use, ineffective use, as well as in terms of active misuse.

We are looking at these programs now. I think the Commissioner of Education is looking at them, and I have asked our whole Office of Planning and Evaluation to look at them.

Mr. ROYBAL. That will include a study of how school districts are using these moneys?

Secretary CALIFANO. Yes, sir.

Mr. ROYBAL. Because it is my understanding that different school districts place a different interpretation on what bilingual education is.

Secretary CALIFANO. Yes, I have heard the same thing, and we are in the process of looking at that.

One of the things that seems to plague the program is that you can't put your finger on it; there is not a clear sense of direction, or clear sense of purpose, and we are getting into that now.

Mr. ROYBAL. I was the author of the original bill in the House, Senator Yarborough was the author in the Senate, and it was definitely our intent that the language of the home be used as the vehicle for the teaching of English.

Secretary CALIFANO. I am not saying there isn't a clear Congressional intent. My point was that there doesn't seem to be a clear purpose or intent driving the program within HEW as it administers that program with the school districts.

Mr. ROYBAL. I understand. Thank you.

ARCHITECTURAL BARRIERS REMOVAL

I have one other question I would like to ask with regard to aid to the handicapped. $50 million to aid higher education institutions in eliminating barriers is planned for fiscal year 1979.

Secretary CALIFANO. That is correct.

Mr. ROYBAL. Estimates, however, in my State vary from $24 million on up to make facilities accessible. Do you think that the $50 million is sufficient for this purpose?

Secretary CALIFANO. Mr. Roybal, two points, I guess: One, under the regulations we put out last April, there is a 3-year period before any structural changes have to be made. Number two, the most significant change I made in those regulations from the draft that was completed before I arrived at HEW was to put the focus on program accessibility rather than structural accessibility so you could move the class to a lower floor to reduce those costs.

Number three, we have, over the past several months, been making a much more sophisticated analysis of what the costs to higher education are likely to be in structural terms, and we will have much better numbers for the Congress next year, if not before then.

Mr. ROYBAL. Good.

VOCATIONAL EDUCATION BUDGET

Now the $7 million has been reduced from vocational education in fiscal year 1979, specifically in consumer and home-making education. Instead of complete elimination, why haven't funds been redistributed within the vocational education, for example, to bilingual vocational training or in other appropriate areas?

Secretary CALIFANO. Well, we made an increase of $15 million in the bilingual program.

The concept, we thought, of the Voc-Ed program vis-a-vis consumer and home-making education was to serve as a catalyst. We think we have enough funds to serve as a catalyst, and some local school districts should start picking up some of those tabs.

You know, we just had to make judgments across the line on how much money we could put in the budget, and there was a limit to how much we could put in and a limit to how much OMB would stand for.

TUITION TAX CREDIT

Mr. ROYBAL. Mr. Califano, this is perhaps not a question that you can answer, but perhaps can place in the record; this is with regard to the tuition tax reduction. Educators seem to be on all sides of it. Will you tell us in the future what you think of it, even if you have to do it on a private basis?

Secretary CALIFANO. I will do it on a public basis. I don't have any hesitation in telling you.

Mr. ROYBAL. All right.

Secretary CALIFANO. I think it is the wrong way to go. For higher education it has been debated for many years now, and we have come up with what we think provides adequate relief for middle income families. As Mr. Smith noted, there is likely to be some change in that proposal as it works its way through the Congress. I think the House Education and Labor Committee will make some changes, but they will report out a bill based essentially on existing programs that requires the legislation to go through the Education Committees and the appropriations process, that provides flexibility, and that does not provide funds for the middle class at the expense of the poor people in higher education.

We tend to think of tax credit as being something simple, but it does introduce yet another bureaucracy into the arena of higher education, because there will have to be rules and regulations about what a student is, what a course of study is, how many hours will have to be spent. There is now a difference between HEW and V.A. on what a full-time student is, which the universities and colleges are complaining about.

Mr. ROYBAL. Do you oppose the tax credit allowance now proposed?

Secretary CALIFANO. We do. At the elementary and secondary level, I think it presents a more serious problem. I noted earlier, without going into the detail I went into then, if you take the one tax level that would apply at that level and give it to the pupil in private schools, which that would do, plus the money they are already getting, you will be giving at least three or four times as much money per pupil to private schools as we give to public schools, and that seems to me not to make much sense.

Secondly, with respect to that, that is not a proposal that the Congress has really had much time to kick around and think through and argue about.

I don't defend the lack of administrative aggressiveness on the part of my department in getting funds to private school children that

they are entitled to under Title I and under other programs, but we are doing that now. The President made a commitment during the campaign to do that, and we are in the process of trying to fulfill that commitment. But we would be opposed to a tax credit. I realize it is a very popular thing this year.

Mr. ROYBAL. Popular in certain districts, and it is popular in a section of my district, but not all of it. So, again, the constituency, I think, is on both sides, as are the educators.

We went to an educational meeting one night and were lobbied on both sides, so we don't know where the educators stand; so I thought I would ask that question.

Secretary CALIFANO. The higher education associations, on the whole, strongly support the President's proposal or something like it.

Mr. SMITH. Or both.

Secretary CALIFANO. If you offer a kid two chocolate cakes, he will take them both.

Mr. ROYBAL. Thank you, Mr. Secretary.

Mr. FLOOD. Mr. Stokes.

MALDISTRIBUTION OF PHYSICIANS

Mr. STOKES. Thank you, Mr. Chairman.

Mr. Secretary, firstly, I would like to have some colloquy with you regarding the statement that there are too many physicians or doctors. I would assume that, relative to the position that the department has taken, that you conducted some type of a study?

Secretary CALIFANO. We have conducted studies, and I will submit all the data we have in that area for the record.

I would like to distinguish that general statement from the fact that doctors are not in the right places, either in terms of professional specialties or geographically in terms of the inner city and rural areas.

Mr. STOKES. That is why I thought we should have some colloquy on it, because I thought your statement with a couple of the members earlier today just did not cover the type of situation that I am familiar with.

I am sure your study must reflect the fact that in terms of the innercities, for instance, that there is an extreme maldistribution of doctors in terms of primary patient care?

Secretary CALIFANO. Very serious, and it varies, of course, but in New York City, my recollection is that we now have one physician for every 80 people. In Newark, New Jersey, I think, Mr. Patten, there are more than 800 people per physician.

Mr. PATTEN. 20 years ago there were 400 more doctors on High Street in Newark and they all moved out. You don't look for any easy answers here. We had 400 doctors move off High Street, Newark, in a year or two. You can't just pay a guy $60,000 to go back there to live.

Secretary CALIFANO. It is a serious problem, and, as Mr. Patten knows, there are no easy answers. We are using the National Health Service Corps to put doctors in inner cities as well as in the rural areas, and we have increased that program from 1,435 to 1,735.

MINORITIES IN MEDICAL PROFESSIONS

Mr. STOKES. Well, also, at the same time, I think correlating that problem is the fact that less than two percent of the doctors in America are black. You are familiar with that problem?

Secretary CALIFANO. Oh, yes, that hasn't changed for a long time. In that connection, we are supporting programs to encourage the minority doctors and minority students, including black students, to go into medical school. We have taken a very controversial position in the Bakke case to deal with that, and I think one of the very few places where we have provided funds to create additional capacity, if you will, in terms of medical school, the only one I am aware of in the last year is a black medical school in the South.

Mr. STOKES. Morehouse?

Secretary CALIFANO. Yes.

Mr. STOKES. This committee, in fact, appropriated $5 million of start-up cash for that university.

Secretary CALIFANO. That is right.

Mr. STOKES. That was a realization that in that area there is very serious disparity of black doctors, particularly who are willing to service the innercities, where we find large concentrations of the poor, minorities, blacks, and those who are officially classified as being medically indigent.

Secretary CALIFANO. That other point you are making by qualification is important as well. It is by no means clear that every black doctor we train is going to go into the inner city. In fact, they have the same desires and hopes and aspirations for the benefits of private practice as any other doctor has.

Mr. STOKES. That is certainly true, yet I think, as a practical matter, if I go in the innercity of Cleveland, I don't find white doctors practicing there. The few doctors practicing there happen to be black doctors. I guess that is why I wonder to what degree you feel that the National Health Service program that you made reference to this morning can even impact upon this type of a situation?

Secretary CALIFANO. Well, we think it can. We think over time it should be enlarged even more, and indeed as medical school continues to get more and more expensive, more and more students will go into the National Health Service Corps as the price of their medical education.

We don't have enough experience with that program yet to know in any solid way how many of those doctors will stay beyond the couple of years they owe to the Corps, but we think it looks like we have at least 20 percent retention rate.

Mr. STOKES. Before moving on to something else, I would just like to commend you and the administration for the position taken regarding that Bakke brief and the government's position, because I think in this same area, certainly it was important for the U.S. Government to take a good strong position as it did in the Bakke brief.

HOSPITAL COST CONTAINMENT

You mention, on page 19 of your testimony, that even though it would not affect this particular committee in terms of appropriation

under your hospital cost containment legislation, that it will reduce Medicare and Medicaid outlays by $730 million. I would be interested in any comments where you can explain how your legislation will accomplish that.

Secretary CALIFANO. The hospital cost containment legislation has two impacts on reduction. One relates to the percentage of increase by which hospital charges will be permitted to rise, and we would cap it, in a somewhat oversimplified way, at about 1.5 or slightly more times the general cost of living increases.

Secondly, there is a capital cap which limits the amount of construction that would be permitted, and that is $2.5 billion, with some exceptions to take care of some of the kinds of problems Mr. O'Brien raised.

To make that work, it has to apply to all hospitals, not just to Medicare and Medicaid hospitals. We had an experience in Colorado in which the State put a cap on Medicaid and held it down to about four or five percent and non-Medicaid hospital costs went up there about 40 percent. So we can't push one part of the balloon and let the rest go up. So it would apply to all hospitals.

The portion of the cost that applies to the Federal budget in fiscal 1979 is $730 million. That assumes that this program goes into place on July 1 of this year, which it is not likely to do now. The portion of the cost that it would save the country in 1979 is $2 billion, we estimate. That includes that $730 million. The $730 million comes largely from Medicare and Medicaid, although it comes from other places as well.

Mr. STOKES. I am told by the hospital industry that since you have proposed legislation affecting them, that they have begun policing their own industry. To what degree have you found that to be true?

Secretary CALIFANO. Well, the hospital industry has said that. They said that in 1974, when they asked the Nixon Administration to relieve them of controls. They said if you relieve us of controls, we will hold down the increases, and what happened was, since 1974, they have shot up at an average of 14.1 percent a year. In the month of December, which is after they had committed to this voluntary reduction, the charges for the month of December 1977, are 16.1 percent above the charges for the month of December 1976, so they are galloping along at very extensive increases.

My own judgment, and the President's judgment, is that the voluntary program will not work. If, as they say, they buy the concept of a cap on increases in revenues, if they buy the concept of a cap on capitalization increases, then they agree with us in principle. What they are arguing about is the percentage of reduction from existing increases that should be made. It seems to me the way you make a social compact in this country is that Congress hears everybody out and then passes a law and everybody is subjected to the same law, and you don't have a self-interested association keeping the books on the extent to which they reduced or have not reduced their cost.

BUSING AMENDMENTS

Mr. STOKES. I note, on page 30 of your testimony, Mr. Secretary, that you tell us that you are going to request the Congress to rescind

that provision of the law dealing with clustering with reference to school desegregation matters. I remember debating that particular amendment on the floor at the time our Labor-HEW bill was on the floor. One of the things I said at that time was that this type of emotional amendment put on this bill without any hearings and without any opportunity to scrutinize its effect would be to emasculate Title VII of the Civil Rights Act, Section 4, and I think it would be helpful to us if you can tell us what your experience has been since the amendment has been on the bill.

Secretary CALIFANO. The amendment has not been on the bill that long, but I think it does take away the last vestige of Title VI impact in terms of elementary and secondary education as far as student desegregation is concerned.

I think the President, when he signed the bill, indicated his displeasure with it. He also indicated his concern about the constitutionality of the provision. That is something that the Justice Department is now studying, and I believe is scheduled to file a position in court on the matter next week.

I think if that amendment stays in the legislation, it raises serious questions about HEW's ability to enforce Title VI as far as student desegregation is concerned, and may mean if that funding limitation is on there, that the bulk of that work will have to be done in the Justice Department and through the courts. I think that kind of restriction really hurts school superintendents who are trying to administer schools. My experience with most school superintendents is that they want to finish the job of desegregation and get on to other problems.

We are basically saying we won't give you the money to try and finish it in this way. But it hasn't been there long enough for me to tell you that it has had an impact in this case or that case. It certainly has had an impact in Kansas City, in our negotiations with Kansas City.

NATIONAL HEALTH INSURANCE

Mr. STOKES. One final question, Mr. Secretary: I am asked out in my congressional district quite frequently what the administration position is regarding national comprehensive health insurance. Can you tell us what your position is and what is the likelihood of our being asked to do something in this area?

Secretary CALIFANO. The President has indicated that he supports national health insurance. He will be submitting a proposal. He laid out some broad guidelines in his speech during the campaign. He has indicated that he will announce some principles for his program in the spring and that he hopes to send a legislative proposal to the Congress this year; indeed, in August or by August, before the recess.

Mr. STOKES. Thank you, Mr. Secretary.

Thank you, Mr. Chairman.

Mr. FLOOD. Mr. Early.

Mr. EARLY. Thank you, Mr. Chairman.

Mr. Secretary, as a junior member of this committee with four years in Congress, I think you are doing an outstanding job. I think you have made a fine presentation with the charts and graphs as it shows trends and the administration's position. But, at the same time, your

budget is so large and so complex that it raises more reservations and more questions.

REGIONAL OFFICE PERSONNEL

First, take employees: I notice you are going to reduce your regional office employees by 150 positions by 1980. Is that a trend, or a philosophy, to decentralize, or to centralize even more?

RESULTS OF HEW REORGANIZATION

Secretary CALIFANO. No, Mr. Early, that reflects the results of a reorganization. The objectives of the reorganization were three-fold: One, what had developed in the regional office was a duplication of my office sitting on top of five operating positions. We tried to eliminate the unnecessary part of that duplication and to have the five operating divisions—Social Security, HCFA, the Public Health Service, Education, and Human Development Services—report back to the operating heads here in Washington.

Mr. EARLY. You are not trying to centralize?

Secretary CALIFANO. No, and, secondly, what we are trying to do is get the States and cities to do more and try to give them more flexibility in doing it.

Mr. EARLY. I would like to see us go in that direction. Will you also supply for the record the number of your 150,000 employees are in Washington?

Secretary CALIFANO. Yes, I will.

[The information referred to follows:]

EMPLOYMENT IN WASHINGTON

The Department currently has 30,300 employees in the Washington metropolitan area; an additional 20,800 employees are in the nearby Baltimore metropolitan area. At this time Department-wide employment is 141,200.

NURSING EDUCATION CUT

Mr. EARLY. Can you explain how, on the one hand, you propose a cutback in nursing schools and nursing school support, while, on the other hand, the Labor Department is issuing special work visas to foreign nurses? The Labor Department tells us that nurses are a shortage category. Either you are right, or they are right. Really, it seems like the left hand doesn't know what the right hand is doing.

Secretary CALIFANO. That is not unheard of in government.

Mr. EARLY. I know, but we don't like to make it worse.

Secretary CALIFANO. I don't know whether we are operating under different laws or views. I can say I will get with Secretary Marshall, and we will supply something for the record.

Mr. EARLY. I think you should.

Secretary CALIFANO. I agree.

[The information referred to follows:]

NURSE IMMIGRATION

At the present time the Labor Department does not give any special preference to foreign nurses who wish to enter this country. In February 1977, nurses were removed from the Labor Department's list of preferred occupations for immigration.

EARLY RETIREMENT POLICY

Mr. EARLY. I understand you asked the Civil Service Commission to allow thousands of senior employees to retire early. Why do you need this authority.

Secretary CALIFANO. We need the authority. I think we need it both for our employees and because we need more flexibility. I think the most difficult problem in running HEW is the inability to hire people and the inability to fire people.

Mr. EARLY. I don't think, Mr. Secretary, we are correcting the situation by saying we are going to add 2,200 more employees here. You are asking us to retire them early, and then you say you want to hire 2,190 new ones. Can't they move laterally? In the Office of Civil Rights, you suggest you need 900 new investigators in 1978, and in your statement you suggest they will complete work on the backlog this year. Won't those 900 people be available?

Secretary CALIFANO. The early retirement would give us slots in which we could hire new people. The 900 new people for civil rights are flat-out additions.

COMMITMENT TO CHILD HEALTH

Mr. EARLY. Mr. Secretary, now shifting direction, there were several questions today directed at abortion, and both sides presented their views. In your comments this morning, you said we are not spending enough money to protect unhealthy children. I read recently articles by experts that claim thousands are born with preventable disabilities. "The big problem that is blocking efforts to help infants at risk of developing genetic disorders is ignorance, primarily on the part of the professionals."

In here it suggests that between 30 and 50 percent of the disabilities could be prevented with medical technologies currently available. Also in this item it suggests a study by the General Accounting Office last October which showed that a national investment of $18 million annually for diagnosing and treating seven genetic disorders would produce annual savings of $437.2 million by preventing disabilities from disorders. Do you agree with that?

Secretary CALIFANO. I think it is probably generally correct. That is why we put money first to change Medicaid, so we could take care of women who had their first pregnancy, to take care of women who are poor, who are married and not categorically eligible for Medicaid because they are not under AFDC or are in states which do not have an Unemployed Fathers program, why we propose to change the child health assessment program, because we are not reaching those kids. I think there is no question but that we don't do a good enough job in this case.

PRINTING OF LEGISLATIVE HISTORY

Mr. EARLY. So much of the colloquy in abortion deals with the health disagreements of this committee. How many copies of this did you

print? How much did this cost us? Would you supply it for the record, how many copies of this were printed and how much it cost?

Secretary CALIFANO. Sure.

[The information referred to follows:]

The Department paid $4,648 for printing costs of 450 copies of the legislative summary.

MATERNAL AND CHILD HEALTH SERVICES

Mr. EARLY. I have trouble with this. I think we should be spending much more money in preventing disorders in children rather than on abortion.

Secretary CALIFANO. Let me say, Mr. Early, I agree with you 100 percent on that point, and I hope that our budget reflects that. I went to a school in the South Bronx last year, and every child in that school was on welfare, 647 kids, I think. At the end of the day, I asked the principal and the guidance people and the teachers what would they want if they had some more money, and somebody said, you mean if we had $10,000 or $15,000? I said sure, what would you want? They said a nurse. Why? They wanted a nurse to go to the mothers as soon as they became pregnant to teach them how to take care of their kids and to go to the younger sisters and brothers of the children there and make sure they got the right guidance. It is clear that is the way we should go.

CHILD HEALTH RESEARCH AT NIH

Mr. EARLY. But, at the same time, Mr. Secretary, I understand that plans for an oncampus research center, in the National Institute of Child Health Care and Human Development, have been complete since the late '60's. There has been no movement. Is this factual?

Secretary CALIFANO. That is factual.

Mr. EARLY. It seems we are going in the wrong direction. We know on this committee that we are going to run into the abortion problem. If we had millions of dollars to address this, I think there would be an argument to substantiate the abortion question. All I see us doing is addressing the old problem we have had and not improving the situation. I think this would improve the situation.

Secretary CALIFANO. We looked at that, Mr. Early, as a proposal and possibility, especially since we were increasing by $33 million the amount of funds we were giving to that Institute. The judgment was made that this time was not the time to put that building up.

Mr. EARLY. I hope this committee disagrees with you.

PHS HOSPITALS

Mr. Secretary, you refuse to bite the bullet once again. I see in public health hospitals that you are recommending a proposal to study the past, present and future of the Public Health Service hospitals. I think we have had at least four of those studies. They all said the same thing, yet you are going to study it again. I can appreciate the political problems you have with this, Mr. Secretary.

Secretary CALIFANO. I will be submitting to this committee hospital-by-hospital recommendations this year. We will visit every single Public Health Service hospital.

Mr. EARLY. There are only eight of them.

Secretary CALIFANO. I know it.

Mr. EARLY. You have done four studies.

Secretary CALIFANO. They are in very interesting places in this country.

Mr. EARLY. I have problems with that, Mr. Secretary.

BASIC RESEARCH

One final line of questioning, Mr. Secretary. Recently, the Chairman held a meeting of the leading scientists in the country. They came in and made it clear to us, making their pitch for more basic research money. The President issued a statement that he has done that, and you have commented that he has, but I read your comments and don't see the money in here anywhere. I think, without any question, that you are cutting way back on new grants for basic research. You are increasing ongoing ones, but where does that put us in a year or two?

Secretary CALIFANO. In fiscal 1979 our budget will have a 13 percent increase in basic research.

Mr. EARLY. I meant to tell you about those statistics. You do an outstanding job with them. Let's talk about these Nobel scientists. They stated to us that they had a tremendous fear we were giving incentives to young investigators not to get into that field because we, the Congress, direct them to apply for grants. They identified cancer, and made a great case to me, that that wasn't the most progressive way to go.

Secretary CALIFANO. In terms of how many new scientists we are encouraging and what-have-you, I would have to submit that for the record, if indeed we can give you good numbers on that. I also will make sure that Dr. Fredrickson is ready in this area.

[The following additional information was supplied for the record:]

New investigators encouraged through new research grants

1979 Regular research grant program

Non-competing continuation grants	$913,417,000
Competing grants	155,175,000
New grant awards	137,800,000
Total, regular grants	$1,206,392,000

Of the $2,794,623,000 available to research institutes, about 43 percent or $1,206,392,000 is for the investigator-initiated regular research grant program. Within the regular grant program, about 11 percent is specifically set aside for new research grants. Within the total of 13,009 awards, this will permit about 1,828 new awards.

The increase in basic research dollars in the budget is obviously because of the budget numbers on NIH at the expense of other kinds of research.

Mr. EARLY. That is not really too revealing. I think, without exception, the NIH budget shows drastic cuts in new competing grants projected for fiscal 1979 in every area.

Secretary CALIFANO. Not in the child health and human development area. There, there is an increase of $33 million on a base of about $110 million.

CHILDREN IMMUNIZATIONS

Mr. EARLY. Mr. Secretary, in your statement, on the immunization program, you say we are going to cover from 60 percent to 90 percent of all children. You are only going up $12 million in the budget. Can you tell me why, if it is a question of money, you won't go up more and make it 100 percent?

Secretary CALIFANO. It is not a question of money. That is ample money to do the job. States are putting a lot of money in this. It is a question of reaching the kids and getting a system in place that will continually take care of the kids. I don't believe we need more money for immunization. It is also right up to the authorization.

Mr. EARLY. Your statement says it will only cover 90 percent, I thought.

Secretary CALIFANO. We set, as an objective, immunizing 90 percent of the children under 14 years of age against childhood diseases. That is the best we thought we could do at a maximum effort between now and October 1, 1979.

Mr. EARLY. Thank you, Mr. Chairman.

Mr. FLOOD. I have some questions, Mr. Secretary, that I will submit for the record, and you can supply your eloquent answer at that time.

Mr. Natcher?

REPROGRAMMING IN SUPPORT OF SMOKING AND HEALTH INITIATIVE

Mr. NATCHER. Mr. Secretary, as you recall, this morning, in discussing with you the reprogramming of some of the money for fiscal year 1978 in regard to your program on smoking and health initiative, I said to you that, in my opinion, the $500,000 unearmarked funds added by the Congress to the National Cancer Institute and the $500,000 unearmarked funds added by the Congress to the National Heart Institute did not have to be reprogrammed. The two other items, the million two, and the million one, in my opinion, had to be in the form of a reprogramming requests to the committee.

In answer to Mr. Obey, I believe you stated as far as this reprogramming request is concerned, you would be glad to send it to the committee?

Secretary CALIFANO. Whatever the committee desires, I will do.

Mr. NATCHER. Now, Mr. Secretary, briefly, we discussed this morning Dr. Cooper, who served as Assistant Secretary of Health, and I believe that in 1976 Dr. Cooper, in appearing before a Senate subcommittee hearing on smoking and other matters, said that smoking did not cause heart disease. That, I believe, is a part of the hearings.

Now, I would like to know how you can reconcile your statement that 220,000 deaths from heart disease can be attributed to smoking with Dr. Cooper's statement that cigarette smoking does not cause heart disease.

[The information referred to follows:]

Smoking and Heart Disease

Arteriosclerosis is the underlying condition leading to the great majority of heart attacks (coronary heart disease); strokes (cerebrovascular disease); pain on exercise or gangrene of the leg (peripheral vascular disease); sudden cardiac death and heart pain or exertion (angina pectoris).

Several factors including elevated blood pressure, elevated blood fats, diabetes, and tobacco smoking, particularly of cigarettes, can act to produce arteriosclerotic disease. At the average levels of blood fat, in the United States, cigarette smoking is a major cause of arteriosclerosis and its resultant diseases.

The evidence for this is the fact that the amount of arteriosclerosis found in series of cases at autopsy is directly related to the amount smoked by the deceased patients. Similarly, the amount smoked is directly and closely related to the risk of heart attack, of sudden cardiac death, of peripheral vascular disease, of rupture of the aorta from arteriosclerotic destruction, and, less consistently, of stroke.

Increases above the average in blood pressure and/or blood fats act together with smoking to multiply the risk of arteriosclerotic cardiovascular disease more than would be anticipated from the simple arithmetic sum of the individual risk factors. It is found that elevated levels of any one of the common risk factors carries about a two-fold increased risk of suffering disease; two factors entail about a four-fold increase in risk, and three factors carry more than eight times the risk of experiencing a first event of clinical coronary heart disease compared with persons who do not smoke and are free of elevated blood fats and hypertension.

In view of this it is difficult to explain the statement Dr. Cooper made in 1976. Epidemiological and other research evidence involving cigarette smoking and deaths from diseases of the heart, particularly coronary heart disease, have been reviewed by the National Clearinghouse of Smoking and Health in conjunction with the National Heart, Lung, and Blood Institute and the National Cancer Institute. The consensus of opinion, regarding excess deaths from cigarette smoking, is that smoking is a risk factor estimated to be involved in from 175,000 to 220,000 annual deaths from heart diseases, including 160,000 from the largest single killer, coronary heart disease.

Hazardous Substances in Cigarettes

No levels of tar, nicotine or carbon monoxide are considered safe, and smokers and non-smokers alike are better advised not to use cigarettes or other tobacco products. Epidemiologic studies conducted in the last 25 years indicate that users of an average of 2 cigarettes (of average 1950-1960 vintage) per day could not be found to have an increased risk of mortality, as compared to non-smokers. This amount of smoke would be on the average equivalent to a daily consumption of some 86 milligrams of tar, 6 milligrams of nicotine and amounts of carbon monoxide that would not increase the blood levels of carboxihemoglobin over 3.2 percent.

This analysis is obviously affected by statistical uncertainty, and special additional restrictions would be required for high-risk groups, such as coal, uranium and asbestos workers. Nevertheless, these tolerable limits have been formulated with conservative approaches, and it is likely that a rapid shift in cigarette consumption habits toward such values of smoke intake could result in a substantial reduction of the current epidemic of smoking related diseases.

Less Hazardous Cigarette

Realizing that no cigarette can ever be safe, NIH is trying to develop a cigarette which will subject the smoker to lower risks of lung cancer, heart disease or chronic lung disease than with cigarettes now available.

To develop such a cigarette, three phases are involved:

- Identification of toxic elements in cigarette tobacco smoke by epidemiologic studies oriented toward cancer, heart and vascular disease, and pulmonary disease.

- Evaluation of cigarette smoke toxicity by chemical analysis, skin tests, and inhalation tests.

- Modification of cigarette and/or tobacco to reduce smoke toxicity by testing of non-toxic materials as possible substitutes for tobacco, extraction of toxic elements, modification of physical characteristics of cigarettes, and modification of cigarette tobacco curing and manufacturing process.

The safety of the less hazardous cigarette will be tested by the same methods that are used today to determine the hazards of current cigarettes.

Mr. NATCHER. Further, Mr. Secretary, as an alternative to a higher excise tax, you have suggested a graduated tax based on the tar, nicotine and carbon monoxide content of cigarettes. In your speech announcing your antismoking campaign, you stated that this will give incentives to the manufacturers to market less hazardous brands and to smokers to switch to less hazardous brands.

What specific levels of tar, nicotine and carbon monoxide in cigarette smoke do you believe are less hazardous and how have you determined what those should be?

[The information referred to follows:]

HAZARDOUS SUBSTANCES IN CIGARETTES

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RESEARCH ON CIGARETTES

Mr. NATCHER. Next, Mr. Secretary, you have stated that your antismoking plan will include continued support for research aimed at creating a less hazardous cigarette. How do you propose to develop this less hazardous cigarette, and how will you be able to tell that it is less hazardous once you developed it?

[The information referred to follows:]

LESS HAZARDOUS CIGARETTE

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The safety of the less hazardous cigarette will be tested by the same methods that are used today to determine the hazards of current cigarettes.

Mr. NATCHER. I am concerned, Mr. Secretary, that the people, and especially young people, that they be equally informed about alcohol and drug abuse, unwanted pregnancies, venereal disease, proper nutrition, and so forth. Can you be sure that your particular emphasis on

smoking will not divert funds and personnel away from these matters, which we all believe to be right important?

[The information referred to follows:]

ACTIVITIES DEMONSTRATED TO BE DANGEROUS TO YOUR PEOPLE'S HEALTH

Activities related to smoking and health are a relatively new and small Departmental initiative, although some activities have been conducted in NIH and CDC for the past several years. $30 million in 1979 is modest, and certainly has not diverted resources from the other crucial activities such as alcohol and drug abuse and venereal disease control. The Department is proposing a major new initiative in adolescent health and pregnancy prevention. We are proposing to increase spending in this area from $196 million in 1978 to $338 million in 1979. We are also proposing to increase the budget for alcoholism (from $168 million to $174 million) and drug abuse programs (from $252 million to $275 million).

Mr. NATCHER. Thank you very much.

Secretary CALIFANO. Mr. Chairman, could I just comment on one or two of those points very quickly?

Mr. FLOOD. We prefer you do so for the record.

SMOKING AND HEART DISEASE

Secretary CALIFANO. There is one with respect to numbers Mr. Natcher asked me about this morning. It will take me about one minute to read this into the record.

Dr. Levy, head of the National Institute of Heart, Lung and Blood, whom I talked to at lunch time, said that 220,000 people died from heart disease as a result of cigarettes. The number used in my January 11th speech represents 30 percent of the more than 750,000 people who die of cardiovascular disease. It is generally agreed that 25 to 30 percent of cardiovascular deaths are attributable to smoking.

The 175,000 persons mentioned in the February 5th testimony before the House Subcommittee on Health took the conservative part of that estimate. That is the difference between the two numbers.

There is in this budget $174 million for alcohol, $201 million for drug abuse and $338 million to deal with the teenage pregnancy problems, all of which are substantially more than the $30 million for smoking.

Mr. NATCHER. Thank you.

Mr. OBEY. Will the gentleman yield for one question?

EFFECT OF IMPOSING PERSONNEL CEILINGS

This is, I suppose, along the lines of reprogramming; as you and I know, you are not responsible, but the practical effect is the same. The attempt of this committee is frustrated. I would hope in any conversations you have with either OMB or the President, you will point out the practical problem we have when they impose personnel ceilings, especially when that means these are positions which the committee specifically added by report language and which are, in fact, knocked off.

That puts us in a position where we have to at least look at what the Senate tried to do a couple of years ago when they tried to put in line items for positions. I opposed that in the past. I don't any more.

I think a number of people on this commitee agree with the Senate

position largely out of frustration. If we get to the position where we have to put in line items in the bill, that means those levels won't go up when taken to the floor.

So, it would seem to me that there has to be some accommodation reached, at least to the extent the position which this committee adds by committee report, are exempted by an freeze put on by the President.

I don't know where you come down on that: I won't expect you to comment on it, but for what it is worth, I would hope you would discuss it with both OMB and the President.

Mr. FLOOD. Mr. Michel.

INCREASED HEW EMPLOYMENT

Mr. MICHEL. An employee of HEW was recently quoted by the Washington Post as saying: "There's plenty of fat around here. You could go through the place and wipe out a third of the people and still have effective programs."

I contrast that statement with the increase in your personnel from 145,000 in 1977 to 149,000 in 1978 to 150,000 in 1979 and I have to wonder how efficient your administration really is.

Aren't you simply adding more fat to an already overweight department?

Answer that one for the record, but so they will fall in sequence here.

[The information referred to follows:]

Mr. CALIFANO. We are asking for new jobs to carry out new responsibilities and meet increased workloads. These have been both sought by the new Administration and conferred on the Department through Congressional action. I might note that over half of the staffing increase between 1977 and 1978 is the result of staffing authorizations provided by Congress beyond what the Administration requested.

In fiscal year 1978 we are asking you to authorize 1,279 new jobs beyond the staffing authorization in the 1978 conference report. Most of this staff (898) is for eliminating the complaint backlog in the Office for Civil Rights. We are also requesting new jobs for the Inspector General to expand audits of programs with a high risk of fraud and abuse (100), the General Counsel to keep up with the litigation workload associated with Social Security claims (103) and for the Health Care Financing Administration primarily to implement our new Medicaid Quality Control initiative (125). All of the new positions outside the Office for Civil Rights will more than pay for themselves in further savings of program dollars.

In fiscal year 1979 we are asking for an additional 911 new jobs. This new staff is for workload increases in the Social Security Administration for administration of recent amendments in the food stamp program (300), for 300 additional National Health Service Corps personnel who will be assigned to medically underserved areas, for the Health Care Financing Administration to handle workload increases in Medicare, Medicaid, and PSRO's (140) and for a further expansion of audits which promise a high payoff in reduced fraud and abuse (60).

"ACTING" PERSONNEL

Mr. MICHEL. An employee was also quoted as saying that the department is so overrun with people in simply an "acting" capacity that no one is willing to take responsibility for anything.

What about it? How many positions are currently filled with someone of an "acting" capacity?

Secretary CALIFANO. I will submit that for the record. On the first it went from 144,268 to a figure far below the permanent positions authorized by the Congress, which are the 148,900 that you cited.

[The following information was supplied for the record:]

ACTING DIRECTORS

Within the Department, there are 1,782 organizational components at the Division level and above. Of these, 443 currently have an Acting Director. This situation has been necessitated because of the recent reorganizations. We are currently establishing position descriptions for these positions and finalizing the selection process to make permanent assignments.

TREATMENT OF CAREER EMPLOYEES

Mr. MICHEL. From what I have observed, you seem to be appointing a lot of outsiders to most of the higher level appointive positions, and are passing over people who have worked their way up through Civil Service.

I would be the last to say if there is a change of administration and direction, that there should not be new blood brought in from the top.

How do you answer the argument that someone who really has been good and conscientious and works himself up through Civil Service then feels, "Well, this is as far as I can go; I am obviously going to get x'd out."

Is that a problem, morale-wise?

Secretary CALIFANO. I think I have spent as much time on personnel as anybody. I just cite two among the appointments, the Assistant Secretary for Personnel, Tom McFee, and Dr. Frederickson from NIH, who was there long before I became Secretary.

I have the power to appoint about 150 people——

Mr. MICHEL. You anticipated one of my questions.

Secretary CALIFANO [continuing]. In a department of almost 150,000.

Mr. MICHEL. A total of 150?

Secretary CALIFANO. Yes.

Mr. MICHEL. Out of how many?

Secretary CALIFANO. One hundred fifty thousand almost; less than one-tenth of one percent.

Mr. MICHEL. How many employees in the department have been downgraded or had their salaries reduced during the past year?

Secretary CALIFANO. I can't answer that, but I did get the Civil Service to agree to a moratorium on downgrading until I put the reorganization into effect.

Mr. MICHEL. Do you support that legislation which would, in effect, prohibit downgrading?

Secretary CALIFANO. I wrote a letter to OMB strongly supporting—I will just have to submit it for the record.

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D.C. 20201

MAR 14 1977

The Honorable Bert Lance
Director, Office of Management
and Budget
Washington, D.C. 20503

Dear Mr. Lance: Bert

A great deal of attention has been focused over the past few weeks on ways to minimize the adverse effects of reorganization and downgradings on Federal employees. I know this is being discussed actively in the Civil Service Commission and in the Office of Management and Budget.

Over the past several years the Civil Service Commission, General Accounting Office and our own Departmental people have reviewed 5,800 HEW positions. Nearly 20% were found overgraded. In order to get a handle on the problem and to bring the situation into compliance with the law and with Civil Service Standards, the Department started a systematic review of all its positions to be completed in late 1979. If the error rate experienced thus far were to hold, we are talking about 30,000 overgraded jobs. Even though we avoid permanent adverse impact on 90% of the incumbents of these jobs by reassignment or by restructuring the job, 3,000 employees will get demoted.

As we move on with some of our own reorganizations, the prime resistance will be the employee's fears that the situation will be worsened. The numbers of overgraded jobs and demotions do not tell the whole story. These numbers hide the frustration and disappointment of thousands more employees and managers alike, not to mention the obvious program disruptions. Many hours, dollars and efforts, which should be going into program improvement are expended on letters to Congress, grievances, appeals, legal battles and other nonproductive activities. In addition, even some of

the restructuring efforts to partially alleviate the effects of downgrading actually lead to layering and ineffective organizational arrangements. I do not believe we can afford to tolerate the adverse impact on the programs during a time so critical to this administration's plans.

What is needed is modification of the Civil Service classification legislation or regulation to allow for grade and pay retention for those employees whose job grades are adversely affected by reorganizations or through no fault of their own, such as the past grade-creep situation. Although the present system allows for pay retention for two years for most employees, there is no provision for grade retention. I believe we need an indefinite pay and grade retention capability. I am convinced that the cost of "Grandfathering" is going to be far less than the actual costs of living with the current problems. Industry has long recognized the principle as a "price" for reform.

I recognize there are difficulties with many of the technical details of such a proposal, but I think those problems can be overcome by a concentrated and creative effort by the Civil Service Commission, your office, and the Executive Departments. I stand ready to work with you in drafting specific proposals including new legislation, if necessary, to accomplish the above objective.

Sincerely,

Joe

Joseph A. Califano, Jr.

EARLY RETIREMENT

Mr. MICHEL. I understand Mr. Early asked you something with respect to the Civil Service Commission approving early retirement for HEW employees at the age of fifty, but I wonder if the question was asked whether or not the Commission actually had approved the request?

Secretary CALIFANO. They have not, as yet. We are still in conversation with the Commission on it. I hope that they will.

Mr. MICHEL. Do you get any feel for whether they will say yes or no?

Secretary CALIFANO. No.

Mr. MICHEL. How much will such early retirement cost the government in terms of total increased pension annuities and loss of pension contributions taken?

Secretary CALIFANO. Far less than the government will save by getting new blood in the department and a much more efficient operation in the department.

Mr. MICHEL. For the record, expand on that.

[The information referred to follows:]

COST OF EARLY RETIREMENT

When we first considered the matter of early-out retirement, we looked into the issue of unfunded liability. The result of our study and inquiry into this matter indicated that there would be no increase in cost of an annuity since the annuities are paid from employee and Government contributions. In addition, the 2 percent a year reduction in an annuity for persons who retire under age 55 partially offsets the loss of early-out retirement contributions.

Mr. MICHEL. The Military retirement program has become an increasingly costly endeavor because of early retirement. Isn't the same think likely to happen in HEW if you start promoting early retirement?

Secretary CALIFANO. I think not. The numbers are much smaller and I really believe over the long haul this will save the taxpayers a lot of money.

Mr. MICHEL. If you can justify it and if it makes sense, I am all for it. Lay it out in the record, if you will.

[The information referred to follows:]

Early-Out Retirement

Early-out retirement authorization in the Federal Service is for the specific purpose of opening up jobs for employees who might otherwise be adversely affected due to reorganizations, cut-backs in staff, or similar changes. Such authorization, when granted, is only of a specific period of time, usually of short duration.

As a result of organizational changes in 1977 that I believed were necessary for the effective management of this Department, we determined that about 2,000 positions exist at grade levels higher than currently required. We also had found about 1,500 other jobs orvergraded in classification reviews and anticipated more. To avoid demoting the occupants of those positions, I asked the Civil Service Commission for a "demotion delay" and I also established a special program to assign the affected employees to other properly graded positions as vacancies arose. We recognized that the retirement of a number of people under the early-out retirement option would create more vacancies into which overgraded employees could be placed.

In thinking about the feasibility of an early-out retirement authorization for our Department, we concluded that, in the long run, the Government would save about $15 million annually.

To determine the savings, we estimated 1,300 employees would take an early-out retirement. If this number continued on the rolls until they were eligible for regular retirement, the estimated employee cost would be about $45 million annually, at current salary rates. Under the special placement program we established, the vacancies created by early-out retirement would be filled by the employees in overgraded positions. Once the reassignments are made to these 1,300 positions, the resulting vacancies would be filled at lower grade levels. We estimated the cost of filling these vacancies to be about $36 million. This results in a savings of about $9 million. Additional savings would accrue from the cascade effect of subsequently filling these additional vacated positions, at the proper grade level through our special placement program. These additional savings were estimated to be $6 million.

It should be noted that savings to the Government do not immediately occur when employees are downgraded or separated. The cost of early-out retirement would need to be weighed against the cost of salary retention and severance pay -- benefits which I strongly support but which are costly when large numbers of employees receive them.

SALARIES PAID TO SCHEDULE C APPOINTEES

Mr. MICHEL. The Civil Service Commission has adopted new regulations governing the payment of salaries to new Schedule C appointees which no longer require salaries to be roughly comparable to those received in their previous jobs, but allow so-called education or experience to be taken into account. This resulted, in essence, as I understand it, because Sam Brown in ACTION wanted to bring some radical activists on board in top policy positions at much higher rates of pay than they were previously earning. I find this is not only confined to his shop, but is also going to be an accepted practice through all departments.

Secretary CALIFANO. Mr. Michel, I would have to check. Several of the departments early in the administration had trouble with that in the context of bringing in women and minorities particularly under the comparability provision.

We, to my knowledge, had no problems with employees under the prior regulations, but I think there were other departments which had many problems and that is what caused the Civil Service Commission to change its provisions.

Mr. MICHEL. Are any new HEW appointees receiving higher salaries because of this change?

Secretary CALIFANO. I doubt it, but I can certainly——

Mr. MICHEL. Would you supply whatever you might have for the record, a list as to their previous salaries and positions?

[The information referred to follows:]

As a general rule the Department's approach in hiring Schedule C's has been to grant no more than the equivalent of one GS-grade level increase in earnings (a current promotion from GS-14/1 to GS-15/1 results in $5421 increase; a GS-13/1 to GS-14/1, $4728; GS-12/1 to GS-13/1, $4139, etc.). Of the 72 Schedule C employees who have entered on duty since January 1977 in positions GS-15 and below:

42 were appointed at no more than the equivalent pay increase of one GS-grade level over their previous earnings

7 received little or no change in pay

6 actually accepted salaries lower than their previous earnings

17 received more than the equivalent of a one GS-grade level pay increase. Of this number:

- 6 previously served in various positions with the U. S. Congress
- 4 came from the educational community
- 3 previously worked in positions of significant responsibility as a member of the Presidential campaign staff
- 1 served as a legal assistant with the Center for Law and Social Policy
- 1 worked as an administrative assistant in a professional organization
- 1 served as an associate producer of a news program for one of the major networks
- 1 served the director of a municipal planning group in a city in Florida.

With respect to the 17 who received an increase in basic pay of more than one grade, all but one were women. In many situations we found previous job responsibilities were not necessarily reflected by the salary earned. For example, some organizations historically have compensated their employees at relatively low levels, i.e., state and local governments, and social and community organizations. The expertise gained in such experience, however, is often what we need for many of our policy advocacy positions. In addition, personal benefit packages, stock option plans, expense accounts, grants, tuition payment plans, consultancies, and the like contribute substantially to the earnings of prospective HEW Schedule C's. None of these are "salary", and all are forfeited upon entry to Federal service. Consequently, these factors occasionally are recognized by a larger-than-usual pay adjustment upon appointment.

In summary, none of our Schedule C appointees has received an excessive salary with the Department. All of these individuals are, in fact, receiving salaries that are commensurate to the levels of responsibility they hold and the particular background they bring to their respective positions.

FLEXITIME

Mr. MICHEL. Have you established any overall program of flexitime work weeks in HEW outside of Social Security?

Secretary CALIFANO. I don't think so. I will have to submit the response for the record.

[The information referred to follows:]

FLEXIBLE WORK SCHEDULES

HEW organizations may participate in flexible work schedules on an experimental basis. There are approximately 35 HEW organizations conducting flexitime experiments in addition to those being conducted in the Social Security Administration. These involve a total of approximately 14,000 employees in headquarters and field organizations. The results, to date, have been very favorable.

Mr. MICHEL. Have you ever been asked what your general concept is—what your view is of the concept?

Secretary CALIFANO. I think we are looking at it, but I can't be sure; and I would really like to think about it and submit it for the record.

[The added information follows:]

I believe the concept of flexible work schedules is one well worth exploring. I support the draft legislation now before Congress that would authorize Federal agencies to experiment with flexible and compressed employee work schedules. Such experimentation will, I believe, allow us to determine whether modified work schedules enhance the quality of life for affected employees, and conserve energy.

DOUBLE DIPPING

Mr. MICHEL. Do you know how many individuals receiving military pensions, Secret Service pensions or whatever, are currently employed at HEW?

Secretary CALIFANO. I don't know, but if we have that information, I will submit it for the record.

[The information referred to follows:]

There are 496 employees in this Department who are currently receiving military or civil service pensions. Of this number, 403 are receiving military pensions and 93 are receiving civil service annuities. We have a very small number of employees covered by other retirement systems, but these are not identified in our personnel data system.

PROPOSALS ON WELFARE REFORM

Mr. MICHEL. The special welfare subcommittee in the House recently approved a liberalized version of the already liberal Carter proposal, legislation which the Congressional Budget Office says would cost the Federal Government $21 billion more than the existing program in the first year alone.

Are you still supporting this program the President was talking about initially?

Secretary CALIFANO. We like our proposal better than the proposal that came out of the special subcommittee of the House, although that subcommittee retains the basic principles of the President's program.

Our proposal is less expensive.

Mr. MICHEL. What are your up-to-date figures as to what your program will cost? We had all that talk in that press conference that it would cost only two billion more, but I see a $12.8 billion figure in the administration's budget.

Secretary CALIFANO. That included a host of offsets to show how we got to the $12.8 billion level, which assumed a wellhead tax, a rebate of $45, and it included only the cost of the earned income tax credit which went to people below the poverty line. It was tax relief for middle-income taxpayers. The biggest difference between the congressional budget office estimate of our program and the estimate we put forward relates to the jobs program. I think we are remarkably close to what it would cost to run the cash assistance aspect of the program. I think it is less than ten percent which, in this program, is less than a billion dollars.

We have prepared reconciliations which will show the differences and I will be happy to submit those for the record.

[The information referred to follows:]

A Comparison of Budget and CBO Fiscal Year 1982
Cost Estimates of the Program for Better Jobs and Income

The table below provides a line by line breakdown of the differences in Fiscal Year 1982 cost estimates of the Program for Better Jobs and Income included in the President's Fiscal Year 1979 Budget and those delivered to the House Subcommittee on Welfare Reform by the Congressional Budget Office on January 25, 1978. A detailed explanation is provided in the paper that follows.

Estimates of the Costs of the Program for
Better Jobs and Income in Fiscal Year 1982
(dollars in billions)

	Budget	CBO	Difference
Gross Costs			
Cash	25.95	28.11	+ 2.16
Jobs	9.90	11.51	+ 1.61
EITC	2.95*	2.63*	- .32
(Present EITC)	(1.03)	-0-	(- 1.03)
(New EITC for those eligible for cash assistance)	(.62)	(1.12)	(+ .50)
(New EITC for those ineligible for cash assistance)	(1.31)	(1.51)	(+ .20)
Total Gross Costs	38.81*	42.25*	+ 3.44
(Total gross cost, excluding the EITC for those ineligible for cash assistance)	(37.50)	(40.74)	(+ 3.24)
Offsets	30.04	24.89	- 5.15
Net Costs	8.77*	17.36*	+ 8.59
(Net Costs, excluding the EITC for those ineligible for cash assistance)	(7.46)	(15.85)	(+ 8.39)

Note: Totals may not add due to rounding

*Both the Budget and CBO include in their net costs the amount of EITC benefits paid to persons ineligible for cash assistance benefits. HEW has not included these costs as part of welfare reform in previous estimates.

I. Differences in Cash Program Estimates

CBO has estimated the cash portion of the Program for Better Jobs and Income for FY 1982 at a cost which is $2.16 billion higher than the estimates submitted in the President's FY 1979 Budget. This difference is due to numerous different assumptions about both the state of the economy in FY 1982 and about the operation of the program in that year. Additionally, there are some significant differences in both the estimating techniques and the data bases used. These complex differences can be summarized as follows.

A. Data Base Differences

CBO used as its data base the 1974 Current Population Survey. Budget estimates are based on the 1975 Survey of Income and Education. CBO adjusts the survey data base to 1982 on the basis of economic and population projections and then prepares estimates using the adjusted data base. The Budget estimates are made on an unadjusted data base and the results are then modified to reflect FY 1982 economic and population projections. There appear to be significant differences in the proportion of low income single-parent families and single persons estimated by these methods. An HEW analysis has shown that non-aged, non-disabled single parent families constitute 43% of CBO's recipient population as compared with 33% of the Budget recipient population. This same analysis shows that non-aged, non-disabled single persons constitute 10% of CBO's recipients and are only 4% of the Budget recipient estimate.

This difference in the make-up of the recipient population has significant impacts on Federal cash costs and on hold harmless costs since average payments per person for these groups are higher than for others eligible for the program. HEW has estimated that these differences increased CBO cash cost estimates by $1.82 billion over the Budget estimate.

Budget analysts believe that the Administration's estimates are more accurate for the following reasons:

(1) The Survey of Income and Education, three times larger than the Current Population Survey used by CBO (150,000 households vs. 50,000), was taken specificially to count the number of families with children in poverty . The larger sample size was used to count precisely the kinds of families for which CBO estimates exceed the Budget's.

(2) CBO bases its projection of single parent families on recent growth rates of that demographic group. While such projections are always subject to uncertainty, it is fair to say that a consensus of experts believes that in the future, while this group will continue to grow, its growth will be concentrated among higher income families that would not be eligible for cash assistance.

Additionally, the CBO data base contains lower asset levels than the data base used in the Budget estimates. By including specific questions concerning assets, the Survey of Income and Education provides a more complete picture of the asset holdings of families eligible for PBJI. CBO estimates that the assets test will save $850 million less than the Budget estimate and, accordingly, projects greater outlays for cash assistance.

3. Program Assumptions

CBO has made several assumptions about the operation of the program which differ from the Budget assumptions. First, CBO has assumed that program eligibles would participate at a higher rate: an overall participation rate of 89 percent (on a dollar basis) rather than the 86 percent assumed by the Budget. The participation rates on a person basis are 89% for CBO and 84% in the Budget estimate. This increases CBO estimates by $700 million. Program participation rates (i.e., the percent of eligible persons who receive benefits) under current program provide the only hard evidence on which to base a projection of such rates in the future. Estimates of participation in the existing Food Stamp program, which is open to all low-income persons, ranges from 50 percent to 60 percent. The aged show a 53 percent participation in the Supplemental Security Income program. Single parent families (in AFDC) and the disabled (in SSI) show high participation rates, 91 percent and 81 percent, respectively. However, only an estimated 20-25 percent of two parent families who are eligible for AFDC-UF in 26 states actually claim benefits. Both CBO and the Budget analysts believe overall participation will rise from that in current programs. CBO believes it will rise to a greater extent.

Second, CBO has assumed that the income tax laws which existed in 1977 would prevail through 1982. The Budget has assumed that tax thresholds (i.e., the income levels where tax liabilities begin) would be adjusted upward over time, as they have been in the past. This dramatically affects the cost of the tax reimbursement provision of PBJI which provides for tax reimbursement to cash eligibles whose net earnings have been reduced by income taxes. This tax assumption increases CBO cost estimates by $810 million.

Third, CBO has assumed the program would be implemented in April 1981. The Budget assumption is that the program would not be implemented until July of 1981. Thus the benefits in the first quarter of fiscal year 1982 (October-December 1981) have been adjusted for one more quarter of Consumer Price Index change in the Budget estimate. In addition, the Budget assumes that benefits would be readjusted as of January 1, 1982 for another six months of inflation. Thus the Budget estimates assume benefit levels for the last three quarters of fiscal year 1982 that have been adjusted for three more quarters of Consumer Price Index change. This difference along with differences in assumed level of increases in the Consumer Price Index acts to lower CBO cost estimates relative to the Budget by $1370 million.

C. Economic Assumptions

CBO has a generally more optimistic set of economic assumptions for 1982 than the Budget. General inflation assumptions are fairly similar (averaging 6.1% from FY 1978-FY 1982 for CBO and 6.0% over the same period for the Budget). This increases CBO costs by $30 million for items that are separately estimated such as administrative costs. CBO, however, assumes a slightly lower unemployment rate (4.5% vs. 4.7%). This decreases CBO cost estimates by $120 million.

Additionally, CBO assumes a significantly higher rate of real growth in the economy. This decreases CBO costs by $440 million.

D. Other Cash Differences

1. Puerto Rico Costs:

CBO has estimated that the cost of the cash program in Puerto Rico would be $380 million higher than the Budget estimate. The CBO estimate is based on data from the 1970 Census. The Budget estimate is based on data from the 1975 Food Stamp survey. Both estimates have been adjusted to FY 1982. Budget analysts believe the Budget estimates based on the later Food Stamp Survey are more reliable since the Food Stamp Survey covered roughly the same population as would be eligible for PBJI and has the advantage of being significantly more current.

2. Administrative Costs

While CBO has a higher participation rate and a different mix of recipients than the Budget, it projects a smaller eligible population. This reduces its administrative cost estimates by $330 million.

3. Emergency Needs

CBO has not adjusted the Emergency Needs block grant for inflation from 1978 to the date of implementation. While H.R. 9030 does not specifically provide for such indexing, the Budget estimates have assumed it would be indexed. This decreases their estimates by $100 million.

4. Start-Up Costs

The Budget includes $70 million for non-recurring program start-up costs in FY 1982. CBO does not. This decreases CBO cost estimates by $70 million. (CBO assumes that the program is in full operation in 1982 and thus projects no start-up costs by FY 1982.)

E. Summary of CBO and Budget Differences in Cash Estimates

CBO Estimate	$28.11 billion
Budget Estimate	25.95
Difference	$ 2.16 billion

Reconciliation ("+" indicates CBO greater than Budget):

o Data Base Differences	
Demographic structure of recipient population	+ $ 1.82
Assets information	+ .85
o Program Assumptions	
Participation Rate	+ .70
Current tax system unchanged	+ .81
Implementation date and level of indexing	- 1.37
o Economic Assumptions	
Inflation rate	+ .03
Unemployment rate	- .12
Real growth rate	- .44
o Other	
Puerto Rico costs	+ .38
Administrative costs	- .33
Non-indexing of Emergency Needs	- .10
Start-up costs	- .07
	+ $ 2.16

II. Differences in Jobs Program Estimates

CBO has estimated the costs of the jobs portion of the Program for Better Jobs and Income at $1.61 billion more than the Budget estimate. The difference stems largely from implementation assumptions.

A. Phase-In Assumptions

CBO has assumed that during FY 1982, the jobs portion of PBJI would be fully operating. The Budget cost estimate has assumed that the program would be phased-in over the course of FY 1982 as public jobs in the countercyclical CETA program decline to sustaining levels. This increases CBO cost estimates by $1.24 billion.

B. Different Slot Estimate

CBO has additionally estimated that the total number of jobs slots necessary when the program is fully implemented is 40,000 more than the Budget estimate. This difference is apparently due to the same kind of differences in the make-up of the recipient population discussed in the cash section. This increases CBO cost estimate by $370 million.

C. Summary of CBO and Budget Estimates of Jobs Program

CBO estimate	$11.51 billion
Budget estimate	9.90
	+$ 1.61 billion

Reconciliation

Phase-in assumptions	+$ 1.24
Different slot estimate	+ .37
	+$ 1.61

III. Differences in Estimates of the Earned Income Tax Credit

CBO has estimated its total EITC costs (i.e., benefits to those whose incomes are below and those whose incomes are above the cash assistance eligibility ceiling) at a level $320 million lower than the Budget estimate. This total difference is the result of several accounting and estimating differences.

A. Accounting Practices

The PBJI changes the method of paying the EITC benefits. Under present rules, eligible persons file for an EITC on their tax return, after the end of the tax year. Under the new EITC, Federal withholding taxes will be reduced during the tax year to provide EITC benefits on a continuing basis during, not after, the tax year.

The Budget estimates are based on projected actual Treasury payments during FY 1982. Some of these expenditures are tax refunds made during CY 1982 for claims filed on 1981 tax returns, under the old EITC Program. The CBO estimates assume that there is no carryover of refunds into the following calendar year under the old EITC rules (i.e., prior to the change in method of payment) and reflect only the costs of the new EITC.

The Budget estimate can be broken down as follows:

Outlays from old EITC in FY 1982:	1.03
Outlays from new EITC in FY 1982:	
To persons eligible for cash assistance	.62
To persons not eligible for cash assistance	1.31
Total	2.95*

* Total does not add due to rounding.

The differences between the Budget and CBO estimates can be summarized as follows:

Budget	$2.95 billion
CBO	2.63
Difference	$ .32

Reconciliation:

Inclusion of old EITC costs	+ 1.03 billion
Use of outlays rather than obligations:	
To persons eligible for cash assistance	- .50
To persons not eligible for cash assistance	- .20
	$ .33*

* Total does not add due to rounding.

B. Comparison to Prior Administration EITC Estimates

Two further points should be made about these estimates. First, previous estimates have not included EITC payments made to persons not eligible for cash assistance in the costs of welfare reform. Such payments were and are viewed as desirable but separate tax reductions. Both the CBO and the Budget estimates are therefore higher than prior estimates.

Second, the CBO EITC estimates assumes an implementation date prior to FY 1982. The Administration assumes an EITC implementation date of January 1, 1982. This means that in the Budget estimate, new EITC program costs are incurred for only three-fourths of FY 1982. Since CBO has assumed, as noted earlier that the program will be in full operation in 1982, it has no phase-in of the various program components.

The Budget assumes that the passage of wellhead tax legislation and the subsequent distribution of those tax revenues to PBJI eligibles through the cash guarantee will be a further offset to costs. Finally, the Budget assumes that savings which are realized through reduced fraud in the Medicaid program will be applied to PBJI costs.

Net difference: - $6.5 billion

C. Offsets Included by CBO but not in the Budget

CBO includes two offsets and one additional cost not included in the Budget. The single largest element is a $650 million increase in Federal income tax revenues. These increased revenues appear again to be due to CBO's higher assumptions on wage growth.

CBO additionally includes a negative offset which is due to increased administrative costs in Medicaid. These costs are assumed to occur because of added complexities in integrating PBJI with the existing Medicaid Program. The Budget has assumed the Administration will propose health insurance reforms which will eliminate these costs.

Net difference: + $460 million

Summary of Offset Difference

	Budget	CBO	Difference
AFDC	7.61	8.97	+1.36
SSI	7.08	6.09	- .99
Food Stamps	6.05	6.69	+ .64
EITC	1.03	.56	- .47
Work Incentive Program	.37	.48	+ .11
Increase in FICA taxes	.50	.48	- .02
Regular Unemployment Insurance	.30	.44	+ .14
HUD	.60	.72	+ .12
Included by the Budget but not by CBO:			
Extended Unemployment Insurance	.60	——	- .60
CETA public sector jobs	3.90	——	-3.90
Reduced fraud in medicaid	.50	——	- .50
Wellhead tax revenues	1.50	——	-1.50
Included by CBO but not by the Budget:			
Increased Federal Income Tax	——	.65	+ .65
Child Nutrition	——	.06	+ .06
Medicaid	——	- .25	- .25
Total	30.04	24.89	-5.15

Detailed Summary of Budget and CBO Differences in Cash and Jobs portions

	Budget	CBO ($ B)	Difference
Cash Program detail			
Basic Federal program (including State fee and Puerto Rico)	22.60	24.36	+1.76
Federal share of state supplements	1.99	2.04	+ .05
Hold harmless	.56	1.08	+ .52
Emergency Needs	.73	.63	- .10
Start up costs	.07	——	- .07
Total	25.95	28.11	+2.16
Jobs Program detail			
Wages and overhead	9.40	11.01	+1.61
Administration	.50	.50	——
Total	9.90	11.51	+1.61

Mr. MICHEL. What is your offhand estimate for prospects of new welfare legislation? Are you folks going to be hammering away and rushing it? Is it front burner, or back burner?

Secretary CALIFANO. It is front burner. That committee worked over the Christmas recess, came back for a tough markup——

Mr. MICHEL. I got the idea there was not all that much excitement any more in the Department. Was I reading wrong?

Secretary CALIFANO. There is plenty of excitement in the Department. The question is as to the level of excitement in the House. We are pushing very hard for that program.

MONTHLY INCOME REPORTING EXPERIMENTS

Mr. MICHEL. Last year we gave you funds to launch a demonstration program of the monthly income reporting concept which your director of Policy Research told us could reduce welfare costs by an estimated ten percent. Where does this demonstration program stand at present?

Secretary CALIFANO. The first contracts are going out—the first bids are requested for the State of Vermont. That program is going to pay off.

Mr. MICHEL. In total what is going to be obligated in that whole study in the coming fiscal year? It was ten million dollars we agreed to. I was initially pushing, frankly, for 20 because I wanted to be sure you had a big stake. Our initial studies were done in Colorado, were they not?

Secretary CALIFANO. Boulder and Denver, Colorado, and Oakland, California.

Mr. MICHEL. I thought if the concept was good we ought to make sure by providing a big industrial state——

Secretary CALIFANO. I also went up two weeks ago to New York. In that city they are on a 6-month reporting process. We will move them to monthly. It is still not retrospective.

It will be retrospective in Vermont. The lawyers in New York said they had problems with the state constitution going into an overall retrospective program.

CREATION OF A DEPARTMENT OF EDUCATION

Mr. MICHEL. There has been no secret that you have opposed the creation of a separate Department of Education, but then I see the President says that is one of the big revolutionary things that will happen in government this year.

Where do you stand?

Secretary CALIFANO. I wrote a book. I can't recall the name of the book, but unfortunately this debate hasn't helped sales. The argument has been made; the President has made a decision. The objective is now to put together the best Department of Education we can and try to get the Congress to enact it. That work is ongoing now and I think the first testimony on that subject will be before Senator Ribicoff's committee some time in March, I believe.

STUDENT AID PROPOSALS

Mr. MICHEL. Regarding this $1.5 billion student assistance proposal supposedly designed to aid middle-income families, as I understand it, there is really nothing new here. It would simply expand existing programs, is that correct?

Secretary CALIFANO. There are some legislative changes. They are not substantial, but they are important. There is legislation needed to make the changes in the guaranteed student loan program.

Mr. MICHEL. Would that increase the level from $15,000 to $25,000?

Secretary CALIFANO. Basically it would also set that level at $250 for up to $25,000. It would provide more flexibility than our contribution schedules. In the guaranteed student loan program, the changes would permit us to go to $45,000 in adjusted gross income and there are other provisions to enable us to pay another half percent in loans obtained from banks.

Mr. MICHEL. I assume you are fighting the tax credit approach.

Secretary CALIFANO. That makes less sense than going through the regular authorization and appropriation process. It provides less flexibility and more bureaucracy.

Mr. MICHEL. In the BEOGs program, supply for the record what the range would be as to individual grant size in the range from 15 to 25 thousand dollars.

Secretary CALIFANO. It ranges from an income of $8,650; where the maximum is $1,800, to an income of about $15,000, where it comes down to $250. We would fill in the other needs of the families in that $15 to $25 thousand range with increased authority to give them loans.

Mr. MICHEL. Is there any money in your budget to implement the expanded student assistance program in '79?

Secretary CALIFANO. I would have to know which program in 1979. Yes, it is the $1.46 billion.

Mr. MICHEL. Did you explore any other alternatives for student assistance, such as allowing families to set up a tax trust fund for education similar to the Keogh approach for retirement?

Secretary CALIFANO. We looked at that. We looked at the Abner Mikva approach. Basically that money was not well targeted; if you give a tax credit, you give everybody a tax credit. The President's tax legislation did include credit instead of deductions per child.

PROPOSED INCREASE FOR TITLE I

Mr. MICHEL. On that $400 million, your proposed increase for Title I, that is supposedly earmarked for basic skills. I look back ten, fifteen years ago and that is what I though the whole ballgame was about.

Is that some newfound thing all of a sudden?

Secretary CALIFANO. Title I is a compensatory program for kids to focus on reading and arithmetic. We hope the $400 million would provide a further concentration in terms of high concentrations of poverty in rural and urban areas and hopefully it would provide even greater focus on basic skills.

We are not doing well as a country in transmitting reading, writing and arithmetic skills to our kids.

Mr. MICHEL. We will get into some detail on that, particularly with those indicators as to impact aid. I think I would have taken the entire batch of money that you got there in the form of equalization because that appeared to be the only way in a hold harmless situation, which is a better way of equalizing everybody in the end. It is so doggoned unequal now because of the inequity of that program.

Secretary CALIFANO. We looked at the equalization issue in view of the court decisions and what is happening in the state. We basically decided we did not understand well enough what to do. Requesting a budget for a couple of million dollars will give us a chance to study that and develop a proposal.

MEDICAID QUALITY CONTROL

Mr. MICHEL. Let me ask maybe one or two more questions.

In Health and Quality Control, the budget shows a savings of $399 million in 1979 due to expanded efforts to reduce Medicaid errors. How did you arrive at that figure?

Secretary CALIFANO. The Medicaid budget assumes we can make significant improvements in State operations by reducing errors due to claims processing liability of third parties and payments for ineligibles. The savings estimate assumes a 1 percent reduction in error rates per year, using the 75th percentile of the National error rate—8.6 percent—as a benchmark for deriving the savings.

One of the things we also want to do is increase sharply the sample we take. We sample about 18,000 and would like to take about 40,000. We believe there is about $600 million a year which is not being collected by Medicaid from third party reimburses such as Workmen's Compensation funds and private insurance companies.

We think $200 million is lost through duplicate payments, overpayments and what-have-you.

Basically, with respect to the Medicaid program, one out of eleven dollars is improperly spent. $1.2 billion a year is spent that should not be spent in that program.

RETROACTIVE SOCIAL SERVICE CLAIMS

Mr. MICHEL. On those retroactive claims, several months ago you announced the Department had agreed to settle a number of disputed claims which had been pending for a number of years. The immediate impact would be to require an additional amount to pay for these claims and judgments. Although this wouldn't be in our jurisdiction, I have to ask why, after contesting these clamis for years, the Department is now giving up and is ready to throw in the towel?

Secretary CALIFANO. We made the best judgment we could. We thought those claims were worth about what we settled for in terms of our ability to win and the arguments we were having with the states, litigation that would carry on for years and years. It is the best judgment we could put together.

Mr. NATCHER. Mr. Conte, I understand you have one question.

ARCHITECTURAL BARRIERS REMOVAL

Mr. CONTE. I am getting a lot of complaints from school people as to Section 504 of the Rehabilitation Act.

The regulations from the Department require ramps and other means of accessibility in schools.

Secretary CALIFANO. There are regulations which require programs to be made accessible. There is concern in the elementary and secondary schools that they require expensive changes for handicapped kids. We try to make it as inexpensive as possible. That is something that was passed without a word of debate or a single committee hearing in either house.

Mr. CONTE. We've just heard the beginning of this, haven't we?

Secretary CALIFANO. Well, it depends on how much they are able to do with the additional money we have in the Aid for Handicapped Act. That money could be used for construction.

Mr. CONTE. That's what I'm concerned about because I couldn't find anything in this budget for that item.

Secretary CALIFANO. That money, that $800-plus million, to which we added about $270 million this year, can be used for construction purposes.

Mr. CONTE. That is good. Thank you very much.

Mr. NATCHER. Mr. Secretary, we want to thank you for your appearance at this time in behalf of your budget request for fiscal year 1979. We will have a number of questions for the record.

The committee will adjourn until ten o'clock in the morning.

The following questions were submitted by Members of the Subcommittee with the request that they be answered for the record.

MARCH 1977 REORGANIZATION OF HEW

Mr. FLOOD. Mr. Secretary, this is the first budget which fully reflects last March's reorganization of your Department. The Committee had earlier requested that you supply a table fully reflecting the change in appropriation structure for fiscal year 1978. Do you have such a table which we can make a part of the record at this time.

Secretary CALIFANO. Yes, Mr. Chairman, I will provide the table you have requested.

[Table follows:]

Department of Health, Education, and Welfare
Labor-HEW Appropriations Bill, FY 1978

(Budget Authority in Thousands)

Agency and Appropriation	FY 1978 Per H.R. 7555 (Conference)	Effect of March 1977 Reorganization	Transfers within Labor-HEW Accounts WCF	Transfers within Labor-HEW Accounts Other	Transfer to or From Labor-HEW	FY 1978 Enacted Law	Supplementals Pending in Conference	Pay Cost Supplementals ('79 Budget)	Program Supplementals ('79 Budget)	Total, FY 1978 Request in Labor-HEW
Health Services Administration										
Health Services	1,274,586	-54,895	-1,783	- 6	-	1,217,902	-	+ 9,948	-	1,227,850
(Trust Fund)	(34,934)	(-34,934)				(-)				(-)
Center for Disease Control										
Preventive Health Services	211,505	-	- 667	+ 107	+ 19	210,964	-	+ 6,236	-	217,200
National Institutes of Health										
National Cancer Institute	867,136	-	- 702	-	-	866,434	-	+ 5,836	-	872,270
National Heart, Lung & Blood Institute	445,642	-	- 277	-	-	445,365	-	+ 2,561	-	447,926
National Institute of Dental Research	60,981	-	- 93	-	-	60,888	-	+ 830	-	61,718
National Institute of Arthritis, Metabolism, and Digestive Diseases	258,461	-	- 207	-	-	258,254	-	+ 1,992	-	260,246
National Institute of Neurological and Communicative Disorders and Stroke	177,000	-	- 184	-	-	176,816	-	+ 1,598	-	178,414
National Institute of Allergy and Infectious Diseases	161,042	-	- 175	-	-	160,867	-	+ 1,459	-	162,326
National Institute of General Medical Sciences	230,396	-	- 134	-	-	230,262	-	+ 445	-	230,707
National Institute of Child Health and Human Development	165,261	-	- 135	-	-	165,126	-	+ 1,254	-	166,380
National Eye Institute	85,000	-	- 63	-	-	84,937	-	+ 455	-	85,392
National Institute of Environmental Health Sciences	63,600	-	- 77	- 35	-	63,488	-	+ 712	-	64,200

Department of Health, Education, and Welfare
Labor-HEW Appropriations Bill, FY 1978

(Budget Authority in Thousands)

Agency and Appropriation	FY 1978 Per H.R. 7555 (Conference)	Effect of March 1977 Reorganization	Transfers within Labor-HEW Accounts: WCF	Transfers within Labor-HEW Accounts: Other	Transfer to or From Labor-HEW	FY 1978 Enacted Law	Supplementals Pending in Conference	Pay Cost Supplementals (FY 79 Budget)	Program Supplementals (FY 79 Budget)	Total, FY 1978 Request in Labor-HEW
National Institute on Aging	37,000	-	- 52	-	-	36,948	-	+ 338	-	37,286
Research Resources	144,947	-	- 49	-	-	144,898	-	+ 156	-	145,054
J.F. Fogarty International Center	8,369	-	- 24	-	-	8,345	-	+ 120	-	8,465
National Library of Medicine	36,746	-	- 111	-	-	36,635	-	+ 898	-	37,533
Buildings and Facilities	65,650	-	-	-	-	65,650	-	-	-	65,650
Office of the Director	17,871	-	- 29	-	-	17,842	-	+1,052	-	18,894
Sub-total, NIH	2,825,102	-	-2,312	- 35	-	2,822,755	-	+19,706	-	2,842,461
Alcohol, Drug Abuse, and Mental Health Administration										
Alcohol, Drug Abuse & Mental Health	938,882	-	- 819	-	-	938,063	-	+3,637	-	941,700
Saint Elizabeths Hospital	68,746	-	- 313	-	-	68,433	-	+5,738	-	74,171
Construction and Renovation St. Elizabeths	2,010	-	-	-	-	2,010	-	-	+55,300	57,310
Sub-total, ADAMHA	1,009,638	-	-1,132	-	-	1,008,506	-	+9,375	+55,300	1,073,181
Health Resources Administration										
Health Resources	786,869	- 74,316	- 597	-	-	711,956	-	+2,402	-	714,358
Payment of Sales Insufficiencies and Interest Losses	2,592	-	-	-	-	2,592	-	-	-	2,592
Medical Facilities Guarantee and Loan Fund	41,000	-	-	-	-	41,000	-	-	-	41,000
Sub-total, HRA	830,461	- 74,316	- 597	-	-	755,548	-	+2,402	-	757,950
Assistant Secretary for Health										
ASH, Salaries and Expenses	24,678	+ 95,529	- 373	- 66	-	119,768	-	+3,012	-	122,780
(Trust Fund Transfer)				(+ 90)	-	(90)				(90)
Retirement Pay and Medical Benefits for Comm. Officers	56,948	-	-	-	-	56,948	-	-	-	56,948
Scientific Activities Overseas	11,387	-	-	-	-	11,387	-	-	-	11,387
Subtotal, ASH	93,013	+ 95,529	- 373	- 66	-	188,103	-	+3,012	-	191,115
Health, Total	6,244,305	- 33,669	-6,864	-	+19	6,203,778	-	+50,679	+55,300	6,309,757

Department of Health, Education, and Welfare
Labor-HEW Appropriations Bill, FY 1978

(Budget Authority in Thousands)

Agency and Appropriation	FY 1978 Per H.R. 7555 (Conference)	Effect of March 1977 Reorganization	Transfers within Labor-HEW Accounts WCF	Transfers within Labor-HEW Accounts Other	Transfer to or From Labor-HEW	FY 1978 Enacted Law	Supplementals Pending in Conference	Pay Cost Supplementals ('79 Budget)	Program Supplementals ('79 Budget)	Total, FY 1978 Request in Labor-HEW
Health Care Financing										
Administration										
Grants to States for Medicaid	-	+10,699,000	-	-	-	10,699,000	-	-	-	10,699,000
Payments to Health Care Trust Funds	-	+ 7,242,941	-	-	-	7,242,941	-	-	-	7,242,941
Quality Care Management Research & Administration	-	+ 91,973	-1,530	- 22	+ 23	90,444	-	+2,485	+ 1,063	93,992
(Trust Fund Transfers)	-	(+ 34,934)		(+3,676)		(38,610)				(38,610)
(Limitation on Administrative Expenses)	-	(+ 648,547)	(- 133)		-	(648,547)	-	(+4,233)	-	(652,647)
Sub-Total, HCFA	-	+18,033,914	-1,530	- 22	+ 23	18,032,385	-	+2,485	+ 1,063	18,035,933
Office of Education										
Elementary & Secondary Education	3,181,050	-		- 100	-	3,180,950	-	-		3,180,950
SAFA	800,000	-		-	-	800,000	-	-	+ 31,000	831,000
Emergency School Aid	310,200	-	-	-	-	310,200	-	-	-	310,200
Education for the Handicapped	622,825	-	-	-	-	622,825	-	-	-	622,825
Occupational, Vocational, and Adult Education.	725,750	-	-	-	-	725,750	-	-	-	725,750
Student Assistance	-	-	-	+3,254,503	-	3,254,503	-	-	-	3,254,503
Higher and Continuing Education	3,599,503	-	-	-3,254,503	-11,500	333,500	-	-	-	333,500
Library Resources	253,212	-	-	+ 100	-	253,312	-	-	-	253,312
Special Projects and Training	100,659	-	-	-	-	100,659	-	-	-	100,659
Educational Activities Overseas	2,000	-	-	-	-	2,000	-	-	-	2,000
Student Loan Insurance Fund	280,724	-	-	+ 10,500	-	291,224	+15,000	-	+223,939	530,163
Health Profession Graduate Student Loan Insurance	-	-	-	-	-	-	-	-	-	-
Salaries and Expenses	125,389	+ 1,218	-3,155	-10,500	-	112,952	-	+5,006	+ 2,300	120,258
Higher Education Facilities Loan and Insurance Fund	1,847	-	-	-	-	1,847	+ 5,000	-	-	6,847
Sub-total, OE	10,003,159	+ 1,218	-3,155	-	-11,500	9,989,722	+20,000	+5,006	+257,239	10,271,967

Department of Health, Education, and Welfare
Labor-HEW Appropriations Bill, FY 1978

(Budget Authority in Thousands)

Agency and Appropriation	FY 1978 Per H.R. 7555 (Conference)	Effect of March 1977 Reorganization	Transfers within Labor-HEW Accounts WCF	Transfers within Labor-HEW Accounts Other	Transfer to or From Labor-HEW	FY 1978 Enacted Law	Supplementals Pending in Conference	Pay Cost Supplementals ('79 Budget)	Program Supplementals ('79 Budget)	Total, FY 1978 Request in Labor-HEW
National Institute of Education										
National Institute of Education	89,600	-	- 129		-	89,471	-	+ 600	-	90,071
Assistant Secretary for Education										
Salaries and Expenses	35,879	-	- 36		-	35,843	-	+ 470	-	36,313
Education Division, Total	10,128,638	+ 1,218	-3,320		-11,500	10,115,036	+ 20,000	+ 6,076	+257,239	10,398,351
Social and Rehabilitation Services										
Public Assistance	19,600,150	+19,600,150	-	-	-	-	-	-	-	-
Program Administration	73,000	- 73,000	-	-	-	-	-	-	-	-
Social Security Administration										
Payments to Social Security Trust Funds	7,955,144	- 7,213,941	-	-	-	741,203	-	-	-	741,203
Special Benefits for Disabled Coal Miners	967,623	-	-	-	-	967,623	-	-	-	967,623
Supplemental Security Income Program	5,250,000	-	-	-	-	5,250,000	-	-	-	5,250,000
Assistance Payments Program	-	+ 6,353,412	-	-	-	6,353,412	-	+ 1,212	+187,000	6,541,624
Refugee Assistance	71,950	-	-	-	-	71,950	+124,000	-	-	195,950
(Limitation on Salaries and Expenses)	(2,685,951)	(-2,685,951)								
(Limitation on Construction)	(14,600)	(- 14,600)								
(Limitation on Administrative Expenses)	-	(+2,052,004)	(-19,724)	(- 2,478)	-	(2,029,802)	-	(+ 87,859)		(2,117,661)
Sub-Total, SSA	14,244,717	- 860,529	-	-		13,384,188	+124,000	+ 1,212	+187,000	13,696,400

Department of Health, Education, and Welfare
Labor-HEW Appropriations Bill, FY 1978

(Budget Authority in Thousands)

Agency and Appropriation	FY 1978 Per H.R. 7555 (Conference)	Effect of March 1977 Reorganization	Transfers within Labor-HEW Accounts: WCF	Transfers within Labor-HEW Accounts: Other	Transfer to or From Labor-HEW	FY 1978 Enacted Law	Supplementals Pending in Conference	Pay Cost Supplementals ('79 Budget)	Program Supplementals ('79 Budget)	Total, FY 1978 Request in Labor-HEW
Special Institutions										
American Printing House for the Blind	3,498	-	-	-	-	3,498	-	-	-	3,498
National Technical Institute for the Deaf	14,630	-	-	-	-	14,630	-	-	-	14,630
Gallaudet College	45,976	-	-	-	-	45,976	-	-	-	45,976
Harvard University	99,118	-	-	-	-	99,118	-	-	-	99,118
Sub-Total, Special Institutions	163,222					163,222	-	-	-	163,222
Assistant Secretary for Human Development										
Grants to States for Social and Child Welfare	-	+2,508,650	-	-	-	2,508,650	-	-	-	2,508,650
Human Development Services	2,195,978	+ 25,321	- 2,149	- 94	-	2,219,056	-	+ 2,603	-	2,221,659
(Trust Fund Transfers)	(600)					(600)				(600)
Work Incentives	365,000	-	-			365,000	-	-	-	365,000
Sub-Total, OHDS	2,560,978	+2,533,971	- 2,149	- 94	-	5,092,706	-	+ 2,603	-	5,095,309
Departmental Management										
General Departmental Management	81,877	- 1,742	+ 17,891	-1,437	+1,111	97,700	+1,719	+ 7,024	+ 1,047	107,490
(Trust Fund Transfer)	(9,579)		(+ 19,857)	(-1,553)		(27,883)				(27,883)
Office of Inspector General	25,343	-	- 2,106	+1,553		24,790	-	+ 1,940	+ 2,328	29,058
(Trust Fund Transfer)	(4,290)			(+ 265)		(4,555)				(4,555)
Office for Civil Rights	33,307	-	- 1,871	-	-	31,436	-	+ 1,646	+20,146	53,228
(Trust Fund Transfer)	(514)					(514)				(514)
Policy Research	30,000	-	- 51	-	-	29,949	-	-	-	29,949
Sub-Total, DM	170,527	- 1,742	+ 13,863	+ 116	+1,111	183,875	+1,719	+ 10,610	+23,521	219,725
	(14,383)		(+ 19,857)	(-1,288)		(32,952)				(32,952)

Department of Health, Education, and Welfare
Labor-HEW Appropriations Bill, FY 1978

(Budget Authority in Thousands)

Agency and Appropriation		FY 1978 Per H.R. 7555 (Conference)	Effect of March 1977 Reorganization	Transfers within Labor-HEW Accounts		Transfer to or From Labor-HEW	FY 1978 Enacted Law	Supplementals Pending in Conference	Pay Cost Supplementals ('79 Budget)	Program Supplementals ('79 Budget)	Total, FY 1978 Request in Labor-HEW
				WCF	Other						
HEW, Total	BA	53,185,537	-	-	-	- 10,347 1/	53,175,190	+145,719	+ 73,665	+524,123	53,918,697
HEW, Total	Trust Funds	(2,750,468)	(-)	(-)	(-)	(-)	(2,750,468)	(-)	(+ 92,092)	(-)	(2,842,560)

1/ Transfers to or from Labor-HEW Accounts:

From FDA (to CDC)	+ 19,000
From FDA (to HCFA)	+ 23,000
From OCA (to GDM for WCF)	+ 47,000
From FDA (to GDM for WCF)	+ 1,440,000
From IHS (to GDM for WCF)	+ 722,000
Sub-Total	+ 2,251,000
To Department of Agriculture (from OE)	-11,500,000
To GSA (from GDM)	- 1,098,000
	$-10,347,000

ABORTION

Mr. FLOOD. Last year, the Labor-HEW Appropriation bill again became embroiled in the controversy over the use of public funds to pay for abortions. The issue was finally resolved—to no one's satisfaction—on December 7 when the House and Senate adopted "compromise" language which permits payments for abortions under certain circumstances. You have issued regulations on this subject which have made many people unhappy. I have a letter here from our colleague, Congressman Henry Hyde, which states that, in writing these regulations "Secretary Califano used his broad discretion to resolve each of the basic questions of law in favor of the *permissive* position advocated by the Senate, as opposed to the far more *restrictive* position continually maintained in the *House*. But beyond this overly expansive rendering of the provisions of the new law, of equal or greater concern is the fact that the regulations do not provide for the *enforcement* of the provisions of the law (even liberally interpreted)".

The letter goes on to say,

"While, strictly speaking, the regulations do not in every instance fall outside the letter of the law they most certainly violate the intent, purpose and spirit of the law; and in so doing they render meaningless the oft repeated commitment of the Carter Administration to a strict limitation on the use of federal funds for abortion."

Here is another paragraph from Mr. Hyde's letter.

"HEW had the opportunity to come up with tight regulations that would have effectively limited Federal funding to abortions that actually fit within the stipulations of the law as intended by Congress. By adopting stricter regulations HEW might have limited the number of federally funded abortions to 20,000 or less. In rejecting this possibility, they have opened the door to massive abuse. It is not unreasonable to assume that under these regulations, at least 100,000 abortions could be funded this year and perhaps many more."

Mr. Hyde's letter contains a series of very specific criticisms of your regulations. I shall insert his letter in the record at this point, and I would like to ask you to respond in the record, to each of these criticisms.

HENRY J. HYDE
6th District, Illinois

COMMITTEES
JUDICIARY
BANKING, FINANCE AND URBAN AFFAIRS

1209 Longworth House Office Building
Washington, D.C. 20515
(202) 225-4561

Congress of the United States
House of Representatives
Washington, D.C. 20515

February 15, 1978

Hon. Daniel J. Flood
House of Representatives
Washington, D. C. 20515

FEB 16

Dear Dan:

Insofar as anything can be "definitive," attached is a definitive critique of the HEW abortion regulations. I hope you will take the time to read this carefully so that when Secretary Califano appears before your subcommittee on February 21st, you will be better able to ask him some penetrating questions.

As you know, I did not support the final abortion amendment. However, it is unfortunate that even this compromise cannot provide a fair basis for experience during the next fiscal year in view of the total emasculation thereof by the HEW regulations. Much agonizing debate and many hard-fought victories were nullified by these regulations and, in my view, they will precipitate more, rather than less, controversy.

May I impress upon you the immediacy of this issue since Secretary Califano is to appear before your subcommittee next Tuesday.

As always, my deepest appreciation for your thoughtful consideration.

Sincerely,

Henry J. Hyde

HJH:afs

Comments Respecting HEW's Regulations on Congress' Language Limiting the Federal Funding of Abortions

On December 7, 1977, the U.S. Congress passed the following language on a Continuing Resolution, for the Department of Health, Education & Welfare for the 1978 fiscal year. The purpose of this resolution is to limit HEW funding for abortions:

"None of the funds provided for in this paragraph shall be used to perform abortions except where the life of the mother would be endangered if the fetus were carried to term; or except for such medical procedures necessary for the victims of rape or incest, when such rape or incest has been reported promptly to a law enforcement agency or public health service; or except in those instances where severe and long-lasting physical health damage to the mother would result if the pregnancy were carried to term when so determined by two physicians.

"Nor are payments prohibited for drugs or devices to prevent implantation of the fertilized ovum or for medical procedures necessary for the termination of an ectopic pregnancy.

"The Secretary shall promptly issue regulations and establish procedures to ensure that the provisions of this section are rigorously enforced." (Section 101 of Public Law 95–205.)

On January 26, 1978, the Secretary of HEW, Joseph Califano, Jr., issued regulations respecting the implementation of the above law.

In arriving at these regulations, Secretary Califano had a series of basic policy questions to decide. As Attorney General Bell correctly noted in his letter to Secretary Califano respecting the new regulations: ". . . for the most part, neither the language of the section nor its legislative history provides clear answers." The Attorney General further noted that Secreary Califano had broad discretion on deciding these basic policy issues.

According to the following analysis, Secretary Califano used his broad discretion to resolve each of the basic questions of law in favor of the permissive position advocated by the Senate, as opposed to the far more restrictive position continually maintained in the House. But beyond this overly expansive rendering of the provisions of the new law, of equal or greater concern is the fact that the regulations do not provide for the enforcement of the provisions of the law (even liberally interpreted) in terms of: (a) determining whether abortions are being performed for actual or fictitious serious physical health conditions, or (b) for actual or fictitious incidents of rape or incest. Even assuming that HEW launches a major auditing effort to guarantee that federal funds are being expended only after signed certificates from physicians are received, there can be little hope that such an effort will reduce, by one, the number of fraudulent claims for reimbursement for abortions performed on healthy women; the same applies in cases of rape or incest reports. Finally, the regulations fail to provide for the needs of actual rape and incest victims after the abortion.

While, strictly speaking, the regulations do not in every instance fall outside the letter of the law they most certainly violate the intent, purpose and spirit of the law; and in so doing they render meaningless the oft repeated commitment of the Carter administration to a strict limitation on the use of federal funds for abortion.

Specific concerns with the regulations follows:

(A) The regulations are overly permissive in regard to each of the key provisions of the new law:

(1) "Medical procedures" are interpreted to include abortions. Secretary Califano could have interpreted medical procedures *not* to include abortion. To support such an interpretation he could have cited the history of the use of the phrase "medical procedures" in a) last year's conference report, in b) this year's evolving floor language, and c) as the words were understood by the author of the final language that became law.

(2) Rape is interpreted as including statutory rape. The regulations could have limited rape to forced rape. To support such an interpretation Secretary Califano could have referred to Congressman George Mahon, Chairman of the House Appropriations Committee, when he said on the floor on December 7, that, "If I know anything about words, 'rape' means 'force'. . . ."

(3) Reporting requirements for rape and incest victims are lax and ineffective.

(a) Anyone can report the crime, even the secretary in an abortion clinic; and the report can be made after the abortion has been completed.

(b) The report can be made up to two months after the crime was allegedly committed. Here is a case where both the language in the law and the legislative history were very clear. Nevertheless, HEW adopted the weaker position. The law requires that incidents of rape and incest be "promptly reported." However, the regulations define the word "promptly" to mean a full 60 days. Inclusion of the word "promptly" was first proposed by Senator Helms who said that, "placing the word 'promptly' before the word 'reported' will eliminate the possibility that 2 or 3 months after the fact, a supposed victim could claim to have been raped when as a matter of fact she had not." The Senate initially defeated inclusion of the word because it was too strong, but later in an effort to come up with compromise language that the House would accept, they included it. But in including it Senators Metzenbaum, Brooke and Magnuson said it did not mean what its original author, Helms, had said, but rather it meant months, even 90 days or more. When the House considered and debated the word promptly, three leaders of the compromise forces, Chairman Mahon of the Appropriations Committee, Robert Michel, Minority Leader of the Labor/HEW Subcommittee, and Representative Don Bonker all indicated that 'promptly' meant precisely that, promptly. Representative Michel referred to a 30-day range and Congressman Bonker said, "promptly does not mean it could be done 4 or 5 weeks later and reported and thus qualify for Medicaid abortion." In drafting the regulations HEW disregarded the common sense understanding of the word "promptly," disregarded the intent of the original author of the language, disregarded the intent of the compromise forces in the House who accepted and defined the language, and instead went along with the interpretation provided by the pro-abortion leaders in the Senate.

(c) The report of the crime of rape or incest can even be made by mail, and need only include the victim's name, not address. Nowhere in the law or the legislative history is it indicated that the victim's address need not be reported. Inclusion of the victim's address was specifically referred to by Congressman Michel on the floor (16/6/77 Cong.Rec.H12653). Congressman Michel also said, "and then I would expect . . . some exchange or confirming of interrogation that would take place." (H12652) Yet not even the address is required by HEW.

(B) The regulations fail to establish any procedures requiring accountability on the part of physicians who perform abortions on their patients. Thus, HEW will be unable to determine if the abortions that are allegedly performed for reasons of: a) danger to the life of the mother; b) physical health damage; or c) rape or incest, are actually being done for these reasons.[1] Consequently, rather than discouraging abuse in the area of abortion funding, the regulations invite abuse.

(1) It can reasonably be argued that the Hew regulations could have required that the health conditions that warrant an abortion must be a) pre-existing, or b) present when the abortion occurs. Then HEW could have indicated that its officials would randomly check medical records in order to:

(a) Ascertain if, in fact, doctors were abiding by the regulations; and if not,

(b) Take remedial action whenever abuse was detected.

Instead, HEW requires no medical documentation to support the need for an abortion and accepts as final the doctor's signature that the abortion was necessary. Furthermore, a high-ranking HEW official was quoted saying, ". . . that checking up on 'fraud' would not include second guessing of doctors' medical decisions, by either state or federal officials" (Washington Star 1/27/78).

It is important to note here, that in an effort to justify this lack of accountability by physicians, the regulations misuse statements made by pro-life Congressmen. During the debate on the House floor, Congressman Hyde of Illinois

[1] The potential for abuse in this area by physicians who perform abortions is not remote. Consider the following: In 1967 the state of California adopted an abortion statute that contained a mental health exception. In four years the number of legal abortions skyrocketed going from 700 a year to 116,749. Well over 90 percent of these abortions were done for reasons of mental health. The California General Assembly had attempted to avoid this abuse by defining mental health to mean "mental illness to the extent that the woman is dangerous to herself or to the person or property of others and is in need of supervision or restraint." In addition the California statute required that three physicians certify that the abortion is necessary. Nevertheless, by 1971 well over 100,000 abortions were being performed, for this reason, annually in California. New York state didn't require the subterfuge of "mental health" in its statute. It reported only 2 percent done for this reason.

and Bauman of Maryland, expressed the concern that the exception "severe and long-lasting physical health damage" would be abused. Congressman Hyde said, "the long and short of it is, whatever is serious, whatever is long-lasting, is up to the doctor to decide. It can be a migraine headache or it could be varicose veins; it could be any condition that, in the doctor's medical judgment, is serious and would be long-lasting (Cong. Rec. 12/6/77).

Congressman Bauman said: ". . . as to the mother's health exception it would be left up to the doctor." (Cong. Rec. 12/7/77). HEW included these quotes in its regulations not in the context of accepting them as a warning, signaling the need to formulate regulations that would prevent abuse by holding physicians accountable, but rather as a justification for *not requiring* any concrete documentation of the need for the abortion at all.

(2) HEW could have required that the reporting of the crime of rape or incest include enough information so appropriate authorities could randomly investigate to see if the complaints of a crime were supported by any evidence. This would serve as a deterrent to anyone who would consider making a false complaint of being a victim of rape or incest. Instead, all that HEW requires is for the name of the individual to be sent by mail (by anyone) to a designated law enforcement agency or public health entity. What those institutions can do with only names is obvious, nothing.

(C) Finally, HEW showed an alarming lack of understanding in respect to the kinds of help the actual victims of rape and incest need; and what its responsibility to society in this area should be. In its exercise of tunnel vision to protect an individual from ever having to justify a claim of rape or incest in order to obtain a Medicaid abortion, HEW has effectively precluded the automatic involvement of responsible authorities, legal and social service, to intervene in an attempt to:

(1) Determine if, in fact, there has been the commission of a crime;

(2) If possible get the rapist off the street, so that other girls/women will not be victimized;

(3) Get the victim of an incestuous relationship out of the home; and

(4) Provide counseling where necessary for the victims of rape or incest.

HEW had the opportunity to come up with tight regulations that would have effectively limited federal funding to abortions that actually fit within the stipulations of the law as intended by Congress. By adopting stricter regulations HEW might have limited the number of federally funded abortions to 20,000 or less. In rejecting this possibility, they have opened the door to massive abuse. It is not unreasonable to assume that under these regulations, at least 100,000 abortions could be funded this year and perhaps many more.

HEW RESPONSE TO CRITICISMS RAISED BY REPRESENTATIVE HYDE'S (LETTER OF FEBRUARY 15 TO REPRESENTATIVE FLOOD) TO THE REGULATIONS INTERPRETING SECTION 101 OF PUBLIC LAW 95-205, GOVERNING FEDERAL FINANCIAL PARTICIPATION IN ABORTIONS

The criticisms and the HEW responses are set forth below.

Criticism.—"Medical procedures" are interpreted to include abortions. Secretary Califano could have interpreted medical procedures *not* to include abortion. To support such an interpretation he could have cited the history of the use of the phrase "medical procedures" in a) last year's conference report, in b) this year's evolving floor language, and c) as the words were understood by the author of the final language that became law.

Response.—The conclusion that "medical procedures . . . for the victims of rape or incest" includes abortions is compelled by the words of the Act, the record of debate in the Congressional Record, and the placement of that phrase in the statute. The statute specifies that "[n]one of the funds provided for in this paragraph shall be used to *perform abortions except . . . for such medical procedures* necessary for the victims of rape or incest . . ." (Emphasis supplied) Unless these procedures include abortions, they are not an *exception to a prohibition against funding abortions.*

In addition, the term medical procedures is in the paragraph containing exceptions to the prohibition on funding of abortions rather than in the following paragraph which speaks to procedures and devices which Congress intended to fund, and which clearly are not intended to cover abortions. Had Congress in-

tended that the term "medical procedures . . . for the victims of rape or incest" not include abortions, the only logical place to have dealt with the victims of rape or incest would have been in this later paragraph.

This is in marked contrast to the placement of the term "medical procedures . . . for the treatment of rape or incest victims" in the Conference Report to the HEW-Labor Appropriations Act for FY 1977. In that report, as the Attorney General's opinion of July 27, 1977 interpreting the 1977 Act noted, Congress placed that term in the sentence which covered procedures and devices which Congress intended to fund, and which clearly were not intended to cover abortions. See Fed. Reg. 4832, 35, 37 (February 3, 1978).

The voluminous record of debate in the Congressional Record also forces one to the conclusion that "medical procedures" as used in this clause includes abortions. This record disclosures only one statement where a member interpreted these words to exclude abortions. Although that statement was made by Mr. Michel, the ranking minority member of the HEW Labor Subcommittee of the House Appropriations Committee in a colloquy with another member, 123 Cong. Rec. H. 12652 (daily ed. December 6, 1977), Mr. Michel made two other statements, including one made during the debate in which that colloquy occurred, which indicated his belief that the term "medical procedures" does include abortions. See 123 Con. Rec. H 12170 (daily ed. November 3, 1977); Id. at H 12652 (daily ed. December 6, 1977). Thus, it would have been legally unsupportable for the Department to attach enough significance to the one statement of Representative Michel to overcome the vast preponderance of debate in both Houses of Congress (including other statements by Mr. Michel) plus the words and structure of the Act, all of which compel the conclusion that the term "medical procedures" includes abortions.

Criticism.—Rape is interpreted as including statutory rape. The regulations could have limited rape to forced rape. To support such an interpretation Secretary Califano could have referred to Representative George Mahon, Chairman of the House Appropriations Committee, when he said on the floor on December 7, that, "If I know anything about words, 'rape' means 'force.'. . . ."

Response.—Congress considered and rejected numerous proposals that would have expressly limited the availability of Federal funding of abortions to victims of "forced" rape. See, e.g., 123 Cong Rec. H 12650 (daily ed. December 6, 1977). The failure to use "forced" in section 101 when referring to rape is conclusive evidence that Congress intended Federal funding to be available for the victims of statutory as well as forced rape who meet the reporting conditions of that provision.

Representative Hyde himself recognized this while discussing a version which contained a clause on rape and incest identical with that ultimately enacted:

The other body has removed "forced" from the definition of rape and thus opens medicaid abortions to any woman under the age of consent, whether there has been a forced rape or rape has been consented to or whether there has been any rape whatever in the sense that force has been used or not. 123 Cong. Rec. H 12772 (daily ed. December 7, 1977).

Moreover, the full statement cited by Representative Hyde demonstrates that Representative Mahon believed the Act might make Federal funding of abortions available to victims of statutory rape:

Mr. MAHON. Mr. Speaker, we are voting on the amendment we voted on yesterday without the word "force" in connection with rape. If I know anything about words, "rape" means "force," and therefore, abortion would be permitted after a rape had taken place.

In statutory rape the relationship would be illegal so the courts could very well hold that a statutory rape was forced rape. Well, that interpretation would militate against certain positions. We do not know just what the courts would decide. 123 Cong. Rec. H. 12771 (daily ed. December 7, 1977). (Emphasis supplied.)

Criticism. Anyone can report the crime, even the secretary in an abortion clinic; and the report can be made after the abortion has been completed.

Response. The words of the Act do not specify any limits on who may report an incident of rape or incest in order to satisfy the prompt reporting requirements. The Act allows Federal funding of "medical procedures necessary for the victims of rape or incest, when such rape or incest *has been reported* promptly. . . ." (Emphasis supplied.)

Nothing in those words indicates who must report. Moreover the records of debate demonstrate that the ranking minority conferees of both Houses of Congress agreed that third parties could make the report.

Nor does the Act specify any requirement that the report be made prior to the abortion. The Act simply prohibits the use of Federal funds in the performance of an abortion except "when . . . rape or incest has been reported promptly to a law enforcement agency or public health service." If the providers perform abortions prior to the receipt of documentation that the report has been made, they will be doing so at their own risk should the proper documentation not be forthcoming.

Criticism.—The report can be made up to two months after the crime was allegedly committed. Here is a case where both the language in the law and the legislative history were very clear. Nevertheless, HEW adopted the weaker position. The law requires that incidents of rape and incest be "promptly reported." However, the regulations define the word "promptly" to mean a full 60 days. Inclusion of the word "promptly" was first proposed by Senator Helms who said that, "placing the word 'promptly' before the word 'reported' will eliminate the possibility that 2 or 3 months after the fact, a supposed victim could claim to have been raped when as a matter of fact she had not." The Senate initially defeated inclusion of the word because it was too strong, but later in an effort to come up with compromise language that the House would accept, they included it. But in including it, Senators Metzenbaum, Brooke and Magnuson said it did not mean what its original author, Helms, had said, but rather it meant months, even 90 days or more. When the House considered and debated the word promptly, three leaders of the compromise forces, Chairman Mahon of the Appropriations Committee, Robert Michel, Minority Leader of the Labor/Hew Subcommittee, and Representative Don Bonker all indicated that "promptly" mean precisely that, promptly. Representative Michel referred to a 30-day range and Congressman Bonker said, "promptly does not mean it could be done 4 or 5 weeks later and reported and thus qualify for Medicaid abortion." In drafting the regulations HEW disregarded the common sense understanding of the word "promptly," disregarded the intent of the original author of the language, disregarded the intent of the compromise forces in the House who accepted and defined the language, and instead went along with the interpretation provided by the pro-abortion leaders in the Senate.

Response. There was no clear consensus among the members of Congress as to what time period would constitute prompt reporting. Rather, members expressed their opinions that prompt reporting would encompass time period ranging from as little as two to three weeks to as long as 90 days or "months." Essentially, the members of the Senate envisioned the longer time periods while the members of the House envisioned the shorter ones. The sixty day period fell in the middle range. I would also note that Representative Michel's statement to which Representative Hyde refers envisions a period of "*at least* in the 30-day range . . ." 123 Cong. Rec. H. 12652 (daily ed. December 6, 1977) (emphasis supplied), as opposed to setting that time period as an outside limit.

Of equal importance, however, the Department balanced two competing interests of which Congress was aware when it included this requirement: namely, the need to provide a time period sufficient in length to allow the victims to make reasoned decisions as to how and whether to report the incident, and at the same time, brief enough to discourage fraud. In balancing those considerations, we recognized that an incident of rape or incest may be a traumatic event which may deter the victim from even discussing the incident with her family, let alone publicly reporting it.

Criticism.—The report of the crime of rape or incest can even be made by mail, and need only include the victim's name, not address. Nowhere in the law or the legislative history is it indicated that the victim's address need not be reported. Inclusion of the victim's address was specifically referred to by Congressman Michel on the floor (12/6/77 Cong. Rec. H 12653). Congressman Michel also said, "and then I would expect . . . some exchange or confirming of interrogation that would take place." (H 12652) Yet not even the address is required by HEW.

Response.—The document that forwarded the regulations to the States and established guidelines, HCFA–AT–78–10 (February 3, 1978) (Action Transmittal), required as a condition for Federal funding that the report include the address of the victim. The Department is considering revising the regulations to clarify this requirement at the conclusion of the comment period.

The determination to allow the report to be made by mail was reached because the definition of public health service in the regulations is a very narrow one. Thus, many victims might not have access to such a service if the regulations required the report to be made in person.

In addition, privacy considerations dictated that the report create as minimal an intrusion upon personal privacy as possible consistent with protecting against fraud. So long as the report contains the name and address of the person reporting the incident and the victim—and the regulations and guidelines require this—the States and the Department will be able to detect fraud if the report is made by mail to the same extent as if the report had been made in person.

Criticism.—The regulations fail to establish any procedures requiring accountability on the part of physicians who perform abortions on their patients. Thus, HEW will be unable to determine if the abortions that are allegedly performed for reasons of: (a) danger to the life of the mother; (b) physical health damage; or (c) rape or incest, are actually being done for these reasons. Consequently, rather than discouraging abuse in the area of abortion funding, the regulations invite abuse.

(1) It can reasonably be argued that the HEW regulations could have required that the health conditions that warrant an abortion must be (a) pre-existing, or (b) present when the abortion occurs. The HEW could have indicated that its officials would randomly check medical records in order to:

(a) Ascertain if, in fact, doctors were abiding by the regulations; and if not,

(b) Take remedial action whenever abuse was detected.

Instead, HEW requires no medical documentation to support the need for an abortion and accepts as final the doctor's signature that the abortion was necessary. Furthermore, a high-ranking HEW official was quoted saying," . . . that checking up on 'fraud' would not include second guessing of doctors' medical decisions, by either state or federal officials" (Washington Star 1/27/78). It is important to note here, that in an effort to justify this lack of accountability by physicians, the regulations misuse statements made by pro-life Congressmen. During the debate on the House floor, Congressmen Hyde of Illinois and Bauman of Maryland, expressed the concern that the exception "severe and long-lasting physical health damage" would be abused. Congressman Hyde said, "the long and short of it is, whatever is serious, whatever is long-lasting, is up to the doctor to decide. It can be a migraine headache or it could be varicose veins; it could be any condition that, in the doctor's medical judgment, is serious and would be long-lasting. (Cong. Rec. 12/6/77.)

Congressman Bauman said: ". . . as to the mother's health exception it would be left up to the doctor." (Cong. Rec. 12/7/77.) HEW included these quotes in its regulations not in the context of accepting them as a warning, signalling the need to formulate regulations that would prevent abuse by holding physicians accountable, but rather as a justification for not requiring any concrete documentation of the need for the abortion at all.

(2) HEW could have required that the reporting of the crime of rape or incest include enough information so appropriate authorities could randomly investigate to see if the complaints of a crime were supported by any evidence. This would serve as a deterrent to anyone who would consider making a false complaint of being a victim of rape or incest. Instead, all that HEW requires is for the name of the individual to be sent by mail (by anyone) to a designated law enforcement agency or public health entity. What those institutions can do with only names is obvious, nothing. (Footnote omitted.)

Response to (1).—The regulations require documentation that physicians have made the requisite determination and also require that the States receive this documentation prior to making payment for the procedure. In addition, the Action Transmittal sent to all States requires them to report the number of abortions reimbursed under each category at the close of each quarter.

This information will enable the Department to monitor against significant increases in the number of abortions performed under each category which might indicate fraud. However, the factors of patient privacy, the overwhelming administrative burden, and provider confusion that would occur if State officials were required to review and second guess each physician's judgment in this matter dictated that, in the absence of evidence of fraud, the Department should only require documentation to demonstrate that the diagnosis was made.

The record of debate in the Congressional Record, and the fact that Congress did not indicate any objections to the fact that HEW previously had implemented the life endangering exception in section 209 of the fiscal year 1977 appropriations act in precisely this manner, indicates that this method of enforcement is consistent with Congress' intent. See 43 Fed. Reg. 4832, 36–37 (February 3, 1978).

The motivations behind the statements cited by the Department in the preamble in no way detract from the crucial fact that the statements demonstrate an understanding that the determination of whether these conditions exist would be left to physicians. Moreover, in interpreting these statements, it would be improper for the Department to impute motivations to members making the statements which do not appear on the face of those statements.

With respect to any requirement that a condition be either a pre-existing one or present when the abortion occurs, nothing in the Act would authorize such requirements. Rather, the Act allows Federal funding of abortions if the life of the mother would be endangered or severe and long-lasting physical health damage to the mother would occur if the pregnancy were carried to term irrespective of the nature or timing of the condition that causes these circumstances.

Response to (2).—By the very nature of the statutory requirement, enforcement against fraudulent reporting will be difficult. However, Representative Hyde's characterization that the regulations and Action Transmittal do not require the report to contain sufficient information to allow investigators to randomly investigate against false complaint is in error.

When read together, the regulations and Action Transmittal require that a report contain the names and addresses of both the victim and the person making the report, and the signature of an official of the agency or service which receives the report. In addition, claims for reimbursement will contain names and addresses of providers performing the procedures. The information provided by these documents will enable investigators to make as thorough an investigation of suspected fraud as is possible under the statute consistent with privacy considerations.

Nothing in the statute or legislative history demonstrates explicit Congressional intent to require the reporting of other details of the incident. In the absence of clear evidence to that effect, personal privacy considerations dictated against the regulations containing any such requirement.

Criticism.—Finally, HEW showed an alarming lack of understanding in respect to the kinds of help the actual victims of rape and incest need; and what its responsibility to society in this area should be. In its exercise of tunnel vision to protect an individual from ever having to justify a claim of rape or incest in order to obtain a Medicaid abortion, HEW has effectively precluded the automatic involvement of responsible authorities, legal and social service, to intervene in an attempt to:

(1) Determine if, in fact, there has been the commission of a crime;

(2) If possible get the rapist off the street, so that other girls/women will not be victimized;

(3) Get the victim of an incestuous relationship out of the home; and

(4) Provide counseling where necessary for the victims of rape or incest.

Response.—The regulations in no way prohibit or infringe upon the victim's right to report an incident of rape or incest to law enforcement authorities, and to instigate investigations. Nor do the regulations in any manner preclude the victim from receiving assistance from social service organizations.

However, while other Federal, State, and local programs may make these services available to victims, section 101 simply governs Federal funding of abortions. Nothing in the statute or legislative history indicates any intention on Congress' part to require any further involvement of the aforementioned authorities other than the receiving of reports of incidents of rape or incest. Given the nature of the statute (i.e., an appropriations bill), in the absence of any such requirements it would have been totally inappropriate and an unwarranted intrusion into personal privacy to require the victim to avail herself of these services.

As I have often indicated, neither the President nor I believe that Federal funds should be used to finance abortions except in very limited instances. However, as I indicated in my press statement of January 26, our personal views are irrelevant in the interpretation of Congress' intent in enacting section 101 of Public Law 95–205. Consequently, in developing these regulations, we undertook an exhaustive analysis of each word of the voluminous record of debate in the

Congressional Record on this issue, as well as the words of the statute which was ultimately enacted and the differing versions which were considered. In addition, as you are aware, the Attorney General reviewed these regulations prior to publication to ensure that they properly interpreted section 101. Based upon our analysis and the Attorney General's opinion, I am convinced that the regulations and the HCFA Action Transmittal reflect the best interpretation of Congress' intent in enacting that provision.

[The following questions were submitted for the record:]

INCREASED EMPLOYMENT AS A RESULT OF REORGANIZATION

Mr. FLOOD. We were quite impressed with your estimates of savings to accrue as a result of this reorganization last spring. I believe you mentioned you hoped to save the taxpayers a billion dollars. Unfortunately everytime we turn another page in this budget we find a request for more jobs for these activities rather than less—153 more for the assistance payment program, 125 for Medicaid quality care in the supplemental and another 140 jobs in 1979 for the Health Care Financing Administration. What do you estimate to be the total increase in Departmental staffing associated with your reorganization?

Mr. CALIFANO. Considered by itself, the reorganization did save more than 200 staff positions through administrative consolidations in the three principal agencies involved in the reorganization: Health Care Financing Administration, Office of Human Development Services, and Social Security Administration. What must be recognized, however, is that we do not have a static situation. New responsibilities have been assigned to the Department and workloads have increased. Because of the reorganization we can absorb some of these new responsibilities and workloads within previously existing staffing levels. For others we have found this impossible and must seek additional staffing from Congress.

HCFA (127 POSITIONS)

The reorganization brought together staff for quality assurance and setting of health standards previously existing in the Public Health Service, the Social Security Administration, the Social and Rehabilitation Service and the Office of the Secretary. Prior to the reorganization, 794 positions were devoted to these activities. After the reorganization 752 are now allocated to these functions, a saving of 42 positions. The 42 positions have been assigned to HCFA regional administrators to strengthen Medicaid management and operational coordination.

Initially HCFA assigned 1,765 positions to the Bureau of Health Insurance transferred from the Social Security Administration. After a preliminary review of staff utilization, this allocation has been reduced to 1,680, a reduction of 85 positions. This staff has been reassigned to overall regional coordination (17) and the Office of Management and Budget (68) to strengthen HCFA-wide management of personnel, training, management analysis, and administrative support services.

HDS (100 POSITIONS)

HDS received 454 positions from SRS as part of the reorganization. By revising the HDS structure from 24 separate elements to 8 major components at the headquarters level and by streamlining the regional organization, 100 positions have been made available for reallocation to program operations and to management functions which were previously understaffed. These include a major increase in the Headstart program, equal employment opportunity activities, strengthened information systems, and better administraton of grants and contracts.

SSA (106 POSITIONS)

To strengthen the programs transferred in by the reorganization, SSA reallocated 106 positions to:

Child support enforcement—38 positions to implement the new legislation (P.L. 95-142) requiring health costs to be recovered as well as cash support payments.

AFDC program—68 positions to simplify directives to States, encourage uniformity among State programs, develop performance standards for States, and improve technical assistance.

The total reallocations add up to 333 positions for new or expanded initiatives.

IMPACT AID

Mr. FLOOD. Can you describe to us what new legislation you have in mind with respect to impacted area aid?

Secretary CALIFANO. Our impact aid reform proposal attempts to amend the authorizing legislation to reflect more closely the burden that Federal activities place on those agencies. This proposal establishes the principle that the Federal Government's responsibility extends only to those districts with above average Federal impact, and for such districts, only to the costs of educating students who constitute a real burden. We are proposing to eliminate payments for children whose parents work on Federal property outside the county in which the school district is located. Since parents of these "out of county" children pay residential taxes and since the tax loss from non-residential property occurs outside the county of the school district, there is little or no burden placed on the district. Additionally, payments for public housing children will be held at the 1978 level until being phased out beginning in 1981.

Other reform measures—the change in the method of calculating the local contribution rates, the 3 percent absorption provision, and the inclusion of the hold harmless provision—attempt to remove inequities in the program and dramatically simplify program administration. Our reform package proposes to set the local contribution rate at one-half of the average per pupil expenditure in the State except in the most heavily impacted areas where the comparable district method may be used. Furthermore, under our absorption provision, no payments will be made for the number of Federally connected students equal to 3 percent of the district's non-Federal enrollment. A declining hold harmless provision which guarantees 75 percent of the prior years' funding will ensure that no school district will suffer a sudden decrease in payments as a result of our reform measures. Additionally, the advance funding request to provide early notifications of Federal appropriations would enable school districts to plan for any reductions in Federal payments they might realize.

GSA LEASE SERVICE

Mr. FLOOD. Mr. Califano, changing the subject, this Subcommittee became very concerned about the problems which the Social Security Administration was having with the General Services Administration in getting adequate district and branch office space. As you recall, the media were quite dramatic in their reporting of the situation in New York. I wonder if you could tell us whether you agree with Social Security that the situation is bad enough to warrant changing the way space needs are handled for your Department?

Secretary CALIFANO. Yes, I agree that changes should be made in the current way that General Services Administration (GSA) handles the space needs of the Department. In a report submitted by the Department to the President's Reorganization Project, we discussed space requirements. The report identified, as a major problem, the length of time GSA needs to acquire new space. In calendar year 1977, it took GSA, on the average, 258 days to complete a space request for the Department. The desired processing time, as established by GSA, is normally 180 days. The study did not identify any factors that might be causing the delay. The study did, however, recommend the extension of GSA's accelerated leasing program to projects of 5,000 square feet; currently, GSA limits the programs to projects of up to 2,500 square feet. Adoption of this recommendation would cover the bulk of the Department's space requests.

Mr. FLOOD. Each year we see the Standard Level User Charges increase at what seems a totally unwarranted rate. To put it directly, do you feel the Department is being taken to the cleaners, on these SLUC charges.

Secretary CALIFANO. It is true that SLUC charges have been increased over the years. In FY 1978, the increase was attributed to a new method of computing the SLUC charges—GSA calls it the Fair Annual Rental (FAR) appraisal method. The rates under the new method are based on the prevailing area market property value; under the new system a rate set for a specific building remains in effect for a three-year period. I believe that a judgment on the merits of the new system should be deferred until we have had an opportunity to see how it actually works.

TITLE I, ELEMENTARY AND SECONDARY EDUCATION ACT

Mr. FLOOD. Can you describe to us what new legislation you have in mind with respect to Title I of the Elementary and Secondary Education Act? (The budget proposes an additional $400 million for this legislation.)

Secretary CALIFANO. As you know, the existing Title I, Part A program of grants to local school districts performs a critical function in providing funds for supplemental compensatory services to children from low income families. However, school districts with especially high concentrations of low income students need our special attention. Within each State, the same amount of money per poor child is distributed to each district so that those with high concentrations of poor children receive the same amount per pupil as do less poor districts. Moreover, districts with high concentrations of poor children have special problems. For example, additional educational needs requiring additional educational resources are created by large concentrations of poverty children in schools and school districts. Also, Title I dollars do not go as far in poor urban and rural districts as they do in other school districts because of the high costs in urban areas and low State and local per pupil expenditures in the poorest rural areas. To address these problems, we propose that a targeting provision be added to Title I to provide extra funds, on top of Part A, for these poverty-stricken areas. Funds would be allocated to school districts with Title I eligible children in excess of 5,000 students or 20 percent of the total district enrollment. More than 3,500 districts with large numbers and/or high concentrations of poor children will receive these funds. The $400 million included in the fiscal year 1979 budget's legislative program would be used for this new targeting provision. This provision would be an important addition to Title I. Through it we would be able to provide extra resources where they are most needed, while maintaining a strong program under the current Part A authority.

CIVIL RIGHTS SURVEY

Mr. FLOOD. Another problem which popped up in both the House and Senate last year related to civil rights surveys of elementary and secondary schools. An amendment to prohibit use of funds for civil rights surveys was defeated in the House. A similar amendment was adopted in the Senate. As I recall, you begged us and urged us to drop this amendment in conference, and the Senate Conferees reluctantly agreed to do so, but only on the condition that we include the following language in the conference report:

"Amendment No. 84: Delete section 211 proposed by the Senate. The conferees deleted Amendment No. 84 which would have prohibited the obligation or expenditure of funds in connection with the Elementary and Secondary School Civil Rights Survey: School year 1977–78 in the case of any school district which has completed the 1976–77 survey. The conferees acted after assurance from the Secretary of HEW that this, or any similar type survey, will not be conducted for the 1977–78 school year. The conferees agree that there is a definite need to gather information where the Secretary of HEW has reason to believe that there may be a violation of the civil rights laws in a particular school. Nevertheless, the conferees see no reason to conduct a large-scale or random survey for the 1977–78 school year. In addition, the conferees agree that any questions asked on the Civil Rights Survey for school year 1976–77 should not be repeated under any authority for school year 1977–78, provided, however, that this shall not be construed to preclude any questions to applicants necessary to determine eligibility under the Emergency School Aid Act. This will give the Department adequate time to analyze and interpret the large amounts of data contained in the 1976–77 school civil rights survey before initiating another large-scale survey.

The conferees were in agreement that the paperwork associated with this survey created an unnecessarily large burden upon the Nation's school districts.

If this directive is not followed, it is doubtful that any funds will be provided for any survey for the 1978–79 school year."

My question is: Are you complying with that language in the conference report?

Mr. CALIFANO. The Department has complied with the conference report. At the time the conference was meeting, I indicated that the Department had decided to postpone the 1977 elementary and secondary school civil rights survey, so

that we could improve the survey and ensure that in the future it related to all our statutory responsibilities.

Mr. FLOOD. What are your plans for civil rights surveys in the coming year?

Mr. CALIFANO. The Office for Civil Rights intends to conduct a school survey at the start of the 1978–79 school year. Again, I indicated that this survey would be conducted at the time the conference was meeting. I also indicated that the survey would be conducted every two years in the future, instead of annually as in the past. Consistent with the language contained in the Committee report on the 1978 Labor-HEW appropriation bill, the 1978 survey has been made simpler, the number of data elements being collected has been reduced by 40 percent, and although 16,800 school districts participated in the 1976 survey, only 6,000 districts will be asked to complete the 1978 survey forms. The design of the survey and the questions proposed for inclusion were thoroughly reviewed and discussed within the Department and by civil rights and educational organizations. For example, numerous discussions were held with the Committee on Education Information Systems of the Council of Chief State School Officers. To ease the administrative burden, advance copies of the survey forms have already been mailed to the affected school systems and State education agencies, so that they can make the necessary preparations and will not be forced to complete the survey within an unrealistic timeframe.

Mr. FLOOD. What would happen if Congress decided to put an amendment in the 1979 bill similar to the one inserted in the bill last year by the Senate?

Mr. CALIFANO. Such an amendment would prevent the Office for Civil Rights from conducting the fall 1978 survey, for which funds have already been expended. I must emphasize that to enforce the civil rights statutes, it is essential to obtain certain kinds of basic information from school systems and from other recipients that will permit the Department to determine where possible violations exist, to schedule and conduct compliance reviews and complaint investigations, and to allocate resources according to where the most serious compliance problems appear to exist. The Justice Department, which coordinates government-wide enforcement of Title VI of the Civil Rights Act, has called upon compliance agencies such as HEW to collect basic compliance information from recipients of Federal funds on a regular basis. In addition, that Department relies upon school survey data to carry out its own court responsibilities under the 1964 Civil Rights Act. In sum, to abandon the 1978 survey would represent a severe setback, and would make it impossible to organize and implement an effective compliance program in the elementary and secondary school area.

BUSSING PROVISIONS

Mr. FLOOD. For the past three years, the Labor-HEW appropriation act has carried language prohibiting HEW from requiring the transportation of any student to a school other than the school which is nearest the student's home. This language was originally inserted in the bill at the insistence of the Senate Majority Leader. It was amended last year to prevent HEW from circumventing its intent through legal interpretation. You are proposing to delete this anti-busing provision. Why?

Mr. CALIFANO. The Department opposes this provision because it restricts our ability to enforce Title VI. The amendment removes the kinds of remedies that have long been used, and that the courts have long approved, to correct illegal school segregation. The amendment prohibits HEW from requiring the transportation of a student beyond the nearest school and prevents HEW from recommending desegregation plans that involve such traditional measures as grade reorganization, pairing and clustering, if the effect is to transport any student beyond the nearest school. Under this kind of restrictive amendment, HEW cannot carry out its Title VI responsibilities.

Mr. FLOOD. Please provide for the record a statement which explains (a) How the language currently in effect is affecting your civil rights enforcement activities; and (b) why it should not be included in the 1979 appropriation bill?

EFFECT OF EAGLETON-BIDEN AMENDMENT

This provision is directed at preventing HEW from enforcing Title VI of the Civil Rights Act of 1964. The amendment, first adopted in 1975 and tightened last year, restricts the Department's authority to remedy unconstitutional school segregation where student transportation is involved. Under the amend-

ment, when a Title VI violation is found to exist, HEW is precluded from: (1) requiring the transportation of a student beyond his or her nearest school; and (2) recommending desegregation plans which involve such traditional measures as grade reorganization, pairing and clustering, if the effect is to transport any student beyond the nearest school which offered the appropriate grade level prior to implementing the plan.

If allowed to stand, the amendment would continue to undercut our efforts to carry out a vigorous civil rights compliance program.

In enforcing Title VI, HEW conducts compliance reviews and investigates complaints alleging discrimination in student assignment. If violations are found to exist, the school district is responsible for implementing a plan which remedies unconstitutional segregation. Under the amendment, however, HEW is prevented from requiring the remedies appropriate to the violations, thus raising the specter that we would have to continue providing Federal financial assistance to programs that are discriminatory.

REVERSE DISCRIMINATION/QUOTAS

Mr. FLOOD. Last year, in its consideration of the Labor-HEW Appropriations Bill, the House adopted an amendment which was designed to prevent HEW from imposing numerical quotas for hiring, admissions, or promotions. It was deleted in the Senate, and dropped in conference. There is a good chance that such an amendment will be offered in the House again this year. If offered, it will probably be adopted. What is HEW now doing with respect to the imposition of ratios, quotas, or other numerical requirements? How would the adoption of an amendment similar to last year's affect your activities?

Mr. CALIFANO. As part of the Education Amendments of 1976, an amendment was adopted which restricts the Department's authority to impose quotas or their equivalent with respect to student admissions at higher education institutions. We are, of course, complying with this amendment. The Department does not impose quotas relating to student admissions. However, the amendment adopted by the House last year and dropped by the conference was much broader in scope. It referred to "any ratio, quota, or other numerical requirement," and it applied not just to student admissions but to employment practices as well as to all types of HEW-funded programs. If enacted, this amendment could have prohibited HEW from requiring certain types of remedial action in cases where there is intentional, proven discrimination. Also, it could have interfered with HEW's ability to comply with court orders requiring desegregation. To take an example, to correct past discrimination an employer may be required to adopt a corrective plan that speaks in terms of a "ratio", even though the remedy is stated as a goal to employ women and minorities. A "ratio" may also be a useful tool or index by which to determine an appropriate employment goal and measure progress toward meeting that goal. For these and other reasons, we felt the amendment was ill-advised and we still strongly oppose it.

Mr. FLOOD. Please provide, for the record, a statement which (a) tells how an amendment such as the one adopted last year would affect your civil rights enforcement activities; and (b) give the reasons why you think such an amendment should not be adopted?

EFFECT OF SECTION 211, HOUSE-PASSED FISCAL YEAR 1978 LABOR-HEW APPROPRIATIONS BILL

The provision was directed at the issuance and enforcement of certain civil rights requirements relating to the employment and admissions policies and practices of recipients of Federal funds and Federal contractors. Clearly, the key words are "for purposes of compliance with any ratio, quota, or other numerical requirement related to race, creed, color, or national origin or sex". It is not clear precisely what specific civil rights enforcement activities are intended to be prohibited by Section 211, but its effect could be (1) to prohibit the Department from requiring certain types of remedial action by recipients who have been determined to be in violation of statutes, such as Title VI of the Civil Rights Act of 1964 (prohibiting discrimination on the basis of race, color, or national origin in federally assisted programs) and Title IX of the Education Amendments of 1972 (prohibiting discrimination on the basis of sex in federal assisted education programs), and contractors determined to be in violation of Executive Order 11246 (prohibiting employment discrimination by Federal contractors); and (2) to interfere with the ability of the Department

to comply with several court orders (such as *Adam's* v. *Califano*) which require the Department to issue and enforce desegregation guidelines.

Section 211, as introduced in the House, originally applied to action "for purposes of compliance with any timetable, goal, ratio, quota, or other numerical requirement." However, pursuant to an amendment offered during floor debate, the words, "timetable, goal" were deleted.

The term "goals and timetables" is most commonly associated with implementation of Executive Order 11246, and its use as a remedial device has consistently been held to be appropriate by the courts once a determination of past discriminatory conduct has been made.

Under this Order, a Federal contractor is required to take affirmative action to ensure that it does not discriminate on the basis of race, sex, etc. Where the contractor fails to meet established standards relating to the employment of women and minorities, it must establish in its affirmative action plan timetables and goals to increase the employment of minorities and women. However, the Department would not take any enforcement action against such a contractor to obtain "compliance" with any such timetables or goals unless it determined that the contractor was not making a good faith effort to meet its timetables and goals. Executive Order requirements may be applicable even absent a showing of past discrimination.

Because the provision does not contain the words "goals, timetables," it could be construed as maintaining intact the Department's authority to require goals and timetables as an element of affirmative action under the Executive Order. However, the remaining language, which prohibits the Department from imposing "a ratio, quota, or other numerical requirement," is so broad as to throw this construction into question.

In addition, there remains the issue of the impact of Section 211 on the Department's ability to require appropriate remedies in cases where there is proven, intentional discrimination. Where recipients of Federal funds are found to have discriminated in violation of Title VI, Title IX, or the Executive Order, the Department is obligated to seek appropriate remedies to overcome the effects of such past discrimination.

The Department does not impose "quotas." However, the effect of the language contained in the provision—"ratio, quota, or other numerical requirement"—could be read as preventing the Department from requiring certain types of remedies which are similar to goals and timetables and which are designed to correct past patterns of discrimination.

A ratio may also be a useful tool or index in determining what a useful "goal" might be. Any projection of "goals" or any assessment of progress toward compliance must, of necessity, assume a "numerical" or qualitative cost if evaluations of progress by HEW or indeed any other agency are to be meaningful.

In effect, the prohibited action in the provision may be so sweeping as to seriously impede the Department from carrying out its enforcement responsibilities. It would also tend to confuse Federal grantees and contractors as to their civil rights obligations.

CONSTRUCTION NEEDS

Mr. FLOOD. Local school districts, colleges, universities and other institutions are facing major problems in renovation and construction of their physical plant because of energy conservation, occupational safety and health requirements, and the needs of the handicapped. The budget includes $50 million for construction grants to colleges and universities. But we have heard that several billion dollars are required to meet these construction needs not only at colleges but also elementary, secondary, and vocational schools, libraries, and rehabilitation facilities. Please supply for the record a detailed report on HEW's assessment of the budget impact and fiscal requirements of Section 504 Regulations dealing with the handicapped.

STATEMENT ON ASSESSMENT OF COST

When the Section 504 Regulations were approved and issued, the Department also released a report on the cost, benefits, and economic impact of implementing Section 504. This report was prepared under contract. The conclusions should not be considered definitive although the report does represent the most comprehensive assessment completed to date. The report estimated the cost of implementation to be $2.4 billion, as against benefits estimated at $2.1 billion. The report did not, however, predict that construction needs would come to billions of dollars. The Office for Civil Rights has copies of this report available.

The Department is in the process of developing two major studies relating to the cost impact. One study will cover 200 recipients and will determine compliance problems and cost of implementation. The other study, to be conducted by the National Center for Education Statistics, will cover approximately 700 higher education institutions and will provide a comprehensive data base relating to program accessibility. Results are expected in January 1979. In addition, a smaller survey of 40–50 higher education institutions is underway, and we will be reviewing transition plans required by the regulations in those cases where recipients must prepare for structural changes.

QUARTERLY PUBLIC ASSISTANCE REPORT

Mr. FLOOD. You have been providing to the Committee for several years now a quarterly report of public assistance expenditures. This report has been quite useful to the Committee and we would not want it to fall through the cracks as a result of the reorganization. We would like you to continue this report even though the funding is now being requested in several different accounts.

Secretary CALIFANO. Yes, we are planning to continue the report as long as the Committee finds it useful.

CHILD SUPPORT ENFORCEMENT

Mr. FLOOD. Mr. Secretary, I notice that the net Federal cost to the government in this budget for your child support enforcement program is down from $20 million to $13 million. Everything we hear is that this is a terrific program but when can we see a positive budget figure from these collections? We keep expecting to save a little money with this program.

Secretary CALIFANO. Actually we are saving quite a bit of money, Mr. Chairman. The budget figures you cited only pertain to the Federal share of costs and collections, and here costs do exceed collections somewhat. That is because the Federal government pays 75 percent of the program's administrative expenses and because incentive payments to States and localities are paid from the Federal share of collections. The total picture is much brighter. In 1979, we estimate that total costs will run $333 million while total collections just for AFDC recipients will run $600 million, a savings of $267 million. In addition, $500 million more will be collected for non-AFDC recipients, many of whom would have to come on the AFDC rolls without the child support collection services provided by the program.

WELFARE CASELOADS

Mr. FLOOD. This budget as I read it envisions welfare caseloads as having essentially leveled off. Is that an accurate statement? If so, how do you account for it?

Secretary CALIFANO. Current indications still point to that. Through the first three months of the fiscal year, actual caseload is slightly less than the same three-month period a year ago. The most significant factor is that family size has stabilized and even declined over the past few years. The Administration's job training and employment programs have also had an important impact, especially in limiting the number of new welfare cases. Finally, we believe that our stepped up quality control, anti-fraud and child support enforcement efforts are also responsible for limiting the size of the AFDC caseload.

Mr. FLOOD. I also believe that your AFDC caseload estimates assume the unemployment rate will drop from 6.7 percent to 6.3 percent by 1979. What happens to these estimates if these projections prove overly optimistic?

Secretary CALIFANO. I am not certain about the numbers but changes in the unemployment rate, up or down, don't directly translate into welfare caseload changes. This is because a large part of the welfare caseload are families who are not counted in the unemployment statistics because they are not actively seeking work—mothers with young children to care for at home, for example. Certainly there would be some impact, but not on a one-for-one basis.

TRUST FUND RESERVES

Mr. FLOOD. Mr. Secretary, now that the new Social Security Financing Bill has been signed into law, where do we theoretically stand in terms of the solvency of the various trust funds?

Secretary CALIFANO. Over the next few years, the reserves in the trust funds will improve from about $35 billion currently to nearly $80 billion by the end of 1983. In the longer run, the 1977 amendments reduced the projected social security deficit from roughly 8 percent of taxable payroll annually to about one and one-half percent.

ESTIMATES FOR THE ENTITLEMENT PROGRAMS

Mr. FLOOD. Turning to another area, Mr. Secretary, the accuracy of Departmental estimates for the so-called "uncontrollable" programs have always been a problem with the HEW budget. As you may recall, last year, we were able to reduce the budget authority requirements by almost $1.8 billion because of the overestimating. What are you doing to avoid this type of problem with future appropriations?

Secretary CALIFANO. To a certain extent, Mr. Chairman, these problems will always be with us. Expenditures for these programs depend on economic trends beyond anyone's ability to predict with absolute precision. Nonetheless, we are taking some steps to improve our accuracy. First, we are working on improving our own ability to forecast by developing better models of these programs, particularly Medicaid. Second, we are working with the States to improve their ability to forecast expenditures through better data gathering and analysis, greater specification of the factors which States use to develop their forecasts, and more timely submission of estimates and reports.

WELFARE COSTS IN NEW YORK AND CALIFORNIA

Mr. FLOOD. Last week's U.S. News and World Report carried a very disturbing article comparing welfare costs in the two biggest welfare States—New York and California. I was very surprised to see how much more expensive the New York program is even though they have considerably fewer recipients. Are you doing anything to try to get at this problem?

Secretary CALIFANO. Yes, very definitely. The comparison you referred to concerned administrative costs in the two States. California's administrative costs for running the AFDC and Child Support programs are significantly lower than New York's, even though their caseload is larger. In addition California's error rates are much, much lower than New York's and their child support collections are much higher.

Because of disparities of this type, we are beginning an extensive effort this year to improve the accuracy and the efficiency of AFDC administration in the States. We have requested 100 additional positions for this in FY 1979. We will be developing performance standards to measure State administration, assisting States like New York by transferring proven practices from States like California, providing technical assistance in systems development with particular attention to preventing and detecting fraud and abuse, and rewriting and clarifying our own regulations. This is a top Departmental priority in its own right; it is absolutely essential as a step toward a reformed welfare system.

SOCIAL SECURITY FINANCING

Mr. FLOOD. Many of us on both sides of this table have been hearing about the enormous payroll tax increases which this new financing scheme mandates. Some members have suggested that this issue should be reconsidered even before the increases go into effect. Does the Administration have any plans to reopen this issue this year?

Secretary CALIFANO. In its original financing proposals, as you may recall, the Administration proposed a combination of general revenue and social security tax increases to finance social security's long-term revenue requirements. The President is aware of the impact which increased social security tax obligations can have on disposable income and has taken these into consideration in his proposals for tax reduction and reform. In fact, under the President's proposals, the share of personal income absobed by income taxes and social security taxes will not increase between 1977 and 1979, and every income class up to $30,000 will bear a smaller share of the overall tax burden than it does now. Under the President's proposals, the typical family of four that earns $15,000 a year will save almost $260, a 19 percent tax reduction.

SOCIAL SECURITY ADMINISTRATIVE EXPENSES

Mr. FLOOD. As a result of this reorganization, the budget proposes language in each of the Social Security Accounts which would provide for payments of administrative expenses for both trust fund and Federal funds programs out of a single limitation account. Our Committee is very sensitive to the need to maintain the integrity of the trust funds. Are you fully convinced that there is no risk here to these funds as a result of this new arrangement?

Secretary CALIFANO. Our plan is to account for the funds in the same way that Supplemental Security Income administrative expenses are handled now. Under that arrangement, the trust funds are guaranteed to be in the same financial position at the end of the year that they would have been had they not been used to handle the non-trust fund activities.

We are committed to insuring the integrity of the trust funds. I would also like to point out that we are following up the appropriation language with specific technical legislation to make sure there is no misinterpretation.

SUPPLEMENTAL FOR FISCAL RELIEF

Mr. FLOOD. Do you intend to make this payment out of currently available funds or will you have to wait for a supplemental?

Secretary CALIFANO. We had asked for a supplemental, but we just recently learned about an error we made in our Public Assistance accounting reports. As a result, we now have enough money to pay the $187 million out of existing funds. OMB has just given us the go-ahead to make the payment out of existing resources so your committee does not need to act on the supplemental request.

FISCAL RELIEF TO STATES

Mr. FLOOD. This financing bill also included welfare fiscal relief provisions amounting to $187 million. I believe you have requested that money in this budget. Do you support this program or are you just requesting the funds because the law requires it?

Secretary CALIFANO. We worked very closely with the Senate in working out the details of this program so that it would be acceptable to both the Congress and the Administration.

EXPIRING LEGISLATION

Mr. FLOOD. Now, there are a number of health programs in the budget which require renewal legislation in 1979, such as the Health Services programs, and Community Mental Health Centers. Is it your intention to request simple extension of these program authorities into 1979 or are you planning to request substantive changes in the law?

Secretary CALIFANO. Of the existing health programs which require renewal legislation in 1979, we are only proposing significant modifications in the health planning, health maintenance organization, and preventive health programs. Simple extensions with only minor adjustments are proposed for the remainder of our legislative program, which includes health services, community mental health centers, cancer, heart and lung research, health services research and health statistics.

SUPERGRADE POSITIONS

Mr. FLOOD. I believe our colleagues in the Senate had been particularly concerned about the increase in the number of supergrade jobs as a result of health financing activities. What is the total number of supergrades for HEW estimated in the 1979 budget as compared to the number available before March 8, 1977?

Secretary CALIFANO. Mr. Chairman, our budget requests 458 supergrade positions for FY 1979 as compared to 461 available before March 8, 1977.

Mr. FLOOD. There are a great many programs funded in your budget which require legislative authorization for fiscal year 1979. Will you please provide us with a list of these programs, the amounts budgeted for them in Fiscal years 1978 and 1979, and the current status of the authorizing legislation for each of them?

Secretary CALIFANO. Yes, Mr. Chairman, the information you have requested is provided:

[Table follows:]

Programs Requiring Legislative Authorization in Fiscal Year 1979

	1978	1979 Budget Request
HEALTH SERVICES ADMINISTRATION		
1. Community health services:		
(a) Community health centers	247,000,000	286,000,000
(b) Home health services	6,000,000	6,000,000
(c) Comprehensive health grants to States.	90,000,000	90,000,000
Advance for 1980	---	90,000,000
(d) Hypertension	11,000,000	11,000,000
Advance for 1980	---	11,000,000
(e) Sudden infant death syndrome	2,802,000	2,802,000
(f) Genetic information and counseling	4,000,000	4,000,000
(g) Hemophilia treatment centers	3,000,000	3,000,000
(h) Family planning	135,000,000	145,000,000
(i) Migrant health	34,500,000	34,500,000
(j) National health service corps	---	5,947,000
	(42,565,000)	(62,947,000)*
2. Emergency medical services	6,125,000	8,925,000
	(42,625,000)	(42,625,000)*
CENTER FOR DISEASE CONTROL		
Disease control		
Project grants:		
(1) Venereal diseases	32,000,000	32,000,000
(2) Immunization	23,000,000	35,000,000
(3) Rat control	13,000,000	13,000,000
(4) Lead-based paint poisoning in children	10,250,000	10,250,000

* Total amount requested, including unauthorized amounts.

NATIONAL INSTITUTES OF HEALTH	1978	1979 Budget Request
National Cancer Institute	872,270,000	878,802,000
National Heart, Lung, and Blood Institute	447,926,000	454,336,000
National Institute of Dental Research	4,198,000 (61,718,000)	4,198,000 (62,039,000)*
National Inst. of Arthritis, Metabolism, and Digestive Diseases	16,777,000 (260,246,000)	17,877,000 (267,246,000)*
National Institute of Neurological and Communicative Disorders and Stroke	7,322,000 (178,414,000)	7,322,000 (180,932,000)*
Natl. Inst. of Allergy and Infectious Diseases	7,223,000 (162,326,000)	7,004,000 (166,802,000)*
Natl. Inst. of General Medical Sciences	34,364,000 (230,707,000)	49,320,000 (234,412,000)*
Natl. Inst. of Child Health and Human Development	75,131,000 (166,380,000)	90,076,000 (198,931,000)*
National Institute on Aging	2,390,000 (37,286,000	1,984,000 (37,910,000)*
National Eye Institute	4,643,000 (85,392,000)	3,979,000 (86,428,000)*
National Inst. of Environmental Health Scien.	5,485,000 (64,200,000)	5,320,000 (69,247,000)*
Research Resources	515,000 (145,054,000)	550,000 (149,049,000)*
National Library of Medicine	7,987,000 (37,533,000)	7,987,000 (39,774,000)*

* Total amount requested, including unauthorized amounts.

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	1978	1979 Budget Request
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMIN.		
1. General mental health:		
(a) Rape prevention	4,436,000	6,000,000
(b) Research training	16,137,000	18,691,000
(c) Community programs:		
(1) Conversion	19,372,000	24,366,000
(2) Consultation and education	8,245,000	7,438,000
(3) Financial distress	5,488,000	2,220,000
2. Drug abuse:		
(a) Research training	621,000	784,000
(b) Community programs:		
(1) Project grants and contracts	161,000,000	161,000,000
(2) Grants to States	40,000,000	40,000,000
3. Alcoholism research training	2,148,000	2,350,000
HEALTH RESOURCES ADMINISTRATION		
1. Health planning:		
(a) Local planning agencies	107,000,000	115,400,000
(b) State agencies	29,500,000	30,000,000
(c) Planning methods development/center	6,500,000	6,900,000
2. Nursing Institutional assistance:		
(a) Nurse practioner	13,000,000	13,000,000
(b) Special projects	15,000,000	7,500,000
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH		
1. Health statistics:		
(a) National health surveys and analysis	23,255,000	23,432,000
(b) Cooperative health statistics	11,923,000	16,759,000
2. Health services research	26,169,000	23,812,000
3. Health maintenance organizations grants and contracts	21,100,000	23,910,000
4. Adolescent health, services, and pregnancy prevention (new program)	---	60,000,000

	1978	1979 Budget Request
HEALTH CARE FINANCING ADMINISTRATION		
1. Grants to States for Medicaid (proposed legislation).....	- 5,000,000	-112,900,000
2. Quality care management, research and administration:		
(a) Demonstration and evaluation projects.....	2,000,000	2,000,000
	(13,742,000)	(13,742,000) *
(b) Proposed legislation.....	5,084,000	17,582,000
OFFICE OF EDUCATION		
Elementary and secondary education		
1. Grants for disadvantaged (proposed legislation).....	---	400,000,000
2. Follow through.....	59,000,000	35,000,000
3. Drug abuse education.....	2,000,000	2,000,000
4. Environmental education.....	3,500,000	3,500,000
5. Educational broadcasting facilities	1,000,000	1,000,000
School assistance in Federally affected areas		
Proposed legislation.....	---	- 76,400,000
Special projects and training		
(new programs).....	---	11,365,000
SOCIAL SECURITY ADMINISTRATION		
Assistance payments		
Proposed legislation.....	---	23,000,000

* Total amount requested, including unauthorized amounts.

	1978	1979 Budget Request
OFFICE OF THE ASSISTANT SECRETARY FOR HUMAN DEVELOPMENT SERVICES		
Grants to States for social and child welfare services		
1. Child day care	200,000,000	200,000,000
2. Child welfare services (proposed legislation)	---	84,750,000
Human development services		
1. Children, youth, and families:		
(a) Head Start	625,000,000	680,000,000
(b) Child abuse	18,928,000	21,228,000
2. Aging programs:		
(a) Community services:		
(1) State agency activities	19,000,000	19,000,000
Advance for 1980	---	19,000,000
(2) Area planning and social services	153,000,000	153,000,000
Advance for 1980	---	153,000,000
(3) Model projects	15,000,000	15,000,000
(b) Nutrition	250,000,000	287,000,000
Advance for 1980	---	287,000,000
(c) Research, demonstration and manpower:		
(1) Research	8,500,000	8,500,000
(2) Training	17,000,000	17,000,000
(3) Multi-disciplinary centers on gerontology	3,800,000	3,800,000
(d) Federal Council on Aging	450,000	450,000
(e) Multipurpose senior centers	40,000,000	40,000,000
Advance for 1980	---	40,000,000
(f) National clearinghouse	2,000,000	2,000,000

	1978	1979 Budget Request
3. Programs for handicapped individuals:		
(a) Rehabilitation services and facilities:		
(1) Basic State grants	760,472,000	785,457,000
Advance for 1980	---	785,000,000
(2) Innovation and expansion	18,000,000	19,800,000
(3) Service projects:		
a. Deaf-blind center	2,500,000	2,500,000
b. Special projects	17,328,000	17,430,000
c. Training and facilities grants:		
(i) Training services	5,000,000	5,000,000
(ii) Facility improvement	2,400,000	2,400,000
d. Evaluation	2,500,000	2,500,000
(4) Research	31,500,000	31,500,000
(5) Training	30,500,000	45,228,000
(b) Developmental disabilities program:		
(1) Basic state grants and advocacy	33,058,000	49,880,000
(2) Service grants	19,567,000	5,557,000
(3) University affiliated facilities	6,500,000	6,500,000
4. Native Americans programs	33,000,000	33,800,000

MIDDLE INCOME INITIATIVE

Mr. FLOOD. There is a growing interest in Federal aid to middle-income families for meeting the costs of education. Congress is considering tuition tax credits. The Administration seems to prefer expanding existing aid programs. Why is the Administration opposed to tuition tax credits?

Secretary CALIFANO. The Administration is opposed to tuition tax credits for the following reasons:

Tuition tax credit proposals are generally unrelated to student need, family income, or the varying costs of attendance at different types of postsecondary institutions.

Tuition tax credit proposals are generally very expensive and their costs are not readily controllable.

Tuition tax credits would further fragment Federal education policy among different Congressional committees.

Tax credits would add to the administrative burden of the institutions, the Internal Revenue Service and the taxpayers. Tax credits could make other education funds more scarce.

Children usually attend special schools that have been designed to meet their needs. Most school systems should be able (by providing the required transportation) to assign all of their physically handicapped children to a few of their buildings. For example, even a moderate size school system with 10–15 separate buildings with no new or already accessible buildings should have to modify only one or two of its buildings.

In addition, the costs of complying with the Section 504 requirements are greater for postsecondary institutions than elementary and secondary schools. Post secondary institutions are more likely to have to engage in very costly activities such as the installation of elevators.

AID TO PRIVATE ELEMENTARY AND SECONDARY STUDENTS

Mr. FLOOD. The Administration's proposal only helps college students. What about elementary and secondary students in private or parochial schools?

Secretary CALIFANO. The President and I are both very concerned that, consistent with the Constitution nonpublic school children receive their equitable share of funds provided under Federal elementary and secondary education programs. Although estimates in this area are rough, we estimate that in fiscal year 1978, private school students, who in total number about 5 million, will receive between $100 and $250 million out of the total $6 billion appropriated for Federal elementary and secondary programs. On the average, these funds will provide between $20 and $50 per student. In fiscal year 1979, we expect this amount to increase to between $55 and $75 per student.

In order to ensure that nonpublic school students receive equitable support consistent with sound constitutional interpretation, we have proposed several legislative changes as part of our elementary and secondary education reauthorization proposal. For example, in Title I, we are requiring that spending for educationally deprived nonpublic school children be comparable, consistent with their numbers and educational need, to spending for public school children. We are also proposing that new Title I funds distributed through the targeting and State incentive provisions be subject to the same equitable standard. In addition, we are requiring that State plans include monitoring and enforcement provisions concerning the participation of non-public school children. For Title IV of the Elementary and Secondary Education Act, we are requiring States to make information and technical assistance available to private non-profit school officials who want to arrange for children in those schools to participate in Federal elementary and secondary programs. We are also proposing to strengthen and clarify the "by-pass" authorities in Title I and Title IV which the Federal Government may use to provide constitutionally permissible services directly to nonpublic school students if States and localities fail to discharge their statutory obligations. We are also taking other legislative steps, in the Bilingual Education program for example, to ensure the equitable participation of private school students.

In addition, we have also taken or will take administrative steps to fulfill the President's commitment to private education. For example, we will establish a new Office for Nonpublic Schools within the Office of Education. This office will coordinate all Federal education programs calling for the participation of

private school students, obtain information about the level of nonpublic student participation in federally funded education programs, and process complaints. We have already established a more precise and systematic complaint process. Moreover, we will make sure that qualified representatives of private schools are placed on educational advisory committees.

REMOVAL OF ARCHITECTUAL BARRIERS

Mr. FLOOD. Is the Federal Government going to subsidize construction costs across the board to meet the law and regulations on the handicapped, and for occupational safety and health requirements?

Secretary CALIFANO. The law and regulations were designed to provide most recipients of HEW funds with enough flexibility to comply without excessive cost. To encourage voluntary compliance and keep costs to a minimum, we are initiating a technical assistance program to provide recipients with detailed guidance. The President has submitted a FY 1978 Supplemental request which includes 72 positions (26 for education) and $9,474,000 to conduct the Section 504 technical assistance program. In addition, for the purposes of Section 504, we have asked Congress to permit $30 million now in the Higher Education Facilities and Loan Insurance Fund to be used for the removal of architectual barriers and energy conservation. The 1979 budget includes a request for $50 million to help colleges and universities to remove architectural barriers.

In the interim, studies are planned to gauge more accurately where the most pressing needs will arise so that the additional funds, when made available, can be put to use in the most effective way.

RECONSTRUCTION AND RENOVATION OF EDUCATION FACILITIES

Mr. FLOOD. Local school districts, colleges, universities, and other institutions are facing major problems in renovation and construction of their physical plant because of energy conservation, occupational safety and health requirements, and the needs of the handicapped. The budget includes $50 million for construction grants to colleges and universities. But we have heard that several billion dollars are required to meet these construction needs not only at colleges but also elementary, secondary, and vocational schools, libraries, and rehabilitation facilities.

Why have colleges and universities been singled out for Federal assistance?

Secretary CALIFANO. The only authority for reconstruction and renovation of facilities to make them more energy-efficient and to help them comply with occupational, safety and health standards is in Title VII of the Higher Education Act which only covers postsecondary institutions.

Most of the concerns about removal of architectural barriers expressed by school officials have come from the higher education community rather than from the elementary and secondary area. In elementary and secondary schools, only a small fraction of all handicapped children have impairments that hamper their gaining access to the average school building. More severely handicapped children usually attend special schools that have been designed to meet their needs. Most school systems should be able (by providing the required transportation) to assign all of their physically handicapped children to a few of their buildings. For example, even a moderate size school system with 10–15 separate buildings with no new or already accessible buildings should have to modify only one or two of its buildings.

In addition, the costs of complying with the Section 504 requirements are greater for postsecondary institutions than elementary and secondary schools. Postsecondary institutions are more likely to have to engage in very costly activities such as the installation of elevators.

QUALITY CONTROL PROGRAMS IN WELFARE

Mr. FLOOD. Your budget assumes a considerable increase in the commitment of resources to both the Aid to Families with Dependent Children (AFDC) and Medicaid Quality Control activities. How much additional improvement in these welfare error rates are you estimating can be achieved with the additional funds?

Secretary CALIFANO. The payment error rate in the AFDC and Medicaid programs is currently an estimated 8.6 percent. We believe that error rates can be reduced by improving the management and operation of AFDC and Medicaid. We can achieve this by providing technical assistance and support to State agencies and State legislatures on the types of improvements which we think

are appropriate. In Medicaid, for example, we plan to concentrate our efforts on errors related to ineligibility, claims processing, and third-party liability. States will provide feedback to us on problems and unique ways of reducing errors. If this general plan is put in place, we believe that we can reduce the payment error rate in AFDC from 8.6 percent in 1977 to 6.0 percent by 1981. In the Medicaid quality control program, we estimate a 1 percent reduction per year in the payment error rate for the next 3 years.

ADOLESCENT HEALTH

Mr. FLOOD. Mr. Secretary, the budget before us includes several new legislative proposals for health programs. One of these proposals is for adolescent health services, and pregnancy prevention. Now, as I understand the proposal, this legislation will provide project grants to help States and communities integrate existing pregnancy prevention and pregnancy-related programs. Why do you need additional legislative authority, why can't you accomplish this with the existing authorities?

Secretary CALIFANO. We considered using existing authorities but we concluded that we would be able to move faster and to stimulate more innovative approaches to the problem if we had new legislation. Existing programs are targeted to specific problems which are important, but the programs are not well coordinated at the local level. To get these programs to change their priorities and to provide incentives for local cooperation would have required modifying each program's authority and that would have taken too long. This new legislation will provide a mechanism for coordinating existing categorical funded services and also allow for the development of services which currently may not be available.

The new legislation gives communities the flexibility to design a program which meets their needs and to develop a service network which reflects local priorities. Since traditionally HEW funded agencies such as Community Health Centers, family planning clinics, and school districts are not the only potential grantees, we feel that each community will be able to select the most appropriate type of grantee.

New legislation has the added advantage of providing a clear statement of our objectives and of identifying this effort as a major program priority and not just a temporary shift in emphasis.

Mr. FLOOD. Mr. Secretary, has this legislation been introduced?

Secretary CALIFANO. Not yet, but it will be sent to the Congress within the next few weeks.

PROFESSIONAL STANDARDS REVIEW ORGANIZATION

Mr. FLOOD. Your agency spent over a million dollars on an evaluation of the Professional Standards Review Organization. This study raised serious questions about the value of this program over the voluntary programs already in place. Despite this negative report you are asking for $174 million for the PSRO program in 1979. Why bother to do evaluations if you're just going to ignore them?

Secretary CALIFANO. We are taking the evaluation very seriously, and we have addressed many of the weaknesses identified in the evaluation in the 1979 budget. But before I discuss those proposals, I would like to make two points. First, the evaluation relied on data from a time period when only 18 of 195 designated PSRO areas had sufficient review experience to permit any assessment of program impact. The limited scope of the study sample means that the results should not be generalized for the nation. Nevertheless, the evaluation has given us baseline data that can and will be used to measure future progress. Even more importantly, the report has provided us, for the first time, with hard data pointing out some program weaknesses at an early stage in program development. This gives us the opportunity to take corrective action as we move toward full implementation.

Secondly, I do not agree with the view that the evaluation report was totally negative in its findings. Although the report concluded that there was no aggregate effect on hospital utilization for the 18 PSROs studied, almost half of them had lower utilization rates compared to their matched, non-PSRO areas. So PSROs can be effective. The challenge for us is to learn more about the conditions that are conducive to good performance and to apply those lessons to other PSROs that have performed less satisfactorily.

The report also observed that Medical Care Evaluation Studies appear to be an effective means of identifying and correcting clinical and administrative deficiencies in care, and found some evidence that PSRO review results in more effective rationing of hospital beds. All of these are indications that PSRO review can have a positive impact on quality of care, though clearly a lot more needs to be done.

Now with respect to the FY 1979 budget, the request of $174 million provides for a number of actions designed to improve PSRO performance. In the area of costs, we believe that the detailed review of all Federally funded admissions is expensive and wasteful. The budget assumes a progressive shift away from the current approach of reviewing 100 percent of Medicare, Medicaid and Maternal and Child Health admissions and toward a focus on previously identified problem areas. At the same time that we are reducing the cost of hospital review, we will also be developing guidelines for improved financial management to minimize PSRO unit costs and overhead.

Improvements in the effectiveness of PSRO review is another major goal of our activities in FY 1979. PSROs will be required to develop specific, measurable objectives related to local problems in utilization and quality, such as reduction in lengths of stay for specific diagnosis and reduction in overall lengths of stay for hospitals that exceed local norms. Moreover, the ability of PSROs to set and achieve these objectives will be a major factor in refunding decisions.

All of these actions show clearly that we have learned a great deal from the evaluation report and that we are committed to improving the performance of PSROs.

Mr. FLOOD. The budget suggests that you will be rechecking this PSRO evaluation data. Can we expect to hear the results of this reevaluation effort before we mark up a bill in early May?

Secretary CALIFANO. We do not expect to have any more evaluation data by May. As I indicated earlier, the evaluation report provided us with baseline data that will be updated periodically to enable us to measure improvements in program impact over time. We view this as an on-going process. We will also be conducting more in-depth studies of selected aspects of the original report such as factors related to the effectiveness of PSROs. But I do not expect any new information before the end of the year. Of course, it will be even longer before we know the impact of the program improvements that we will be putting in place this year and next.

ACTIVITIES DEMONSTRATED TO BE DANGEROUS TO YOUNG PEOPLE'S HEALTH

Mr. NATCHER. I am concerned, Mr. Secretary, that the people, and especially young people, that they be equally informed about alcohol and drug abuse, unwanted pregnancies, venereal disease, proper nutrition, and so forth. Can you be sure that your particular emphasis on smoking will not divert funds and personnel away from these matters, which we all believe to be right important?

Secretary CALIFANO. Like you, we are extremely concerned that our young people be informed of threats to their health.

Activities related to smoking and health are a relatively new and small departmental initiative, although activities have been conducted in NIH and CDC for the past several years. $30 million in 1979 is modest, and certainly has not diverted resources from the other crucial activities you mentioned. We are proposing a major new initiative in adolescent health and pregnancy care, with a proposed increase in spending from $196 million in 1978 to $338 million in 1979. We are also proposing to increase the budget for alcoholism (from $168 million to $174 million) and drug abuse programs (from $262 million to $275 million).

NATIONAL INSTITUTE OF CHILD HEALTH

Mr. MICHEL. There has been a heavy lobbying effort to add money for a new building for the Institute of Child Health. I understand you asked for funds for such a building in your budget submission, but the President turned it down. Is that correct?

Secretary CALIFANO. $37.2 million for a new Child Health building was included in the Department request to OMB. After consideration was given to

total competing funding demands, it was decided not to approve construction of this new building at this time.

HEALTH AND QUALITY CONTROL

Mr. MICHEL. Your budget appears to be quite generous in including cost reductions which might result from cost-saving proposals. For instance, the total for hospital cost containment and Medicaid quality control is $1.1 billion alone, including $730 million for hospital cost containment. Why were these savings shown in the budget when the proposed legislation is nowhere near passage, and probably will not be adopted in the form you proposed?

Secretary CALIFANO. The Medicaid Quality Control proposal is not assumed to be effective until October 1, 1978 and about three-fourths of the savings you cited for that provision are possible through our own actions under current law. We have assumed an effective date for the enactment of both these legislative proposals that we believe to be realistic. In particular, the Congressional Committees are working actively on the hospital cost containment proposal, which is assumed in the budget to be effective July 1, 1978.

GUARANTEED STUDENT LOANS

Mr. MICHEL. I keep hearing a lot about your efforts to collect defaulted loans, but I don't see much in the way of results. Can you show any progress?

Secretary CALIFANO. We are making progress on the collection of defaulted guaranteed student loans. First, bills have been sent to over 100,000 defaulters, and, by the end of March, bills will have been sent to all 344,000 borrowers currently in default under this program. Second, over the past six months, approximately 1,500 cases have been referred to U.S. Attorneys for litigation. About 900 of these cases have resulted in borrowers agreeing to repay their loans or judgments being obtained against them. Third, we have begun to check the Federal payroll against the Guaranteed Student Loan default file to identify Federal employees who have defaulted on their loans, and stringent efforts are being made to get them to repay these loans. In addition, HEW's Inspector General is investigating and taking appropriate action against lenders and educational institutions who have allegedly committed fraud with respect to the Guaranteed Student Loan program.

Mr. MICHEL. There seems to be considerable confusion in your Department as to how to increase this collection. First we hear about the use of collection agencies, and now you are apparently backing away. Then we hear about the number of HEW employees in default, but there appears to be no effort with teeth in it to get them to repay. Frankly, it appears to me there is a lot of motion, but no direction. What about it?

Secretary CALIFANO. At the present time, we are intensifying our effort to collect on defaulted guaranteed student loans. We will rely primarily on HEW employees to make these collections and we are beginning new training programs in debt collection practices. However, we also are going to contract with a private collection agency on an experimental basis in two regions.

In carrying out these collection efforts, we are taking strict measures to respect the privacy and other civil rights of the borrowers, and will require that the guidelines set forth in the Fair Debt Collection Practices Act be scrupulously observed. It is for that reason that I wanted to proceed slowly with private collection agents.

With respect to HEW employees who have defaulted on their guaranteed student loans, we have established administrative procedures at HEW to get them to repay these loans. Of the 317 HEW employees who have defaulted on their loans, 184 have already agreed to repay them, 33 accounts have been written off due to the death, disability or bankruptcy of the borrower, and 62 of these individuals no longer work for HEW.

For the 38 remaining cases, the following procedures will apply:

For those who have responded to our letter and deny or dispute the liability, we will work with those employees to resolve the matter.

For those HEW employees who have not yet responded to our letter. one more contact by mail or telephone will be attempted to the last "best" duty station address available from our payroll records. Attempts to contact these employees will be completed by March 1, 1978. If no response results in about two

weeks, the Assistant Secretary for Personnel Administration has agreed to arrange for a "counselling contact" on a face-to-face basis with the individual by a representative of the agency personnel office. At this point, privacy will be maintained and the individual's supervisor will not be informed.

Counselling will consist of informing the individual of the disciplinary and litigative steps which the government will consider should there be a flat refusal to pay in a reasonable time period, or should the individual deny the legitimacy of the debt.

If the individual denies the legitimacy of the debt, the case will be returned by the Assistant Secretary for Personnel Administration to the Bureau of Student Financial Assistance (BSFA) for their follow-up action. BSFA will review the merits of the case and determine whether to seek court action, or to write off the account.

If the individual confirms the debt but refuses to pay, the supervisor will then be informed for the first time, and asked that he further counsel the individual. The usual range of actions are available for appropriate use. These include a letter of reprimand, suspension, or dismissal. The Assistant Secretary for Personnel Administration will monitor closely the case-by-case decisions made so as to assure uniformity and fairness. The goal is to obtain restitution; if, however, employees still adamantly refuse to repay a just debt, adverse action procedures will be considered.

If all of the efforts fail, and it is the view of the Assistant Secretary that the individual is in a position to begin repayment but that continued effort will not result in repayment, then the case will be referred back to BSFA. The BSFA will then determine whether to refer the case to the U.S. Attorney.

As for those cases where it is apparent that the ability of the individual to repay is marginal, the Assistant Secretary for Personnel Administration may decide to close the case and recommend to the Deputy Commissioner, BSFA, that it be written off.

MIDDLE INCOME INITIATIVE

Mr. MICHEL. Would you provide for the record all the alternatives you considered and the reasons for their rejection?

Secretary CALIFANO. In developing alternative proposals, we gave serious consideration to using different configurations of existing programs to provide assistance to middle-income families to help relieve them of the burden of the costs of postsecondary education. The following are six examples of the alternatives that were considered. The first three alternatives involved changes only in the Basic Grants program as follows:

The first "Basic Grants Only" approach would maximize the impact on middle income families without requiring legislative changes to the program. This approach involved reducing the assessment rate on family income which would have the effect of reducing the amount of money that families are expected to contribute to the costs of postsecondary education. This approach was similar to an earlier proposal by Senator Pell.

The second "Basic Grants Only" approach would increase the income range for which families would be eligible for the maximum award as well as increase the average award for all families. This would be accomplished by excluding a portion of discretionary income from the assessment rate which determines how much a family is expected to contribute to the costs of postsecondary education. This approach was similar to the "Blue Collar" change proposed earlier by Congressman Ford.

The third "Basic Grants Only" approach included changes to both enhance access to postsecondary education for disadvantaged students and to help reduce the cost burden on middle-income families. Those objectives would be accomplished by increasing the amount of the maximum award, reducing the assessment rate on discretionary income, and liberalizing the treatment of independent students.

The fourth alternative considered involved a "Flat Grant" approach. An award of $250 would be guaranteed to each student who was pursuing postsecondary training.

The last two alternatives involved a mixture of existing student aid programs and addressed the problems of both disadvantaged students and students from middle-income families.

The fifth alternative involved changes to only the Basic Grants and Work-Study programs. It increased the funding level for the Work-Study program and made the same changes in the Basic Grants program as described in alternative No. 1.

The sixth alternative was a "mixed" approach and involved all of the student aid programs with the exception of the Direct Loan program. It incorporated the following changes:

Raising the ceiling on BEOG maximum award.

Reducing the BEOG assessment rate on discretionary income.

Liberalizing the treatment of independent students.

Increasing the funding levels of the Work-Study program and the Supplemental Grant program in exchange for greater discretion for the Commissioner in allocating these funds among States and institutions.

Increasing the funding of the State Student Incentive Grant program possibly in exchange for a strong maintenance of effort requirement to insure a true 1:1 match with new State money.

Increasing the funding of the Guaranteed Student Loan program to permit: an increase in the adjusted income eligibility cutoff for the interest subsidy from $25,000 to $40,000; raising the special allowance paid to banks on notes in repayment by ½%; and creating a 1% floor for the special allowance.

We rejected these six alternatives for the following reasons:

Some of the alternatives were very expensive—such as alternatives #2 and #4.

Some of the alternatives did not target the aid on middle-income families who are bearing the heaviest burden for the costs of postsecondary education—such as alternatives #5 and #6.

Some alternatives did not include loan programs that middle-income families need to address their liquidity problems—alternatives #1 through #5.

Under the alternatives involving only the Basic Grant program, it would be very expensive to extend eligibility far enough into the income range to provide significant relief to middle-income families.

In general, the other alternatives were too complex or not as equitable and as effective in targeting the amount and type of aid most needed by middle-income families.

Mr. MICHEL. Your proposal may provide some small amounts of assistance to some middle-income families, but how does it assist those parents sending children to private colleges, where the costs are quite substantial?

Secretary CALIFANO. Approximately 70 percent of the $1.2 billion for the student aid initiative will be targeted on students from families with incomes above $16,000.

Over $1 billion of the additional funds will be used to increase the funding levels of the Basic Grant and Guaranteed Student Loan programs. These funds are awarded directly to students and the student can use the funds at the institution of his or her choice. We expect that as a result of the increase in student aid funds, more students will be able to attend private colleges.

EXTRA 1978 SSI PAYMENT

Mr. MICHEL. You have a little manipulation in the budget which shows a lower expenditure in 1979 for SSI than in 1978 because 11 payments will be made then versus 13 in 1978. The budget thus shows an expenditure of $5,974,000,000 in 1978, but we only appropriated $5,250,000,000. You haven't submitted any supplemental request, so the question is: where is the extra $721 million coming from?

Secretary CALIFANO. I don't believe it is accurate to characterize the extra SSI payment in 1978 as budgetary manipulation. There is an extra payment due to a provision in the Social Security Amendments which states that whenever the SSI payment date—the first of the month—falls on a weekend or holiday, the payment must be moved up so that the check is received by the recipient before the weekend or holiday. It happens that October 1, 1978, the start of FY 1979, falls on a Sunday so the October 1978 SSI payment by law must be paid at the end of September 1978. Hence, the extra 1978 payment, which actually amounts to $425 million.

The reason a supplemental is not needed is two-fold.

First, we estimate about $266 million in excess 1978 funds not needed for currently projected regular 1978 payments.

Second, the 1978 appropriation language provides authority to draw against 1979 funds in the case of shortfalls in 1978. $159 million is being advanced from the 1979 account to meet the balance of the $425 million extra payment.

ABORTION

Mr. MICHEL. Would you provide for the record the specific statutory provisions, and corresponding legislative history, which show the intent of Congress to authorize the use of Medicaid funds for abortions?

Secretary CALIFANO. Section 101 of Public Law 95-205 is presently the only statutory provision that specifically mentions abortions in the context of whether, and when, Federal funds will be available for those procedures under title XIX. During my testimony before the committee on February 21, I provided a copy of the legislative history to that section to each member who was present. I have included an additional copy with these answers.

Mr. MICHEL. Would you also provide for us the specific language the Administration would like included in the Labor-HEW Appropriation Bill governing the payment of Medicaid funds for abortion.

Secretary CALIFANO. We do not believe that an appropriations bill is the proper vehicle for implementing Federal policy on the funding of Medicaid abortions. By doing so, you create a myriad of administrative problems that are never considered in the debate on the issue. Accordingly, we have no specific language which the Administration would like included in the Labor-HEW Appropriations Bill governing the payment of Medicaid funds for abortions.

However, both the President and I believe that a statute governing Federal funding of abortions should provide for funding those procedures only where the life of the mother would be endangered or for treatment of rape and incest victims when the rape or incest is promptly reported. I have attached hereto a copy of my letter to Chairman Flood, dated February 21, 1978, delivered in response to a request made during my testimony, which clearly sets forth the Administration's position.

Mr. MICHEL. A proper set of regulations would have defined the words "severe," "long-lasting," and "physical health damage." By not doing so, your regulations leave the way open for unscrupulous doctors to claim payment for almost any abortion. Why did you provide this massive loophole?

Mr. CALIFANO. It is our belief that the determination of when a woman would suffer severe and long-lasting physical health damage is a medical determination that must be made on a case by case basis by physicians. As the preamble to the regulations indicates, this interpretation is clearly supported by the record of debate in both Houses of Congress. 43 Fed. Reg. 4832, 4836-37 (February 3, 1978).

If there is a massive loophole created—and we presently have no statistics to indicate whether this is so—then it is created by the statute and not by the regulations. The defining of the terms "severe," "long-lasting," and "physical health damage" in the regulations would do nothing to deter the unscrupulous physician, for any physician who intended to circumvent the regulations would do so no matter how we defined those terms.

Mr. MICHEL. Your regulations require no documentation from physicians as to the basis for their judgment that severe and long-lasting physical health damage to the mother would result. Why not?

Mr. CALIFANO. The regulations do require documentation that two physicians have made this determination and also require that the States receive this documentation prior to making payment for the procedure. In addition, an Action Transmittal sent to all States requires them to report the number of abortions reimbursed under each category at the close of each quarter. This information will enable the Department to monitor against significant increases in the number of abortions performed under each category which might indicate fraud. However, the factors of patient privacy, the overwhelming administrative burden, and provider confusion that would occur if State officials were required to review and second guess each physician's judgment in this matter dictated that, in the absence of evidence of fraud, the Department should only require documentation to demonstrate that the diagnosis was made.

Mr. MICHEL. Your regulations establish no limitation as to who can report rape or incest, thus leaving it totally open-ended. Why is that?

Mr. CALIFANO. The regulations do not limit who may report for two reasons. First, the words of the statute set no limits upon who may report, but rather allow Federal funding of abortions "when such rape or incest has been reported. . . ." Second, the ranking minority conferees of both Houses of Congress agreed that third parties could make the report.

Mr. MICHEL. No standards have been established to determine the legitimacy of rape or incest reports. Why not?

Mr. CALIFANO. This is not so. The regulations require that the report be in writing and contain the name and address of the person reporting the incident of rape or incest, the name of the victim, and the signature of an official of the agency or service which received the report. In addition to these requirements, the HCFA Action Transmittal which sets forth guidelines to the regulations requires that the report include the address of the victim, and the Department is considering revising the regulations at the conclusion of the comment period to clarify this requirement. Moreover, the reports must be received prior to payment of any claim for reimbursement which will contain the name and address of the physician or facility performing the abortion. The information provided by these documents will enable investigators to make as thorough an investigation of suspected fraud as is possible under the statute consistent with privacy considerations. However, nothing in either the statute or legislative history indicates explicit Congressional intent to require the reporting of details of the incident. In the absence of clear evidence to that effect, personal privacy considerations dictated against the regulations requiring the report to contain that information.

Mr. MICHEL. The regulations make no reference to whether the applicable sections of the Medicaid-Medicare Fraud and Abuse Amendments of 1977 apply to the abortion language. Do they apply or do they not?

Mr. CALIFANO. The preamble to the regulations is clear on the fact that these amendments do apply to fraudulent acts committed under these regulations. The preamble specifies that "any person who knowingly submits a falsified claim for Federal funds, or who aids or abets in the submission of a falsified claim, may be subject to prosecution under section 1909(a) of the Social Security Act [which provides penalties for Medicaid fraud] or another applicable provision of law." See 43 Fed. Reg. 4832, 4842 (February 3, 1978).

Mr. MICHEL. The use of two physicians was undertaken essentially to limit the possibility for fraud. The only way this can be effective is if the physicians are not associated with each other in the same clinic or practice. Your regulations make no such requirement. Why not?

Mr. CALIFANO. Nothing in either the Act or the record of debate indicates any Congressional intent to prohibit the physicians who are professionally associated with each other from both certifying that the woman would suffer severe and long-lasting physical harm if the pregnancy were carried to term. However, we are aware of the potential conflict of interest in this situation—and in all situations where two opinions are required—and I have instructed the Administrator of the Health Care and Financing Administration to prepare regulations as soon as possible to eliminate, to the extent possible, this potential conflict.

IMPACT AID

Mr. MICHEL. Would you describe for us your proposed changes in the Impact Aid program and their long range cost impact?

Mr. CALIFANO. Our Impact Aid reform proposal attempts to create a more rational and equitable program structure. This would be accomplished gradually over the next several years by adjusting payments for local school districts to reflect more closely the actual burden Federal activities place on those agencies and to simplify program administration. To achieve these objectives we are proposing to eliminate payments for children whose parents work on Federal property outside the county in which the school district is located, phase out payments for public housing children beginning in 1981, and reduce payments to districts that are lightly impacted by the inclusion of a 3 percent absorption provision. Moreover, the local contribution rate will be set at one-half the average per pupil expenditure in the State for all districts except the most heavily impacted areas who may use the comparable district method. A hold harmless provision which guarantees that no district will receive less than 75 percent of the previous years payments will ease the adjustment to these reform measures. Additionally, we are proposing to advance fund this program

to provide districts with early notification of their allocations. In 1982, when the reform measures would be fully implemented, it is estimated that the reformed program would cost $717 million, a savings of approximately $336 million from what we project the current program would cost in that year.

TITLE I, ELEMENTARY AND SECONDARY EDUCATION ACT

Mr. MICHEL. You're asking for another big increase for the Elementary and Secondary Title I program. How much in total has been spent on this program since its inception?

Secretary CALIFANO. A total of $23 billion has been appropriated for Title I of the Elementary and Secondary Education Act from fiscal year 1966 through fiscal year 1978.

Mr. MICHEL. What accomplishments can you show for all the money expended?

Secretary CALIFANO. Several recent studies have shown that compensatory education programs, particularly those supported by ESEA Title I, are having positive results. For example, one study of compensatory reading programs found that Title I funds are reaching the most educationally disadvantaged students and are providing compensatory services that supplement the regular reading program. Moreover, students appear to benefit from these additional services by achieving at a rate equal to or greater than that of non-disadvantaged students. In addition, data from the National Institute of Education's study of compensatory education show that Title I students are receiving extra services, including more instruction time, smaller group size, and more time with qualified teachers. The NIE study showed other positive results about compensatory instructional programs. For example, first graders in the sample made average gains of 12 months in reading and 11 months in mathematics in the seven-month period between fall and spring testing. Third graders gained eight months in reading and 12 months in mathematics. Other measures, such as percentile gains, were also positive.

ZERO BASE BUDGETING AND TITLE I

Mr. MICHEL. As part of the zero base budgeting process, what kind of cost-effectiveness standards did you apply to this program?

Mr. CALIFANO. Throughout deliberations on the fiscal year 1979 budget, we examined the relative importance of priorities for education, as well as priorities for the rest of the Department. This is in keeping with the concepts of zero base budgeting. With regard to Title I, for example, we looked at the effect that various funding levels would have on program operations, taking into consideration the degree to which specific dollar amounts would either serve more eligible students or increase per pupil spending for existing participants. We also considered trade-offs between different funding level increments for Title I with other education priorities such as education for the handicapped, desegregation assistance, and aid for postsecondary students. We also took into consideration the findings of studies of Title I, such as the study conducted by NIE which found that the Title I program is carrying out the intent of the Congress of providing funds to poverty districts and disadvantaged students.

COMPARATIVE COST ANALYSES OF WELFARE REFORM PROPOSALS

Mr. MICHEL. Would you provide for the record a cost analysis of the House Welfare Subcommittee Bill, the Carter Bill, the Ullman Bill, the Bill I have introduced (H.R. 19193), and the Senate Finance Committee Welfare proposal as contained in H.R. 7200?

Secretary CALIFANO. We will supply those estimates to your Committee as they are prepared.

FINANCING WELFARE REFORM

Mr. MICHEL. Where are we going to come up with the money to pay for such sizeable increases?

Secretary CALIFANO. No specific revenue program or proposal can be matched up with a particular spending increase. The projected 1982 budget contained in the President's 1979 budget submission demonstrates, I believe, that a modest increase in assistance for the low income population, principally in the form of more money for jobs, is consistent with the President's economic policy.

WELFARE RECIPIENT REFERRAL TO PUBLIC SERVICE JOBS

Mr. MICHEL. The law establishing Public Service jobs requires that welfare recipients be given priority. Is there any requirement that welfare agencies funnel recipients to such jobs, and secondly, is the work requirement being enforced for recipients who may turn down such jobs?

Secretary CALIFANO. The answer to both parts of your question is yes, Mr. Michel. Priority for CETA Title VI public service jobs goes to three groups of people: (1) welfare recipients, (2) people who have exhausted their unemployment insurance, and (3) the long-term unemployed. Welfare recipients are funnelled to CETA prime sponsors for public service jobs by the Work Incentive (WIN) program, an arm of the Employment Service. The State Employment Services certify a list of eligible recipients to the CETA prime sponsors for priority consideration.

As far as enforcing the work requirement is concerned, a recipient who turns down a public service job—or any other bonafide offer of employment, for that matter—is referred by the WIN program back to the welfare agency for action. The welfare agency reviews the case and determines whether good cause existed for the refusal. If good cause cannot be shown—as, lack of child care, inadequate transportation, a change in health status, etc.—the recipient is removed from the welfare roll by recomputing the grant considering only the needs of the dependent children.

FEDERAL V. STATE ADMINISTRATION OF WELFARE

Mr. MICHEL. Why does the Administration in essence want to nationalize the Welfare Program? What's wrong with allowing the States to set their own benefit levels and otherwise administer the program in keeping with the desires and circumstances within each State?

Secretary CALIFANO. The Administration's proposal does not nationalize the Welfare Program. The Bill would institute a minimum benefit but would in fact encourage States to supplement that minimum benefit. We estimate most States would supplement. Thus most States would retain control over ultimate benefit levels. While some Federal presence in overseeing the Administration of the program, computing benefits, and issuing checks is desirable, the States would retain the option to perform the intake and eligibility determination functions. This will allow flexibility for States to adapt administrative procedures to local circumstances.

ALTERNATIVES TO WELFARE REFORM

Mr. MICHEL. In view of the sharply escalating cost of the Carter Welfare Reform Concept, would it not be better to go back to the drawing board in that regard and in the meantime simply concentrate on improving the existing system through such things as monthly retrospective reporting, incentives for quality control, greater leeway for State experimentation, etc?

Secretary CALIFANO. The costs of the Administration proposal are not sharply escalating. The original estimates of outlays have been largely confirmed by subsequent analysis. I believe the concepts are sound and the program affordable. Of course, given the need for careful planning before implementation of the basic program, we may wish to introduce interim changes in our existing programs to ease the transition to the new program. In addition, the Department is in the process of expanding its experimentation with monthly reporting and continues to improve its quality control program. Through such efforts as Operation Match we plan to reduce fraud, error, and abuse.

COST OF WELFARE REFORM

Mr. MICHEL. When the President first proposed his Welfare Plan, he estimated the increased costs at $2.8 billion. Later estimates put the increased costs at anywhere from $11–20 billion. Now the Committee Bill is $21 billion. Where does the Administration stand now as far as the cost increases it is willing to accept is concerned?

Secretary CALIFANO. Our initial estimate of $2.8 billion compared projected outlays in FY 1978 at an unemployment rate of 5.6 percent compared to the expenditures we expected to actually take place in FY 1978. The President's FY 1979 budget contains a net Federal cost for FY 1982 assuming implementation of H.R. 9030 on July 1, 1981. This amount, about $7.5 billion, is higher because of the inflation in benefit levels and the projected increase in the minimum wage. This

estimate also employs a lower offset for existing CETA jobs, $3.9 billion vs. $5.5 billion used in our FY 1978 estimate, consistent with the Administration's proposal for CETA reauthorization.

The only estimates I know of near $20 billion are the estimates submitted by CBO. The principal difference is in the offset column. We have prepared a detailed reconciliation between our 1982 estimate and the one prepared by CBO. I'll be glad to furnish a copy of that paper to your committee.

While the Administration did not support several of the changes made by the Subcommittee including some which raised costs, we are not setting any arbitrary maximum on acceptable costs. We hope to work together with the three House committees to achieve a program that meets the President's goals and is consistent with the Administration's overall budget objectives.

FOOD AND DRUG ADMINISTRATION

Mr. MICHEL. It is my understanding that the Food and Drug Administration (FDA) is requesting funds for a new building to consolidate its laboratories. However, I understand that they are not planning in Phase I to relocate the Bureau of Biologics from the National Institutes of Health campus. It would seem to me that rather than constructing a new Child Health building, a new FDA building without biologics, and then in several years constructing an addition to the FDA building to accommodate biologics. It would be cheaper to construct a larger FDA building initially, and then give the $5,000 square feet of space in NIH occupied by biologics over to the Child Health Institute. Have you examined the cost implications of this approach?

Secretary CALIFANO. We have not examined the cost implications of including Bureau of Biologics in our Phase I facility plan at Beltsville. The Phase I activities at Beltsville are intended to replace those FDA headquarters laboratories which currently occupy facilities that are the most inadequate and the most in need of replacement. These are the laboratory facilities of the Bureau of Foods, Bureau of Drugs, and the Bureau of Veterinary Medicine. The laboratory facilities occupied by the Bureau of Biologics are among the best laboratory facilities occupied by any FDA component and are currently considered those that should be given the lowest priority for replacement. Furthermore, the National Capital Planning Commission has established a ceiling of 1,800 employees for our present Beltsville site. We are concerned that the laboratories now included in our Phase I construction project will be very close to this 1,800 employee ceiling by the time we are able to occupy the new facility at Beltsville The addition of the Bureau of Biologics to Phase I would entail the addition of approximately 400 more employees at the Beltsville site.

Mr. MICHEL. Would you provide for the record a cost analysis showing the amount to construct a new Child Health building, the amount to expand Phase I of the FDA building to include biologics, and the amount to move Child Health into the space which would be vacated by biologics.

Secretary CALIFANO. We have a preliminary estimate of the 1980 cost for design and construction of the alternative projects. Experience over the past several years suggests that 10 percent should be added to these estimates to cover construction cost escalation for each year beyond 1980. For example, if the Bureau of Biologics were added to Phase I of the FDA facility, then the present Bureau of Biologics buildings would not be available for renovation until 1983 and the cost stated below should be increased by 30 percent; i.e., from $11.3 million to $14.7 million. However, these estimates on renovation costs are tentative.

1980 estimated cost

Project:	*Millions*
Alternative I:	
Construction of a new structure for the National Institute of Child Health and Human Development (85,400 net square feet)	$37.2
Alternative II:	
Expansion of phase I of the FDA facilities to accommodate the Bureau of Biologics (117,000 net square feet)	38.6
Adaptation of the present Bureau of Biologics building to accommodate child health research	11.3
Total cost, alternative II	49.9

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Based on this tentative analysis, it would be about $307 million more expensive to move the Bureau of Biologics to Beltsville than to construct a new facility for Child Health on the NIH campus. The reasons for this are that (1) the Bureau of Biologics needs more space than Child Health does and (2) the current space occupied by the Bureau of Biologics, though in good condition and suitable for the Bureau's needs, would have to be modified extensively to be suitable for child health research.

COMMUNITY MENTAL HEALTH CENTERS

Mr. CONTE. Last year you indicated that the inclusion of community mental health centers under the Medicaid reimbursements was being studied. Have you taken a position on this matter in the current budget? Wouldn't the inclusion of mental health centers under Medicaid reimbursement reduce the need for categorical funds in this area?

Secretary CALIFANO. States still have the option to include mental health coverage under their State Medicaid plan. We have not changed this optional coverage provision for 1979. However, studies are being conducted by the Department in conjunction with the President's Commission on Mental Health concerning the short-comings in financing mental health services under Medicaid and Medicare. In addition, as part of our development of a national health insurance proposal, we are examining the impact of expanded mental health benefits.

Regardless of the studies undertaken, you are correct in that expanded outpatient mental health coverage by third-party payors would tend to reduce the need for categorical grant assistance.

PURPOSE OF NIH RESEARCH

Mr. CONTE. Isn't it true that your research efforts at NIH are not directed to prolong our citizen's lives, but mainly to increase the quality of life? Please comment.

Secretary CALIFANO. Research related to prolonging life is different from research related to improving the quality of life. The former deals more exclusively with basic cellular biology, what makes biological systems run down, what triggers the growth of cancer cells—as compared to research related to acute illness that affects the quality of life of all ages. NIH pursues both types of research. However, research related to the prolonging of life is pursued predominantly in the National Institute of Aging.

BASIC RESEARCH

Mr. CONTE. Lately the concept of basic research has been given widespread publicity. Basic studies would illuminate the interrelationships of reproduction and human development. These studies seem essential to the assurance of healthy children and families. The coordination of basic research studies involved in producing a child seem essential in understanding the laws of nature and its peculiarities and deviations. Could you comment on the advantages of such basic research?

Secretary CALIFANO. Your question addresses the basic premise upon which the NICHD operates—that only as we pursue an interdisciplinary mix of basic research in reproductive and developmental biology can we fully understand the processes involved in assuring a healthy infant population.

The health of a child is linked not only to the health of the mother but also to whether the child is wanted and planned for. The Institute supports research on reproductive biology so that new knowledge can be developed on the regulation of fertility. Moreover, basic studies on egg and sperm transport, fertilization, and implantation are vital to understanding the development of an organism. Research on developmental biology is focused on the changes that occur from fertilization of the egg through embryonic development and infancy. From this research is derived a basis for understanding processes of normal development as well as aberrations of development that cause problems such as congenital defects, mental retardation, and prematurity. Basic studies in this area yield new information on genetic diseases; on environmental factors, such as smoking and

the ingestion of alcohol, that compromise fetal growth; on optimal nutrition for the mother; and on processes that facilitate full-term birth.

Coordinated research in reproductive and developmental biology encompasses the most critical phases of human development—beginning with studies on the genetic components that are brought together in the fertilized egg, and including the processes of intrauterine development, pregnancy, birth, and early infancy.

Mr. CONTE. Currently a new basic research and training facility is under consideration which would provide 154 biomedical laboratories. Who would decide what research would be conducted in each, and how would the funds be allocated? In such basic research, how basic would it be?

Secretary CALIFANO. The proposed facility would house the Institute's Intramural Research Program. This program is responsible for the Institute's in-house studies on reproductive biology and the special health problems of women, children, and families.

Decisions on the assignment of space and allocation of funds are made by the Scientific Director, NICHD, who is responsible to the Director, NICHD. Their priorities are based upon several factors including the consonance of proposed research with the Institute's mission; congressional, Departmental, and NIH initiatives; Institute planning and priorities; and scientific opportunity. The Board of Scientific Counselors of the NICHD, a group of non-Federal scientists who advise the Institute Director, is an active participant in research planning for the intramural program.

The basic research supported by the program ranges from studies at the molecular level, such as the work of the Laboratory of Molecular Genetics, to clinical research on problems of fertility and infertility as conducted in the Endocrinology and Reproduction Research Branch, to studies of behavioral development of children within the context of the family.

STUDENT AID AND PRIVATE COLLEGES

Mr. CONTE. Your proposed increase in Student Aid programs should do much to aid both college students and the universities they attend. However, the small private colleges of this nation will still suffer from strapped resources. Have you undertaken any programs for FY 1979 to help these private colleges?

Secretary CALIFANO. We have not undertaken any special programs designed specifically to help private colleges. However, by increasing the total amount of student aid funds and by providing most of this additional aid to students from middle-income families, we expect that more students will be able to attend private colleges.

BASIC SKILLS

Mr. CONTE. It seems to me that the national direction of education priorities has been for several years to try and provide the same educational opportunities to *all* Americans, with HEW's budget again emphasizing these prerogatives. But the data is in—on egregiously low test scores, and millions of children seem not to be being educated, no matter what their economic background.

What is going wrong? Could you comment on initiatives for improvement in this area?

Secretary CALIFANO. Many reasons have been suggested for the decline in test scores: changing composition of students who are taking tests, insufficient classroom time on the three R's, the erosion of academic standards, instability in the family structure, impact of television, and violence in the schools. The explanation for declining test scores may be arguable but the result is not. There is an intense concern all across the nation about the quality of elementary and secondary education because it is essential that our nation's children attain the basic skills necessary for their effective participation in society.

The President and I are committed to continuing efforts already begun in this area and to seeking new ways to help the States and localities ensure that students attain basic skills. Let me emphasize that although I oppose any form of national curriculum or national standards of scholastic achievement, there is an important role for the Federal Government on improving basic skills and testing. By assisting State and local governments, this Administration is seeking to improve student achievement through a focus on innovation, achievement testing and a concentration on basic skills.

As part of the ESEA reauthorization legislation, we are seeking to promote the effective use of achievement testing, sponsor programs to involve parents in the process of educating their children, develop improved technology and materials, and disseminate the most promising basic skills programs to State and local authorities. The proposed legislation also attempts to strengthen and refocus the National Reading Improvement Act into a Basic Skills demonstration authority, which would include writing, oral, and mathematical skills and would seek to improve basic skills instruction and achievement in Federal, State and local programs.

Our 1979 budget reflects our effort to significantly strengthen our compensatory education programs. An increase of $644 million for the Title I program is requested which would be targeted on basic skills achievement. Additionally, we are proposing a State-run demonstration program to find improved methods for providing compensatory education which could be multiplied throughout the Title I program as appropriate.

The National Institute of Education will continue and expand research efforts to study why students fail to perform well on tests and lack basic skills. Emphasis will be placed on the use and evaluation of achievement tests to raise the level of student achievement. Working towards this objective, NIE is sponsoring a National Conference on Achievement Testing and Basic Skills. It is expected that this Conference will lead to spirited discussion about the benefits and limits of testing and at the same time give us at HEW a sense of direction of what our role should be in order to meet State and local needs.

I believe that by exploring better methods of education—for example, through summer school programs, more teacher training, improved State and local testing—we can help the States and localities to advance attainment of basic skills.

VETERANS EDUCATION

Mr. CONTE. What are you planning to do for FY 1979 to finance veterans' educational needs? Will you increase funding to veteran's cost assistance programs?

Secretary CALIFANO. We are not proposing to increase the funding level of the Veterans' Cost-of-Instruction program. In fact, we are proposing to decrease the funding level of this program because the number of veterans enrolled in eligible institutions is declining.

However, we are recommending significant increases in the student aid programs. Veterans can receive funds under these programs when they meet the eligibility requirements.

FRAUD AND ABUSE

Mr. CONTE. How is the continued emphasis on fraud and abuse going to work throughout the various programs? Abuse is certainly not restricted to Medicaid and Medicare.

Secretary CALIFANO. No, it certainly is not. In Aid to Families with Dependent Children, we are beginning a major effort in 1978 to improve the administration of the program. This will include the development of performance standards to enable us to review State administrative practices and procedures, particularly those in the area of fraud detection and prevention, and targeted technical assistance to States to enhance their systems capability to detect fraud and abuse. In addition we have already taken steps to lower error rates in the SSI program.

HEADSTART EXPANSION

Mr. CONTE. I note, with some pleasure, that you are proposing an expansion of the Head Start program in light of its demonstrated successes.

Can you specify how the increased funding sought for this program will be spent? I am especially interested in knowing if more will be spent on the excellent Follow Through Program.

Secretary CALIFANO. The $55 million increase will be used to expand regular Head Start projects. We are planning to work with some of the Head Start projects to expand their programs of skills development in order to prepare children for academic subjects when they reach elementary school.

All of the Head Start budget goes for Head Start activities. Follow Through is not included—that program is in the elementary and secondary education appropriation in the Office of Education. In FY 1979 we are proposing a phase-out of separate Federal support of the Follow Through program by not funding

a new entering class. However, as part of our elementary and secondary reorganization legislation we are proposing beginning in FY 1980 to fold in the FY 1979 level for Follow Through into a new compensation education demonstration program under Title IV of the Elementary and Secondary Education Act. Local school districts now receiving Follow Through funds would be held harmless in fiscal years 1980, 1981 and 1982 at 75, 50 and 25 percent, respectively, of their FY 1979 Follow Through grant.

SECTION 504 REGULATIONS

Mr. CONTE. The regulations in Section 504 of the Rehabilitation Act of 1973 appears to provide a "civil rights" approach to the handicapped, regarding right of access to Federal buildings. However, deciding how best to implement this regulation is proving to be perplexing. Can you indicate what approach your Department is recommending in this area? How do you propose that cost of providing access be financed?

Mr. CALIFANO. Section 504 prohibits discrimination against handicapped persons in federally assisted programs. The Department has issued regulations which outline the specific obligations of HEW-funded programs. The approach taken in the regulations is to require that the programs be made accessible to handicapped persons, and this can usually be achieved without undertaking substantial structural changes to existing facilities. We believe the regulations provide most recipients with the flexibility they need to achieve compliance without excessive costs. At the same time, we recognize that in some instances, recipients may have to alter existing facilities and that the expense may be considerable. We are asking for authority to utilize unobligated balances in the Higher Education Facilities Loan Fund under appropriate circumstances and after developing policies and guidelines. We have also requested an appropriation of $50 million to help higher education institutions comply with the program accessibility requirements. Technical assistance material will be provided to all recipients to help them comply with Section 504 at minimal cost. And, we will continue to evaluate the impact of the cost on recipients as we gain more experience in enforcing the regulations.

ZERO BASE BUDGETING

Mr. CONTE. Would the consolidation of existing programs in the new department survive the scrutiny of zero base budgeting?

Secretary CALIFANO. I believe that the concepts of zero base budgeting can be effectively applied to education programs, regardless of whether the programs are administered by the Department of Health, Education, and Welfare, or under a separate Department of Education. Therefore, I believe that if a particular education program was considered a sufficiently high priority under the zero base budgeting process within HEW, it would certainly have as good an opportunity to survive this process under a separate Education Department.

ERRONEOUS REPORTING OF PHYSICIAN REIMBURSEMENT

Mr. O'BRIEN. Last year the Department issued a list showing physician reimbursements under Medicare. It was subsequently determined that there were many errors in this publication causing great embarrassment to many doctors and possibly irrevocable damage to their profession.

There is a Federal regulation, 45 CFR Part 17 which states, "The . . . regulation insures that persons or organizations adversely affected by issuances of the Department are provided adequate opportunity for obtaining correction or retraction if the content of such issuances is shown to be inaccurate."

Does the Secretary feel that the Department has met their obligation to these physicians as required by this regulation?

Secretary CALIFANO. Yes. We contacted every physician who informed us of possible error in the listing and reconciled any discrepancy between his records and ours. In all cases when a physician requested it, information that was found to be in error through this process was corrected and republished.

BIOMEDICAL RESEARCH

Mr. O'BRIEN. In 1978 Congress appropriated $2,776 million for the National Institutes of Health (NIH) biomedical research, an increase of $300 million over

1977 or 12 percent. The Carter budget for 1979 proposes an increase of $78 million over 1978, less than 3 percent. The budget level for NIH will support new starts in "high priority" research, but would not provide the same number of new research grants as in prior years. Given an approximate 8–10 percent rate of inflation in research costs, the total increase of less than 3 percent represents a reduced level of biomedical research funding.

Given Congress' prior disposition for research funding, how does the Department justify this decrease in funding considering inflation?

It appears from the budget recommendations for research that the Administration feels that possibly more money is being spent on research that can be efficiently utilized? Does the Secretary agree with this assumption?

Secretary CALIFANO. In the last several years, NIH has received significant increases in resources. Since 1970, total NIH appropriations have almost tripled, and NIH funding currently constitutes about 41 percent of the Public Health Service budget. We are proud of the accomplishments of NIH, and expect the excellence of the research to continue. However, we believe that funds are already available to pursue high priority research opportunities and that internal shifts from less to more promising opportunities for research can occur at current budget levels. We believe that when consideration is given to competing funding demands which must be addressed within limited resource levels, the request for NIH is reasonable and will support the most promising research proposals in biomedical research.

HEALTH MAINTENANCE ORGANIZATIONS

Mr. O'BRIEN. What initiatives does the Department plan to encourage the establishment of Health Maintenance Organizations (HMOs)?

Secretary CALIFANO. The Administration is committed to the use of HMO's as an effective and cost-saving means of providing high quality health care. We have developed a number of initiatives to encourage the establishment of more HMOs in a shorter period of time and stimulate enrollment in existing HMOs. The initiatives include administrative, legislative, and programmatic activities.

Administrative activities include reorganization of the program into a single office to permit coordination of the grant program and compliance activities. A new program director has recently been named. A reprogramming request has just been approved to allow hiring of 37 new positions in 1978 for crucial qualification and compliance activities.

We have proposed a number of legislative amendments to create a more favorable environment for HMO development and to ensure greater fiscal and quality control. These include provisions to encourage Medicare and Medicaid participation in HMOs, provision for increases in the limits on initial development grants and initial operating loans, provisions to amend the certificate-of-need program to promote fair treatment of HMOs, and provisions regarding financial disclosure of transactions between HMOs and related organizations.

We want to improve technical assistance to both developing and operational HMOs. We are mounting a national promotional program to encourage development of new HMOs, expand enrollment in HMOs, and increase private investment in HMOs.

Mr. O'BRIEN. Do you view HMOs as a possible alternative to mandatory cost containment efforts?

Secretary CALIFANO. No. I see HMOs as showing how cost control might be achieved not as replacing the establishment of national limits.

Mr. O'BRIEN. Will the Department take any action to reduce the complicated application process necessary to establish HMOs as indicated by Kaiser's 600 pound application?

Secretary CALIFANO. The complicated application process, lack of consistent standards, and inadequate staffing have all resulted in enormous paperwork requirements and unreasonable delays.

We have recently begun to restructure the qualification process. We want to reduce the average waiting period from 180 to 90 days. We will lower the time necessary to process the average qualification application by at least 25 percent, by reducing application requirements, developing consistent guidelines, making more productive use of site visits, and increasing staff.

From a high of 51 pending applications last summer, we have already reduced the backlog to 29.

ELIMINATION OF STRUCTURAL BARRIERS

Mr. O'BRIEN. In your Education Highlights (number 8 of your charts) in Other Higher Education, you indicate $50 million to aid higher education institutions to eliminate structural barriers to the handicapped. Can these funds also be used by higher education institutions for renovation for the purpose of energy conservation measures?

Secretary CALIFANO. The $50 million proposed for FY 1979 can only be used to eliminate structural barriers so that handicapped students can gain access to postsecondary programs.

However, in a FY 1978 supplemental request, we are proposing to release $30 million in loans from unobligated balances in the Higher Education Facilities Loan and Insurance Fund. These funds would be used to renovate and reconstruct existing academic facilities to make them more energy-efficient, to help them comply with Federal, State and local health and safety standards, and to help them meet the requirements of Section 504 regulations.

Mr. O'BRIEN. With the recent publication by the Department of Health, Education, and Welfare of regulations for carrying out the mandates of Section 504 of the Rehabilitation Act of 1973, State and local agencies and institutions receiving HEW funds are under a Federal civil rights obligation to make programs and facilities accessible to the handicapped. Failure to comply is ultimately subject to a suspension or termination of Federal funds. The total nationwide cost of meeting the requirements set forth in the Section 504 Regulations is as yet uncertain. Estimates which we have received from only 12 states and territories range from $646.3 million to $766.3 million. Has the Department made any assessment of the impact of the requirements of this Act in removing architectural barriers?

Mr. CALIFANO. In May of 1977 an impact statement was prepared by a contractor who estimated that the total cost of implementation would amount to $2.4 billion. The cost of achieving program accessibility was estimated to be between $299 million and $544 million. However, I should emphasize that these are estimates only, and that we intend to assess the cost impact more carefully.

Mr. O'BRIEN. Wouldn't the mere fact that money was available for loans and grants provide an incentive for states to make detailed assessments of the cost of the Act?

Mr. CALIFANO. Legislation providing funds for this purpose has been introduced. However, the approach is costly and it may not be the most efficient way to obtain accurate information. Also, there are practical problems in that the regulations require program accessibility by 1980, and it would take time to get such a program under way.

Mr. O'BRIEN. Does the Secretary feel that the Federal government has any responsibility in providing financial assistance to meet the requirements of the Act?

Mr. CALIFANO. Certainly, we do have a responsibility to help recipients comply. In the near future we intend to provide technical assistance materials. We plan to evaluate the compliance problems and learn more about the financial impact. In the fiscal year 1979 budget request, the Department included an appropriation of $50 million in matching grants, and we have also asked for authority to expend unobligated funds in the Higher Education Facilities Loan Fund.

Mr. O'BRIEN. Is it realistic to believe that the mandate requiring accessibility by June 1980 can be achieved without substantial Federal assistance?

Mr. CALIFANO. We believe that the regulations provide flexibility to allow most recipients to comply without incurring excessive cost. The regulations permit a three-year transition phase when structural changes are deemed to be necessary, and this should encourage recipients to identify those acceptable measures that involve the lowest cost. Consultation with groups representing handicapped persons, as required by the regulations, should also help the planning process. We also believe our technical assistance program will prove helpful. In short, we feel the 1980 deadline is realistic and at the same time consistent with the nondiscrimination mandate of the statute.

DEPARTMENT OF EDUCATION

Mr. O'BRIEN. The President proclaimed his support for a separate Department of Education in his State of the Union. Over the past year arguments supporting a new Department have ranged from "Education has been lost in the burgeoning D.H.E.W." to "Education should not be tied to the abortion issue." Neither of these arguments hold much water considering ho well educatio

has fared in the new budget and that it is unlikely Education would be separated from the abortion controversy anymore than Labor is.

Isn't this purely a political decision? What are the reasons supporting a new department? What is the Secretary's position?

Have there been any cost estimates on what a new department will cost the taxpayers?

Mr. CALIFANO. I do not think that it is purely a political decision. The President believes that establishing a separate Department would give education greater prominence among competing Federal programs and also facilitate better coordination of education programs not now in the Department of HEW. It is likely that some of these non-HEW education programs will be proposed for inclusion in the new Department of Education.

It is no secret that I have argued against the establishment of a Department of Education. However, now that the President has made his decision, I will support the new Department and do my best to implement the decision as effectively as possible.

There should be no significant costs associated with the new Department beyond the one-time costs of relocating staff and making administrative adjustments.

CONSTRUCTION FUNDS REQUESTED

Mr. O'BRIEN. Why were funds requested only for higher education and not any other areas?

Secretary CALIFANO. First of all, we believe that the renovation costs of elementary and secondary schools are low compared with the costs for institutions of higher education.

Secondly, most of the concerns expressed by school officials have come from postsecondary schools rather than from the elementary and secondary schools. Unlike higher education institutions, only a small fraction of all handicapped children have impairments that hamper their gaining access to the average elementary and secondary school building. Most severely handicapped children usually attend special schools that have been designed to meet their needs. Most school systems should be able (by providing the required transportation) to assign all of their physically handicapped children to a few of their buildings. For example, even a moderate size school system with 10–15 separate buildings with no new or already accessible buildings, should have to modify only one or two of its buildings.

Because most school systems will be able to deal with eliminating structural barriers to the handicapped at minimum cost, we have placed the highest priority on services for the handicapped in elementary and secondary schools rather than structural modifications.

Mr. FLOOD. We will insert at this point in the record a series of investigative and special reports prepared for the Subcommittee for use during its consideration of the 1979 budget request for the Department of Health Education and Welfare. The first three reports were prepared at the request of the Subcommittee by the Surveys and Investigations Staff of the full Appropriations Committee. The second group of reports were prepared by HEW as required by the Subcommittee in their report on the 1978 Labor-HEW Appropriations bill (H. Rept. 95–381). The other materials are supplied annually by the Department.

SPECIAL AND INVESTIGATIVE REPORTS

NOT FOR RELEASE UNTIL AUTHORIZED BY THE COMMITTEE

A REPORT TO

THE COMMITTEE ON APPROPRIATIONS

U.S. HOUSE OF REPRESENTATIVES

on

EMERGENCY MEDICAL SERVICES SYSTEMS

in the

UNITED STATES

Surveys and Investigations Staff

February 1978

NOT FOR RELEASE UNTIL AUTHORIZED BY THE COMMITTEE

February 13, 1978

MEMORANDUM FOR THE CHAIRMAN

RE: A Study of the Emergency Medical Services Systems in the United States

By directive dated July 11, 1977, the Committee requested that a study be made of the emergency medical services systems and programs of the Department of Transportation and the Department of Health, Education and Welfare.

The investigation has been completed and the results are included in this report.

Respectfully submitted,

David A. Schmidt, Director
Surveys and Investigations Staff
House Appropriations Committee

C. R. Anderson
Chief of the Surveys and
Investigations Staff
House Appropriations Committee

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SUMMARY AND RECOMMENDATIONS

A. Summary

The Investigative Staff has reviewed the Emergency Medical Services (EMS) Systems programs of both the Department of Health, Education, and Welfare (HEW) and the Department of Transportation (DOT) and evaluated the relationship of these agencies with respect to EMS systems development in the United States. The EMS program was also reviewed at the State level, particularly with regard to the roles of the State EMS coordinator and the Governor's Representative.

The investment by HEW and DOT in the Federal program to develop 300 EMS regions in the United States by 1985 could exceed $800 million. HEW's emergency medical services system development program has received nationwide support from State, local, and private organizations. It has resulted in improved emergency medical care in many sections of the country. Despite these successes, there are problems with the EMS systems development as there is a need for improved control over and evaluation of this program by HEW, and better coordination and cooperation at both the Federal and State levels.

The Division of Emergency Medical Services (DEMS), within the Health Services Administration (HSA), was created to administer the EMS systems development program of HEW.

1. Long-Range Plans Call for Full Development of the 300 EMS Regional Systems at a Total HEW Grant Cost of $475 Million

As envisioned by DEMS officials, the program for full development of the 300 EMS regional systems (HEW grant cost of about $475 million) will require another 3-year extension of the EMS Systems Act with Section 1203 and 1204 funding provided through FY 1985. To date the HEW EMS systems program has not been evaluated and the Investigative Staff believes that there are questions which need to be studied before the program is extended. Some areas which require study include:

-- The nationwide effect on systems development that an anticipated reduction in DOT Section 402 funding will have.

-- Whether EMS regional systems capable of providing advanced life support can be developed wall-to-wall throughout the United States. Evidence indicates that many regions will be unable to develop or support such a system.

-- Whether the EMS systems which have already received the maximum 5 years of HEW systems grants will continue to operate as systems. If the regions reviewed by the Investigative Staff are typical, many will not.

2. Administrative Problems Impair Effectiveness of HEW's EMS Program

DEMS administers the EMS systems development program of HEW.

a. Inadequate Guidance Provided for Systems Development

HEW lacks a formal structured system (current written procedures and instructions, manuals, etc.) for providing program guidelines to States, regions, and local bodies. In the absence of a formal HEW system, the development of an EMS systems program has, to a large extent relied on the Director of DEMS to personally provide information on program direction at all levels. Typically, because of noted internal shortcomings and limited staffing, planning is on a short-term ad hoc basis (less than 6 months), not in writing, and usually not coordinated with the central office staff and HEW regional personnel. The Director of DEMS is also called on to provide technical assistance, conduct national symposia, regional workshops, and travel extensively to personally provide information on EMS priorities and program changes.

State EMS officials do not always have ready access to the Director of DEMS. Much of the program information is received thirdhand via the grapevine--by word of mouth from other participants in the programs. Complaints were made that the HEW regional offices were often not aware of program changes made by the Director of DEMS, and so the regional offices were unable to provide proper and timely guidance to program participants. In particular, the officials criticized HEW's failure to publish revised regulations and guidelines reflecting the changes made by amendments to the EMS Systems Act in 1976.

As a result of these deficiencies, there has been a fragmented, uncoordinated departmental approach to implementing a viable, standardized EMS program. A further fallout of the department's informal approach to the program has been the creation of dissatisfaction and confusion among the program participants at the operational levels.

b. DEMS Central Office Was Not Provided Sufficient Staffing to Properly Administer the EMS Program

If the EMS grant program is to continue beyond FY 1979, there is a need for a permanent and adequately staffed

DEMS central office. Although DEMS was delegated responsibility for administering the EMS program for HEW, no permanent positions have been budgeted for this purpose. Since FY 1975, requests for permanent staffing and additional personnel have been rejected by either the Secretary of HEW or OMB. Legislative changes in 1976 provided additional administrative central office responsibilities with no increase in personnel. This shortage of personnel has impaired the management of the EMS program. As previously mentioned, the Director of DEMS traveled a total of 106 days during FY 1977 providing onsite technical assistance. His extended absence from the central office, together with the personnel shortage, added to the backlog of unfinished business. Thus, the central office was operating shorthanded with an increased workload, and mounting unfinished administrative responsibilities. The following areas suffered from lack of attention:

-- Reports required by Congress were not prepared, or were submitted late.

-- A suitable data bank for purposes of making evaluations of EMS was never started.

-- Support of the Interagency Committee on Emergency Medical Services was inadequate.

-- The EMS program monitoring effort was limited primarily to review of written quarterly and annual reports.

-- The clearinghouse functions were reduced to an information response activity.

3. HEW Research Unresponsive to Needs of Developing Systems

The National Center for Health Service Research (NCHSR), Health Resources Administration (HRA), is responsible for developing and administering EMS research projects under Section 1205 of the EMS Systems Act of 1973.

a. Most EMS research projects awarded were long-term, multiyear studies, the results of which are not timely in meeting the current needs of the developing systems. Timeliness of information is critical because the capital investment for EMS systems development is being made now. NCHSR officials have exhibited the "purest" point of view and have not generally funded short-term projects addressing immediate high priority problems because technically they consider these projects to be analyses as opposed to research.

b. NCHSR has denied grant proposals because of design weaknesses without considering the merit of the research proposed

for study or the possibility of offering design assistance. As a result, proposals submitted by persons involved with EMS systems development are denied and grants are awarded to academically oriented medical centers, which write well-designed research proposals concerned with problems peripheral to those of the developing systems.

c. The Interagency Committee on EMS was not monitoring the Federal EMS research effort nor making suggestions to HEW concerning the type of EMS research that was needed.

4. HEW Training Programs Have Created Confusion

Within HEW, both DEMS and HRA conduct programs which provide funds for training emergency medical technicians (EMT's). These programs were not well coordinated and have created confusion and dissatisfaction at the State and local levels. State EMS officials criticized the HRA program for not complementing EMS systems development, for its lack of coordination with State EMS personnel, and for the manner in which the program was administered. The Investigative Staff believes that both DEMS and the State EMS coordinators should have more control over short-term EMT training programs.

5. DOT Reluctant to Accept HEW Leadership Role in EMS

DOT and HEW conduct EMS programs under separate laws, DOT under the Highway Safety Act of 1966, and HEW under the Emergency Medical Services Systems Act of 1973, as amended.

The DOT program emphasizes the prehospital functions of EMS, particularly as they relate to highway accident victims. The HEW program includes the prehospital EMS functions and focuses on the development of comprehensive regional systems capable of providing the wide range of emergency medical care. The two programs have overlapping features and there is a need for better coordination.

Since 1974, HEW and DOT have been trying to develop a Memorandum of Understanding clarifying their respective roles in EMS development. HEW, as the lead agency for EMS, wants DOT's programs to be coordinated with and approved by HEW. DOT is reluctant to relinquish the leadership role derived from its earlier association with emergency medical care, established in the late 1960's and early 1970's, and actively resents having to coordinate any of its programs with HEW. Constant bickering between the two agencies has had an adverse affect on the national EMS program.

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6. DOT Has Little Control Over State's Use of DOT Highway Safety Funds

The Highway Safety Act provided, under Section 402, Federal formula grants to help States develop and operate a highway safety program. DOT established 18 uniform highway safety standard programs around which State highway safety programs were to be developed. Standard 11, titled "Emergency Medical Services," outlines DOT requirements for a State EMS program.

The decision on how Section 402 funds should be allocated and spent within the 18 uniform standard program areas is left to the State. Neither the DOT central office nor DOT regional offices have much influence over the State's decision. For this reason, there is little if any coordination between HEW and DOT concerning Section 402 funding.

7. State EMS Officials Oppose the Proposed Deletion of EMS as a Required Part of the Highway Safety Program

In July 1977, the Secretary of Transportation issued a report to Congress entitled "An Evaluation of the Highway Safety Program." The report recommended that the present 18 uniform highway safety standard programs be replaced with a reduced number of uniform requirements. Standard 11, Emergency Medical Services, along with 11 other standards would no longer be a mandatory requirement of a State's highway safety program. State EMS officials were adamant in their opposition to this change. They believed, as did many DOT officials, that it would result in a significant decrease in Section 402 funds allocated for EMS. Section 402 funding for EMS in 1977 totaled approximately $17 million, as compared to HEW EMS systems grants which totaled about $33 million. Section 402 funding plays an important role in many State's EMS programs.

8. The Department of Labor (DOL) Failed to Coordinate its EMS Training Activities

DOL, at the time of this report, could provide only fragmented and inconclusive information concerning the extent of its support for EMS training. DOL support is provided primarily under the Comprehensive Employment and Training Act (CETA). Preliminary responses from only four regional offices showed that over $10 million was spent on this program during the period FY 1974 through FY 1977. The overall magnitude of this program appears substantial. Our review of one DOL program, the EMT apprenticeship program, disclosed that it had not been properly coordinated with other Federal and State EMS programs. The need for a DOL EMT apprenticeship program was questioned by State EMS officials who believed that it duplicated existing State and Federal programs. It is possible that other DOL training programs suffer from the same deficiencies.

9. Interagency Committee on Emergency Medical Services (IAC-EMS) Failed to Coordinate Federal EMS Programs

The IAC-EMS was established under Section 1209 of the EMS Systems Act. Its purpose is to coordinate and provide for communications and exchange of information among all Federal programs and activities relating to EMS. This Committee has not been effective in coordinating the Federal EMS program in a number of areas:

a. The IAC-EMS has not satisfied Congressional reporting requirements. These include an evaluation and report on adequacy, technical soundness, and redundancy of all Federal programs and activities relating to EMS; development of a comprehensive Federal EMS funding and resource-sharing plan; and a report describing the sources of Federal support available for the purchase of vehicles and communication support equipment.

b. State EMS coordinators criticized the IAC-EMS for not addressing or seeking answers to critical problems faced by EMS providers at the State level. The officials said there is a need for State representation on the IAC-EMS.

c. The IAC-EMS review of Federal EMS activities has, at best, been superficial. There is a reluctance on the part of Federal agencies to coordinate their EMS programs with the IAC-EMS. Agencies (especially DOT and HEW) jealously guard what they consider to be their own "turf."

d. The IAC-EMS has operated without adequate staffing and, therefore, meetings have not been properly planned and coordinated. Although required to meet four times a year, the IAC-EMS met only twice during CY 1977.

10. EMS is a State and Local Responsibility

The success of the Federal EMS program is dependent upon how well the programs are executed at the State and local levels. DOT and HEW programs were not always well managed or coordinated at this level and Federal program requirements were not always met.

a. Continuation of Regional EMS Systems is Dependent Upon State Support

Should Federal funding end, State support will be necessary to keep EMS systems intact. EMS regions are not political entities with direct taxing authority and must rely on the local governments participating in the system for financial and other support.

The degree of support that the EMS regions might receive is unknown. In view of the competing demands for limited tax dollars, it appears doubtful, however, that adequate financial help will be forthcoming in many areas. As a consequence, the future of many in-place EMS systems will be in jeopardy, unless the States decide to actively support the program.

b. State Health Department is the Lead Agency for EMS

Within the State health department, the State EMS coordinator is responsible for developing a statewide EMS program. The State EMS coordinator assesses EMS needs statewide; works extensively with regions developing EMS systems; and, in most States, determines how DOT funds made available for EMS by the Governor's Representative will be spent.

c. Governor's Representative Controls the Use of DOT Highway Safety Funds

The day-to-day operation of the highway safety program in each State is handled by a Governor's Representative. He determines how funds provided by DOT under Section 402 of the Highway Safety Act of 1966 will be spent. Standard 11, Emergency Medical Services is just one of 18 uniform highway safety standards competing for his attention.

d. Uncoordinated EMS Programs Exist in Some States

In 9 of the 28 States in which EMS programs were reviewed by the Investigative Staff, two separate EMS programs were run at the State level, both funded through Federal grant programs. In these States, the Governor's Representative does not rely on the State EMS coordinator's assessment of EMS needs but instead makes an independent evaluation. This allows local governments which do not wish to be part of the regional EMS system to circumvent State and HEW program requirements and still obtain Federal funding. In addition, the independent assessment of EMS needs is duplicative and creates confusion at the State level.

e. Requirement for State EMS Plans by DOT and HEW Cause Confusion

Both DOT and HEW require a State EMS plan. The DOT plan is primarily an inventory of prehospital resources. The HEW plan details the establishment, operation, and expansion of regional EMS systems. DOT and HEW officials have not enforced or clarified their requirements for a State EMS plan. Development of a State plan requires extensive coordination and a considerable resource commitment. For these reasons, most State plans were

either not completed or are outdated. Many States consider their current DEMS grant application to be the updated State EMS plan, satisfying both DOT and HEW requirements.

f. Complexity of HEW Systems Grants Limits Use in Some Regions--DOT Funding More Flexible

Rural and "have not" regions are at a distinct disadvantage when applying for funding under Sections 1202, 1203, and 1204 of the EMS Systems Act of 1973. These regions lack the necessary resources to develop an EMS grant application, and the hospitals, facilities, and medical personnel required for systems development. In addition, they lack a sufficient financial base to guarantee continuance of the program when Federal funding ends. As an alternative, DOT Section 402 funds have been used to purchase ambulances and EMS equipment in these regions. Section 402 funding requires only identification of the problem and the Governor's Representative's approval.

g. Standard Recordkeeping Requirements Not Supported by State and Local EMS Officials

DEMS grant guidelines required that EMS systems establish standardized medical recordkeeping systems which cover patient treatment from initial entry into the system through discharge. Standard recordkeeping is necessary to provide data for program evaluation and management purposes. However, there is considerable resistance at the local level to standardized recordkeeping. Hospital administrators are reluctant to handle the extra paperwork or to provide information because of patient confidentiality and the possiblity of malpractice suits. In addition, the costs of gathering and compiling information are considered prohibitively high by State and local officials. As a result, adequate data bases do not exist for evaluation purposes.

B. Recommendations

1. The Investigative Staff recommends that HEW be required to:

a. Develop an agencywide staffing plan for all EMS functions (central office and regional offices) and prepare justifications for the permanent personnel positions needed to ensure effective management, implementation, and evaluation of the EMS program in the United States.

b. Develop a formal structured system for providing program direction, technical assistance, and guidance to regional, State, and local EMS offices. The system should include provisions requiring the DEMS central office to provide, as necessary,

specific written guidance to HEW regional offices so that the regions can act uniformly and successfully monitor, manage, and provide guidance in the field.

c. Develop and issue revised EMS regulations, procedures, and program guidelines based on legislative changes of October 1976. State EMS coordinators and regional systems need this information (now past due) to adequately develop grant applications and administer their programs in accordance with the legislative changes.

d. Evaluate the impact that the continuation of DEMS grant support will have on EMS nationwide. HEW should determine whether the development of regional EMS systems consisting of the 15 required components is practical or possible in all regions; and, if so, can this be accomplished at the presently estimated cost of $475 million. In addition, HEW should determine whether EMS systems will continue to operate as systems when they are no longer Federally funded; and, if not, how effective were the Federal dollars spent on systems development. HEW should be required to submit a detailed plan with firm target dates indicating when and how it will make such evaluations.

e. Provide direction, adequate staffing, and support for the administration of the Interagency Committee on Emergency Medical Services (IAC-EMS), so that it can carry out its legislative responsibilities in coordinating EMS at the Federal level.

f. Assign sole responsibility to DEMS for support of emergency medical technician (EMT) training. This will centralize EMT training with the State EMS coordinators who are in the best position to assume this role because they are the most knowledgeable of their State's need for such training.

g. Reevaluate the HEW EMS research program to assure that it addresses and is responsive to problems faced in the development of regional EMS systems.

h. Reevaluate the extensive use by HEW of symposia and workshops to promote EMS systems development in view of the high cost associated with such activities (approximately $2.3 million in 1977).

2. The principal EMS providers, HEW and DOT, should increase their efforts at program coordination. Specifically they should be required to:

a. Jointly determine what constitutes a satisfactory State EMS plan and issue joint guidelines for developing the plan.

b. Emphasize to their respective regional offices and to State officials that the EMS program is a joint coordinated effort. DOT should also encourage Governor's Representatives to accept the State EMS coordinator's assessment of the State's EMS needs and priorities.

3. DOL should be required to improve the overall coordination of its EMS training programs with the IAC-EMS and State health departments.

4. All Federal agencies should formally be required to coordinate through the IAC-EMS before implementing new EMS activities.

5. The House Appropriations Committee may desire to reemphasize the importance of previously established reporting requirements and ask that both HEW and the IAC-EMS submit required reports in a timely manner.

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I. INTRODUCTION

A. Directive

By directive dated July 11, 1977, the Committee requested that a study be made of the Emergency Medical Services Systems and programs of the Department of Transportation (DOT) and the Department of Health, Education, and Welfare (HEW). The investigation was to include but not to be limited to the following areas:

-- The extent of DOT and HEW effectiveness in utilizing and coordinating the existing legislative authorities to develop emergency medical services (EMS) systems.

-- The relationship at the Federal level of DOT and HEW with regard to disaster coordination, communications, training and education, and procurement and placement of equipment such as ambulances.

-- The relationship at the State level of the principal departments responsible for managing EMS programs within the State.

-- The extent to which Federal agencies impose conflicting requirements on States, resulting in competing statewide EMS plans.

-- Evaluations made by Federal agencies with respect to the EMS programs, and how such data is being used in planning and implementation.

B. Scope of Inquiry

This report is based on information obtained by interview; attendance at workshops, review and analysis of budget justifications, Congressional hearings and reports, organizational charts and functional statements and studies, correspondence, reports, and other statistics concerning emergency medical services systems grants and staffing; and a review of applicable laws, regulations, guidelines, and instructions.

The Investigative Staff interviewed DOT and HEW central office officials responsible for EMS, and also representatives of the Department of Labor concerning their EMS training program. The planning and development of the regional EMS systems in the United States were discussed with appropriate representatives of DOT and HEW in six regional offices (Atlanta, Chicago, Kansas City, Philadelphia, San Francisco, and Seattle), and the DOT representative in Baltimore.

Additionally, the Investigative Staff attended EMS workshops at Chicago and Phoenix, and the EMS training workshop at Kansas City. Interviewed at these workshops were State EMS coordinators and EMS regional administrators, and representatives of medical associations and foundations. State EMS coordinators were also interviewed at Montgomery, Alabama; Sacramento, California; Atlanta, Georgia; Tallahassee, Florida; Baltimore, Maryland; Portland, Oregon; and Olympia, Washington. Administrators of regional EMS systems were interviewed at San Jose, California; Jacksonville, Florida; and Washington, D.C.

II. BACKGROUND

A. Overview

Emergency medical services, neglected for many years, seem to be catching on in the United States. In 1966, the National Academy of Science-National Research Council published a report which noted various deficiencies in emergency care such as misguided attempts at first aid, absence of physicians at the scene of emergencies, unsuitable ambulances, and lack of voice communication facilities. The report noted there was a lack of adequately trained emergency medical personnel, adequate local government support of emergency medical services, and information on the effects of deficiencies. This document reflected professional concern for the lack of a comprehensive approach to treating the accident victim and called for many of the components that now exist in the Emergency Medical Services Act of 1973.

The number of preventable deaths and disabilities identified as resulting from inadequate or antiquated medical emergency care are grim evidence of the compelling urgency for action to deal with this problem. The need for improved emergency medical services was supported at the time of the passage of the act by statistics, summarized as follows:

-- Estimates are that 15 to 20 percent of the deaths due to traumatic injury could be saved each year by improved emergency medical services. This would result in 60,000 lives saved, based on estimates of the National Academy of Sciences. Accidental injury is the leading cause of death among all persons aged 1 to 38 and is the fourth highest cause of all deaths in the United States. In 1972, traumatic injury resulted in 117,000 deaths and 11.5 million cases of disabling injury.

-- Heart attacks claim twice as many victims as the next nearest killer, cancer. In 1972, over 675,000 deaths were due to ischemic heart disease and myocardial insufficiencies. About one-half the heart attack deaths occurred within 2 hours of the attack and before the patient arrived at the hospital. The American Heart Association estimated that between 15 and 20 percent of prehospital coronary deaths could have been prevented if proper care were administered at the scene en route to an appropriate medical facility.

-- According to the National Center for Health Statistics, there were approximately 68,000 deaths involving newly born infants in 1971. Many of these deaths could have been prevented with an appropriate interhospital referral system to identify the newly born infant with a threatened chance of survival and to transport the infant to intensive care facilities.

-- Poisonings occur 5 million times annually (90 percent are children) and 50,000 die.

-- Burns injure 2 million each year; 70,000 require hospitalization and 10,000 die.

Until recently, the nation's hospitals, medical personnel, and public safety services had not been organized in ways to provide effective emergency medical services. Realization of this fact led the National Academy of Sciences to appoint a study panel which in 1972 published a report on the roles and resources of Federal agencies in support of comprehensive EMS. This report stated:

> "Accidental injury and acute illness generate a staggering demand on ambulances and rescue services, allied health personnel, physicians, and hospitals for the delivery of emergency medical services * * * (such) service is one of the weakest links in the delivery of health care in the nation. Thousands of lives are lost through lack of systematic application of established principles of emergency care."

In the 5 years since publication of the Academy report urging a coordinated national effort, major changes have taken place. Now in many communities, systems are being put in place to coordinate an entire region's approach to EMS. During these 5 years, EMS has been transformed from an idea with limited, erratic, and uncoordinated support to a major national initiative with more than 100 EMS regions functioning and a goal of 300 regions operating by 1985. Further, improved service in emergency medical care will result in additional savings of lives, and could substantially reduce the occurrence and severity of disability.

B. Federal Legislation

1. Department of Transportation

The Highway Safety Act of 1966 (PL 89-564) was enacted on September 9, 1966 and was the first real Federal initiative addressing the nationwide inadequacy of emergency medical care. The act called for a coordinated national highway safety program and provided financial assistance to the States to accelerate highway safety. Funds are made available to the States under the matching grant provisions of Section 402 of the act and are administered by the Governor, through his representative for highway safety. There is no direct Federal funding for political subdivisions. Project application by a political subdivision must be made to the State for inclusion in the State annual work program.

The Highway Safety Act of 1966, as amended, required that States have a highway safety program developed in accordance with uniform standards promulgated by the Secretary of Transportation. The 18 uniform highway safety standard programs including Standard 11 captioned "Emergency Medical Services" were created by joint efforts between the States and DOT. The purpose of Standard 11 is to improve life-saving capability of emergency medical services through personnel training, proper equipment, communications, operational coordination, and comprehensive planning at both the State and local levels. Standard 11 was intended to establish procedures and criteria for upgrading prehospital emergency medical care.

Section 403 of the Highway Safety Act authorized the Secretary of Transportation to carry out safety research either independently or in cooperation with other departments or agencies. The Section 403 program includes research and development relating to communications, emergency medical care and transportation of the injured.

2. Department of Health, Education, and Welfare

In November 1973, the Congress acted to further improve emergency medical care by adding the Emergency Medical Services (EMS) Systems Act of 1973 (PL 93-154) to the Public Health Service Act. The act was intended to assist and encourage the development of comprehensive, regionalized emergency medical services systems throughout the country and thereby improve the quality of patient care and reduce morbidity and mortality. The act provides also that all Federal EMS-related programs are to be coordinated through the Interagency Committee on Emergency Medical Services (IAC-EMS).

EMS systems, developed under the act, are to have adequate personnel, facilities, and equipment for the effective and coordinated delivery of emergency health care services. These regional systems are to be administered by a public or nonprofit entity with the authority to provide effective administration of the system. HEW, working with the States, has now defined the boundaries of 300 contiguous regions which will eventually make up a national emergency medical service network. A major benefit of the regionalized approach as envisioned by Congress is that it provides rural communities with greater access to the medical centers and facilities of large cities.

To receive grants under the act, regional systems must provide care to all emergency patients within a region. Fifteen components, mandated by law, must be in place and working to qualify for grants as follows:

(1) Provisions of manpower,
(2) Training of personnel,
(3) Communications,
(4) Transportation,
(5) Facilities,
(6) Critical care units,
(7) Use of public safety agencies,
(8) Consumer participation,
(9) Accessibility to care,
(10) Transfer of patients,
(11) Standard medical recordkeeping,
(12) Consumer education,
(13) Review and evaluation,
(14) Disaster linkages, and
(15) Mutual aid agreements.

In conjunction with the EMS program, HEW is encouraging the design of clinical systems for the major categories of EMS care, which are trauma, burns, poisonings, spinal cord injury, high-risk infants, and certain behavioral problems.

The Emergency Medical Services Amendments of 1976 (PL 94-573) enacted October 21, 1976, revised and extended the provisions of Title XII of the Public Health Service Act. The amendments extended the use of the appropriations through FY 1979 for development of EMS systems, for research activities, and for training purposes. As amended, the act established a burn injury program for the treatment and rehabilitation of burn victims. It also substantially increased the responsibilities of HEW's administrative unit for EMS and those of the Interagency Committee for Emergency Medical Services.

III. FEDERAL AGENCIES SUPPORTING EMS DEVELOPMENT

In 1975, the Interagency Committee for Emergency Medical Services identified 64 Federal programs that provided some type of assistance for EMS development. Forty-two of these programs appeared to support the development of one or more components of an EMS system through grants, contracts, loans, or other forms of assistance. DOT and HEW were identified as major financial supporters of EMS.

The Investigative Staff is of the opinion that the EMS systems development has been adversely affected at the Federal level by the inability of DOT and HEW to coordinate their respective EMS programs. Likewise, HEW's delegation of management responsibilities for EMS systems development, research, and training within HEW to three separate internal organizations has had a detrimental affect on the administration of the EMS program. The roles of the principal Federal agencies are discussed below.

A. HEW Program Management

The Secretary of HEW administers the EMS systems program through the Office of the Assistant Secretary for Health, Public Health Services, the Health Services Administration (HSA) and the Health Resources Administration (HRA). The Division of Emergency Medical Services (DEMS) established within the Bureau of Medical Services, HSA, is responsible for administering HEW's EMS systems development program. The Health Resources Administration is responsible for implementation of the research and training programs.

1. Grants Management Procedures

The basic purpose of the EMS program is to provide assistance and initial development money for the establishment of regional EMS systems. The program is authorized through FY 1979 and provides a maximum of 5 years of grant support. The program is intended to develop regional systems capable of providing emergency medical care in any eventuality. The EMS program is viewed as a national health priority. It is designed to serve all of the population, not just the indigent, disadvantaged, or a specific segment of society.

The EMS program is the first regionalized medical care services program that considers the entire sequence of a major national health problem from the incident to and through definitive care and rehabilitiation. It is also a program that involves the widest spectrum of public, private, local, primary, and regional medical care providers and educators. The EMS grant program conducted by HEW is intended to act as a catalyst for bringing total Federal resources to bear on the problem of

emergency medical care. HEW grants provide only a fraction of the funds needed for EMS systems development. The program is intended to direct the implementation of a systematized approach.

A major impediment to systems development is the diversity of governmental units which must be involved. Without the encouragement provided by Federal technical assistance and funding, many communities would be unable to conduct joint discussions with surrounding communities, inventory their health resources, and develop a common program to provide emergency medical services on a regional basis.

DEMS is the lead agency of HEW for administration and systems development. In order for a grant application to be seriously considered by DEMS, it must address each of the 15 Congressionally mandated systems components. Even so, DEMS takes into account regional and sectional differences as well as rural, wilderness, and metropolitan considerations, and allows for some flexibility in the award of EMS system grants.

The DEMS program offers a series of grants to plan, establish, and improve regional emergency medical care systems. An EMS system is defined as an arrangement of personnel, facilities, and equipment for the effective and coordinated delivery of health care services in an appropriate geographical area under emergency conditions. The DEMS awards 1-year grants for feasibility studies and planning of an EMS system; 2-year grants for the establishment and initial operations of an emergency medical services system, providing for basic life support (BLS); and 2-year grants for projects to expand or improve the EMS system to the advanced life support (ALS) level. DEMS administers the grant program under three separate sections of the act as follows:

Section 1202--Feasibility studies and planning
Section 1203--Establishment and initial operations
Section 1204--Expansion and improvement

DEMS has defined Section 1203 in terms of basic life support (BLS) services and Section 1204 in terms of advanced life support (ALS) services. ALS is an advanced phase of emergency medical care and the logical outgrowth or progression of BLS. The essential aspects of basic life support and advanced life support are outlined as follows:

Basic life support services is the minimal acceptable level of care services available in an areawide EMS system. Services include universal access and central dispatch of approved national standard ambulances, with appropriate medical and communication equipment, operated by a complete complement of emergency medical technicians (EMT's); availability of a category II hospital facility staffed by physicians and nurses with emergency

medical knowledge and skills; and full areawide implementation of the 15 mandatory components.

Advanced life support is a more sophisticated progression of BLS in which extensively trained EMT-Paramedics provide both resuscitation and specific interventive measures. ALS includes transportation vehicles with full equipment and telemetry, staffed by advanced EMT-Paramedics providing onsite, prehospital, and interhospital mobile intensive care; specialized physicians and nursing staffs operating critical care units and emergency departments; and full regional implementation of the 15 mandatory components. The specific adaptation of ALS services will of necessity be different in varying geographic areas of the country.

The basic life support system is designed to impact primarily on urgent patients. For these patients, it can provide a full spectrum of immediate care. However, it will have minimal impact on the critical patient. On the other hand, the advanced life support system is designed to impact fully on all patients and especially the critical patient; i.e., trauma, burn, spinal cord injury, acute cardiac, high-risk infant, poisoning, and behavior problems. It is among these patients where the majority of lives can be saved, disability reduced or prevented, and period of convalescence decreased.

Important legislative changes affecting grant awards were made by Congress in the EMS Systems Act Amendments of 1976. Section 1202 was amended to provide authority to make a second grant to (a) study the feasibility of/or plan for expansions and improvement of an EMS system to provide for the use of ALS techniques, or (b) update a State's EMS plan to improve delivery of EMS in rural and medically underserved areas. Also under Sections 1202, 1203, and 1204, grant applicants are required to provide specific new assurances to receive grant funding. These include evidence of certain public, private, and volunteer organization participation and continuing financial support of the EMS system during and after Federal funding; and commitments from executive or legislative government bodies of political subdivisions located in the system's service areas who govern substantial portions of the population in the area.

From FY 1974 through FY 1977, 264 of the 300 State-designated EMS regional systems received grant assistance totaling $111 million under the EMS Systems Act. Detailed funding of the HEW EMS program is shown in the schedule on page 43 of this report. Under the long-range grant plan proposed by DEMS, Federal support for all 300 EMS regions would require about $475 million. DEMS plans to have all 300 regions completed and operational by 1985. At present, 12 systems have fully completed their eligibility and 150 systems are in some phase of operational development.

Once a nationwide network of 300 viable regional EMS systems has been established (by 1985), HEW officials claim there should be no further need for DEMS grant assistance. The DEMS role will gradually be phased down to one of providing technical assistance and coordination at the Federal level. Health systems agencies will be responsible for reviewing and integrating EMS systems into the total health care delivery system. It is anticipated that national health insurance and other third parties (insurers) will be in a position to reimburse operators for many emergency services, thereby covering a large portion of the operating costs during and following the Federal grant support. When Federal support ceases, the entire program is to be handled by local governments.

Program Successes

The Investigative Staff learned that Dr. David Boyd, Director, Division of Emergency Medical Services, has been credited by many for much of HEW's success in promoting regional EMS systems development throughout the United States. Some described Dr. Boyd as an EMS missionary who preached systems to anyone who would listen. The need for a strong EMS program is recognized nationally by many professional, political, and governmental institutions. The public has become increasingly aware of EMS through public education, local and national television, and other media.

HEW provides hard cash, leadership, and other assistance for communities to develop regional EMS systems. With Federal aid, numerous communities have upgraded their EMS resources, purchased better equipped ambulances, improved their communications networks, upgraded hospital emergency departments, and improved the quality of people providing emergency medical care.

The provisions of EMS have become more widely accepted and services provided by EMS systems are considered by many to be as important as those services provided by the police and fire departments. More and more local and State governments have enacted taxes, and allocated funds to support EMS. Some, but not all, envision the day will come when EMS regions will no longer require any further Federal grant support to assist their programs.

2. Problems in Managing the EMS Grant Program

Although the DEMS grant program has improved EMS systems by providing funds for facilities, equipment, and training opportunities, progress has been slowed by administrative problems. This is especially true in the HEW regional offices where representatives stated they had difficulty in carrying out grants management because of inadequate program direction or guidance.

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The DEMS grant program is administered by the 10 HEW regional offices. Grant funds are allocated by the DEMS central office to the regions. The regional activities include:

-- Announcing the availability of funds under the EMS Systems Act and distribution of application kits to applicants.

-- Providing technical assistance to applicants, and assisting in preparation of the applications.

-- Performing initial review of applications to determine eligibility and compliance with the 15 required components.

-- Performing joint regional and central office reviews of applications recommended for funding.

-- Awarding grants to successful applicants.

Need for Issuance of Official EMS Program Regulations and Guidelines

HEW regional officials as well as State EMS coordinators interviewed were critical of DEMS failure to issue new program regulations and guidelines for implementing the legislative changes of October 1976. Despite the fact that draft instructions were issued and discussions conducted at the regional EMS workshops on grants management policies and procedures, many officials regarded the steps taken by DEMS as inadequate to properly carry out the program. The Investigative Staff was told by some State EMS coordinators that the verbal instructions issued at regional workshops were frequently changed by the time they returned home to prepare their grant applications.

One State EMS coordinator said that he received considerable information by the "grape vine" from other State officials who had been in contact with DEMS. He believed this practice of randomly furnishing selected officials with oral information resulted in delay and confusion and was basically because of HEW's inability to provide its HEW regional offices and EMS systems with adequate formal guidelines.

The following is an example of the difficulties caused by DEMS failure to issue appropriate regulations. The October 1976 legislative changes to the EMS Systems Act, allowed for Federal funding of a second year Section 1202 EMS planning grant. This grant would provide a year of funding and enable EMS systems, which had developed a basic life support capability (Section 1203), to develop a plan for an advanced life support system (Section 1204). The changes in the law were discussed during several of the national EMS meetings and subsequently several

States prepared Section 1202 second year planning grant applications. These applications were not funded because DEMS had not developed the required guidelines for second year Section 1202 grants. One EMS State coordinator estimated that a second year planning grant application takes approximately 120-man days to prepare.

As of January 1978, HEW had still not issued revised regulations encompassing the legislative changes made by Congress in 1976. A DEMS central office official informed the Investigative Staff that further delay on issuance of the final EMS regulations by HEW could have a critical effect on grant applications due for review at the HEW regional offices in April 1978. He stated that if HEW does not proceed in a timely fashion, it is entirely possible that DEMS will be faced with a situation wherein grant applications will be submitted using the old outdated regulations for the second straight year. As a result, applicants will probably encounter processing problems, delays, and confusion in receiving grant approvals.

Only Limited Monitoring and Technical Assistance Provided By the Regional Offices

The HEW regional offices are also responsible for monitoring grants and providing technical assistance to applicants and grantees in their regions. Regional office personnel assigned to EMS vary from two to three persons, and usually include one clerical staff member. HEW personnel not assigned to EMS may also provide limited support particularly during the grant review process. Because of the small staffs, the Investigative Staff found that very little monitoring or technical assistance is provided by field personnel. Most monitoring of grantees are made by telephone and few site visits have been made to applicants and grantees because of limited manpower and travel funds.

The Investigative Staff was told that during the early years of the grant program (1974-1975), a few EMS grantees were improperly funded under Section 1204 (expansion and improvement) funds. For example, the State of North Dakota was awarded a Section 1204 grant even though the EMS regions in that State were not ready for advanced life support development and instead should have applied and been funded under Sections 1202 or 1203 of the program. However, once a system has been funded under Section 1204, it cannot legally obtain prior section funding. As a result, the EMS regions in this State still need assistance to take full advantage of the EMS program. DEMS officials suggest that regardless of the mistakes made by HEW in the early days of the program, relief should be provided.

Most HEW regional personnel are generalists and are unable to provide technical assistance in specialized areas such as medical direction or critical care capabilities. Consequently,

technical assistance in these specialized areas has been the almost exclusive responsiblity of the Director of DEMS who travels extensively for this purpose. The regional workshops and national symposia sponsored by DEMS also provide some technical assistance to applicants and grantees.

To provide additional technical assistance, beginning in FY 1977, DEMS recruited and trained physician technical advisors known as "Super Docs" for each of the 10 regions. These Super Docs will provide technical assistance at the regional office level. Some HEW regional representatives expressed concern that the DEMS central office is bypassing the HEW regions when developing programs and working through the Super Docs, leaving the regions "out in the cold" and "out of touch."

Need for Data Base and
Evaluations of the EMS Program

The EMS Systems Act requires HEW to conduct periodic evaluations to determine the impact EMS systems have had on the mortality and morbidity of patients using such EMS. The Investigative Staff determined that DEMS does not have an adequate data base to develop meaningful evaluations and, therefore, none have been made to date.

Program evaluation by HEW is essential to:

-- Determine the impact of the assistance provided under the EMS Systems Act.

-- Develop a framework in which EMS systems may be evaluated in an independent fashion.

-- Assist in providing standarized information approaches to improve EMS system management.

-- Provide leadership in strengthening future policy both for grantees as well as the Federal Government.

During the past 3 years there has been a great deal of confusion concerning the type, comprehensiveness, and magnitude of evaluations necessary to meet the intent of the EMS law. DEMS officials acknowledged that no data base exists which would be useful for the purpose of evaluations. They said that only limited process and resource data are available from the EMS grantee program; and, reports provided are on a case-by-case basis, and of little value in making a total program evaluation.

In an effort to develop a data base for evaluating the progress of EMS systems development, DEMS issued an evaluation workbook during FY 1977 to all EMS grantees. Workbook information will be collected from each grantee during the first

quarter of CY 1978, compiled, and used to portray the national impact of the EMS program. The evaluations are intended to cover 10 of the 15 congressionally mandated components of an EMS system as well as the clinical care categories involved. DEMS officials stated that the results should provide, for the first time, the necessary data base on which to make judgments as to actual EMS progress.

Use of Regional Workshops and National Symposia as Principal Means for Providing Technical Assistance

Because of the limited staff, the Director of DEMS instituted the use of regional workshops and national symposia to provide professional and technical assistance to communities seeking to initiate or improve EMS programs. When the EMS program first started in 1974, there was little or no information available on how to go about systematizing the regions. To provide the largest number of EMS representatives with EMS strategy, the workshop and symposia methods were adopted. The Director said he firmly believes that this method has been a most effective way to systematize EMS regions.

In FY 1976, four national and one international symposia were conducted to improve understanding of EMS, components of the systems, and the management capability. Also during this period, a total of 11 regional workshops were offered to provide technical assistance to grantees involved in program implementation. The regional workshops presented a comprehensive overview of the national EMS program and included discussions in categorization, evaluations, communication design and integration, training, and other significant subjects. Over 2,000 people attended the symposia gatherings and 2,600 attended the workshops.

In FY 1977, DEMS provided technical assistance by offering four national symposia on a wide range of EMS-related subjects including: model EMS legislation, program evaluation, planning and design of communications and transportation systems, and manpower development. These national symposia were attended by over 2,100 participants and 326 faculty instructors. In this same period, regional workshops were conducted at 3 different locations before about 1,200 participants and 225 faculty instructors. The workshops presented specific guidelines and criteria for grant management, technical assistance on the 6 critical care patient areas (trauma, burn, cardiac, poisoning, behavioral, and neonatal), and the 15 EMS components.

During the course of this study, the Investigative Staff attended two regional workshops covering a wide range of EMS subjects similar to those conducted in FY 1977. The workshop sessions covered grant implementation, management of EMS systems, resource coordination, and the role of State and regional EMS

authorities. A number of State EMS coordinators interviewed at these meetings by the Investigative Staff commented that the workshops and symposia have achieved the purpose for which intended, but are now overdone, repetitive, and no longer effective. These representatives voiced objections to the extensive use of national conferences for disseminating information because:

-- 264 of the 300 EMS regions have already been provided some type of grant support by HEW. Many EMS officials are already familiar with most of the instruction provided and believe the symposia are no longer as important as in the early years of the EMS program. However, attendance by State and local officials is necessary to obtain continued support from HEW. Many said the functions are becoming social gatherings.

-- Attendance at these meetings is expensive and EMS officials believe the limited funding available for EMS could be put to better use. In addition, some States limit the amount of out-of-State travel permitted their employees.

-- Despite all the meetings, the HEW regional offices and EMS managers are still without suitable written regulations or guidelines to carry on the program.

The Investigative Staff agrees with State EMS coordinators that HEW should reevaluate the use of the workshops and symposia especially in view of their high cost. DEMS officials estimated that the annual cost of workshops and symposia is in excess of $2.3 million of which about $1.9 million is from scarce HEW grant and operational funds. Those funds could have been used to support additional EMS grantees.

3. Administration of EMS Program by the DEMS Central Office

If Congress plans to support the EMS grant program beyond FY 1979, then the Investigative Staff believes there is an urgent need for a permanent DEMS central office staff. DEMS, with the administrative responsibility for EMS, was established in March 1973 within the Bureau of Medical Services, Health Services Administration. All 29 budgeted positions of DEMS were allocated to the HEW regional offices by direction of the Administrator, HSA. There are no positions included in the EMS budget for the central office. The DEMS central office is currently staffed with 13 positions assigned from the patient care activity, Bureau of Medical Services.

Since 1974, the DEMS central office has managed its program by using these borrowed positions. HEW initially viewed its EMS program as one temporarily providing support to a series

of demonstration projects. Each year since 1975, a zero based budget analysis of DEMS manpower requirements has been conducted by the DEMS central office. These analyses showed the need for increased central office staffing. Requests for additional staffing by DEMS were refused by either the HEW Secretary's Office or the Office of Management and Budget. As a result, the DEMS central office was left to drift with a relatively small staff, an increased workload, and mounting administrative problems.

The 1976 amendments to the EMS Systems Act, under Sections 1208 and 1209, added additional administrative responsibilities to an already understaffed DEMS central office. The amendments require DEMS to:

(a) Be responsible for collecting, analyzing, cataloging and disseminating all data useful in the development and operation of EMS systems, including data derived from reviews and evaluations of EMS systems assisted under Sections 1202, 1203, and 1204.

(b) Publish suggested criteria for collecting necessary information for the evaluation of projects and program funds under the act.

(c) Participate fully in the development of regulations, guidelines, funding priorities, and application forms relating to activities involving training, research, and the burn program.

(d) Be consulted in advance of the awarding of grants and contracts for training, research, and the burn program.

(e) Be consulted in advance of the issuance of regulations, guidelines, and funding priorities relating to research or training in the area of EMS carried out under any other authority of the EMS Systems Act.

(f) Provide technical assistance (with special consideration for applicants in rural areas) and monitoring with respect to grants under Sections 1202, 1203, and 1204, and the burn program.

(g) Provide for periodic, independent evaluations of the effectiveness of, and coordination between, the programs carried out under the act.

Also, DEMS and the Interagency Committee on Emergency Medical Services were to collaborate on preparing and publishing reports on the progress of EMS.

DEMS provided an analyses of its current manpower needs which projected a total requirement of 79 positions--42 to carry

out the central office functions and 37 for the regional activities. We do not fully agree with this staffing assessment which would increase the DEMS staff from a present combined total of 42 positions to 79 positions. However, as discussed above, it appears that an increase in personnel is needed in the DEMS central office to make sure the following activities are properly administered: the clearinghouse program, technical assistance, support of the Interagency Committee on Emergency Medical Services, the burn program, and an evaluation program to measure the progress being made by grantees. Likewise, some HEW regional offices could more effectively manage their EMS programs with the addition of a professional staff member.

The Investigative Staff also believes HEW should make an across-the-board accounting of its personnel needs in all grant areas including EMS to ensure that there is an equitable distribution of manpower. In reevaluating its personnel needs, DEMS should keep in mind that its regional workshops and national symposia meetings might be reduced, thereby freeing some manpower and operational funds for other administrative activities. After such an evaluation, HEW could reprogram some operational positions and dollars from other areas to DEMS for use in bolstering the central and regional office staffs.

The Director of DEMS is the central figure in the management of HEW's EMS program. He formulates national EMS objectives, and establishes current priorities. Planning, such as it is, has been on a short-term ad hoc basis (less than 6 months), not in writing, and usually with a noted absence of staff and regional coordination. In the absence of formal program guidance, the Director's inability to provide timely oral guidance to everyone has contributed to the confusion existing in the field.

For more than a year, the addition of new responsibilities with no increase in personnel or operational funds has resulted in a serious breakdown in the management of the EMS program. To further complicate matters, the Director of DEMS traveled a total of 106 days during FY 1977 providing technical assistance, attending workshops, symposia, and visiting prospective EMS grantees and other officials. His absence from the central office also contributed to the DEMS backlog of unfinished tasks.

The small staff and lack of permanent (career) positions has produced serious morale problems and a high personnel attrition rate at the DEMS central office. The requirements of the grant program and the need to provide urgent ad hoc technical assistance, left DEMS personnel with very little time to fulfill their other legislative responsibilities. The small staff and lack of administrative leadership resulted in the following:

-- The clearinghouse functions were reduced to an information response activity.

-- Support of the Interagency Committee on Emergency Medical Services was inadequate and limited to preparation of agenda, announcement of meetings, and preparation of minutes.

-- The program monitoring effort was limited primarily to review of written quarterly and annual reports.

-- A suitable data bank for purposes of making evaluations of the progress of EMS was never started.

-- Reports required by Congress were either not prepared or were submitted late.

-- Many of the mandated functions listed under Sections 1208 and 1209 of the act were not addressed or not being carried out in a timely fashion.

Required Congressional Reports Given Low Priority

Indicative of the lack of support given the EMS program by HEW is its handling of congressional reporting requirements. An example of this is the reporting requirements under Section 1208(c)(1) of the EMS Systems Act requiring HEW to study and report on a continuing basis the roles, resources, and responsibilities of all Federal programs and activities related to EMS. Reports were due to the Congress on June 15, 1977, February 1, 1978, and annually thereafter. The June 15, 1977, and February 1, 1978 reports were not prepared. After a long delay, the Office of Planning, Evaluation, and Legislation (OPEL), HSA, contracted on September 30, 1977, for two evaluation studies (costing about $116,000) from which data will be used to prepare the required report. The OPEL contracts are scheduled to be completed by September 30, 1978. DEMS officials said that, in their opinion, they do not believe the OPEL contracts will provide sufficient information to allow development of a report satisfying congressional requirements.

Despite assurances by the Secretary of HEW to a member of the Senate in a letter dated October 4, 1977, that the report is scheduled for completion in April 1978, the Investigative Staff believes that if the required report is ever issued, it will not be until at least 1979, a delay of almost 2 years.

Similar conditions are delaying the meeting of other congressional reporting requirements including:

(a) A coordinated, comprehensive Federal EMS funding and resource-sharing plan.

(b) A description of the sources of Federal support for the purchase of vehicles and communications equipment and for training activities related to EMS.

(c) A uniform patient report system to be used to evaluate the effectiveness of EMS systems and the burn injury program.

DEMS's failure to meet congressional reporting and other requirements and to provide written guidance in a timely manner has had a detrimental effect on the EMS program. The EMS Systems Act provides for a significant expenditure of Federal funds to grantees over a 5-year period, and then an end to Federal involvement. In this respect, the establishment of an information system, producing timely and reliable data, is critical to the successful operation of the EMS program.

In summary the EMS program under DEMS is not administered consistent with many other Federal health programs sponsored by HEW. This is due mainly to a (1) shortage of staff and support funds, (2) lack of formal program guidance, and (3) insufficient direction and planned program objectives. Some DEMS officials believe that the program has not been supported adequately by the parent Health Services Administration or the Public Health Services offices.

4. EMS Training Activities

A number of Federal agencies support EMS training and provide assistance to programs which promote their interests. Such Federal assistance is provided primarily through the HEW, DOT, and the Department of Labor.

Dual Funding Sources and Differing Program Guidelines Complicate HEW Training Activities

Within HEW, two agencies, the Health Services Administration (HSA) through DEMS and the Health Resources Administration (HRA), provide assistance for EMS training activities. DEMS officials estimated that between 6 to 10 percent of the $32.8 million in grants awarded in FY 1977 for EMS systems development was devoted to training activities. HRA awarded $5.9 million for EMS training in FY 1977 under Section 789 of the Public Health Service Act.

Both HRA and HSA support short-term emergency medical technician (EMT) training programs. HSA support of EMS training has been limited to funding short-term EMT training as part of DEMS systems grants, while HRA provides Section 789 funding for both short-term EMT training and long-term training of emergency physicians and nurses. The two overlapping funding sources for EMT training have been a constant source of confusion and

dissatisfaction for State personnel managing the development of EMS systems. Seventeen of 20 State EMS coordinators interviewed expressed dissatisfaction with the HRA training program and cited the following problem areas:

-- The planning and managing of the State EMS program is complicated by different funding cycles for HSA and HRA. HSA's fiscal year funds from July 1 through June 30; HRA's is from October 1 to September 30.

-- States are uncertain whether to request EMT training assistance from DEMS or HRA. It is advantageous for a State to use HRA grants to fund EMT training and DEMS grants to fund the development of the other EMS system components. Each State receives a relatively fixed amount of assistance in the form of DEMS systems grants and HRA Section 789 grants represent an incremental source of funding. The decision on how to fund EMT training is complicated because DEMS systems grants are awarded several months before HRA grants.

A State which relies on HRA funding places itself in a precarious situation; for if the HRA grant is disapproved, the State will not have DEMS funds available for training requirements. If a State requests assistance from both DEMS and HRA for EMT training, the training is included in the DEMS systems grant and for that reason the HRA grant is disapproved. State EMS officials were dissatisfied with this arrangement and stated that HEW should better coordinate its training programs to ensure adequate support for EMT training.

-- State EMS officials complained that they were not given sufficient lead time to develop HRA grant applications nor the reasons when their applications were not funded.

-- EMS grant applications take a considerable amount of time and effort to prepare. By filing grant applications with both HRA and DEMS, the States are required to increase the time spent developing applications.

-- Some State EMS officials were unhappy over their lack of involvement with HRA grants. Although the State EMS office is responsible for developing and managing a comprehensive statewide EMS program, in some States, these officials had limited involvement with HRA training applications. This lack of involvement is

due to the HRA practice of soliciting grant applications directly from the academic institutions. When requested, State EMS officials endorse such applications regardless of coordination at the State level because they represent potential sources of additional Federal funds. Lack of input by the State is a major failing of the HRA program, since the State EMS coordinator is responsible for evaluating the State's EMS needs. The HRA program fails to provide the State EMS coordinator with sufficient leverage to ensure that the HRA training grant assists in the development and implementation of a comprehensive State EMS program.

-- One State EMS coordinator, although he did not assist in the HRA grant preparation, did evaluate and rate the State's HRA grant applications. Despite this assistance, the State EMS official's comments were not considered by HRA in the grant selection process.

The Investigative Staff sees no need for both HRA and HSA to fund EMT training. EMT training is a basic requirement of EMS systems development and should be funded through the HSA mechanism and completely controlled by DEMS. HRA support for the program should be limited to the present funding of long-term training for physicians and nurses.

5. HEW's Research Unresponsive to EMS Needs

The Investigative Staff believes that HEW research has been unresponsive to the needs of the developing EMS systems. Within the Health Resources Administration (HRA), the National Center for Health Service Research (NCHSR) is responsible for administering EMS research projects under Section 1205 of the EMS Systems Act. From the program's inception in FY 1974 through FY 1977, 65 research projects have been funded at a cost of almost $15.9 million, with another $3 million planned for FY 1978.

NCHSR officials view Section 1205 as a separate portion of the act. As these officials see it, their mission is to respond to a broad range of emergency medical problems as opposed to the specific needs of DEMS. Interviews with HEW officials disclosed that no evaluations had been made to determine the effectiveness of EMS research conducted under Section 1205. DEMS officials, for whom the research is intended, stated that the Section 1205 effort has been only marginally responsive to the needs of DEMS and its grantees. These DEMS officials said very little NCHSR research has produced specific results immediately applicable to operational EMS systems development.

NCHSR officials claim one reason for research being unproductive is that they have not received quality research proposals addressing problems faced by the developing EMS systems. EMS officials believe the NCHSR grant selection process is partially responsible for this shortcoming. Under the NCHSR grant selection process, research applications with design weaknesses are rejected without considering the merits of the area proposed for study. Most State EMS officials responsible for EMS systems development are not research oriented and consequently their research proposals are rejected due to poor project design, even though the subject matter proposed for study is perhaps critical. As a result, NCHSR has been awarding research grants and contracts to academically oriented medical institutions which write well designed research proposals concerned with problems peripheral to those of the developing systems.

Most EMS research projects awarded were long-term, multi-year studies aimed at evaluation or model development and are not timely in meeting the needs of the developing EMS systems. DEMS officials complained that NCHSR research funds are not available to solve high-priority, short-term operational problems. NCHSR considers studies of this nature to be short-term analysis as opposed to research and, therefore, they have not provided funding. The Investigative Staff believes this is a major failing on the part of NCHSR. Timely information is essential because the Federal EMS program contains a built-in "sundown clause," or a specific time limit (by FY 1979) for having these systems in place and ending Federal involvement. If NCHSR research cannot provide help in solving problems within this time frame, it is of little value to DEMS in EMS systems development.

The EMS regional systems are faced with a multitude of problems requiring study and analysis. The Investigative Staff believes NCHSR has been unresponsive in answering those problems. The NCHSR grant selection process should be reexamined. Research proposals by State EMS officials should not be automatically rejected because of minor project design errors; consideration should be given to the proposal's merit and research design assistance made available to applicants who propose to study high-priority problems facing EMS systems.

In summary, the Investigative Staff feels that the ability of research to respond to problems facing DEMS should be evaluated. If it is determined that the HEW research programs cannot address issues critical to EMS systems development, and provide timely information for use by these systems, then funding for research under Section 1205 of the act is not meeting its objectives and should be applied to other areas of EMS systems development.

B. Role of the Department of Transportation in EMS

The Office of the National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT), is responsible for administering the 10 year old DOT emergency medical care program. The Highway Safety Act of 1966 provided, under Section 402, Federal formula grants to help States develop and operate a highway safety program and authorized DOT under Section 403 to carry out highway safety research and development activities. The act also required DOT to establish uniform highway safety standards around which States and local communities were to organize their highway safety programs. DOT satisfied this requirement by developing 18 uniform highway safety standard programs. Standard 11, titled "Emergency Medical Services," outlines the requirements for a State EMS program.

HEW and DOT have traditionally played different roles in emergency services. In contrast with HEW's EMS program which emphasizes regional development, DOT concentrates its effort in the prehospital sector. DOT is primarily concerned with providing emergency medical care for persons injured on the highways. NHTSA funding under Section 402 for EMS activities is used by the States to finance the individual elements of a community's emergency medical care system.

During the past 10 years, NHTSA has contributed significantly to the improvement of emergency medical care nationally. In the first few years after passage of the act, NHTSA developed program guides and manuals emphasizing the value and effectiveness of various system components such as the use of helicopters in the delivery of emergency services. Training standards for ambulance and rescue personnel, and a series of training programs were also developed. Transportation and communication equipment were purchased by local governments with NHTSA funds. From FY 1967 through FY 1977, NHTSA provided over $106.4 million to the States for Standard 11 EMS programs under Section 402. In this same period, over $9.3 million was obligated by DOT for EMS research and development programs under Section 403 of the Highway Safety Act.

1. DOT Has Little Control Over State Spending of Section 402 Funds for EMS

To manage the EMS program, the NHTSA central office has a staff of 10 people. In addition, approximately 1 1/2 man-years of effort is expended in each DOT regional office to oversee EMS activities. Neither the NHTSA central office nor the DOT regional offices have much influence over how the States obligate their Section 402 funds for any of the 18 uniform highway standard programs. How these funds are spent is left to the discretion of the State. The amount of funds a State

receives is determined through a formula grant involving population and road mileage.

Because each State, through the Governor's Representative, exercises almost full control over spending of Section 402 funds, DOT has only a minor role with respect to managing the EMS program and, for this reason, has only limited contact with HEW regional and State EMS officials. The role of the Governor's Representative is discussed in Section V of this report.

The Investigative Staff believes that DOT regional officials should encourage Governor's Representatives to coordinate EMS funding with the State EMS coordinators. Close cooperation at the State level will eliminate independent assessment of EMS needs, encourage the orderly development of EMS systems, and eliminate confusion for those seeking Federal assistance.

2. DOT Research Effort Supports EMS

The DOT research program, Section 403 of the Highway Safety Act, is administered by the NHTSA central office. DOT has supported numerous demonstration projects in urban and rural areas to improve emergency medical practices and technology. Since 1967, approximately $9.3 million has been obligated for 42 EMS research projects. Research has been conducted, for example, into areas of emergency vehicle deployment, communications systems, and helicopter evaluation. Section 403 funding has been used to develop EMS training courses and equipment specifications.

DOT and HEW officials stated that there has been very little coordination on research or exchange of information between the two departments. As previously discussed in this report, DOT research has emphasized prehospital emergency care, while HEW research has been of a more general nature. In view of the potential for overlap and duplication of research effort and the consequent ineffective use of research funds, the Investigative Staff is of the opinion that the research efforts of both departments should be reviewed, evaluated, and coordinated through the Interagency Committee for Emergency Medical Services.

3. Deemphasis of Standard 11 is Cause for Concern

A major cause for concern for many EMS officials is the proposed deemphasis of Standard 11 by DOT. In July 1977, the Secretary of Transportation issued a report to Congress, mandated by the 1976 Highway Safety Act, entitled "An Evaluation of the Highway Safety Program." The report is part of a continuing

effort to review and improve the Federal role in highway safety. The review evaluated the adequacy and appropriateness of the 18 uniform highway safety standards and led DOT to make two basic conclusions concerning the program's future:

-- A more flexible approach is needed for management of a State and Community Highway Safety program; and

-- Insistence upon mandatory compliance with the 18 uniform highway safety program standards is no longer appropriate.

The report also concluded that (a) State highway safety agencies have developed to the point where they should be relied upon to identify their own safety problem areas and develop means of addressing these problems; and (b) only where nationwide standardization is an essential component of the safety program should mandatory compliance with Federal standards be required by the Federal Government.

DOT recommended that mandatory compliance with the present 18 uniform highway safety standards be replaced with a limited number of uniform requirements that must be satisfied by the States. These would be developed in the following six areas:

(a) Rules of the Road
(b) Driver Licensing
(c) Vehicle Registration, Titling, and Theft
(d) Traffic Control Devices
(e) Highway Design, Construction, and Maintenance
(f) Traffic Records Systems

Standard 11, Emergency Medical Services, along with other standards, not included above, would serve only as guidelines for States and local governments.

The Investigative Staff noted that State EMS coordinators were adamant in their opposition to the deletion of Standard 11. They claimed that a significant reduction of DOT Section 402 funds for EMS would result from elimination of Standard 11 as a mandatory program. Many State EMS programs rely heavily upon Section 402 funding for support. Although DOT officials stated they were not deemphasizing EMS, most agreed that EMS funding would probably be reduced. The Investigative Staff was told by several Governors' Representatives that should EMS be deleted as a mandatory requirement, EMS would receive low priority in their States. Already there is a trend in some States to reduce DOT EMS funding whenever HEW awards an EMS systems grant.

The Investigative Staff believes that deletion of Standard 11 as a mandatory requirement will result in reduced funding for

EMS and will adversely effect EMS systems development throughout the United States.

C. Department of Labor Supports EMS Training Activities

The Department of Labor (DOL) supports EMS training under a number of DOL programs, and is a participating member of the Interagency Committee on Emergency Medical Services (IAC-EMS). Funding for DOL training is offered primarily under the Comprehensive Employment and Training Act (CETA), approved December 29, 1973, and amended on December 31, 1974. State and local governments use CETA funds to sponsor a variety of EMS training programs for the unemployed, underemployed, and the economically disadvantaged.

The Investigative Staff requested DOL to provide funding information on the extent of Federal support of CETA EMS training activities from FY 1974 through FY 1977. DOL canvassed its regional offices for data which had to be collected from various levels of State and local governments. Information available at the time of this report was fragmented and inconclusive, however, it appears that a significant amount of CETA funds have been expended on EMS training programs. An interim response provided by DOL covering four regional offices (Atlanta, Denver, San Francisco, and Seattle) showed that for the period FY's 1974 through 1977 almost $11 million was expended for EMS training activities. However, this information was considered incomplete by a DOL official who advised that the amount should be significantly higher when final tabulations are completed.

DOL Fails to Coordinate EMS Initiative Through Interagency Committee on Emergency Medical Services

The Investigative Staff determined that at least one DOL training program had not been adequately coordinated before inception with the IAC-EMS or with existing Federal and State EMS training programs.

The DOL emergency medical technician (EMT) apprenticeship program sponsored by the International Association of Fire Fighters and the International Association of Fire Chiefs duplicates existing HEW and State EMS programs. EMS training needs are currently identified by State and local EMS officials and funded on a priority basis as funds become available. In most States, professional fire fighters were already being provided an appropriate level of training.

The EMT apprenticeship program was designed to develop, promote, and implement EMT training programs for professional fire fighters. To accomplish this goal, DOL, in June 1977, awarded a contract for $1.26 million to the International Association

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of Fire Fighters and the International Association of Fire Chiefs. The contract provided little money for actual EMT training and most of the money was earmarked primarily for funding the administration of the national apprenticeship program and promoting public awareness of the need to improve prehospital care, especially the need for an apprenticeship program for professional fire fighters.

Of 22 State EMS coordinators interviewed, 20 saw no need in their State for an EMT apprenticeship program for training professional fire fighters. State EMS coordinators said that an EMT apprenticeship program would duplicate existing State EMT training programs and that fire fighters were already receiving this training when appropriate. State EMS officials were concerned about the cost of supporting an EMT apprenticeship program at the State and local levels considering the limited funding available for EMS. Some questioned the use of Federal funding for a promotional campaign designed to influence State and local communities to establish an expensive EMT training program for a special interest group, when what was needed was Federal funding for existing EMT training programs.

The Investigative Staff noted that DOL failed to coordinate or consult with the IAC-EMS before signing a contract with the International Associations of Fire Fighters and Fire Chiefs establishing the national EMT apprenticeship program. The IAC-EMS did not explore the need for this program nor the possibility of duplication. Although the national EMT apprenticeship program was not a well coordinated effort, it was approved by the Director of DEMS. The approval was in response to assurances that the program would be run in conformance with nationally established EMS standards.

The Investigative Staff found that the utility of the Federal dollars that will be spent on the DOL national EMT apprenticeship program did not receive serious consideration by the Director of DEMS or by the IAC-EMS. It is believed this situation occurred because: (1) neither has significant control over programs enacted by other Federal agencies, and (2) DOL funds are viewed as an additional source of funding and while the utility may be low, the incremental funding "can't hurt."

The Investigative Staff recommends that DOL, in coordination with the IAC-EMS, critically review its CETA and other EMS training programs to ensure that duplication does not take place with existing Federal and State EMS programs. DOL EMS training programs should be coordinated with State health departments to obtain the State EMS coordinators input, thereby reducing the possibility of duplication and increasing the effectiveness of DOL training dollars.

IV. NEED FOR IMPROVED COORDINATION AMONG FEDERAL AGENCIES

A. The HEW/DOT Relationship

Since passage of the EMS Systems Act in 1973, petty bickering over the roles of HEW and DOT by DEMS and NHTSA officials has marred the orderly process for EMS systems development by these two major financial providers. In addition, some EMS programs conducted by other Federal agencies have not been adequately coordinated with HEW and DOT. As discussed previously in this report, the EMS program in the United States is Federally supported principally by HEW and DOT under two separate acts.

The principal objective of the EMS Systems Act is the development of an effective health delivery system. It is not a program to just develop sophisticated communications networks, and provide expensive fleets of ambulances, emergency facilities, and more employment. It is a system designed to bring these components together in a coordinated manner to provide effective and efficient care for persons faced with emergency health care needs. Funding provided by HEW, DOT, and other Federal agencies must be used in the best interests of systems development. A team effort by all concerned Federal agencies with respect to planning, execution, and operation of the EMS system can significantly increase the impact of the Federal dollar.

The Investigative Staff, in its review, observed that the spirit of cooperation and coordination is obviously missing at the Federal level despite the claims by some HEW/DOT representatives that they are attempting to coordinate their programs. Many of the State EMS coordinators interviewed expressed disappointment and concern over the poor relationship between HEW and DOT. One State EMS coordinator stated that HEW and DOT "fight like cats and dogs." This lack of Federal leadership and coordination has had a negative effect upon many State and local representatives involved in the EMS program.

A major stumbling block in coordinating the HEW/DOT programs has been the reluctance on the part of DOT officials to recognize that EMS systems development requires medical leadership. Such leadership can obviously be best provided by HEW with its extensive medical resources and background. The fact that DOT has been active in prehospital EMS programs since 1966 (before HEW) has made it difficult for some DOT officials to accept the lead agency role that HEW now exercises. According to HEW officials, major areas of controversy between the two departments include implementation of new standards, new investigative studies, and EMS program priorities. Generally, these efforts are very poorly coordinated by both HEW and DOT.

Despite differences of opinion concerning who is the lead agency for EMS and other turf problems, officials of HEW and DOT agree that the separate laws under which they function leave ample opportunity to carry out systems development and to complement each other in the process. Both agencies are concerned with providing EMS care; DOT primarily in the prehospital phase, HEW in developing an entire EMS system. To ensure that the programs complement each other and also to simplify State EMS planning, the Investigative Staff recommends that DOT and HEW develop a single set of program guidelines satisfying the requirements of both departments.

Coordination Between HEW and DOT with Regard to Communications and Disaster Preparedness

Communications is a major system component requiring a large resource commitment and is an important consideration of State and local officials working toward development of EMS systems. HEW and DOT along with the Federal Communications Commission share the principal Federal agency responsibility for communications planning. Their efforts are coordinated through a workgroup on communications established by the Interagency Committee on Emergency Medical Services. Primarily, Federal coordination is directed toward development of specifications and has little to do with initial funding. In part, this is because DOT has little influence on how a State spends DOT provided funds.

The responsibility for disaster preparedness has been fragmented among many Federal agencies including HEW, the Department of Defense through its Defense Civil Preparedness Agency, and the General Services Administration. Neither DOT nor HEW EMS programs directly address disaster preparedness. The Investigative Staff believes the Interagency Committee on Emergency Medical Services should review Federal planning for disaster preparedness and determine the ability of State EMS coordinators and EMS regional systems to participate in the program when called upon.

B. Memorandum of Understanding Between HEW and DOT is Waiting for Approval

HEW and DOT have been working since 1974 to develop a written memorandum of understanding defining responsibilities for EMS systems development. During this study, HEW and DOT officials informed the Investigative Staff that a draft memorandum of understanding has been drawn up and is waiting for final approval from both departments. The administrative responsibilities of HEW under Title XII of the Public Health Service Act and of DOT under the Highway Safety Act, respectively, are formally delineated in this agreement. When signed by both parties, the document will represent the first real effort to coordinate EMS activities. As of January 1978, the agreement had not been finalized.

Basically the agreement is intended to prevent confusion and duplication of effort by DOT and HEW. Pursuant to their respective statutory requirements, and the terms of the agreement, DOT and HEW will cooperate when developing, establishing, and implementing comprehensive national uniform standards, regulations, procedures, resources, and technical assistance for the prehospital and interhospital transportations phases of emergency care.

The Investigative Staff believes that the two departments appear to be making a sincere effort to arrive at an understanding of their respective roles. This is a step in the right direction. However, implementation of this agreement will demand a continuous, joint, coordinated effort by DEMS and NHTSA central office officials to make it workable. Also the regional offices of DOT and HEW, the State EMS coordinators and the Governors' Representatives must be fully cognizant of the joint agreement in all details to ensure a sound and orderly development of EMS nationwide.

C. Interagency Committee on Emergency Medical Services Fails to Coordinate Federal EMS Programs

Establishment of an Interagency Committee on Emergency Medical Services (IAC-EMS) was required and its duties authorized in Section 1209 of EMS Systems Act. The act provided that the Secretary of HEW or his designee chair the IAC-EMS and that its membership include five individuals from the general public, appointed by the President, as well as representatives from Federal agencies involved in EMS. The act required that the IAC-EMS meet four times a year at the call of the chairman. The Secretary of HEW is tasked with making available to the IAC-EMS such staff, information, and other assistance as it may require to carry out its activities.

The purpose of the IAC-EMS is to coordinate and provide for the communication and exchange of information among all Federal programs and activities relating to EMS. Specific responsibilities of the IAC-EMS are to:

(1) Evaluate on a continuing basis the adequacy, technical soundness, and redundancy of all Federal programs and activities relating to EMS.

(2) Develop and annually update the Federal EMS funding and resource-sharing plan and recommend uniform standards with respect to EMS equipment and training.

(3) Make recommendations to the Secretary of HEW regarding the administration of the EMS program.

Presently, the IAC-EMS is composed of 23 Federal representatives and 5 public members. IAC-EMS work groups on training, communications, transportation, financing and administration, perform staff work and provide recommendations for consideration at IAC-EMS meetings.

1. IAC-EMS Fails to Satisfy Congressional Requirements

The IAC-EMS has successfully endorsed uniform standards with respect to EMS equipment and training but has failed to adequately evaluate or coordinate the Federal EMS effort. As of January 1978, the IAC-EMS had not evaluated and reported upon the adequacy, technical soundness, and redundancy of all Federal programs and activities relating to EMS (the act required a report be issued to Congress not later than June 15, 1977); had not developed a comprehensive Federal EMS funding and resource-sharing plan; and had not developed a useful description of the sources of Federal support available for the purchase of vehicles and communication equipment (the act required both these reports be developed and published by July 1, 1977).

2. State EMS Coordinators Criticize IAC-EMS

State officials were extremely critical of the IAC-EMS and the Federal Government's failure to coordinate Federal EMS programs. They emphasized that State personnel have a limited amount of time available to acquaint themselves with Federal program guidelines and cited the need for consolidation of Federal funding and for a useful description of the sources of Federal funding available to their State. Twenty of the 24 State EMS coordinators interviewed stated that coordination at the Federal level was inadequate with respect to EMS funding and program guidelines.

State EMS coordinators also criticized the IAC-EMS for not addressing or seeking answers to the critical problems faced by EMS providers at the State level. They argued that the EMS program is implemented at the State level and that the IAC-EMS did not fully appreciate the problems encountered by State and local officials. State EMS coordinators saw the IAC-EMS as basically a rubber stamp for formalizing Federal EMS standards and expressed the need for State representation.

The Investigative Staff agrees that the IAC-EMS has not addressed or taken an apparent interest in problems faced by State and local officials implementing Federally funded EMS programs. In our opinion, State representation on the IAC-EMS could serve to focus Federal attention on critical EMS problems and help promote cooperation between Federal agencies.

3. Federal Agencies Reluctant to Coordinate

To date, the IAC-EMS's review of Federal EMS activities has been superficial. A public member of the IAC-EMS at the September 14, 1977, meeting, commented that IAC-EMS members just hear reports on what different Federal agencies do (stating how good their programs are) and then go home until the next meeting. Public members of the IAC-EMS were concerned over the IAC-EMS's failure to come to grips with problems facing EMS. These members felt that they were not being asked to come up with recommendations for better methods of implementing EMS, particularly, in relation to Federal agencies.

The Investigative Staff found a general reluctance on the part of the Federal agencies involved in EMS to coordinate their activities through the IAC-EMS. The Federal agencies appear content to go their own way and carry out their own programs without outside involvement. Each Federal agency functions in accordance with its laws and carries out its mandates and procedures in accordance with those laws. There is no mandate requiring coordination of Federal EMS activities. These agencies do not feel the need to obtain IAC-EMS approval for new or existing EMS activities and jealously guard what they consider their turf.

One example of the lack of coordination is the Department of Labor's EMT apprenticeship program discussed in Section III of this report. The Investigative Staff found that the need for this program is questionable in light of HEW and State training programs.

4. IAC-EMS Provided Inadequate Staffing

The IAC-EMS lacks directions. Its inability to address problems facing EMS is, in part, a result of the Secretary of HEW's failure to provide the IAC-EMS with staffing, information, and other assistance necessary to carry out its activities.

The Secretary of HEW delegated the responsibility for IAC-EMS staffing to the Director of DEMS. The Director of DEMS has a small central office staff which has difficulty managing the DEMS program. IAC-EMS meetings are arranged only during periods when DEMS personnel are available to coordinate them. During the year 1977, the IAC-EMS met only twice, on February 9 and September 14, 1977. (The act requires that the IAC-EMS meet at least four times yearly.) The IAC-EMS meetings were not properly planned or coordinated. At the September 14, 1977, meeting neither the minutes of the previous meeting nor the agenda for the September 14, 1977, meeting had been distributed to the IAC-EMS members beforehand. Thus, IAC-EMS members had no time to familiarize themselves with the topics presented, to consider associated problem areas, and to develop appropriate input.

The Investigative Staff believes that the IAC-EMS cannot successfully address problem areas or monitor Federal involvement in EMS by meeting for only one day twice a year, with little or no contact in between these meetings. Adequate staffing must be provided if the IAC-EMS is to function properly.

V. EMS PROGRAM AND HOW IT WORKS AT THE STATE LEVEL

A. EMS Systems Dependent Upon State Support

The Director of DEMS stated that continuation of quality emergency medical care to all persons within a State is dependent upon strong State direction and financial support. State support is necessary to keep EMS systems intact. An EMS system uses the combined resources of the counties, cities, and townships in a designated geographic region to provide quality emergency care to all persons regardless of their ability to pay. The promise of Federal funding by HEW has promoted coordination by local governments and other providers, such as hospitals, for the development of EMS systems. When Federal funding is discontinued, many systems may fall apart as the individual local governments and hospitals making up the system seek to promote their own parochial interests.

It is very difficult to hold together an EMS regional system composed of perhaps 30 or more counties. Funding of an EMS system on a local level is complicated because the EMS region is not a political unit with direct taxing authority or other means of generating revenue. Therefore, should Federal funding end, EMS systems would have to rely upon the local governments making up the system to finance operational costs. Difficulties arise in determining what each county feels is a satisfactory level of EMS and what each feels its fair financial contribution to the EMS system should be. Resource availability and willingness to fund vary from county to county; and persons from one county may refuse to pay for medical care for persons from another county. Another problem is that many local governments and service providers do not fully accept the regional system concept. They want to run their own independent EMS program. Many local governments are reluctant to relinquish management and operational control over EMS resources to an EMS system and will do so only if it is to their personal advantage. It is, as long as Federal funding is provided.

The State government is the political body which must assume responsibility for continuation of these systems. The State government has the ability to (1) provide direct funding, (2) coordinate State agencies and resources, (3) provide policy leadership, (4) program from the State legislature, and (5) use regulatory powers to promulgate standards. The Investigative Staff believes that the establishment of a strong State EMS program is necessary to maintain current advances in EMS.

B. EMS Councils Vital for EMS Systems Development

The availability of HEW grant dollars has brought together EMS providers, public agencies, community leaders, and EMS users for concerted analysis and study of EMS problems facing their regions. These EMS councils or committees were formed to provide a team approach to planning, execution, and operation of an EMS system.

Staffing for EMS councils is provided by the State EMS office or from a local management entity. This staff acts to write the EMS grant application, keep the EMS council together, and do the legwork necessary to implement and monitor system development. In most EMS regions, staffing is paid from DEMS grant awards. During discussions with State and local EMS officials, the Investigative Staff found a great deal of concern stemming from State EMS staff members not knowing whether their region's DEMS grant application had been approved. If the grant was not approved, EMS staff personnel would not be paid and in all likelihood would have to seek other jobs. A source of intense dissatisfaction was HEW's failure on many occasions to promptly notify the field of a grant award.

The establishment of regional and State EMS councils has led to a growing awareness at the grassroots level of the profound problems inherent in existing emergency medical care. The future of EMS councils after the EMS region has received the maximum 5 year of DEMS funding is uncertain. Some EMS officials said the regional EMS councils will not continue to operate without State or Federally funded staffing and the incentive of Federal grants. In our opinion, the loss of the EMS council as a sounding board, monitor, policymaker, and guidance mechanism would seriously impair an EMS system's chance of remaining intact.

C. State Health Department Lead Agency for EMS

The management structure of the State EMS program varies from State to State depending upon the State's financial support of EMS, geographic and demographic conditions, and the personalities of people involved. In virtually all States, the State health department is the lead agency responsible for the development and implementation of a comprehensive State EMS program.

Within the State health department, the State's EMS coordinator is responsible for developing a statewide EMS program and plays a critical role in EMS systems development. The State EMS coordinator's more important functions are described below:

(1) Relays information from DEMS central and regional offices to the developing EMS systems within the State.

(2) works to organize local EMS councils and resources for development of EMS systems in each region within the State.

(3) Develops a staff to provide technical assistance to the EMS regions. In most States, the EMS coordinator and his staff assist in preparation of DEMS Section 1202, 1203, and 1204 grant applications, monitor EMS systems development and troubleshoot statewide as necessary.

(4) Lobbies for financial and legislative support for the State's EMS program. He seeks support from the State as well as from Federal sources, he establishes EMS priorities (with assistance from the State EMS advisory council) and in most instances has considerable influence on how DOT and HEW money made available for EMS is spent.

(5) Because State EMS coordinators are responsible for developing adequate systems of EMS care statewide, they are confronted with the problems facing rural areas and regions lacking the human and financial resources necessary to develop an EMS system. They represent the interests of these regions and work on their behalf to provide Federal and State funding.

In summary, the State EMS coordinator works with regional EMS councils and EMS systems managers to develop a statewide network of comprehensive EMS systems consisting of the 15 required congressional components. Development of each EMS system requires a significant resource commitment as well as input and cooperation from all EMS providers. The State EMS coordinator's ability to provide guidance and assist the region in obtaining financial support is critical to the development of these EMS systems.

D. Governor's Representative Controls the Use of DOT Highway Safety Funds

To accomplish the objectives of the Highway Safety Act, the Governor of each State was charged with the responsibility for developing a highway safety program in accordance with 18 uniform highway safety standard programs. The day-to-day operation of this highway safety program in each State is handled by the Governor's Representative. Most of a Governor's Representatives's time is spent managing the Federal grant program (Section 402 of the Highway Safety Act); very few have a major impact on the allocation and use of State or local funds.

Each Governor's Representative develops an annual work plan detailing how Section 402 funds will be spent. In preparing this annual work plan, the Governor's Representative reviews accident data, identifies and sets priorities on reasons for accidents, and works to develop adequate countermeasures. The

Governor's Representative is in the business of accident prevention. Although concerned with postcrash care, the major interest is in the precrash prevention area.

The annual work plan is submitted to the DOT regional office where it is reviewed to ensure compliance with the 18 uniform standard areas. Even so, the Governor's Representative has almost complete discretion on how available monies will be spent for Section 402 including funding for Standard 11, Emergency Medical Services.

The Governor's Representative, in most States, permits the State EMS coordinator to develop the EMS portion of the annual work plan, detailing how funds for EMS will be obligated. Nineteen of 28 State EMS coordinators interviewed by the Investigative Staff stated that they planned the EMS needs under Section 402. In these States, the Governor's Representative compares the State EMS coordinator's input to alternatives identified in the other 17 standard areas and determines what proportion of the funds will be allocated for EMS.

Those Governor's Representatives who chose not to have the State EMS coordinator develop the EMS portion of the annual work plan determine EMS needs through requests received from local communities, input from the State EMS coordinator, data derived from vehicle accident reports, and local politics. The degree to which the Governor's Representative uses these sources varies from State to State. For example, in some States, the State EMS coordinator has no input into the annual work plan while in other States his input is given serious consideration.

The Governor's Representative's view of the EMS program varied from State to State as did the portion of Section 402 funds allocated for EMS. In some States, the State EMS coordinator lamented the lack of support given the EMS program by the Governor's Representative. In one such State, the Governor's Representative told the Investigative Staff that DEMS officials had created unrealistic expectations by telling EMS personnel and elected public officials that the State highway department had a large amount of money available to fund EMS equipment. He resented DEMS officials putting pressure on his office to provide EMS with what he considered a disproportionate share of the available Section 402 funding.

E. Complexity of EMS Systems Grants Limits Availability for Rural Areas

The DEMS program favors EMS regions having the administrative and financial resources necessary to develop an EMS system consisting of the 15 required components. The Investigative Staff was told by concerned State EMS coordinators that rural and "have not" regions are at a distinct disadvantage when applying for

sections 1202, 1203, and 1204 funds. These areas do not have the hospitals and medical personnel necessary for development of an EMS system. In addition, the financial base is not sufficient to guarantee continuance of the program when Federal funding ends. DEMS grant funds have been used for numerous purposes--support of the State EMS office, travel, ambulances, training, and communications equipment, among others--all in conformance with EMS systems development. However, these funds are not available to develop EMS care capabilities in regions which cannot support EMS systems development.

Many State EMS programs rely heavily upon DOT funds under section 402 of the Highway Safety Act. Section 402 funds, unlike DEMS grants, are not subject to a complicated set of guidelines and provide a fast simple method of financing. A Governor's representative in one State said he made available Section 402 funding within a week to satisfy an urgent EMS requirement. Basically, all that is required for Section 402 funding is an identification of the problem.

The principal guidelines affecting Section 402 funding for EMS are those established by the Governor's Representative and concern the type of expenditures deemed appropriate. Use of funds must be in conformance with DOT established standards for quality; for example, an ambulance, to be purchased, must meet DOT specifications. Section 402 funding is not limited to EMS systems development and can be used to assist rural and "have not" regions which do not have the human or financial resources to develop an EMS system or even a DEMS grant application.

The Investigative Staff learned that Section 402 funding was often used to prepare a region for a DEMS grant. In these instances, Section 402 funding was used to purchase basic EMS components which would increase the region's chances for DEMS assistance. Many State EMS coordinators said that Section 402 funding played a vital role in their efforts to develop a statewide EMS program and expressed concern that Section 402 funding for EMS might be withdrawn or reduced.

F. Uncoordinated EMS Programs Exist In Some States

The Investigative Staff found that some State EMS coordinators and Governor's Representatives did not enjoy a close working relationship. In some States, they disagreed on what their respective roles should be, on EMS priorities, or on the proportion of Section 402 funds which should be allocated to support EMS. As a result, in 9 of the 28 States in which EMS programs were reviewed by the Investigative Staff, 2 uncoordinated EMS programs were run at the State level, both funded through Federal grant programs. DOT does not require the Governor's Representative to coordinate his funding of EMS in

conjunction with the State EMS coordinator who is responsible for the development of a statewide EMS program.

By establishing a separate EMS program, the Governor's Representative reduces the necessity for local communities to band together to form regional EMS systems. Instead of working together to develop an EMS regional system composed of the 15 required components to obtain HEW funding, local groups can go directly to the Governor's Representative, thereby, avoiding DEMS requirements. Such a procedure does not enhance EMS systems development.

In addition, Governor's Representatives, working from the State highway department, do not have the contacts with local EMS providers that the State EMS coordinators working from the State health departments have. Governor's Representatives have difficulty getting guidelines out to local EMS officials so they can identify EMS problem areas. Local EMS officials in a large western State told the Investigative Staff that information on how to obtain Section 402 funding was kept a "big secret."

The Investigative Staff believes that lack of cooperation and bad feelings between DOT and HEW at the federal level, have directly contributed to the operation of uncoordinated EMS programs in some States. DOT and HEW need to clarify the roles they expect the State health and State highway departments to play in EMS development. The Governor's Representative should be encouraged to accept the State EMS coordinator's assessment of EMS needs and not run an independent EMS program. Dual assessment of EMS needs is duplicative, creates needless confusion at the local level, and retards EMS systems development.

G. Individual Guidelines for DOT and HEW State EMS Plans Cause Confusion

The State EMS plan submitted to DEMS is a comprehensive document detailing the establishment, operation, and expansion of EMS systems. This plan is developed as follows. DEMS divides each State into regions. Each region plans for development of its EMS system by addressing in a DEMS grant application the 15 system components required by the EMS Systems Act. The plan is developed at the local level with persons controlling local EMS resources playing the major role in its preparation. Combined, the regional EMS plans form the State DEMS plan. The prehospital EMS function is an integral part of the State DEMS plan and DOT specifications for prehospital resources are mandatory.

The purpose of the DOT State EMS plan, developed by the Governor's Representative with input from State EMS officials, was to encourage States to inventory their prehospital resources, identify gaps in service, and seek remedies for EMS deficiencies.

The DOT State EMS plans were developed in accordance with guidelines contained in the Highway Safety Program Manual and are essentially an inventory of prehospital resources. Because of this, in the opinion of one DEMS official, the word "plan" is actually a misnomer. In visits to the DOT regional offices, the Investigative Staff found that many DOT State EMS plans were dated in 1974 and had not been updated since.

Confusion exists at both the State and Federal level concerning the requirements for DOT and HEW State EMS plans. The respective purpose of the DOT and HEW State plans, and what each state should have in terms of current updated plans is unclear.

Fifteen of the 28 State EMS coordinators interviewed said their State had developed a single comprehensive State EMS plan which, in their opinion, satisfied both DOT and HEW requirements. Development of a State EMS plan takes a great amount of time and coordination. An EMS plan, if it is to remain useful as a workable document for EMS implementation, needs periodic updating. Due to limited State resources, most States consider their current DEMS grant application to be the State's updated State EMS plan, satisfying both DOT and HEW requirements.

The Investigative Staff recommends that DOT and HEW determine what is acceptable in terms of an updated State EMS plan. In the opinion of the Investigative Staff, two sets of guidelines and two State EMS plans are not useful. Since HEW plans to fund "wall-to-wall" EMS systems within each State and since the HEW plan encompasses the prehospital function as well as making DOT specifications for prehospital resources mandatory, we feel the HEW plan should suffice for both DOT and HEW. HEW plan guidelines should be reviewed by DOT and, if necessary, changes recommended so the plan satisfies both departments.

h. Standard Recordkeeping and System Evaluation Inadequate

DEMS grant guidelines require that EMS systems establish standardized medical recordkeeping systems which cover patient treatments from initial entry into the system through discharge. Standard recordkeeping is necessary to provide data for program evaluation and management purposes.

The Investigative Staff found that standard medical recordkeeping systems have not been fully implemented by the regional EMS systems visited. EMS officials said that it is extremely difficult to get hospitals to use standard forms. Hospital administrators are reluctant to handle the extra paperwork or provide information because of patient confidentiality and the possibility of malpractice suits. Some EMS officials questioned the usefulness of any information which might be provided. They believed that data submitted would be self-serving and that the

seriousness of the patient's condition is a judgment call which varies from hospital to hospital making comparisons difficult. The cost of gathering and compiling information is considered prohibitively high by State and local officials.

State EMS officials were frustrated by DEMS standard record-keeping and evaluation requirements. To date evaluations have not been made by State and local officials showing the impact EMS systems have had on patient care. State EMS officials were uncertain of what was expected since adequate data bases do not exist upon which to develop evaluations. One EMS official estimated it would take twice the number of people presently on his staff a full year to develop useful data for evaluation purposes. In addition, State EMS officials were concerned about the use which might be made of evaluations performed by State and local authorities. Would further Federal assistance be dependent upon good figures?

In summary, standard recordkeeping and system evaluation are costly propositions and are viewed unfavorably by hospital administrators and EMS providers. The Investigative Staff believes that action will not be taken in this area unless increased Federal emphasis is placed on standard recordkeeping and evaluation, and incremental funding is made available specifically for this purpose.

VI. FISCAL DATA

Although the Interagency Committee for Emergency Medical Services has identified 64 separate Federal programs that provide support for EMS, it was unable to develop fiscal data reflecting the amount of Federal, State, or local funds that have been expended over the years on EMS. However, by the end of FY 1978, the two major agencies, HEW and DOT, will have allocated more than $300 million for EMS program support in the United States.

A. Department of Health, Education, and Welfare

During the period FY's 1974 through 1978 inclusive, HEW through the Public Health Services, Health Services Administration and the Health Resources Administration, will have obligated $192 million for EMS programs. During these 5 years, HEW will have provided direct grant support under Sections 1202, 1203, and 1204 totaling $143 million, research support of $18.9 million, training support of $13.6 million, and burn injury program support totaling $6.1 million. The allocation of HEW funds by program and fiscal year are summarized below:

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EMERGENCY MEDICAL SERVICES PROGRAM
ALLOCATION OF FUNDS UNDER THE PUBLIC HEALTH SERVICE ACT
FISCAL YEARS 1974-1978

Program	FY 1974	FY 1975	FY 1976	FY 1977	Estimate FY 1978	Totals
Feasibility and Planning Section 1202	$ 2,250,000	$ 4,617,800	--	$ 986,563	$ 925,000	$ 8,779,363
Initial Operations Section 1203	10,400,000	19,500,000	$21,636,475	21,767,304	14,800,000	88,303,779
Expansion Section 1204	4,350,000	8,125,000	7,278,825	10,021,133	20,900,000	50,674,958
Research Section 1205	3,333,000	4,500,000	4,175,000	3,925,000	3,000,000	18,933,000
Training Sections 776/789	6,667,000	--	--	5,910,496	6,000,000	18,577,496
Burns Section 1221	--	--	--	3,130,314	3,000,000	6,130,314
Administration*	--	257,200	334,700	294,686	--	886,586
TOTALS	$27,000,000	$37,000,000	$33,625,000	$46,035,496	$48,625,000	$192,285,496

* Used primarily for evaluation of EMS program.

D. Department of Transportation

During the period FY's 1967 through 1977, DOT allocated $839 million for the 18 uniform highway safety standard programs under Section 402 of the Highway Safety Act of 1966. Of this amount, $106 million or 12.7 percent was used for Standard 11 EMS activities, principally in the area of prehospital care. For FY 1978, DOT officials advised that $168.7 million has been appropriated for Section 402, but they could not estimate the amount the States will obligate for EMS-type expenditures during the year because of the uncertainty regarding Standard 11 continuance as a mandatory standard. Some officials believe that because of the deemphasis, the percentage of funds going into EMS will be much less in FY 1976 than in FY 1977.

The following table shows the total amount obligated each year for FY's 1967 through FY 1977 under Section 402, and the amount and percentage obligated for Standard 11.

DEPARTMENT OF TRANSPORTATION
EMERGENCY MEDICAL SERVICES PROGRAM
NHTSA SECTION 402 OBLIGATIONS UNDER THE HIGHWAY SAFETY ACT
FISCAL YEARS 1967-1977

Fiscal Year	Total Funds Obligated Under Section 402 (000)	Standard 11 EMS (000)	Standard 11 As Percent of Total
1967	$ 646	$ --	--
1968	23,900	1,646	6.9
1969	63,800	6,801	10.7
1970	67,950	6,942	10.2
1971	72,100	7,631	10.6
1972	76,360	10,883	14.3
1973	91,307	11,652	12.8
1974	76,241	10,949	14.4
1975	96,202	13,715	14.3
1976	145,189	19,237	13.3
1977	125,700	16,996	13.5
Total	$839,395	$106,452	12.7

NOTES: FY 1976 includes Transition Quarter.

FY 1977 excludes funds appropriated for FHWA Highway Safety Standards.

The following table shows that a total of $9.3 million in DOT funds were obligated under Section 403 for 42 research and development projects during the period FY's 1967 through 1977:

Fiscal Year	Number of Projects	Amounts (000)
1967	6	$1,311
1968	13	2,503
1969	8	2,893
1970	2	505
1971	-	-
1972	-	-
1973	-	-
1974	-	-
1975	2	1,361
1976	2	13
1977	9	704
Total	42	$9,290

C. Funding of EMS by State and Local Communities

DOT could not provide data showing the amounts spent by States and local communities for EMS requirements. Officials stated that fiscal data available at State and local levels varied and that the definitions of what constituted capital and operating expenditures were never uniformly interpreted by State and local EMS officials. As a result, a compilation of data on hard cash spending and other types of contributions would be very difficult to accumulate.

DOT officials advised that the accounting for the totality of State and local annual expenditures for emergency medical care has not been required, nor is it considered economically feasible. State and local grantees, who receive Section 402 funding, report their contribution to show they have satisfied the minimum 30 percent matching requirements. However, data are not available from jurisdictions having no Federal grant awards.

Annual Federal funding has continued to provide limited financial support to a relatively small number of the 20,700 plus rural and urban jurisdictions. Accordingly, it is unlikely that those communities which have not received Federal grants for this purpose, would be concerned or interested in responding annually to a request for expenditure data. DOT representatives said making such inquiries mandatory would result in significant costs, with uncertain validity as to the product, and would impair and diminish the credibility of Federal program administration.

Alternative methods of estimating these expenditures have been attempted. DOT provided "best estimates" of State and local expenditures based on a study in FY 1967 which showed that emergency medical services cost $32.8 million ($24.2 million local and $8.6 million State) exclusive of any Federal funds prior to enactment of the Highway Safety Act of 1966. Their figures were conservatively estimated annually by adding a plus 3 percent inflationary factor. Estimates of combined State and local expenditures for EMS activities under this formula are as follows:

Fiscal Year	Amount (in millions)
1971	$37.9
1972	39.0
1973	40.2
1974	41.4
1975	42.6
1976	43.9
1977	45.2

3. Ambulance Procurement With HEW and DOT Funds

Both HEW, through DEMS systems grants, and DOT through Section 402 Standard 11 funding have assisted States, local communities, and regional EMS systems in procuring ambulances. According to information provided by DEMS officials, HEW supported the purchase of 577 ambulances during the period FY 1974 through FY 1977 at an average support per unit of $11,592 as summarized below:

Fiscal Year	Number of Ambulances	Total Support	Average Support Per Unit
1974	223	$2,391,412	$10,724
1975	144	1,821,906	12,652
1976	130	1,477,527	11,366
1977	80	997,510	12,469
Totals	577	$6,688,355	$ 11,592

During the period FY 1968 through FY 1976, DOT participated with States in the purchase of at least 3,502 ambulances with Section 402, Standard 11 funds at an average support of $5,632 per unit. Information on procurement of ambulances in FY 1974 was not readily available because DOT changed over to a new management information system, and complete data can now only be obtained by surveying the individual States. This was not

considered feasible by DOT. DOT officials said the individual States have varying policies regarding the amount of Section 402 funds that are provided for ambulance purchases. The local communities pay the difference between total cost and the amount covered by Section 402 funds.

The following tabulation shows the number of ambulances procured, Section 402 dollars used, and the average Federal support per unit purchased for the period FY 1968 through FY 1976:

Fiscal Year	Number of Ambulances	Section 402 Funds Used	Average Support Per Unit
1968	124	$ 654,370	$5,277
1969	334	1,781,097	5,333
1970	379	2,092,270	5,521
1971	379	2,118,030	5,588
1972	520	3,128,057	6,015
1973	466	3,113,082	6,680
1974*	-	--	--
1975	647	3,045,000	4,706
1976	653	3,792,000	5,807
Totals	3,502	$19,723,906	$5,632

* Information on ambulance procurement not available for FY 1974 because of changeover by DOT to a Management Information System.

E. HEW'S Long-Range Plans for Grant Support of the 300 State-Designated EMS Regions

The purpose of the Emergency Medical Services Systems Act was to establish EMS regions and to assist each region in developing an effective system for emergency medical care delivery. At the end of FY 1977, 264 of the 300 EMS regions had received Federal grants for planning or systems development. Twelve regions had completed the maximum 5 years of grant support. PL 94-573 enacted in 1976 extended the Federal EMS program for 3 years. However, the nationwide network of systems is not expected to be fully in place by the end of FY 1979 when the current legislation expires.

Officials from the Division of Emergency Medical Services (DEMS), HEW, estimate that to fully develop the 300 EMS regional systems a total of $475 million in HEW Sections 1202, 1203, and 1204 grant support will be required. As envisioned by DEMS officials, the program will require another 3-year extension of the act with Section 1203 and 1204 funding provided through FY 1985. Combined with continued DOT support the total investment in EMS by these two agencies could exceed $800 million by 1985.

The Investigative Staff believes that before HEW is given authorization to extend the EMS program, there are several areas which require serious consideration. Among these are:

(1) It appears that there will be a significant reduction in DOT Section 402 funds provided for EMS, nationwide. We believe the effect this will have on developing EMS systems should be studied.

(2) The EMS regions which were initially funded were considered the most likely candidates for successful EMS systems development. EMS systems which are presently in the early stages of development and those which are not yet funded will be more difficult to develop. The Investigative Staff doubts that EMS regional systems capable of providing advanced life support can be developed wall-to-wall throughout this country. Perhaps HEW should consider a less ambitious EMS program; one designed to provide an adequate level of emergency medical care in those regions which cannot support more advanced systems.

(3) Evidence indicates that many EMS regional systems will cease to operate as a system when Federal funding ends. The primary cause of a system breakdown is the large number of local governments and EMS providers involved. Difficulties will arise in obtaining local funding for the system and in settling disputes among EMS providers stemming from professional jealousy. The Investigative Staff visited EMS management officials in Jacksonville, Florida, and the Washington, D.C., Metropolitan area (Northern Virginia, District of Columbia, and adjacent Maryland). It found that the eight counties in the Jacksonville region were providing EMS care on an independent basis and that Maryland had pulled out of the D.C. Metropolitan EMS region. Discussions with officials in these regions indicated that the failure to operate as integrated systems definitely affected the quality of EMS care provided.

(4) There is little doubt that when the maximum 5 years of funding has been completed under Sections 1202, 1203, and 1204, the withdrawal of HEW support will have a decided effect on many EMS systems. The Investigative Staff was told by 5 of 27 State EMS coordinators interviewed that some regional systems in their State would definitely collapse; an additional 6 said it was too early to tell. To date, the problems experienced by regional EMS systems, when Federal funding ends, have not been adequately studied.

To summarize, many EMS systems will have difficulty remaining intact. In some instances, the Federal dollars spent to coordinate systems development should be reviewed in this context. HEW should include an evaluation of the EMS program with any proposals to Congress for extending the act beyond FY 1979.

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NOT FOR RELEASE UNTIL AUTHORIZED BY THE COMMITTEE

A REPORT TO

THE COMMITTEE ON APPROPRIATIONS

U.S. HOUSE OF REPRESENTATIVES

on the

HEALTH MAINTENANCE ORGANIZATION PROGRAM

ADMINISTERED BY THE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Surveys and Investigations Staff

February 1973

NOT FOR RELEASE UNTIL AUTHORIZED BY THE COMMITTEE

February 21, 1978

MEMORANDUM FOR THE CHAIRMAN

Re: Health Maintenance Organization Program
Administered by the Department of Health,
Education, and Welfare

By directive dated July 12, 1977, the Committee requested that an investigation be made of the Health Maintenance Organization Program administered by the Department of Health, Education, and Welfare. The study has been completed and the results are set forth in the report.

Respectfully submitted,

David A. Schmidt, Director
Surveys and Investigations Staff
House Appropriations Committee

C. R. Anderson
Chief of the Surveys and
Investigations Staff
House Appropriations Committee

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SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

The Investigative Staff has reviewed the Health Maintenance Organization (HMO) program administered by the Department of Health, Education, and Welfare (HEW). The review concentrated on evaluating the effectiveness of HEW's management of the program from a central and regional office perspective.

The HMO Act of 1973 authorized HEW to establish a Federal demonstration program to develop alternatives to traditional forms of health care delivery and financing by assisting and encouraging the establishment and expansion of HMO's. The act provided Federal financial assistance for a 5-year period consisting of grants, loans, and contracts to public or private nonprofit organizations. The HMO program was established as an alternative health care delivery system intended to reduce costs and enhance the quality of health care. The HMO concept calls for the delivery of specified health services to the members of an HMO, either directly or through arrangements with others, in return for compensation at predetermined, prepaid rates.

The act authorized $325 million in grants and loans for HMO development. Of this amount, $250 million constituted grants for feasibility studies and for planning and development of HMO's, and $75 million to capitalize a loan fund to cover initial operating deficits of HMO's.

Dissatisfaction with the HMO Act of 1973 and the slow progress by HEW in implementing the program led the Congress to pass the HMO Amendments of 1976. These amendments modified some restrictive elements in the act which had been cited by HEW as reasons for failing to make sufficient program progress.

The amendments also extended the HMO program for 2 additional years through 1980, and authorized grant assistance of $45 million for FY 1978, and $50 million for FY 1979. Loan and loan guarantee authority was extended through September 30, 1980--no loans can be made or guaranteed after that date.

Grant Program

HEW initiated HMO grant funding in July 1974. As of December 31, 1977, 170 organizations had received 306 grant awards totaling approximately $62.7 million. Of the organizations funded, 35 had become qualified HMO's, 68 were in various stages of development although not all continued to receive grant funds, and the remainder, or 67, were no longer operational.

Briefly, grants support the following phases of HMO development:

-- Feasibility Phase--Applicants consider factors such as local need for an HMO, marketing of a plan, legal requirements, sources and extent of financial support, and structure of an HMO that best meets local conditions.

-- Planning Phase--Entails expansion of the information identified in the previous stage and the formulation of detailed activities which must be put into effect.

-- Initial Development Phase--Involves the legal establishment of an HMO, beginning enrollment and marketing, providing facilities, contracting with providers of health services, and employing needed staff.

Loan Program

HMO loans and loan guarantees are used to finance the HMO's operational deficits during the period of initial operations, which is characterized by the actual delivery of health services.

As of December 31, 1977, loan and loan guarantee assistance totaling $71.4 million had been approved for 36 qualified HMO's. This assistance consisted of 40 direct loans for $69.1 million, and 2 loan guarantees for $2.3 million.

HEW Organizational Structure has Impeded Progress of HMO Program

Prior to a reorganization plan announced in December 1977, the administration of the HMO program had been divided between two different offices of HEW. The grant and loan functions were assigned to the Division of HMO's in the Health Services Administration, and the qualification and compliance functions were assigned to the Office of HMO Qualification and Compliance in the Office of the Assistant Secretary for Health. Until this reorganization was announced, no single unit within HEW ever had responsibility for the entire HMO program.

The regional operations of the HMO program have been conducted by the 10 HEW regional offices. Their responsibilities include monitoring of and providing technical assistance to the HMO grant and loan projects. The Regional Health Administrators who are responsible for this program, as well as other health-related programs, report directly to the Office of the Assistant Secretary for Health and are not accountable to either of the two central office heads responsible for the program.

The separation of the developmental and regulatory functions was highlighted in several internal HEW memoranda which pointed out that these activities were badly coordinated and understaffed. According to the memoranda, the lack of cooperation between these

two central office entities has caused confusion and has delayed the progress of the HMO program.

Central office and regional office officials contacted by the Investigative Staff agreed that a lack of coordination existed between the Division of HMO's and the Office of HMO Qualification and Compliance, and they acknowledged that the existing conflicts have impaired the development, implementation, and effectiveness of the HMO program.

The deficiencies noted, among other factors, have had adverse effects on the program, including:

-- A lack of central office direction and management because of communication and coordination difficulties between the two headquarters groups and between these groups and the regional offices.

-- A lack of uniform guidelines for the HMO program and the failure to develop a set of uniform criteria for evaluating the qualifications of an HMO.

-- Constant delays which confront the HMO's seeking to obtain qualification as they move from the developmental to the operational stage.

-- Acknowledgement that 100 percent of all applications submitted for qualification contain deficiencies.

Administration of the
HMO Program Reorganized

Under a December 2, 1977, reorganization plan, responsibility for the administration of the HMO program was consolidated into a new Office of Health Maintenance Organizations in the Office of Health Programs, Office of the Assistant Secretary for Health. The intent of the reorganization is to unify, for the first time, responsibility for the grant and loan functions and the qualification and compliance functions.

The Office of Health Maintenance Organizations will have as its objectives to (1) implement and administer the grant, contract, and loan aspects of the HMO Act and is HEW's advocate in efforts to improve the organization and delivery of health services by use of the HMO approach; (2) develop national policies and objectives for the planning and initial development of HMO's; (3) develop long- and short-range program goals and objectives; and (4) serve as the departmental focal point in the area of HMO qualification, ongoing regulation, and employer compliance efforts. To undertake these responsibilities, the Office of HMO's will consist of two divisions: the Division of Health Maintenance Organizations Development and the Division of Health Maintenance Organization Qualification and Compliance.

Reorganization Excludes
Role of Regional Offices

The reorganization plan failed to provide for (1) giving the HEW regional offices more responsiblity or (2) making them directly accountable to the newly formed Office of HMO's. The Investigative Staff believes the central office and regional offices should report and be accountable to a single identifiable administrative unit in HEW. The consolidation of authority would provide a single focal point for the entire HMO effort. It would also facilitate administration of the program and provide HMO qualification applicants and others with a better understanding of how the HMO process works.

Qualification Application
Process is Lengthy

An HMO seeking qualification must submit an application which provides information on the principal aspects of the HMO's structure and function. The information required relates to its legal status; marketing practices and enrollment goals; patterns of health care delivery, including methods of quality assurance; and sources of income and fiscal soundness.

According to program officials, the qualification review process should normally take between 4 to 6 months from the time an application is received until a determination is made to either approve or deny a request for qualification. The Investigative Staff noted that of the HMO's qualified as of December 19, 1977, final determinations within the normal processing period took place in only about 20 percent of the cases. Moreover, about 62 percent of the HMO's still in the review process had been under consideration for at least 6 months.

The Investigative Staff found that a number of factors contributed to the delays including:

1. Lengthy qualification applications--HEW has not prescribed a format for applicants to follow or placed a limit on the length of the applications. In the absence of specific instructions, multivolume applications containing several thousand pages have been sent to HEW in boxes, cartons, and even footlockers. The sheer bulk of the applications overwhelms and frustrates reviewers and, as a result, greatly extends the review process.

2. Late establishment and understaffing of the Office of HMO Qualification and Compliance--HEW has for some time largely ignored the qualification and regulation functions of the HMO program. The Office of HMO Qualification and Compliance was not officially established until June 1975, some 18 months after passage of the act and the office has been chronically understaffed since that time. The limited staff resources of the

office and the need to write regulations, develop the qualification application, and handle the requests for qualification resulted in a qualification backlog which has continued to the present time.

3. Shortage of necessary staff skills--Program officials advised the Investigative Staff that the requisite skills such as corporate finance, legal, and medical service marketing necessary to effectively implement the act and related regulations are lacking in the current staff. The dual choice and continuing regulation requirements have been described as very complex pieces of labor law legislation which require special skills to properly administer.

4. Lack of regulations and guidelines--The time required by HEW to publish final regulations implementing various features of the HMO Act of 1973 ranged from 10 months to 22 months, and regulations on one important subpart have never been published in final form. The delay in issuing final regulations and guidelines to implement specific provisions of the act has been a serious hindrance to organizations seeking to become Federally qualified HMO's.

5. Delays caused by HMO Amendments of 1976--The HMO Amendments of 1976 prohibited payment of Federal matching funds under the Medicaid program to any State for services provided under a risk-based contract with an HMO, unless the HMO was qualified by HEW or specifically exempted under the legislation. According to program officials, many HMO's with such contracts, which had not previously sought qualification, were forced to submit applications because of these amendments. As a result, a large influx of applications was received by HEW in a short time, which further added to the delays in the qualification process.

Impact of Delays

The Investigative Staff noted that the delays in the qualification review process required the expenditure of additional Federal funds to keep some grant supported HMO's active until a qualification determination could be made. During the period July 1, 1974, to December 31, 1977, supplemental grant funds totaling about $4 million were provided to 19 HMO's affected by the delays in the qualification process.

As a result of the HMO Amendments of 1976, many HMO's in California with Medicaid contracts submitted qualification applications. Most of these Medicaid contracts were due to expire during the first quarter of 1977. HEW felt that many of these HMO's might go out of business unless their Medicaid contracts were renewed. The Investigative Staff was advised that because of the number of applications and the short time in which to make a determination, not all applications could be reviewed in the

required time. Therefore, HEW's efforts were concentrated on HMO's with the largest number of Medicaid enrollees.

The Investigative Staff identified one instance where a financial loss was suffered by an HMO as a result of HEW's failure to act on the qualification application in a timely manner. This application was submitted about 8 months before the HMO's Medicaid contract with the State expired. The Investigative Staff was advised that, as a result, the HMO lost about $250,000 per month in revenues and was forced to reduce staff and close facilities.

Loan and Loan Guarantee Programs

The HMO Act of 1973 provides for loans and loan guarantees to qualified HMO's requiring financing for planning, initial development, and initial operating deficits. Responsibility for the loan and loan guarantee function was vested in the Loan Branch of the Division of HMO's. The monitoring of HMO loan recipients was divided between the Loan Branch and the Compliance Branch of the Office of HMO Qualification and Compliance.

The Investigative Staff found that the Loan Branch had not developed a formal loan policy manual and the loan application documents have not been updated to include revisions required by the Amendments of 1976. Standards and criteria are not presently available to objectively and uniformly evaluate loan applications. A loan program official advised that he has been unable to find the time necessary to write policy statements. This is due to the severe shortage of staff, preoccupation with reviewing and processing current loan requests, and assistance required by some loan recipients who are experiencing financial problems. He noted, however, that preparation of new operating instructions for the Loan Branch is in process.

The Investigative Staff believes that the lack of formal, uniform loan policies and guidelines could result in the granting of loans to organizations which are not financially viable with resultant defaults on the loans. It is realized that an element of risk is involved in providing loans to HMO's; therefore, definitive written loan policies and guidelines are needed to reduce these risks.

Shortage of Qualified
Personnel in Loan Program

Administrative changes within HEW have almost completely stripped the Loan Branch of its ability to effectively carry out its functional responsibilities. At the present time, only four of the six staff authorized for the Loan Branch are assigned on a permanent basis. The branch has limited financial analysis capability, since only two people have the background and experience to do financial reviews.

Divided Responsibility

for Loan Monitoring

HMO loan and loan guarantee recipients must be monitored on a continuing basis to determine if they are meeting enrollment projections, controlling costs, and generally meeting growth assumptions to become self-supporting and ultimately repay the loan. The Investigative Staff found that responsibility for this function is not clearly defined or formally delegated, and is divided between the Loan Branch of the Division of HMO's and the Compliance Branch of the Office of HMO Qualification and Compliance.

The Loan Branch's responsibility is to ensure compliance with the terms of the loan and loan guarantee agreements. The monitoring for this responsibility has consisted primarily of reviewing monthly and quarterly reports submitted by the HMO's and an annual independent audit of the HMO's financial statements. A program official acknowledged that few site visits have been made by the Loan Branch to verify the accuracy of the information reported by the HMO's. However, he agreed that such visits are necessary but, because of the shortages of staff, the continuing requirement to develop loan policy and standards, and the need to review loan requests, the monitoring aspect has been sadly neglected.

The Compliance Branch has responsibility for monitoring HMO's to ensure that they remain in compliance with the legislative and regulatory requirements of the HMO Act. An integral part of this function is assessing the financial soundness of HMO's to determine their potential for success in the marketplace. According to Compliance Branch officials, monitoring of HMO's operational and financial activities has been limited and largely superficial. To date, the monitoring performed has been on a crisis management basis, or limited to reviewing periodic reports submitted by the HMO. It was acknowledged that the data submitted by the HMO's was not verified or authenticated by HEW and the possibility existed that inaccurate or deceptive data could easily be submitted to and accepted by HEW.

The Investigative Staff believes that unless formal guidelines and criteria are developed and loan monitoring responsibilities clearly delineated and implemented, serious problems with many qualified HMO's may go undetected. Millions of dollars in outstanding Federal loan funds could be seriously jeopardized.

Technical Assistance

Technical assistance is an important aspect of the HMO program for HEW staff in the central office and regional offices, and for HMO personnel engaged in organizational development and operations. Technical assistance is often required in specialized

areas such as accounting and financial management systems, actuarial work, marketing of the benefit package, medical care delivery, and management information systems.

Technical Assistance Provided by the Central Office

Providing technical assistance to HMO's is imperative because often they do not have the requisite skills to develop and operate a successful organization. Formal definitive policies or criteria have not been developed for use by central and regional office staffs in providing technical assistance to HMO's, nor have guidelines been issued for HMO's to follow when assistance is not available from the HEW staff.

Technical assistance available in the central office is provided by the Division of HMO's through the Technical Assistance Branch. This branch has responsibility for:

-- Providing national leadership and guidance in the form of technical expertise to HMO's and HMO supported projects.

-- Coordinating and providing technical assistance to central and regional office staffs and active HMO's through direct staff assistance or use of consultants.

-- Developing regulations, guidelines, and other materials for specialty areas.

-- Providing or arranging necessary training to central and regional office staffs in the technical aspects of HMO's.

The Investigative Staff was informed by HEW officials that inadequate staffing is the primary problem in the Technical Assistance Branch. To perform the functions outlined above, this branch has only three or four professional staff members, including a marketing expert assigned on a temporary basis. During a recent 1-year period, this branch was able to perform only 30 technical assistance site visits to 21 developing and qualified HMO's. Since the passage of the act, no comprehensive training has been provided to the HMO staff in the regional offices.

The Investigative Staff believes that inadequate staffing has been the cause for the central office's inability to provide sufficient technical assistance to HMO's and adequate training to the regional office staff. As a result, the ability of the regional offices to provide quality technical assistance to HMO's has been severely impaired. All of these factors have contributed significantly to problems HMO's have had in preparing satisfactory qualification applications, and added to the delays in the qualification process.

Technical Assistance Available From the Regional Offices

The HMO staff in the HEW regional offices are required to provide onsite technical assistance during the developmental phases. They are also responsible for assisting each grantee to become a qualified HMO, to achieve fiscal viability, and to attain the maximum enrollment possible in each service area.

Recently, central office officials questioned the technical capabilities and future needs of the regional HMO branch staffs. Based on information provided by the regional offices and an analysis of deficiencies in HMO qualification applications, the officials concluded that the regions generally lacked sufficient technical expertise.

The Investigative Staff believes that HEW needs to develop a comprehensive training program and recruit more qualified regional office staff before the quality of technical assistance can be improved so that active and prospective HMO's can benefit to the maximum extent.

Technical Assistance Available From Other Sources

In view of the technical assistance deficiencies within HEW, as related above, the HMO's, especially during the developmental phase, must use grant funds to contract with private consultants for such services as financial planning, marketing, organizational planning, actuarial, and delivery systems design.

The consultants hired by HMO's are known either by the HMO management from prior contact or are recommended by the central or regional office. The Investigative Staff found that a greater variety of firms and consultants were used when the consultants were selected based on the HMO management's prior experience. However, the recommendations from the central and regional offices usually included the same consultants and/or firms. HEW has not developed an extensive list of qualified consultants, thus, HMO's have a relatively limited number available when selecting technical assistance. The Investigative Staff believes HEW should make a concerted effort to develop a broader, more comprehensive list of qualified private firms and consultants.

Outside Technical Assistance Hired by the Central Office

The central office staffs have been assisted in the reviews of complex and detailed grant, loan, and qualification applications through the use of consultants and experts hired primarily on a noncompetitive basis. In addition, three major contracts

have been competitively awarded by the central office to provide technical assistance considered necessary to the HMO program staff. The Investigative Staff reviewed the process through which these contracts were awarded and could find no irregularities in the methods used.

Irregularities Noted in Technical Assistance Administration at the Central Office

During the review, some irregularities in the practices followed by the central office in its use of technical assistance consultants were noted. Although an attempt was not made to determine to what extent or degree these problems existed, it was felt that they should be brought to the attention of the Committee.

On several occasions, HEW reimbursed consultants for their travel and expenses incurred on official business before officially appointing them to Government positions. The utilization of consultants in this manner is in direct conflict with the rules and regulations applicable to hiring consultants. In at least two instances, these consultants were not subsequently appointed to official status by HEW. Moreover, on two other occasions, HMO program officials convened task forces in Washington, D.C., without proper authorization. These groups were composed of several individuals who served on the task force without pay, but received travel and expenses from HMO program funds.

The Office of HMO Qualification and Compliance, which performs a regulatory function over HMO's, has utilized consultants and/or experts to assist in-house staffs conducting reviews of HMO applications and facilities. The Investigative Staff noted that several of the consultants and/or experts being used for this purpose were in positions where an appearance of conflict of interest existed. For example, one consultant still employed by a private firm, on his own time assisted that firm in preparing a proposal to HEW on a project related to the program area in which he was working. Although the Investigative Staff did not find specific examples of direct conflicts of interest, the opportunity and appearance of conflicts of interest clearly exist.

Employees are responsible for avoiding actions which might result in or create the appearance of

-- Giving preferential treatment to any organization or person,

-- Losing complete independence or impartiality of action,

-- Making a Government decision outside of official channels, or

x

-- Adversely affecting the public's confidence in the integrity of Government.

The Investigative Staff was informed that the basis for these hiring practices was the need for specialized abilities which may not have otherwise been readily available, however, it is not believed that this is adequate justification for the methods used to obtain the services of these individuals.

The Investigative Staff also found that funds appropriated for the HMO program had been improperly used to pay travel and expenses for Professional Standards Review Organization (PSRO) Council members in FY 1977. According to HEW officials, the HMO funds used for travel by the PSRO Council members were approved because of an administrative error.

In addition, at the time of the Investigative Staff's inquiry, the use of first-class travel for PSRO Council members was routinely approved by HEW. However, the HEW policy as stated in a "Travel Handbook" states that consideration must be given to use of less than first-class air accommodations when such accommodations are available. HEW should more rigorously enforce its own policy regarding this use of first-class travel.

Staff Travel

HMO program administration has required extensive travel by central office personnel to the regional offices and to developing and qualified HMO's.

The Investigative Staff reviewed a random number of trips made by certain program officials for the past 2 fiscal years. In general, documentation was available and confirmed the basis for the trips. However, documentation for some of the trips was not submitted directly by the individual traveler and only made reference to that person's presence. Also, that person's contribution or work accomplished was not documented. The Investigative Staff was advised that neither the Office of HMO Qualification and Compliance nor the Division of HMO's had any written policies which require individuals to report on the purposes for taking trips or work accomplished on the trips.

The Investigative Staff believes that conformance with Federal travel regulations and procedures should be strictly enforced to avoid the appearance or opportunity for nonessential travel. As a minimum, HEW should require that HMO travel from central office be justified. In addition, the establishment of internal control procedures within the HMO program should emphasize written documentation on the nature of travel, purpose and objectives to be achieved, and the work performed and results obtained.

Recommendations

To more effectively achieve the HMO legislative objectives and to improve overall management control of the program, the Investigative Staff recommends the Committee require the Secretary of HEW to initiate the following actions:

-- Regulations and guidelines for the HMO loan program and the qualification and compliance processes should be drafted and finalized immediately. If necessary, present qualification work should be suspended until these guidelines can be developed. The Investigative Staff believes that the longer the HMO program operates without guidelines, the more arbitrary and inconsistent will be the overall decisions made by the staff.

-- The new director of the Office of Health Maintenance Organizations should, as a priority, develop a definitive plan to ensure the more orderly transition of the HMO program from the grant through the qualification process and into the HMO operational stages.

-- Regional offices should be given larger and more clearly defined roles in the HMO program. The HMO central office should make every effort to acquire accountability over the regional offices' operations and should provide adequate guidelines, training, and technical assistance to regional office staffs.

-- The central office should be provided with qualified staff to properly administer the loan, qualification, and compliance aspects of the complex HMO program.

-- Responsibility for monitoring loan and loan guarantee recipients should be clearly defined and a monitoring program be implemented on a regular basis to protect the financial interests of the Federal Government.

-- A policy should be developed requiring the adequate documentation of all staff travel.

-- Audit policies should be established to eliminate:

(1) Inappropriate reimbursement and use of travel funds for consultants and task forces, and

(2) The hiring of consultants with appearances of conflicts of interest.

I. INTRODUCTION

A. Directive

By directive dated July 12, 1977, the Committee requested that an investigation be made of the Health Maintenance Organization (HMO) Program administered by the Department of Health, Education, and Welfare (HEW).

The investigation was to include the following:

-- A review of the relationship of the Office of HMO Qualification and Compliance in the Office of the Assistant Secretary and the Division of Health Maintenance Organizations in the Health Services Administration. Of particular concern was the appropriateness of this arrangement and its impact in carrying out the objectives of PL 93-222 and PL 94-460.

-- The extent to which HEW was complying with the legislative mandates of the HMO Assistance Act, particularly the provisions governing loans and loan guarantees.

-- A review of the timely processing of HMO qualification applications and the impact, if any, on HMO applicants of delays in this process.

-- The extent of monitoring HMO loan recipients to determine that the HMO is meeting its enrollment projections, controlling its costs and is generally meeting its growth assumptions in order to become self-supporting and ultimately repay the loan.

-- A review of staff travel for the Office of HMO Qualification and Compliance and the Division of Health Maintenance Organizations.

-- A review of how HEW has utilized over the last 4 years funds appropriated for HMO technical assistance contracts and the mechanisms employed for selecting contractors and consultants to provide the assistance.

B. Scope of Inquiry

The Investigative Staff interviewed officials with HMO program responsibilities at HEW headquarters in Washington, D.C., and Rockville, Maryland; and at three HEW regional offices--Chicago, Dallas, and San Francisco. The Office of General Counsel, Public Health Service was also contacted. Applicable legislation, regulations, policy, and guidelines, as well as prior General Accounting Office (GAO) and other agency reports, were also reviewed.

In addition, the Investigative Staff interviewed officials and reviewed pertinent documentation at the California State Health Agency in Sacramento and at developing and qualified HMO's in Englewood, Long Beach, Los Angeles, and San Jose, California; Chicago, Illinois; Portland, Oregon; Dallas and Houston, Texas.

The Investigative Staff also contacted an investigator from the Subcommittee on Permanent Investigations of the Senate Government Operations Committee who has been extensively involved in investigations of prepaid health plans throughout the country, with particular emphasis on the State of California. The thrust of the Senate Subcommittee investigation has been to ascertain how HMO's are structured and operating on a day-to-day basis under current State and Federal laws and regulations, rather than HEW's management of the program under the HMO Act of 1973, as amended.

It was ascertained that the Senate Subcommittee staff will issue a report early in 1978 addressing such issues as the corporate structure of some HMO's, the possibility for self-dealing and underutilization of medical services, the need to develop methodology to assess quality of care afforded by HMO's, the use of selective criteria by HMO's to screen out potential high utilizers of medical services, and other factors brought out during the Medicaid fraud hearings held by the Subcommittee in the spring of 1975. It will basically address the potential for fraud and abuse in the HMO program.

II. BACKGROUND

The Health Maintenance Organization (HMO) concept is not a recent innovation in the United States. The first prepaid health plan was established in Los Angeles in 1929 and currently there are approximately 165 such plans serving over 6 million enrollees. The HMO concept calls for the delivery of specified health services to the members of an HMO, either directly or through arrangements with others, in return for compensation at predetermined, prepaid rates. The prepayment approach differentiates the HMO from the more common fee-for-service concept whereby health care providers are reimbursed for each service provided.

In response to the rapid escalation of health care costs in this country, President Nixon in February 1971 announced in a health message to Congress the Administration's intention to stimulate the development of HMO's as an alternative health care delivery system intended to reduce the costs and enhance the quality of health care. HMO legislation was introduced in the Congress in early 1971, passed by the Senate in September 1972, but was not considered by the House before the end of the year. The legislation was reintroduced in both the House and Senate in 1973 and after extensive debate on the different House and Senate versions of the HMO legislation, a compromise bill was passed and became law on December 29, 1973--The Health Maintenance Organization Act of 1973 (PL 93-222).

PL 93-222 amended the Public Health Service Act and authorized HEW to establish a Federal demonstration program to develop alternatives to traditional forms of health care delivery and financing by assisting and encouraging the establishment and expansion of HMO's. The act authorized Federal financial assistance for the 5-year demonstration program consisting of grants and contracts to public or private nonprofit organizations for HMO feasibility studies and for planning and initial development costs, loans to public or private nonprofit organizations for initial operating assistance, and loan guarantees to non-Federal lenders on loans made to private profit making organizations for planning, initial development, and initial operating assistance for HMO's serving the medically underserved.

The act defines an HMO and its operating requirements in considerable detail, and among other things specifies the basic and supplemental health services to be provided the HMO member; the basis for fixing the rate of prepayment; the organizational structure of an HMO; and the requirement

for open enrollment periods during which individuals may join without restriction (such as preexisting medical conditions).

The act authorized $325 million in grants and loans for HMO development. Of this amount, $250 million constituted grants for feasibility studies and for the planning and development of HMO's, and $75 million to capitalize a loan fund to cover initial operating deficits of HMO's.

Dissatisfaction with the act and the slow progress in implementing the program led to the passage of the HMO Amendments of 1976 (PL 94-460), which was signed into law on October 8, 1976. PL 94-460 modified some restrictive elements in the HMO Act of 1973 which had been cited as reasons for the failure to implement the act as rapidly as had been expected.

Among other changes, the amendments reduced the services that HMO's are required to offer; exempted HMO's from the open enrollment provision until they have enrolled 50,000 members or until they have been in operation for 5 years, provided they did not incur a deficit in the most recent fiscal year; provided a grace period of 48 months for an established HMO to meet the requirement that its contracts be community rated; and changed the requirements for medical group practices, including a provision that medical groups would be required to provide at least 35 percent of their services, rather than a majority of their services, to HMO members.

Under the act, as amended, Federal financial support is available to HMO applicants in the form of grants, loans, and loan guarantees. The only requirement is that the group be a legal entity showing fiscal responsibility and the capability to carry out HMO development to comply with the HMO application requirements.

The amendments increased the grant limits for feasibility studies from $50,000 to $75,000, planning from $125,000 to $200,000, and from $1.0 million to $1.6 million for HMO expansion activities. The amendments extended the HMO program for 2 additional years through 1980, authorizing grants of $45 million for FY 1978, and $50 million for FY 1979. Loan and loan guarantee authority was extended through September 30, 1980--no loans can be made or guaranteed after that date.

Amounts authorized and appropriated follow:

Fiscal Year	Authorization 1/	Appropriation (millions) Total	Grants	Loans	Program Operations 4/	Positions 5/
1974 2/	$25	$60.7 3/	$25.0	$35	$0.7	100
1975	55	18.5	15.0	-	3.5	125
1976	40	18.6	15.0	-	3.6	129
1977	45	22.8	18.1	-	4.7	129
1978	45	26.2	21.1	-	5.1	138

1/ For grants and contracts.

2/ Because of late supplemental was available until June 30, 1975.

3/ Includes $35 million for loan revolving fund.

4/ Authorized under Section 301 of the Public Health Service Act.

5/ Includes all central and regional office personnel handling HMO grant, loan, and qualification activities.

HEW's HMO effort until December 1977 was implemented by two separate units within HEW and the 10 HEW regional offices. Developmental and loan assistance activities were centered within the Division of Health Maintenance Organizations, Bureau of Medical Services, Health Services Administration. Its program efforts were directed toward grants and contracts, technical assistance, monitoring and reporting, market development, and loan activities.

The Office of HMO Qualification and Compliance was located within the Office of Quality Standards, Office of the Assistant Secretary for Health and carried out qualification and continued regulation activities. The functions of this office include review and determination of qualification for HMO applicants in compliance with the HMO Act, continued regulation of qualified HMO's and implementation of the dual choice provisions of the HMO legislation.

The 10 regional offices serve as the primary point of contact for all HMO-related activity in their geographic areas.

Grant and Loan Programs

Grants have been used to support the formative phases of HMO growth and development and loans have been used to assist qualified HMO's during the early periods of actual operations.

Grants

HMO grant funding began in July 1974, initiating HEW's effort toward achievement of its legislatively mandated goal. HEW in its December 1976 Program Status Report stated this goal to be:

> "To demonstrate the extent to which the HMO approach to health care can be 'transplanted' to new environments, with new participants putting it into operation supported by Federal assistance as authorized in the HMO Act."

As of December 31, 1977, 170 organizations received 306 grant awards totaling approximately $62.7 million. Of these grantees, 35 had become qualified HMO's and 68 were still active in various stages of development although not all were still receiving grant funds. The remainder were defunct.

Briefly, grant funds provided under the act support the following phases of HMO development:

(a) Feasibility phase--during this phase, applicants consider factors such as the local need for an HMO, marketing of a plan, legal requirements, sources and extent of financial support, and structure of an HMO that best meets local conditions. This phase ends when a final decision is made concerning the feasibility of proceeding to establish an HMO.

(b) Planning phase--this phase entails expansion of the information identified in the previous stage and the formulation of detailed activities which must be put into effect. The planning stage ends when all activities necessary for successful development of a proposed HMO have been delineated.

(c) Initial development phase--this phase involves actual physical implementation of the work plan. It includes such activities as the legal establishment of the HMO, beginning enrollment and marketing, providing facilities, contracting with providers of health services, and employing needed staff. The development phase prepares the HMO for actual operation.

Loans

HMO loans and loan guarantees are used to finance the HMO's operational deficits during the period of initial operations. This phase is characterized by the actual delivery of health services. The operational HMO has completed its development and has begun to serve its membership in the intended manner.

HMO loan and loan guarantee assistance amounting to $71.4 million had been approved for 36 qualified HMO's as of December 31, 1977. These were composed of 40 direct loans to 34 HMO's totaling $69.1 million, and 2 loan guarantees amounting to $2.3 million.

III. RESPONSIBILITY FOR THE HMO PROGRAM HAS BEEN DIVIDED

Prior to a recent reorganization announced in the Federal Register on December 2, 1977, the administration of the HMO program had been divided between two different offices of HEW. The grant and loan functions were located in the Division of Health Maintenance Organizations in the Health Services Administration, while responsibility for the qualification and compliance functions was located in the Office of HMO Qualification and Compliance in the Office of the Assistant Secretary for Health. Until the new reorganization, no single organizational unit within HEW ever had responsibility for the entire HMO program. For the first 4 years of its existence, the program had been functionally organized within various HEW headquarters offices.

The regional operations of the HMO program have been conducted by the 10 HEW regional offices. Regional office responsibilities included assisting in the monitoring of and providing technical assistance to the HMO grant and loan projects. The Regional Health Administrators who are responsible for this program, as well as other health related programs, report directly to the Office of the Assistant Secretary for Health and are not accountable to the heads of either of the two offices in headquarters with responsibility for the HMO program.

A. Program Objectives

The act authorizes a program whose objective is to provide assistance and encouragement for the establishment and expansion of HMO's. This is to be accomplished by, among other things, supporting feasibility studies, planning and developmental activities, and initial operation of HMO's through grants to public and private nonprofit organizations, and loans and loan guarantees.

The Investigative Staff found that under the organizational structure that existed prior to the recent reorganization, the HMO program had not been able to carry out, in a timely and economical manner, the objectives of the HMO Act, as amended. The Investigative Staff found during its review that this organizational arrangement, among other things, had contributed to delays in HMO's receiving qualification, the expenditure of additional grant funds as a direct result of these delays in qualification, and had a negative impact in general on the progress of the HMO program.

B. Organizational Structure Has Impeded Progress of HMO Program

The Division of HMO's, in cooperation with the HMO staff in each HEW regional office, performed the developmental tasks of the program. This responsibility included the planning of HMO's by reviewing grant applications, funding acceptable projects, providing technical assistance, and monitoring and evaluating individual project performance. This division provided some of the same services for loan and loan guarantee applicants and recipients.

The Office of HMO Qualification and Compliance was the regulatory body of the HMO program. It was responsible for ascertaining that an applicant met the qualification requirements as set forth in the HMO Act of 1973, as amended, and for ongoing regulation to assure that these requirements continued to be met.

The potential for problems resulting from the separation of the developmental and regulatory functions was highlighted in a June 1977 memorandum from the Assistant Secretary for Planning and Evaluation to the Secretary. Among other things, this memorandum identified major problems in current policy and stated that:

> "HEW is responsible for both planning and qualifying HMOs, but these activities are badly coordinated and understaffed; issuance of regulations is slow, and compliance monitoring is virtually absent."

The Assistant Secretary listed other important issues and stated that the major barrier to the growth and development of HMO's currently is HEW's management of the program. He continued that:

> "The development function and qualification function are separated organizationally--The qualification function is in OASH; the development function is in HSA. There is little coordination between these two offices, with the unfortunate result that long delays occur between the granting of development funds to HMOs and qualification for loan eligibility."

This problem was further highlighted in a June 20, 1977, speech by Hale Champion, Under Secretary of Health, Education,

and Welfare, before the Group Health Association of America. He stated that:

> "We recognize that in HEW the grant program and the office of qualification have been hopelessly divided and that the resulting lack of cooperation has led to confusion and delay. We understand how important it is for a new HMO to have a smooth transition between the two offices."

In an August 1977 report entitled "Moving Ahead With HMO Development," a consultant to the Assistant Secretary for Health in HEW stated:

> "It is hardly a family secret that rivalry or even distrust characterizes the relationships between the two principal divisions involved at DHEW headquarters. In the discussions held with scores of persons in all sectors of the program, on no issue was there greater consensus among all parties: the urgent need for coordination of all components of the HMO program, if improvement is to be achieved."

The Investigative Staff discussed the lack of coordination between the Division of HMO's and the Office of HMO Qualification and Compliance with central and regional office officials. The officials agreed that a lack of coordination existed for various reasons and that this problem was causing undue hardships to the HMO program.

The Director, Office of HMO Qualification and Compliance, stated that he felt this problem was improving, but that the major reason for the two offices being unable to coordinate was philosophical. He felt that the differing objectives of the two groups--Division of HMO's to promote the development of HMO's and Office of HMO Qualification and Compliance to regulate HMO's--had caused friction between them. He acknowledged the need for the two groups to coordinate, cooperate, and develop uniform guidelines and standards.

The Investigative Staff believes that the organizational separation of the group responsible for qualification and compliance from the group responsible for the development of HMO's has been one of the primary reasons for the lack of success initially expected of the HMO program. Throughout the history of this program, there has been a continued lack of coordination between these two groups.

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This lack of coordination, among other factors, has caused adverse impacts on the program including:

-- A lack of central office direction and management because of communication and coordination difficulties between the two headquarters groups and between these groups and the regional offices.

-- A lack of uniform guidelines for the HMO program and the failure to develop a set of uniform criteria for evaluating the qualifications of an HMO.

-- Constant delays which confront the HMO's seeking to obtain qualification as they move from the developmental to the operational stage.

-- Acknowledgement that 100 percent of all applications submitted for qualification are found to be deficient.

These and other problems which the Investigative Staff has noted are discussed in detail in the following chapters of this report. These chapters describe how funding and staffing problems, in conjunction with the lack of coordination between the Division of HMO's, the Office of HMO Qualification and Compliance and the regional office staffs, have impacted on the ability of HEW to carry out the objectives of the HMO Act, as amended.

C. Administration of the HMO Program Reorganized

Under the December 2, 1977, reorganization, responsibility for the administration of the HMO program was consolidated into a new Office of Health Maintenance Organizations in the Office of Health Programs, Office of the Assistant Secretary for Health. This reorganization was effective immediately upon its announcement in the Federal Register.

Under this reorganization, the Deputy Assistant Secretary for Health Programs serves as the principal deputy to the Assistant Secretary for Health for, among other things: (1) matters concerning health standards, quality assurance, and HMO's; (2) developing national policies and objectives for the planning and initial development of HMO's; (3) assuring the continued compliance of HMO's with statutory and regulatory requirements of the HMO program; and (4) providing direction over the HMO loans assessment functions.

To assist the Deputy Assistant Secretary for Health Programs in accomplishing the above tasks will be the Office of HMO's. This office will have as its objectives to (1) implement and administer the grant, contract, and loan aspects of the HMO

Act and is HEW's advocate in efforts to improve the organization and delivery of health services by use of the HMO approach; (2) develop national policies and objectives for the planning and initial development of HMO's; (3) develop long- and short-range program goals and objectives; and (4) serve as the departmental focal point in the area of HMO qualification, ongoing regulation, and employer compliance efforts. To undertake these responsibilities, the Office of HMO's will consist of two divisions: the Division of HMO Development and the Division of HMO Qualification and Compliance.

The Division of HMO Development will (1) promote development of HMO's; (2) provide resources, through grants and contracts, to public or nonprofit private entities for the planning and initial development of HMO's; (3) make or guarantee loans to HMO's to cover certain operating expenses; (4) develop national policies and objectives; (5) provide technical assistance to HMO's, entities seeking HMO status and others concerned with HMO aspects of the health care system; (6) interpret program policies, regulations, guidelines, standards, and priorities; (7) develop long- and short-range program goals and objectives; and (8) provide leadership and direction for related legislative activities.

The Division of HMO Qualification and Compliance will have as its responsibility to (1) determine the qualification of entities seeking HMO qualification; (2) oversee the ongoing activities necessary to assure the continued compliance of HMO's with the statutory and regulatory requirements of the HMO program; (3) assure compliance with a mandatory offering of the HMO alternatives in employee health benefit plans; and (4) provide technical support to the Federal Government in the recommendation and preparation of legal actions against HMO's, entities claiming to qualify as HMO's, and employers considered not to be in compliance with the statutory and regulatory requirements.

D. Reorganization Does Not Include Role of Regional Offices

Although the recent reorganization did consolidate into one office the two headquarters groups responsible for HMO's, it did not, however, include provisions for (1) giving the 10 HEW regional offices more responsibility or (2) making them more accountable to the newly formed Office of HMO's.

In February 1976 GAO sent a memorandum to the Assistant Secretary for Health requesting information on why the regional offices had not been included in a November 1975 reorganization of the HMO program. The Assistant Secretary, responding in a February 24, 1976, memorandum stated that the regional offices were excluded because their restructuring was still under review.

A June 1976 draft report concerning HMO's, prepared for the Assistant Secretary for Health by his office, stated that:

> "There have been several attempts to open the question of regional organization but it is fair to say that it has received little real consideration. * * * At the present time, the Regional Office role is primarily providing technical assistance to grant and loan applicants, employers and other organizations interested in HMOs and making recommendations to the central office with respect to decisions to be made. In short, all formal authority remains in headquarters. From time to time, questions have been raised about this mode of operation."

On December 1, 1977, the Director, Office of Quality Standards, signed a memorandum concerning the regional office role in the HMO program. This memorandum defined the role of the regional offices with respect to grant projects, loan/loan guarantee applications, qualification, loan monitoring, compliance of qualified HMO's and employer compliance.

However, the Investigative Staff does not believe that the memorandum will have any significant impact on the regional offices because (1) it was signed by an official, who as of the December 2, 1977, reorganization, no longer has responsibility over any part of the HMO program; (2) it does not affect the extent of control the central office has over HMO activities in the regions; and (3) the memorandum was signed only one day before a regional office reorganization was announced in the Federal Register.

In addition, central office officials informed the Investigative Staff that guidelines would have to be issued to the regional offices in the areas of loan monitoring, compliance, and qualification, before the regional offices could take an active role in administering these parts of the HMO program.

The regional office reorganization announced in the Federal Register on December 2, 1977, places responsibility for HMO's in the Division of Health Care Systems within each region. The regional office will have responsibility to monitor, evaluate, and assist the development of federally assisted and privately funded prepaid delivery systems to maximize the number of such organizations which apply for and receive qualification as HMO's. However, the regional office role as stated in the Federal Register does not specifically include responsibility for such things as qualification, compliance of qualified HMO's, and employer compliance.

Conclusions

The Investigative Staff believes that there is an urgent need for coordination among all components of the HMO program if improvement in the effectiveness of the program is to be achieved. The recent consolidation of central office responsibility was an extremely important initial step. However, the Investigative Staff believes there is a need for this responsibility to be shared with the regional offices. The regional offices' HMO staff now report directly through the Regional Health Administrators to the Assistant Secretary for Health. The Investigative Staff believes the regional HMO staff should be more responsive and accountable to the head of the newly formed Office of HMO's. It is believed that such a consolidation would facilitate administration of the program and provide HMO qualification applicants and others with a better understanding of how the HMO process works as well as providing a single focal point for the entire HMO effort.

The Investigative Staff believes that there is a need for a strong administrator to head the new Office of HMO's. The functions of the two divisions within this office must be brought together if there is to be an integrated HMO program effort.

IV. QUALIFICATION APPLICATION PROCESSING IS LENGTHY AND HAS ADVERSE IMPACTS

Those HMO's which have been "qualified" by HEW as complying with the requirements of the HMO Act of 1973, as amended, and attendant regulations, may benefit from all the provisions of the act. These include the dual choice provisions (Section 1310) which provide a market access by requiring certain employers to include in any employees' health benefits plan the option of membership in a qualified HMO, and the eligibility to receive Federal financial assistance in the form of loans and loan guarantees. In addition, a qualified HMO has the benefit of increased status and credibility in the eyes of the public since "qualification" amounts to a Federal seal of approval.

An HMO seeking qualification must submit a qualification application which provides information on several principal aspects of the HMO's structure and function. This information includes such things as its legal status; marketing practices and enrollment goals; patterns of health care delivery, including methods of quality assurance; and sources of income and fiscal soundness. There are many subdivisions to each of these topics and formal documentation of some kind is required for narrative statements.

The qualification review process, according to program officials, should normally take 4 to 6 months from the time an application is received until a determination is made regarding qualification or denial. However, the Investigative Staff noted that only about 20 percent of the HMO's qualified as of December 19, 1977, had received a determination in that amount of time. Many of the qualified HMO's had been in the review process for a year or more.

The Investigative Staff has found that the delays in the qualification review process can be attributed to a number of factors including:

-- Lengthy qualification applications;

-- Understaffing of the regulatory function;

-- Shortage of necessary skills;

-- Lack of regulations, guidelines and policy; and

-- Impact of the HMO Amendments of 1976.

These delays have caused financial impacts on both HEW and the HMO's themselves.

A. Qualification Review Process

As previously noted, an HMO seeking qualification must submit an application containing detailed information with supporting documentation on various aspects of HMO structure and function. Applications are theoretically handled on a "first come-first serve" basis by HEW. Upon receipt, the application is logged in and assigned a case number, and the applicant is notified of the date of receipt.

The present application review process begins with a desk review, performed in the Office of HMO Qualification and Compliance. This desk review consists of completeness and marketing screens, followed by legal, marketing, financial, and medical care reviews.

The completeness and marketing screens were adopted in February 1977 and were intended to identify as early as possible in the review process those applications which were either incomplete or had major compliance problems. The completeness screen is a quantitative review to ascertain if all the elements contained in the application instructions have been addressed and to verify that all necessary documents have been filed with the application. The market screen is a quantitative review to ascertain that there are no gross deficiencies in the marketing plan and enrollment projections. The screening process is supposed to be completed within 30 days of receipt of the application. Applicants are notified of any deficiencies resulting from the completeness and marketing screens and are given a specified period of time to supply the missing information or correct the marketing deficiencies.

Those applications which pass the completeness and marketing screens are assigned to case officers for qualitative, in-depth legal, marketing, financial, and medical care reviews. The marketing plan desk reviews and some of the financial desk reviews are done by consultants under contract to HEW, while the legal and medical care desk reviews are generally done by in-house personnel. The result of the desk review is an evaluation letter to the applicant from the case officer outlining the deficiencies noted during the review. These deficiencies must be corrected by the applicant in a given period of time before a site visit will be scheduled.

Following receipt of a satisfactory response to the evaluation letter, a site visit to the applicant will be made to verify the information contained in the application and to address those issues raised as a result of the desk review which can only be resolved on site. The site visit is usually made by the case officer together with specialists in marketing, financial matters

and health care. Ordinarily, a regional office representative participates in the site visit as an observer.

Following the site visit, each specialty reviewer must complete a report on his or her area of concern, and the case officer thereafter prepares a report summarizing the individual specialty review reports, with a recommendation for qualification or denial. If there are any issues still to be resolved as a result of the site visit, the applicant is notified and must submit a satisfactory response before a final determination regarding qualification can be made.

B. Delays in Qualification Process

In discussions with program officials, the Investigative Staff ascertained that the qualification review process should usually take about 4 to 6 months from the time the application is received until a final determination as to qualification or denial is made by HEW. However, it was noted that this process was actually taking much longer.

The Investigative Staff studied the 49 HMO's qualified as of December 19, 1977, and graphed their progress from the date the application was received by HEW until they were qualified. It should be noted that the time from submission of application to qualification may be distorted in some instances, since several organizations withdrew their original applications for various reasons and resubmitted them at a later date. However, to be consistent and provide a general indication of the time involved, the original date of submission was used in each instance. The results of the Investigative Staff study showed the following:

Time From Submission of Application to Qualification (Months)	Number of HMO's	Percentage of Total
0-4	3	6.1
4-6	7	14.3
6-8	11	22.4
8-10	4	8.2
10-12	7	14.3
12-18	8	16.3
18-Over	9	18.4
	49	100.0 %

The above analysis shows that it took in excess of 6 months for about 80 percent of the HMO's to become qualified from the time of application.

The Investigative Staff also noted that of the 34 applications in process as of December 19, 1977, 21 (approximately 62%) had been in the process for over 6 months and of those, 11 (approximately 32%) had been in the process for over a year.

1. Lengthy Qualification Applications

The Investigative Staff noted that there is no prescribed format for applicants to use in submitting their qualification applications and no limit is placed on the length of responses to various items in the application. The result has been multi-volume applications containing several thousand pages being sent to HEW in boxes, cartons, and even footlockers. The sheer bulk of some applications overwhelms and frustrates some reviewers, and could be considered a deterrent factor in the review process.

In a November 15, 1976, memo to the Assistant Secretary for Health, the Director of the Office of Quality Standards noted that the qualification application review averaged approximately 650 person hours over a period of 6 to 9 months. Similar but less complex processes in the Civil Service Commission and Social Security Administration required about 200-300 person hours. Applications, which must be reviewed for the HMO's financial viability, marketing realism, adequacy of medical services, and legal requirements, are very complex and often contain 2,000 pages or more. In addition to a desk review of the application, a 2-3 day site visit is necessary to validate statements contained in the application and to obtain information that cannot be adequately described in the application.

The memo noted that the review process was quite subjective with no formal criteria or guidelines for use by the reviewers. As a result, the review process had not been efficient, objective, or consistent and was subject to considerable criticism. It was proposed, among other things, to revise the present application form to reduce the amount of material required, organize the information to better facilitate specialty reviews and focus questions on items that would facilitate desk reviews. In addition, it was proposed to improve the quality of new applications by developing step by step instructions for completing the applications and by establishing a formal communications system with the HMO community to explain changes in procedures and policies and to communicate other important announcements.

The Investigative Staff was informed that as of December 31, 1977, these proposals had not yet been accomplished. However, it has been proposed that the revision of the qualification application and applicant instructions be done by an outside consultant and that a Request for Proposal had been drafted to accomplish this work.

In addition to the bulk of some applications, deficiencies in various aspects of the submissions also contribute significantly to the length of the review process. The Investigative Staff was informed that virtually 100 percent of qualification applications submitted are deficient in some respect, which necessitates additional correspondence between HEW and applicants and further delays the qualification process.

The Investigative Staff believes the qualification application could and should be modified to permit HMO's to submit the required information in a more concise, abbreviated format, and at the same time be fully responsive to HEW's legislative and regulatory requirements for determining qualification.

2. Late Establishment of Office of HMO Qualification and Compliance and Subsequent Staffing Deficiencies

The qualification and continued regulation of HMO's were largely ignored by HEW for some time following passage of the HMO Act of 1973. Major emphasis was placed on promoting and developing HMO's through the grant and loan process, while the regulatory function was almost nonexistent. The Office of HMO Qualification and Compliance, which has the regulatory function, was not established until June 1975, some 18 months after passage of the act, and was functionally located in the Health Services Administration. Following passage of the HMO Amendments of 1976 in October of that year, the Office of HMO Qualification and Compliance activity was transferred to the Office of the Assistant Secretary for Health and assigned to the Office of Quality Standards. This office has been chronically understaffed since its establishment.

In a May 1977 memorandum, the Director of the Office of Quality Standards noted that in FY 1975, the regulatory component had 3 positions compared to 97 in the grant and loan component, and in FY 1977 the allocation was 21 to 106 positions respectively.

The same memorandum further noted the staffing situation:

> "* * * has thrown the program significantly out of balance. The grant and loan program funded developing HMOs without knowledge of how they were to be judged, because the HMOQ&C activity had insufficient resources to both develop adequate guidelines and process the large number of applications being received. Some grantees probably should never have been funded had qualification guidelines been known. On the other hand, some viable grantees have nearly gone

out of business because of the long wait for qualification."

The Director of the Office of HMO Qualification and Compliance advised the Investigative Staff that he could not start filling the 15 positions authorized in June 1975, until about December 1975 since position descriptions had to be completed and the jobs advertised. Prior to that time, he "gerrymandered" as best he could, utilizing personnel on unofficial detail from other sections in the Public Health Service. He stated that with the limited staff resources at the time, and the need to write regulations, develop the qualification application, and handle the requests for qualification submitted during that time, the qualification backlog began and has continued to the present time.

A GAO report issued in September 1976 (Factors That Impede Progress in Implementing the Health Maintenance Organization Act of 1973) noted that the Director of the Office of HMO Qualification and Compliance indicated in January 1976 that his office, which had been receiving about six qualification applications per month, had the staffing capacity to process only about two. Consequently, for each month of progress, his office was falling behind an additional 2 months.

In April 1976, the Director of the Office of HMO Qualification and Compliance was interviewed regarding the severity of his staffing problem. His response, as published in the Group Health and Welfare News in May 1976, was as follows:

"Very serious. The whole qualification process got started late compared to the grant program. There were fifty people working on grants before the first qualification person was hired. Thirteen are now working on qualification compared to 110 working on grants in Washington and the regional offices. We need 17 more people right now. A staff of 30 is really necessary to handle our present and projected workload through fiscal year 1977. Our staff shortages have resulted in a current backlog in excess of five man-years in terms of the effort required to review applications. By June 30, the backlog will likely exceed ten man-years for only our qualification responsibilities. Compliance, dual choice, and writing regulations are also time-consuming responsibilities of our office. Without relief of some sort, that level of backlog will continue through fiscal year 1977. The qualification process now generally takes

> about four to six months for an individual applicant. I would like to get to the point where the process takes three to four months and our backlog is eliminated. Cutting two months off the long end is about the best we can do. By comparison, it takes three months alone just to process grant applications."

According to HMO program officials, various attempts were made to reduce the mounting backlog of qualification applications, including assignment of several additional personnel; detailing six Division of HMO's loan program personnel for a 120-day period during June-October 1976; and detailing three regional office personnel for a 120-day period during January-May 1977. These measures temporarily alleviated the backlog problem and reduced the number of qualification applications in process by about 10.

However, although the backlog of applications was reduced to 32 as of December 31, 1977, a program official advised the Investigative Staff that the projected workload anticipated receipt of 16 additional applications during the remainder of FY 1977, 70 applications were projected for FY 1978, and 30 applications for FY 1979.

It was indicated that with current staffing constraints and a review requirement of approximately 100-man days per application, a deficit of 4,000 professional staff days and 1,000 secretarial support days was projected for the remainder of FY 1977; an additional deficit of 5,000 professional staff days and 1,500 secretarial support days for FY 1978; and an anticipated deficit in excess of 1,000 professional staff days and 450 secretarial support days for FY 1979.

The May 17, 1977, memo from the Director, Office of Quality Standards, noted that the projected application submissions for FY's 1977 and 1978 would include those from 43 HMO grant-supported organizations. It stated:

> "These organizations present a special problem because they must have qualification determination prior to the expiration of their initial development grant or they will go out of business. Should this situation occur, the Department will be in the position of promoting HMO development with one hand while putting them out of business with the other. Generally, a grant-supported HMO is unable to submit a responsive application more than three to five months prior to the completion of its development activities.

> Current applications now spend about nine months total in the review process. The nature of the problem is thus self-evident."

The May memo concluded by stating:

> "If the Department is to respond to the requirements of the HMO legislation, it must develop an adequate regulatory activity. * * * Substantial, additional staff resources must be committed to the HMOQ&C activity on a long-term basis. Short term solutions, such as contracting or detailing of personnel, are not a viable answer.
>
> "An additional 27 permanent, 6 temporary clerical, and 2 expert appointment positions are needed this fiscal year. Given our expectations regarding the increases in the number of requests for qualification and the number of HMOs that must be regulated, an additional 16 positions over the FY 1977 level will be required in FY 1978."

3. Shortage of Necessary Skills

Program officials advised the Investigative Staff that in addition to a shortage of staff, the requisite skills necessary to effectively implement the legislation and related regulations were lacking in the current staff. The dual choice and continuing regulation requirements have been described as very complex pieces of labor law legislation involving, among other things, State's rights and interrelationships between government and union groups. In addition, since the potential exists for court actions in both the qualification and compliance procedures, every facet of the HMO's corporate structure, benefit package, and contractual arrangements with medical care and other service providers must be consistent with the legislation and regulations. It was indicated that for these reasons, special skills were needed--corporate finance, legal, and medical service marketing.

According to program officials, the legal capability within the Office of HMO Qualification and Compliance is very limited and the financial and marketing capabilities have been acquired through contracts with consulting firms or through the use of the expert appointment mechanism.

Officials responsible for the program have not been able to recruit or hire the personnel with the necessary skills to perform these functions. When vacancies have been filled or

staff increases made, it has usually been done by transferring or detailing personnel with generalist backgrounds from other sections within the Public Health Service. These individuals have had no prior HMO experience and have not been afforded the required training because of the necessity to work on the qualification backlog, as well as carry out other qualification and compliance functions.

An HEW consultant hired because of the mounting qualification application backlog noted in August 1977 that:

> "The case officers principally responsible for the review of applications are not highly qualified, by training or experience, for their task. As a result they are very slow in their work. If they were more sophisticated, they could undoubtedly carry out the whole review process much more expeditiously."

4. Lack of Regulations and Guidelines

The regulations implementing the HMO Act of 1973 are contained in the Code of Federal Regulations; Title 42--Public Health; Chapter 1; Subchapter J--Health Care Delivery Systems; Part 110--Health Maintenance Organizations. HEW has established 9 subparts labeled A to I, and an additional section dealing with reimbursement of HMO's serving American Indians.

The time required for publishing the final regulations on these subparts ranged from about 10 months to 22 months, and regulations on one important subpart, dealing with continued regulation of HMO's, have never been published in final form. They were issued as a Notice of Proposed Rulemaking on September 17, 1976--almost 3 years after passage of the act.

The passage of the HMO Amendments of 1976 on October 8, 1976, gave rise to the need for HEW to publish new or revised regulations to implement the act, as amended. Interim regulations were published on June 8, 1977, which amended those previously issued by deleting all provisions that were inconsistent with the HMO Amendments of 1976 and by adding, as appropriate, the text of the statutory amendments.

HEW officials advised the Investigative Staff in December 1977 that the final regulations relating to some of the subparts were almost ready to be published in the Federal Register, while others were still being promulgated or going through the review process.

Program guidelines for some subparts of the regulations implementing the HMO Act of 1973 were printed in November 1975. These guidelines related to subparts B (Federal Financial Assistance: General); C (Grants for Feasibility Surveys); D (Grants and Loan Guarantees for Planning and for Initial Development Costs); E (Loans and Loan Guarantees for Initial Operating Costs); and G (Restrictive State Laws and Practices). These guidelines have never been revised or updated to take the HMO Amendments of 1976 into consideration, and guidelines for the other subparts have never been issued.

The "Guide to Conducting an HMO Feasibility Study," which is furnished to entities contemplating the establishment of an HMO, was prepared in 1973, prior to the passage of the Act. According to one program official, this "Feasibility Guide" is outdated, does not address what constitutes an HMO, and is in need of revision and updating.

As noted in the September 3, 1976, GAO report, the HMO Act of 1973 could not be fully implemented or enforced until HEW published regulations in the Federal Register and issued administrative guidelines to program participants. The GAO report concluded that the delay in issuing final regulations and guidelines to implement specific provisions of the act was a hindrance to organizations seeking to become Federally qualified HMO's.

Further, in a June 17, 1976, draft report concerning HMO's prepared for the Assistant Secretary for Health by his office, it was stated:

> "Guidelines have not been issued for Part A and their absence has been quite harmful. Since the rules of the game are not clear an HMO does not at this point have a good understanding of what it must do to qualify. Each HMO is subjected to a 'try us' obstacle course. Recognizing the complexity of the subject it should have been possible to produce a set of guidelines."

In limited contacts with HMO officials and HEW regional office personnel, the Investigative Staff heard the same story again and again, almost without exception--no one knew what had to be done to get an HMO qualified. No guidelines, criteria, policy decisions, or standards had been developed or issued to assist the HMO's in their qualification efforts, or to permit regional office staff to give adequate guidance and assistance to HMO's in the process. The resultant delays in obtaining qualification have placed increased financial

burdens on HMO's because of the additional time required to respond to various deficiencies in the qualification applications.

According to HEW officials, the purpose of the HMO grant activities--from feasibility to planning to initial development--is to prepare and assist the HMO for qualification. Yet, the Investigative Staff was advised that virtually 100 percent of the qualification applications submitted were deficient in some aspect or other. Personnel involved in the grant activities in both the central and regional offices advised the Investigative Staff they are frustrated in their efforts to assist HMO's to prepare for qualification since they do not know what is or isn't qualifiable.

The Director of the Office of HMO Qualification and Compliance acknowledged the need for a common set of standards, guidelines, and policies, but attributed the failure to promulgate and issue such criteria to the lack of staff and demands on their time due to the backlog of qualification applications. In September 1976, he proposed that a notice be placed in the Federal Register announcing a moratorium on new qualification applications effective with the date of publication, to last until March 31, 1977. It was planned to reduce the current backlog of applications during the moratorium as well as modify existing procedures for submitting and reviewing applications to permit more timely review and determination of future applications. His recommendation was not adopted or implemented.

An HEW consultant hired because of the mounting qualification application backlog reported in August 1977 that:

> "The speed of the review process would undoubtedly be expedited if case officers had available a manual of 'acceptable responses'--or a set of standards--by which which to evaluate all applications. Strangely, after three years, such standards or criteria * * * have not been prepared. The Head of the DHMOQ&C explains that he and his staff have been 'too busy reviewing applications' to make such a compilation * * * some criteria must be applied by case-officers and technical consultants, to approve an application. * * * Such documentation would be of great assistance to all application-reviewers, not to mention assuring consistency in the review of various applications by different reviewers."

5. Delays Caused by HMO Amendments of 1976

The HMO Amendments of 1976 (PL 94-460), which were signed into law on October 8, 1976, among other things, prohibited payment of Federal matching funds under the Medicaid program to any State for services provided under a risk-based contract with an HMO, unless the HMO was qualified by HEW as meeting the requirements of the HMO Act, or was specifically exempted from the requirements of the act. The amendments also permitted States to issue a "provisional qualification" to HMO's who submitted an application for qualification to HEW 90 days prior to the expiration of their Medicaid contracts, if a qualification determination was not made by HEW within that time.

According to program officials, many HMO's with such Medicaid contracts had not previously sought qualification. As a result, these HMO's were required to submit qualification applications within the specified time period to have their contracts renewed. Since the amendments were passed in October 1976 and many of these contracts were due for renewal in the first quarter of 1977, there was a large influx of applications within a short time. The number of applications received by HEW almost doubled, further aggravating an already severe backlog and added to the already lengthy delays in the qualification process.

C. Impact of Delays

The Investigative Staff noted that the previously described delays in the qualification review process required the expenditure of additional Federal funds to keep some HMO's active until a qualification determination could be made.

Grant supported organizations present a special problem in the qualification process because they must have a qualification determination prior to the expiration of their initial development grant or it is likely they will go out of business. According to program officials, a grant supported HMO is generally unable to submit a responsive qualification application sooner than 3 to 5 months prior to the completion of its development activities.

However, because of the excessive delays being experienced, applications spend a far longer time than that in the review process. As a result, HEW has made additional funds available to these impacted HMO's to keep them afloat until a qualification determination can be made.

The Investigative Staff ascertained that during the period from July 1, 1974, to December 31, 1977, supplemental grant

awards totaling approximately $4 million were made to 19 HMO's affected by the delays in the qualification review process.

The Investigative Staff believes that a more expeditious review process must be developed for the qualification applications to prevent the further needless expenditure of such large sums of Federal funds.

While the impact of these delays on other HMO's could not generally be quantified, the Investigative Staff identified one instance where a severe financial loss was suffered as a direct result of HEW's failure to act on the qualification application in a timely manner.

In this instance, an HMO in California submitted its application on August 4, 1976. As previously indicated, the HMO Amendments of 1976, which required an HEW qualification determination prior to renewal of Medicaid contracts with the State, were signed into law on October 8, 1976. This HMO's Medicaid contract was due to expire on March 31, 1977--almost 8 months from the date the application was received by HEW.

Notwithstanding the timeliness of the application submission, a qualification determination was not made by HEW by the time this Medicaid contract expired, and as a result, the State did not renew this contract. The Investigative Staff was informed by California Department of Health (DOH) officials that this HMO was licensed in the State and while it did have some problems, corrective measures could be taken. DOH officials further stated that renewal of the Medicaid contract would have been recommended by DOH had HEW made a timely qualification determination.

Officials from this HMO advised the Investigative Staff that loss of the Medicaid contract led, in turn, to a determination by the Social Security Administration that the HMO was no longer a qualified prepaid contractor for Medicare purposes and terminated its contract with the HMO in May 1977. The loss of these contracts meant the loss of about $250,000 per month in revenues and forced the HMO to reduce its professional and administrative staff and close medical facilities.

In citing this example, the Investigative Staff is not judging the relative merits of whether or not the HMO should have been qualified by HEW. However, the fact remains that if appropriate attention had been given to the qualification application, whatever deficiencies existed could probably have been corrected so as to permit renewal of the Medicaid contract by the State.

The Investigative Staff noted during its review of some HMO files, particularly in the case of HMO's in California, that it

appeared that some applications were handled in a more expeditious manner than others.

Program officials advised that the bulk of qualification applications received by HEW as a result of the amendments were from HMO's in California. HMO's in other States either did not submit applications or modified their Medicaid contracts with the State from risk-based to cost-based contracts and did not have to seek qualification. In addition, some States utilized the provisional qualification mechanism authorized by the amendments.

The California State Department of Health initially notified the affected HMO's on October 28, 1976, that it would consider provisional qualification. However, on November 10, 1976, the prepaid plans were notified that the State Health and Welfare Secretary had decided not to grant provisional qualification as allowed under the HMO Amendments. The reasons given for the decision were: (1) concern about the Federal Government not sharing in the financial participation during the period of provisional qualification, and (2) the technical ability and time required to make determinations were not available to the State to ensure that it would contract with plans that could reasonably be expected to meet HMO qualifications.

Finally, on January 28, 1977, after numerous meetings between HEW program officials and representatives from the State of California, the DOH notified the prepaid plans that the situation had changed and that the State would again consider provisional qualification. This was due to (1) HEW assurances that they would share in the financial participation if the State granted a provisional contract, even if a final qualification decision turned out to be negative and (2) HEW had developed a process to immediately screen out nonqualified plans and determine those plans with a high probability of becoming qualified.

The Medicaid contracts of many of the HMO's in California which submitted qualification applications were due to expire in the first quarter of 1977 and it was felt by HEW that many of these HMO's might go out of business if their contracts were not renewed. According to program officials, this meant that HEW had to make qualification determinations on approximately 16 HMO's in a very short time.

The Investigative Staff was advised that given the shortage of staff, the already unacceptable delays in the review process, the number of applications to be reviewed, and the short time in which to accomplish these reviews, it was apparent to program officials that not all the applications could be reviewed for a qualification determination in the required time. Therefore, HEW's efforts were concentrated on HMO's serving the greatest number of Medicaid enrollees. Several program officials felt

these actions were warranted because the entire HMO program would have suffered a serious setback if some plans--including those with enrollments of over 100,000 enrollees--had "gone down the tube."

In the opinion of the Investigative Staff, a regulatory function such as that of the Office of HMO Qualification and Compliance, requires that equal, impartial, and objective consideration be afforded to each entity to be regulated, regardless of size or other considerations. In the absence of such impartiality, the entire function loses credibility and stature with those whom it seeks to regulate and defeats the very purpose of the function.

V. LOAN AND LOAN GUARANTEE PROGRAMS

The HMO Act of 1973, as amended, provides for loans and loan guarantees to qualified HMO's requiring financing for planning, initial development and initial operating deficits (the amount by which operating costs exceed revenues in the first 60 months of operation). Applicants for loans and loan guarantees must demonstrate an inability to obtain financial assistance from other sources to meet initial operating losses before receiving Federal financial assistance and it is required that the recipient be fiscally sound to repay the loan.

Until the December 1977 reorganization of the HMO program, responsibility for the loan and loan guarantee function was vested in the Loan Branch of the Division of HMO's. Loan and loan guarantee recipients must be monitored to determine that they will become self-sufficient within the loan period to repay the loan. The responsibility for this monitoring function has been divided between the Loan Branch and the Compliance Branch of the Office of HMO Qualification and Compliance.

In any fiscal year, the amount disbursed to an HMO under the loan and loan guarantee function may not exceed $1,000,000 and the maximum loan amount cannot exceed $2,500,000.

As of December 31, 1977, a total of 40 direct loans totaling $69.1 million had been approved for 34 qualified HMO's (some received more than one loan). In addition, loan guarantees were approved for two HMO's amounting to $2.3 million.

The Investigative Staff has found that the loan and loan guarantee function is hampered by the lack of a uniform policy and procedure for the loan program and a shortage of qualified personnel to perform the function. In addition, responsibility for monitoring loan recipients to determine that they will become self-sufficient within the loan period and able to repay the loan has been divided between the Loan and Compliance Branches. The result has been that very little monitoring of loan recipients is being done.

A. Lack of Uniform Policy for Loan and Loan Guarantee Program

The Loan Branch of the Division of HMO's has the primary function of making direct loans to qualified HMO's for initial operations and significant expansion to cover operating deficits for up to 60 months. The branch also makes loan guarantees to profit and nonprofit entities for initial operations--the difference between this and a direct loan is that the interest rate may vary since the loan is made by a private lender.

Other functions of the branch include developing and implementing loan program policies and procedures, including those for application review and loan award; evaluating data submitted by applicants for loans and loan guarantees and making recommendations whether loans and loan guarantees should be awarded; and monitoring all supported loan and loan guarantee projects to assure compliance with terms of the loan and loan guarantee agreements.

The Investigative Staff ascertained that the Loan Branch had not developed a formal loan policy manual and the loan application documents have not been updated to include revisions occasioned by the Amendments of 1976. Standards and criteria are not presently available to objectively and uniformly evaluate loan applications. A loan program official advised the Investigative Staff that due to the severe shortage of staff and his preoccupation with reviewing and processing current loan requests as well as assisting some loan recipients who are experiencing financial problems, he has not been able to devote the time necessary to write policy. However, he noted that preparation of new operating documents for the Loan Branch is in process and work is progressing on a draft loan policy manual. In addition, revisions are being made in the loan application kit to bring it up to date. He is hopeful this will all be accomplished in the near future.

One of the issues to be addressed in the revised operating documents is the loan drawdown schedule. The Investigative Staff ascertained that some HMO's were drawing down loan funds during periods when no deficits were incurred, and accelerating payments of current debts or establishing reserves with these funds. Under current policy, the drawdown cannot be postponed during periods when deficits are not incurred and then increased by that amount should a subsequent deficit be incurred. Any amount not drawn down as scheduled is not longer available to the HMO.

This practice seemed to subvert the legislative mandate that loan funds be used only for operating deficits and not to establish reserves or accelerate payment of current obligations.

The loan program official informed the Investigative Staff that the proposed revisions to the regulations will enable HMO's to defer the drawdown of funds in non-deficit periods and still have the use of those amounts should it suffer subsequent periods of deficit operations.

In the September 3, 1976, report GAO noted that:

"HEW has not developed uniform policies for administering and monitoring its loan and loan guarantee programs, including HMO activities. Loan applications were handled case by case, with guidance or policy decisions being sought as issues arose.

"A program staff official responsible for HMO loan review * * * noted in January 1976 that the only Department loan policies are based on a series of memorandums and his personal knowledge. No formal HEW policy manual for loan programs comparable to the one for grant activity exists. The closest thing to such a document is the HMO loan application kit instructions, which the official considered to be a draft document needing revision.

"Lack of a firm, uniform loan policy for HMOs is serious because the relationship between the HMO loan-loan guarantee program and the HMO qualification process is symbiotic. That is, for an HMO to receive a loan, it must operate as a qualified HMO; but to become qualified, it must be fiscally sound."

The Loan Branch official stated that some loan recipients might default on their loans. In his opinion, the risk rating of loans made to HMO's ranged from "bad to very bad" since under the legislation, loans and loan guarantees may be approved only for those applicants who demonstrate a need for Federal assistance. As part of the loan application, this need must be demonstrated by submission of verification, from at least two lending institutions, that funds in whole or in part in the amount requested have been denied, or that funds are available only at an interest rate substantially in excess of that offered by the loan or loan guarantee program. In effect, any project that could secure a commercial loan couldn't be funded under the legislation.

In view of this requirement, the loan official felt there was limited assurance that the loans will be repaid. He emphasized the point that the HMO Act provided for a demonstration program and that HMO's are risky, competitive businesses which have to be sold in the marketplace. He believes it is HEW's task to try and select those organizations which it feels to have the best chance to succeed and there is no way to insure 100 percent success.

The Investigative Staff believes that the lack of formal uniform loan policy and guidelines could result in the granting of loans to organizations which are not financially viable with

resultant defaults on the loans. The Investigative Staff realizes there are risks involved in making loans to HMO's and believes that definitive written loan policies and guidelines must be developed and utilized in order to reduce the risks related to the making of these loans.

B. Shortage of Qualified Personnel in Loan Program

Various administrative changes within HEW have almost completely stripped the Loan Branch of its ability to effectively carry out its functional responsibilities. The loan program functions were originally assigned to a division within the Bureau of Community Health Services in the Health Services Administration (HSA). In November 1975 they were consolidated with the grant functions into the Division of HMO's in the Bureau of Medical Services, HSA.

Initially, the Loan Branch and the Office of HMO Qualification and Compliance did separate, independent marketing and financial reviews of HMO's. Since the HEW staff did not possess the expertise in these areas, and to consolidate the review process to some extent, two contracts were awarded to outside consulting firms in July 1975 to do the marketing and financial reviews for both groups. However, the loan staff continued to review the financial plans submitted by HMO's in conjunction with the loan application to determine if they could reasonably expect to become self-sufficient and begin repaying the loan in the time prescribed by the legislation.

At that time, a separate loan application was usually submitted concurrent with the qualification application and had to provide statements which described in detail the applicant's adequate accomplishment of feasibility survey, planning, and development activities and the HMO's management capability. Detailed information was required on the HMO's marketing plan and enrollment forecasts and experience, as well as a narrative statement describing all existing or planned provider contracts, including copies of all executed contracts and all facilities to be used in the delivery of health services. The regulations outlined the required financial information to be submitted, in addition to evidence that any certificate of need required under State law for the operation of the HMO had been obtained by the applicant.

Then in June 1976, the entire Loan Branch, consisting of 5 professional and 1 support personnel, was detailed for a period of 120 days to the Office of HMO Qualification and Compliance, with the intent of effecting permanent transfers during the detail. Thereafter, it was not required that a separate loan application be submitted and the financial data furnished in the qualification application was utilized in making a determination of fiscal viability.

As the HMO Amendments of 1976 proceeded toward approval, containing the provision that all elements of the program except qualification and compliance functions be administered by a single agency head, it was determined that the loan program should go back to the Division of HMO's.

In October 1976, the Loan Branch detail to Office of HMO Qualification and Compliance ended, but since arrangements had been made for the Loan Branch staff to complete their primary tasks assigned during the detail, they could not be utilized for Loan Branch functions for several months. Just as they were finishing these assignments, the entire staff, except for the chief assistant, was transferred to the Office of HMO Qualification and Compliance in January 1977 and new staff had to be obtained and trained for the loan program.

The Loan Branch now has only four of the six authorized positions filled on a permanent basis to manage a national loan program. One position is vacant and one is being filled temporarily by a person on detail from another section in the Division of HMO's. The branch has limited financial analysis capability, since only two persons in the branch have the background and experience to do financial reviews. In addition, the very nature of the loan function calls for legal and accounting expertise, both of which are lacking not only in the Loan Branch, but throughout the HMO program of HEW.

Under current procedures, the financial viability determination is made by the Office of HMO Qualification and Compliance, while the Loan Branch reviews the financial plan with respect to the legal, statutory, and program limitations placed on the HMO under the loan policy dictated by the legislation, i.e., cannot exceed $1,000,000 in any fiscal year, cannot be used for capital expenditures, etc.

Since the requisite skills for determination of financial viability are also lacking in the Office of HMO Qualification and Compliance and the contracts for the marketing and financial reviews have not been renewed, these reviews are done primarily by consultants obtained through purchase order or the expert appointment mechanism.

The Investigative Staff believes that sufficient qualified personnel are needed to adequately manage the various aspects of the loan program. Expertise is needed to adequately assess the financial viability of HMO loan recipients so as to minimize the potential for loan defaults which would adversely impact the financial interests of the United States.

C. Divided Responsibility for Loan Monitoring

HMO loan and loan guarantee recipients must be monitored on a continuing basis to determine if they are meeting enrollment projections, controlling costs, and generally meeting growth assumptions in order to become self-supporting and ultimately repay the loan. The Investigative Staff found that responsibility for this function is not clearly defined or formally delegated, and is divided between the Loan Branch and the Compliance Branch of the Office of HMO Qualification and Compliance.

1. Loan Branch Monitoring Activities

The Loan Branch's responsibility is to assure compliance with the terms of the loan and loan guarantee agreements. The monitoring of this function has consisted primarily of reviewing monthly and quarterly reports, as well as annual independently audited financial statements submitted by HMO's. These reports are considered by HEW to be good indicators of an HMO's progress toward achieving success or failure in the marketplace. They are also said to provide a means of checking if the HMO is properly administering the loan funds in accordance with the agreements made with HEW.

The Chief of the Loan Branch advised the Investigative Staff that the need to monitor HMO loan recipients to determine their progress toward achieving fiscal solvency so as to ultimately repay the loan, had long been recognized. He assumed his branch had that function and responsibility, although no formal delegation of this authority has been made. He acknowledged that little monitoring of HMO's has been done because of the limited staff resources available.

This program official acknowledged that few site visits had been made by the Loan Branch--only 5 to his knowledge--and agreed with the Investigative Staff's observation that such visits are necessary to verify the accuracy of information reported by the HMO's. He indicated that a site visit should be made about 6 months after the loan is closed and then on an annual basis thereafter. However, because of the shortage of staff and the continuing requirement to review loan requests, handle loan closings, and develop loan policy and standards, the monitoring aspect has been sadly neglected.

2. Compliance Branch Monitoring Activities

Qualified HMO's, including those which have received loans and loan guarantees, must be monitored on a continuing basis to ensure they remain in compliance with the legislative and regulatory requirements of the HMO Act. An integral part of

this function is assessing the financial soundness of HMO's to determine their potential for success in the marketplace. Additionally, it has been shown that the HMO format encourages abuse through "self-dealing" by doctors, rejection of chronically ill patients, and cutting quality corners. There have been inferior prepaid plans which have provided low-quality care, engaged in deceptive marketing practices, and been guilty of fraud and abuse. All these factors directly affect the security of outstanding Federal HMO loans and loan guarantees and, for this reason, must be monitored vigorously.

These functions are the responsibility of the Compliance Branch of the Office of HMO Qualification and Compliance, which was administratively created in January 1977 by informally separating the qualification and compliance functions within that Office. As previously indicated, the monitoring responsibility related to financial viability is shared with the Loan Branch of the Division of HMO's.

According to program officials, monitoring of HMO's operational and financial activities has been limited and largely superficial. To date, monitoring performed has been primarily on a "crisis management" or "management by reaction" basis, in response to financial problems experienced by some HMO's which had reached serious proportions. The Chief of the Compliance Branch advised that his staff spends most of their time "fighting the forest fires" in the HMO universe, while giving scant attention to the other qualified HMO's where similar problems have not yet surfaced. At the present time, the "monitoring" function consists primarily of reviewing periodic reports, including an annual audited financial report, which are submitted by the HMO's and purportedly illustrate their financial condition and progress in the market place. However, it was acknowledged by program officials that the data submitted by the HMO's was not verified or authenticated by HEW and the possibility existed of inaccurate or deceptive data being submitted.

The Director of the Office of HMO Qualification and Compliance advised that inadequate staff resources and the need to utilize available staff to control the serious qualification application backlog had led to the compliance function being virtually ignored. He indicated that monitoring procedures and scope of work had been identified, but had not yet been implemented.

The Chief of the Compliance Branch advised that he has four compliance officers in addition to himself, and three support personnel. In a study done by his Branch of the workload requirements, it was concluded that each compliance officer could realistically handle about four HMO's. As of December 31, 1977, there were 51 qualified HMO's which is indicative of the problem facing his Branch.

Additionally, no procedures, guidelines or criteria have been established to implement the compliance function. According to the Branch Chief, definitional requirements, which should be addressed in guidelines for Subpart A of the regulations, are crucial to the development of the compliance function. However, these guidelines have not yet been promulgated and issued. Without standards by which to measure the performance of the HMO, the compliance function cannot be properly and objectively initiated.

In a November 1976 memorandum to the Assistant Secretary for Health, the Director of the Office of Quality Standards acknowledged that:

> "Because of the backlog and lack of staff, there was no operating compliance function within OHMOQ&C."

Again in a May 1977 memorandum, the Director of the Office of Quality Standards noted that:

> "The OHMOQ&C workload increases with each HMO qualified because a qualified HMO must be regulated on a continuing basis. Currently, no formal compliance system exists * * *."

The problem of the Office of HMO Qualification and Compliance was succinctly stated in the May 17, 1977 memorandum, as follows:

> "The present situation can best be summarized as an imminent disaster. The qualification application backlog that existed in October 1976 has increased. The creation of a separate Compliance Branch has served to document the compliance deficit developed over the prior two and one-half years. This deficit is the logical product of devoting nearly all resources on the immediate problems of qualification and neglecting the qualified HMOs. In addition, Administrative Hearings will consume enormous portions of staff time, while new implementing regulations and associated guidelines are urgently needed by the amendments of 1976. In short, the years of understaffing the critical functions

of HMOQ&C are now about to surface as a major embarrassment for the Department."

The Investigative Staff believes the responsibility for monitoring HMO's should be clearly delineated and implemented on a regular basis to protect the financial interests of the Federal Government. In addition, a regular monitoring function is essential to minimize the potential for fraud and abuse which exists in the HMO concept of health care delivery.

VI. TECHNICAL ASSISTANCE

Technical assistance is an important aspect of the HMO program for HEW staff in the central office and regional offices, as well as individuals in HMO's engaged in organizational development and operations. Technical assistance is often required in specialized areas such as accounting and financial management systems, actuarial work, marketing of the benefit package, medical care delivery and management information systems.

Several methods are used to provide technical assistance to an HMO, including use of central office staff or consultants employed by the central office; regional personnel; and consultants hired by the HMO's for those services which they do not have the capability to perform.

Also, the Investigative Staff, as part of its review, evaluated the methods used by the HMO program people to hire consultants and experts, and award contracts when technical assistance is needed by the central office. It was noted that there was a general lack of policy and guidelines for acquiring technical assistance. Only for the awarding of large contracts was any selection criteria followed.

A. Technical Assistance Provided to HMO's

The provision of technical assistance to HMO's is imperative because often they do not have the requisite skills to develop and operate a successful organization. Formal definitive policies or criteria have not been developed for use by central and regional office staffs providing technical assistance to HMO's, nor have guidelines been issued for HMO's to follow when technical assistance is not available from the HEW staff.

1. Technical Assistance Available From Central Office

The technical assistance available in the central office is provided by the Division of HMO's through the division's Technical Assistance Branch. This branch has many responsibilities including:

-- The provision of national leadership and guidance in the form of technical expertise to Division of HMO supported projects and to HMO's developed through non-Federal resources.

-- The coordination and provision of technical assistance to the Division of HMO's staff, regional office staff,

and to developing and operating HMO's through direct staff assistance or the use of contract consultant resources.

-- The development of regulations, guidelines and necessary guides, manuals and other materials in the specialty fields for use by individual projects and program staff, and

-- The provision or arrangement of necessary training of the Division of HMO's staff and regional office staff in the technical aspects of HMO's.

The Technical Assistance Branch provides these services with a small staff supplemented by consultants whenever funds and people are available. In addition, two contracts were awarded in early fiscal year 1976 in the areas of financial planning and marketing. These contractors provided the branch with expertise to help in processing applications for grants, analyzing financial and marketing projections, and provided expert advice to the central office. Also, a contract was awarded for the purpose of monitoring and analyzing legislative and other legal actions affecting HMO's. These three contracts are discussed in detail later in this chapter.

The Investigative Staff was informed by agency officials that a lack of staffing is the primary problem of the Technical Assistance Branch. To perform the functions outlined above, this branch has had only three or four professional staff members, including a marketing expert on a temporary basis. During FY 1977 the entire Division of HMO's spent about $34,000 on consultants, including $21,750 for the marketing expert assigned to the Technical Assistance Branch. During a recent 1-year period this branch was able to perform only 30 technical assistance site visits to 21 developing and qualified HMO's.

The Investigative Staff was advised that since the passage of the HMO Act no comprehensive training has been provided to HMO staff in the regional offices. The only training of any significance was provided during CY 1976 to grantees and HEW/HMO regional office staff. The training consisted of two separate courses; one on the marketing viability of an HMO and one on the development and review of a financial plan for an HMO. The marketing course was 2 to 3 days in length and the financial course was 1 1/2 to 2 days in length.

The Investigative Staff believes that inadequate staffing has been the cause for the central office's inability to provide sufficient technical assistance to HMO's and adequate training to the regional office staff. As a result, the ability of the regional offices to provide quality technical assistance to

HMO's has been severely impaired. These factors have contributed significantly to the HMO's problems in preparing satisfactory qualification applications and added to the delays in the qualification process.

2. Technical Assistance Available From the Regional Offices

Of primary importance is day-to-day contact with HMO developers from the staff of the 10 HEW regional offices. The regional office staff provides onsite technical assistance to projects during their developmental phases. Periodic visits are made to projects as part of a regular monitoring program and coincident with reviews of applications for grant assistance. More specifically, this technical assistance has as its purpose to assist each grantee to become a qualified HMO, to achieve fiscal viability, and to attain the maximum enrollment possible in its service area.

In February 1974, fifty positions were allocated to the regional HMO program by the Administrator of the Health Services Administration. Because of the highly technical nature of this program, emphasis was placed on the need for specialists in the areas of marketing, actuarial analysis, and financial management. According to administration officials, these skills were not adequately present in the regional offices.

In early 1977 questions were raised by the central office administration concerning the presence of this technical capacity in the regional HMO branch staffs and what their future needs might be. As a result, the regional offices were requested to provide information regarding their technical capabilities.

In an August 15, 1977, memorandum, the Director, Office of Regional Program Coordination, provided an analysis of the regional office survey. This analysis pointed to considerable inconsistency in the perception of the level of training, experience, and technical capability in these specialized areas in the regional offices. However, it was believed that the regional offices generally had the required technical abilities in varying degrees. The report concluded that the regional responses pointed out the need for a number of new skills that would be helpful in the implementation of the program both currently and in the future.

However, in an August 22, 1977 memorandum, a program official in the central office commented on the analysis from the Director, Office of Regional Program Coordination. The memorandum stated that:

"If the Regional Offices (RO's) have the technical capacity they reported in the survey, then it is apparent that the expertise is not being applied in the technical assistance the RO's are providing to the grantees in the development of applications for HMO qualification."

The memorandum further stated:

"I do not believe that the regions in general have sufficient technical expertise in marketing and finance. If they did then the quality of the applications received in the Central Office should be much better. All we have to do to validate this conclusion is to cite the deficiencies in the evaluation letters to applicants in the areas of marketing and finance."

The program official based his position on an analysis completed in late 1976 by the Technical Assistance Branch which listed the reasons for HMO's being delayed or denied qualification by the Office of HMO Qualification and Compliance. The following chart identifies the rate at which deficiencies were noted in a particular area in the deficiency letters sent to qualification applicants.

Classification	Frequency of Deficiency In Letters
Marketing	92 %
Legal	70 %
Financial	78 %
Medical Care Component	92 %
Plan Management	50 %

The report noted that if the marketing and financial areas were considered as one, deficiencies would have occurred in 100 percent of the applications reviewed. The report concluded that (1) there was a great need for technical assistance in all areas and (2) the timeliness of the technical assistance is also of great concern.

The Investigative Staff visited three of the HEW regional offices and found that the level of staffing and expertise varied significantly among these offices. In one regional

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office only two full-time staff were available to the HMO program. It was admitted to the Investigative Staff by some regional office personnel that they could only provide limited technical assistance because of their inexperience in the HMO program and the limited amount of time they had available because of their workload.

The Investigative Staff believes that, in general, the regional offices lack the number and expertise of staff needed to provide good quality technical assistance to developing HMO's. The Investigative Staff also noted that unless a program for training and recruiting of staff is developed, the ability of the regional office to assist in the development of qualified HMO's will continue to be limited.

3. Technical Assistance Available From Other Sources

Because of the lack of staffing, both in number and expertise, the amount of direct technical assistance available to the HMO's from the HEW central and regional offices has been limited. As a result, the HMO's, especially during developmental periods, must use grant funds to contract out to private consultants for such services as financial planning, marketing, organizational planning, actuarial, and delivery systems design.

In an effort to estimate the amount of grant funds used to hire consultants, the Investigative Staff analyzed data available on 250 of the 306 grants awarded to HMO's. The following table is a summary of that analysis.

Type of Grant	Number	Total	Spent or Budgeted for Technical Assistance	% of Total
		($ in millions)		
Feasibility ---------	117	$ 5.68	$ .94	16.6
Planning ----------	77	10.02	1.34	13.4
Initial Development -	56	30.79	2.64	8.5
Total ----------	250	$ 46.49	$ 4.92	10.6

As is shown in the schedule above, almost $5 million, or about 10.6 percent, of the $46.5 million in grant funds was spent or budgeted by the HMO's evaluated for the purpose of obtaining technical assistance.

The basis for the expenditure of such large amounts of grant funds by HMO's for technical assistance has been the

experience that emerging HMO's lack the basic organizational abilities required to become successfully operational. As a result, there has been extensive use of contractors to provide the types of technical assistance needed by an HMO. This has enabled the HMO's to obtain the necessary assistance on a timely basis if it could not be furnished by the HEW staff.

The consultants hired by HMO's are generally identified through one of two methods. Either they are known by the management of the HMO from prior contact, or are recommended by the central or regional office. The Investigative Staff found that the names of the firms and consultants used varied widely when the consultant was known by the HMO's management through prior experience. However, the recommendations from the central and regional offices usually included the same consultants and/or firms. HEW has not developed an extensive list of qualified consultants for use by HMO's in selecting technical assistance. As a result, only a limited number of private firms and consultants have developed the majority of the expertise in the HMO program.

HMO's almost always acquired their consultants by negotiating a sole-source contract with either an individual personally known to them or with one of the few consultants recommended by HEW. Once this contract is negotiated, it is reviewed by the regional office for content and quality then either approved or rejected. The Investigative Staff was informed by regional office officials that these contracts are seldom rejected.

The Investigative Staff noted that, as a result of the above process, a limited number of consultants are used to provide a large amount of HMO technical assistance. The Investigative Staff was informed by central and regional office officials that this is primarily due to the fact that the health care delivery field as it relates to HMO's is so new.

The Investigative Staff believes that since HMO officials feel there are only a limited number of experienced consultants in the health care area, an effort should be made by HEW to enable other consultants and firms to gain access to the field. Also, the Investigative Staff believes that in areas such as financial planning, consultants do not really need HMO experience. Therefore, the Investigative Staff believes that an effort should be made by the central office to identify more consultants for use by HMO's in selecting their technical assistance.

B. Outside Technical Assistance Hired by the Central Office

As previously stated, consultants and experts have been hired and three large contracts were awarded to assist the central

office staffs in the complex and detailed reviews of grant, loan, and qualification applications. The consultants and experts have been used by the Division of HMO's, as discussed earlier, and also by the Office of HMO Qualification and Compliance.

1. Technical Assistance Provided to the Office of HMO Qualification and Compliance

The Office of HMO Qualification and Compliance primarily performs a regulatory function over HMO's in the qualification process and in doing so provides little direct technical assistance. However, to properly and adequately perform this regulatory function, the office needs a certain level of staff expertise.

During the past years the Office of HMO Qualification and Compliance has acquired some of this expertise through the hiring of consultants and experts. They provide technical assistance to the Office of HMO Qualification and Compliance staff in reviewing qualification applications and performing site visits. These tasks require expertise in areas such as financial planning, marketing, medical care delivery systems and HMO benefit packages. During FY 1977, about 10 consultants and 5 experts were employed to supplement the Office of HMO Qualification and Compliance staff at a total cost of approximately $87,000.

The consultants are hired by the Office of HMO Qualification and Compliance using an advisory allowance fund with which it has been provided. The consultants are hired on sole-source contracts and are individuals who are considered to have broad administrative, professional, or technical experience. These consultants are appointed for a service year on an intermittent basis for up to 130 days for programs, projects, problems, or phases thereof requiring intermittent service. They may also be temporarily employed on a regular, full-time basis for 1 year or less.

The Office of HMO Qualification and Compliance hires experts through the Office of the Assistant Secretary for Health with funds available from a personnel and benefits allowance. These experts are hired on a non-competitive basis to advise and consult with the HMO staff, and must be authorities of unusual competence and skills. An expert may be appointed for 1 year or less on programs, projects, problems, or phases thereof, requiring temporary service.

2. Contracts Awarded to Provide Technical Assistance to the Central Office

During the past 6 years three major contracts have been awarded by the central office to provide technical assistance in

some form to the HMO program staff. These contracts were to Aspen Systems Corporation for a legal surveillance project; Arthur Young and Company for the development of a financial protocol and assistance in reviewing the financial sections of HMO grant, qualification, and loan applications; and to the Charter Medical Development Corporation for the development of a marketing protocol and assistance in reviewing the marketing sections of grant, qualification, and loan applications.

The Investigative Staff reviewed the process through which these contracts were awarded and could find no irregularities in the methods used. Following are some of the details concerning these contracts.

a. Aspen Systems Corporation Contract

The purpose of this contract was to monitor and analyze legislative, administrative and judicial actions and Attorney General's opinions in the areas of HMO and prepaid group practice legislation in the 50 States, the U.S. Territories, Washington, D.C. and at the Federal level. The contract called for the monitoring and analysis activity to be documented by preparation and periodic updating of a digest of State laws. The contractor was also required to make available legal consulting services as requested and perform and report on analyses of selected aspects of State laws as directed by the project officer.

This contract was advertised in the Commerce Business Daily on May 1, 1972, and the RFP was issued May 10, 1972, to 70 organizations. By the closing date of May 30, 1972, seven proposals had been received, of which five were judged to be technically acceptable. Competitive negotiations were conducted between all five technically acceptable offers and the contract was awarded to Aspen Systems Corporation on the basis that it had submitted the lowest technically acceptable bid. The contract was awarded in June of 1972 for $87,580.75. The initial completion date was December 1, 1974.

The original contract was modified and extended until October 28, 1975. At that time, a new contract was awarded to Aspen Systems as a noncompetitive procurement. The noncompetitive nature of this contract was justified by HEW on the basis that Aspen Systems was the only one intimately knowledgeable and experienced with the development of the project materials to date. The contractor had established an information gathering system and had legal analysts on staff familiar with the various legal information needs of the HEW-HMO program. It was stated that Aspen Systems was the only source known at that time to possess the unique capabilities and qualifications necessary to accomplish the requirements of this contract within the

specified period. As a result, it was concluded to be in the best interests of the Government to negotiate this contract on a noncompetitive basis.

Since the contract was let on October 28, 1975, for $59,200, there have been eight modifications in the contract bringing the total amount to $164,720, an increase of $105,520. The modifications were for extensions in the period of performance and the addition of work and services to be performed.

This contract will expire on March 31, 1978 and HEW officials informed the Investigative Staff that they will award a new contract under the competitive bidding process.

b. Charter Medical Development Corporation

The purpose of this contract was to review the marketing strategies of developing HMO's and to provide HEW with information it could use to assess the adequacy of an HMO's marketing strategy and procedures. This was generated by HEW's expectation that as many as 300 organizations would be submitting applications for funding under the HMO program.

The notice for this contract was sent to the Commerce Business Daily on September 27, 1974. Five proposals were received and a complete evaluation was made of the proposals submitted. The contract was awarded on July 15, 1975, for a total of $208,016. Results of the review session showed that Charter Medical Development Corporation had received the highest average score from the contract reviewers. The amount of this contract was increased $27,000 on September 14, 1976 to $235,016. The contract expired on December 31, 1976.

c. Arthur Young and Company

The purpose of this contract was to perform a review and analysis of the financial plans of HMO projects. The project was to determine the validity of projected cash flow forecasts as well as the fiscal soundness and feasibility of a proposed HMO operation. As part of the contract, the contractor would agree to submit protocols which could be used by HEW in conducting financial feasibility reviews.

Notice of the contract was sent to the Commerce Business Daily on September 27, 1974. Twenty-one proposals were received by HEW for this contract and were reviewed on December 16, 1974, and January 6, 1975. As a result of those reviews, the contract was awarded to Arthur Young and Company effective July 14, 1975, for a total cost of $244,848. The contract was subsequently modified several times and, as a result of

additional work and services provided, the completion date was extended to September 30, 1977. Also, the total amount of the contract was raised $41,909 to $286,757.

C. Irregularities Noted in Technical Assistance Administration at the Central Office

The Investigative Staff, during its review, noted some irregularities in the way the central office used technical assistance consultants. Although an attempt was not made to determine to what extent or degree these problems existed, the Investigative Staff felt they should be brought to the attention of the Committee.

The Investigative Staff found that:

-- Consultants traveled on official HMO business and were reimbursed by the Government for such travel prior to official appointment by HEW to consultant status.

-- The Office of HMO Qualification and Compliance has utilized a number of consultants and experts in situations where appearance of conflicts of interest may be involved.

1. Unauthorized Use of Consultants

The Investigative Staff noted that on several occasions consultants were utilized and traveled on official business prior to their official appointment to consultant positions. The HMO program reimbursed these consultants for their expenses, and reportedly the consultants were paid for the services provided on these trips after official appointment to consultant status.

It was also noted that on at least two occasions, consultants traveled on official business for the HMO program for which their expenses were reimbursed, but they were not subsequently appointed to official status.

The Investigative Staff was able to identify at least eight instances in which travel expenses were paid to unauthorized consultants. The Government funds for these trips totaled about $3,500.

Central office officials informed the Investigative Staff that they were aware that the consultants traveled and were reimbursed for trips taken prior to their appointment. However, they stated that such travel was approved only because the expertise provided by these consultants was not otherwise available at the time it was needed.

In addition, the Investigative Staff noted that on at least two occasions, HMO program officials convened task forces in Washington, D.C. without proper authorization. These task forces met to review issues surrounding the dual choice provisions contained in Section 1310 of the regulations, and to revise the National Reporting Requirements for qualified HMO's. Each of these groups were composed of several individuals who served on the task force without pay, receiving travel and expenses only from HMO program funds.

An HMO program official acknowledged that payment for the travel and expenses of the individuals who constituted these task forces was made by HEW improperly and without authorization. However, the official stated that the impropriety of the action was not known at the time these task forces were convened and that it was just recently brought to his attention.

2. Use of Consultants With Appearance of Conflicts of Interest by the Office of HMO Qualification and Compliance

The Office of HMO Qualification and Compliance, which performs a regulatory function over HMO's, has utilized consultants and/or experts to assist in-house staff in conducting reviews of HMO applications and facilities. The Investigative Staff noted that several of the consultants and/or experts being used for this purpose were in positions where an appearance of conflict of interest existed.

The Investigative Staff believes that an individual in such a regulatory position must objectively (1) evaluate and make recommendations on the quality and adequacy of an HMO's qualification application, and (2) work and deal with consultants and consulting organizations.

It should be noted that although the Investigative Staff did not find specific examples of individuals who were guilty of a conflict of interest, the potential for such situations clearly exists. During the review, the Investigative Staff found some instances of appearances of a conflict of interest. For example:

-- While on an expert excepted appointment from the Arthur Young firm, a financial expert assisted the Office of HMO Qualification and Compliance in the review of HMO qualification applications. Also, on his own time, he helped Arthur Young in preparing a proposal to HEW, Office of the Secretary, for a project entitled "Health Maintenance Organization Viability."

-- An individual who is reviewing HMO qualification applications had recently worked as executive director of an HMO which is now being considered for qualification. This individual helped prepare the HMO's application for qualification and is still working for the hospital which is sponsoring the HMO.

-- An expert hired by the Office of HMO Qualification and Compliance to primarily do marketing reviews is presently employed by a firm in which he is responsible for a department which, among other things, engages in the consulting of HMO's.

The Investigative Staff believes that the above are potential problems in the hiring of consultants and the potential for or appearance of conflict of interest could damage the integrity of the qualification process for HMO's and as a result the HMO program itself. The Investigative Staff believes that allowing the regulatory function of this office to be carried out by individuals or private sector organizations who may at sometime represent the organization to be regulated is not in the best interests of the Government.

Employees are responsible for avoiding actions which might result in or create the appearance of

-- Giving preferential treatment to any organization or person,

-- Losing complete independence or impartiality of action,

-- Making a Government decision outside of official channels, or

-- Adversely affecting the public's confidence in the integrity of Government.

The Investigative Staff realizes that many of the consultants hired for the HMO program may possess specialized abilities which may not be readily available within the Government. However, the Investigative Staff believes that the Office of HMO Qualification and Compliance should (1) select individuals with the needed expertise who do not have the potential for or appearance of conflicts of interest and (2) increase its efforts to obtain permanent staff who have these expert abilities.

3. Unauthorized Use of HMO Funds

The Investigative Staff found that funds appropriated for the HMO program had been improperly used to pay travel

and expenses for Professional Standards Review Organization (PSRO) Council members in FY 1977. In addition, use of first class air travel is routinely approved for PSRO Council members although meetings are scheduled several months in advance.

The Investigative Staff noted that on two occasions in FY 1977, HMO funds totaling $4,662 were used for travel of PSRO Council members to Washington, D.C. to attend meetings. The official who approved the use of these funds advised that such meetings were held six times per year at 2 month intervals, and are scheduled about 6 months in advance. The PSRO program had run out of travel funds near the end of FY 1977 and still had meetings scheduled. The HEW official advised that he requested and received approval to use the HMO funds for PSRO travel rather than cancel the meetings because this would have "crippled" the PSRO program for a number of months. He felt the expediency of the situation justified the action.

The Investigative Staff contacted the HEW official who had been requested to approve the use of additional funds for travel by the PSRO Council members. This official stated that an increase in the travel ceiling had been incorrectly requested and approved for the HMO program rather than for the PSRO program. The wrong program budget designation had been used in the request and the error had not been noticed. As a result of this administrative oversight, HMO program funds were improperly, and without authorization used for travel of the PSRO Council members. The Investigative Staff was advised that appropriate actions have been taken to preclude such occurrences in the future.

The Investigative Staff believes that funds appropriated by Congress for specific purposes should be used only for those purposes, unless otherwise authorized by Congress. In this instance, the priorities of the PSRO program should have been examined and perhaps realigned to make funds available from within the program.

At the time of the Investigative Staff's inquiry, the use of first class air travel by PSRO Council members was routinely approved by HEW. The official responsible for approving such travel justified it on the basis that he was told it is "standing policy" of HEW to permit these individuals to utilize first class accommodations. He was aware this practice contradicted normal Government travel policy but assumed that an exception was made in the case of PSRO Council members.

The Investigative Staff noted that under Department of HEW policy, as stated in a "Travel Handbook," consideration must be given to the use of less than first class air accommodations when such accommodations are available. Justification

for the use of first class accommodations is not required, however, they should be obtained only when necessary.

The Investigative Staff recommends that HEW follow its own policy and not routinely approve first class travel for the PSRO program. It is difficult to envision why other accommodations would not be available when travel can be scheduled 6 months in advance.

VII. STAFF TRAVEL

During the Investigative Staff's review of the HMO program, the staff travel of the Office of HMO Qualification and Compliance and the Division of Health Maintenance Organizations was examined.

The administration of the HMO program has required extensive travel by central office personnel to the regional offices and to developing and qualified HMO's. Central office responsibilities requiring travel include:

-- Training of regional office and HMO personnel,

-- Providing technical assistance to HMO's during the grant and operational phases,

-- Visiting HMO sites to verify grant and qualification application data, and

-- Assisting HMO's with organizational, financial, and/or marketing problems that occur during their loan periods.

From July 1974 to December 31, 1977, 306 HMO grant awards had been made to 170 organizations. The central office provided technical assistance and training to many of these organizations. Also, about 100 organizations had applied to HEW for qualification, many of which have received site visits conducted by officials from central office. In addition, meetings and conferences have been held and speeches given to explain and present the program to various groups and individuals. The limited delegation of authority to the regional offices has added to the need for central office travel.

The Investigative Staff reviewed a random number of trips made by certain HMO program officials for the past 2 fiscal years. Documentation was sought, such as trip reports or site visit reports, which could support the purpose for which the trip was taken and what was accomplished on the trip.

In general, the Investigative Staff found that documentation was available and confirmed the basis for the trips. However, documentation for some of the trips was not submitted directly by the individual traveler, but only reference was made to that person's presence. However, that person's contribution or work accomplished was not documented.

The Investigative Staff was advised that neither the Office of HMO Qualification and Compliance nor the Division of HMO's had any written policies which required HMO officials to report on the purpose and accomplishments of their trips. In some

instances, especially in the case of speeches or participation in seminars by higher level officials, no documentation was entered into the files by the officials themselves.

The Investigative Staff believes that conformance with Federal travel regulations and procedures should be strictly enforced to avoid the appearance or opportunity for nonessential travel and the resultant waste or misuse of Government funds. As a minimum, HEW should require that HMO travel from the central office be justified in advance and in writing and adequate documentation be prepared and filed for future reference, as appropriate. In addition, the establishment of internal control procedures within the HMO program should emphasize the official purpose and objectives to be achieved by the travel, related costs, and written reports to management explaining the work performed and the results obtained.

VIII. CONCLUSIONS AND RECOMMENDATIONS

During the 4 years the HMO program has been in operation, it has undergone numerous reorganizations and changes and has had many problems. Some reasons for these problems were identified by officials at various levels both inside the HMO program and in the HMO's themselves. Although the Investigative Staff in this report, as well as other groups in the past 2 years, have confirmed a number of deficiencies which exist within the program, little has been done by HEW to correct the situation. For this reason, the Investigative Staff believes that the major problems with the program are the result of a lack of leadership and an unwillingness by HEW to commit adequate resources to the program.

Conclusions

Program responsibility has, for several years, been divided in various agencies within HEW and the regions. Until the December 2, 1977, reorganization no single agency had responsibility for the central office operation of the program. The HMO program had been divided organizationally between the developmental and regulatory functions. Even under the newly adopted reorganization, the role of the regional office has not been clearly defined and the degree of guidance and control which the central office can assert on the HMO staffs in the regions is not clear.

Since its inception, the HMO program has been seriously understaffed and has operated almost exclusively on a crisis basis. The program does not yet have a complete set of finalized regulations and the developmental staffs in the HEW central and regional offices, as well as HMO officials, have informed the Investigative Staff that even now they are not sure what the requirements are for a qualifiable HMO. No guidelines or policy decisions have been issued on what is expected of an HMO for qualification and as a result, it has become a subjective process. Long delays have resulted in the qualification process and about $4 million in additional grant funds have been expended because of these delays.

The technical assistance available to developing and qualified HMO's is limited because of a lack of sufficient expertise in the central and regional offices. As a result, HMO's rely mostly on private consultants for technical assistance. The number of consultants recommended to HMO's by HEW has been rather limited. HEW officials informed the Investigative Staff that this was because the health care field as it relates to HMO's is fairly new. The central office itself relies on consultants to a great extent. Several consultants, however, were in positions where appearances of conflict of interest existed. Employees are responsible for avoiding actions which might result in or create the appearance of conflicts of interest.

The Investigative Staff believes that HEW should make a greater effort to identify and bring more expertise into the HMO area. This should be done both by developing adequate headquarters and regional office staff and by promoting competitiveness in the development of qualified experts in private industry.

Qualified HMO's have received several million dollars in loan funds which Congress expects to be repaid. The Investigative Staff has found that responsibility for monitoring these loans is divided between the developmental and regulatory functions of the HMO program. As a result, responsibility for monitoring these loans has not been clearly delineated. One program official informed the Investigative Staff that very little monitoring of the loan program is actually taking place. He also stated that if an HMO chooses not to report financial problems during the loan period, these problems might easily not be identified until the year end certified audit.

The Investigative Staff believes there is a need for strong leadership and management in the newly created Office of Health Maintenance Organizations. Unless an immediate effort is made to develop guidelines, obtain qualified staff, and develop the HMO program so that an orderly process can be implemented for grants, qualification and operation, the HMO program problems for developing and qualified HMO's will continue to increase.

Recommendations

To more effectively achieve the HMO legislative objectives and to improve overall management control of the program, the Investigative Staff recommends the Committee require the Secretary of HEW to initiate the following actions:

-- Regulations and guidelines for the HMO loan program and the qualification and compliance processes, should be drafted and finalized immediately. If necessary, present qualification work should be suspended until these guidelines can be developed. The Investigative Staff believes that the longer the HMO program operates without guidelines, the more arbitrary and inconsistent will be the overall decisions made by the staff.

-- The new director of the Office of Health Maintenance Organizations should, as a priority, develop a definitive plan to ensure the more orderly transition of the HMO program from the grant through the qualification process and into the HMO operational stages.

-- Regional offices should be given larger and more clearly defined roles in the HMO program. The HMO central office should make every effort to acquire accountability over

the regional offices' operations and should provide adequate guidelines, training, and technical assistance to regional office staffs.

-- The central office should be provided with qualified staff to properly administer the loan, qualification, and compliance aspects of the complex HMO program.

-- Responsibility for monitoring loan and loan guarantee recipients should be clearly defined and a monitoring program be implemented on a regular basis to protect the financial interests of the Federal Government.

-- A policy should be developed requiring the adequate documentation of all staff travel.

-- Audit policies should be established to eliminate:

    (1) Inappropriate reimbursements and use of travel funds for consultants and task forces, and

    (2) The hiring of consultants with appearances of conflicts of interest.

* * * * *

NOT FOR RELEASE UNTIL AUTHORIZED BY THE COMMITTEE

A REPORT TO

THE COMMITTEE ON APPROPRIATIONS

U.S. HOUSE OF REPRESENTATIVES

on the

AREA HEALTH EDUCATION CENTERS PROGRAM

ADMINISTERED BY THE DEPARTMENT OF

HEALTH, EDUCATION, AND WELFARE

Surveys and Investigations Staff

February 1978

24-838 O - 78 - 23

NOT FOR RELEASE UNTIL AUTHORIZED BY THE COMMITTEE

February 24, 1978

MEMORANDUM FOR THE CHAIRMAN

Re: Area Health Education Centers Program
Department of Health, Education, and Welfare

By directive dated August 2, 1977, the Committee requested the Surveys and Investigations Staff to conduct a study of the Area Health Education Centers Program of the Department of Health, Education, and Welfare.

This report contains the results of the requested study.

Respectfully submitted,

David A. Schmidt, Director
Surveys and Investigations Staff
House Appropriations Committee

C. R. Anderson
Chief of the Surveys and
Investigations Staff
House Appropriations Committee

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SUMMARY, OBSERVATIONS AND CONCLUSIONS, AND RECOMMENDATIONS

The Congress has declared that the availability of high-quality health care to all Americans is a National goal. The Area Health Education Centers (AHEC) Program, which is administered by the Bureau of Health Manpower (BHM), in HEW's Health Resources Administration (HRA), is one of a number of health manpower programs designed to assist in attainment of this goal.

The purpose of the AHEC Program is to improve the accessibility to needed health services--through changes in the distribution of health manpower (both by specialty and by geography)--by means of (a) decentralization of health professions educational programs, (b) improvements in the professional environment, and (c) upgrading the skills of community-based nursing and allied health professionals.

The program began in 1972 when BHM awarded 5-year incrementally funded contracts, of which the Federal share totaled about $65 million, to 11 medical schools and health science centers to decentralize medical education and meet locally defined health manpower needs. At the end of the first 5 years, the program was providing health manpower training opportunities in 169 mostly rural counties in 13 States.

The Investigative Staff believes that the AHEC concept is a viable one and that the AHEC Program has been relatively successful. There are both objective and subjective indications that the overall program is progressing toward meeting its goals and objectives.

In September 1977, BHM awarded 1-year continuation contracts to the original 11 AHEC's. BHM also awarded contracts to four other medical schools for the planning of 4 new AHEC's, 2 of which are to be in urban areas.

BHM plans to continue the program and provide about $17-19 million for at least each of the next 6 fiscal years. These funds will support a range of about 20-30 AHEC's in any given year. BHM has adopted the policy of decremental funding--new AHEC's are to be initiated as Federal support of existing AHEC's is gradually reduced.

The Investigative Staff noted that HEW needs to significantly improve its administration of the AHEC Program. The program is understaffed, insufficiently monitored, has not been evaluated, and has not been sufficiently coordinated with other related Federal health manpower training programs.

Contracting and Funding (Pages 13 to 40)

BHM and the HRA contracts office failed to properly schedule and staff the FY 1978 AHEC contract award cycle. The Investigative Staff noted that this is a Departmentwide problem and that the Secretary of HEW directed corrective action in May 1977; however, HRA has not taken sufficient action to implement the Secretarial directive. As a result, there were short proposal deadlines, hasty proposal evaluations, and ineffective contract negotiations in relation to AHEC contracts awarded in September 1977.

BHM awarded funds to the original 11 AHEC's for FY 1978 (program year six) primarily on the basis of costs projected for the fifth year (in the initial contracts awarded in September 1972), rather than on the basis of the merits of the technical proposals.

In addition, BHM underfunded the original 11 AHEC's and is now planning to provide about $2 million in supplemental awards to meet the legislative mandate of funding the projects in FY 1978 at their FY 1977 "current services" level.

Recommendations

To correct major deficiencies in HEW's contracting and grant processes and to improve administration of the AHEC Program, the Investigative Staff recommends that the Committee may wish to require the Secretary of HEW to:

(1) Ensure that HRA properly schedule and staff the procurement and contract award cycle.

(2) Ensure that BHM and HRA immediately initiate procurement actions required for completion of AHEC funding for FY 1978.

(3) Ensure that different requests for proposals be issued for new urban, rural, or Statewide AHEC's.

(4) Ensure that criteria for making awards for new AHEC's take into consideration, in addition to cost, such other factors as technical merit of the proposal and geographic location of the project.

(5) Consider awarding contracts for new AHEC's in phase with the academic year of July 1 through June 30, and with sufficient lead-time to enable medical schools to plan before the start of the contract period.

Future Federal Funding
of AHEC's (Pages 41 to 48)

Section 802 of PL 94-484 provided that for FY's 1978 and 1979, there are authorized to be appropriated such sums as may be necessary to continue payments to the original 11 AHEC's.

BHM awarded $14 million to the original 11 AHEC's for the current fiscal year. BHM intends to make supplemental awards of $2 million to bring each of the AHEC's up to at least 95 percent of their FY 1977 funding levels estimated in the initial contracts awarded in September 1972.

Section 802 further provided that FY 1979 funding for the original 11 AHEC's is contingent on the project providing assurances satisfactory to the Secretary that by September 30, 1979, the project comply with certain additional requirements specified in Section 781 for new AHEC's. One of these requirements is that no less than 10 percent of all undergraduate medical or osteopathic clinical education of the school must be conducted in an AHEC and at locations under the sponsorship of the AHEC.

Section 781 requires the Secretary to develop and implement regulations establishing standards and criteria for the Section 781 AHEC's. Although 16 months have passed, these regulations have not been issued. The Investigative Staff believes that it is improper for BHM to place the AHEC projects in the position of having to say whether or not they will meet the 10-percent requirement, without first knowing how the requirement will be defined.

In addition, the resources for clinical instruction are necessarily limited in the underserved areas--at least until they can be upgraded--and to expect a large medical school, or a consortium of medical schools, to give 10 percent of their clinical instruction in remote places where the resources simply do not exist, may prohibit certain medical schools or groups of medical schools from establishing AHEC's.

HEW did not make provisions for funding of the New Mexico project in FY 1979, as required by the Conference Report on PL 94-484. As a result, the Department is now planning to request authority to reprogram funds for FY 1979 from the AHEC appropriation to Section 788(d) for that purpose. In addition, HEW has not developed a long-range funding plan for the New Mexico AHEC, whose principal thrust is the training of Indian people in health professions.

BHM's plans are to gradually decrease funds for AHEC projects. In this way, new AHEC's are initiated as Federal support to existing AHEC's is gradually reduced. The Investigative Staff believes that it was never intended that the Federal Government

support particular AHEC's indefinitely. Therefore, the Investigative Staff concurs with the BHM philosophy that once the AHEC organizations have had an opportunity to demonstrate their value to the area in which they are located, State and local financing must gradually replace the Federal support.

Recommendations

The Investigative Staff recommends that the Committee may wish to require the Secretary of HEW to:

(1) Finalize and implement regulations establishing standards and criteria for the requirements of Section 781.

(2) Develop and provide the Committee with a plan for long-term funding of the New Mexico AHEC.

It is further recommended that the Committee consider taking action toward the enactment of legislation which would permit the Secretary of HEW to grant a waiver, or postponement, of the 10 percent "clinical instruction" requirement of Section 781 in areas that have a special need for an AHEC project, but which lack suitable clinical facilities for teaching the necessary number of students.

Potential For Shifting Funding of AHEC's to State and Local Sources (Pages 49 to 54)

The original 11 AHEC projects perceived there would be Federal funding after the 5-year period, and possibly for an extended period of time. In addition, the contracts provided for relatively level funding after the first year, with no provision for a phase-down of Federal funding and a corresponding increase in funding from State and local sources. As a result, with some notable exceptions, the contractors had not made sufficient efforts to develop alternate funding sources by the end of the 5-year contract period.

The Investigative Staff found that the original 11 AHEC's most likely will have to reduce their scope of activities if Federal funding would terminate at the end of FY 1979 (the seventh year). BHM's funding plan provides for 2 additional years of Federal funding, at decreasing levels, which the Investigative Staff concluded is necessary to ensure that project activities continue while alternate funding sources are developed.

Recommendations

To ensure that AHEC activities do not terminate as Federal funding is phased out, and AHEC's develop alternate funding for

those activities that require long-term financial support, the Investigative Staff recommends that the Committee consider requiring that future Federal funding of AHEC's include (a) a clear understanding on the duration of Federal funding and (b) provisions for increased amounts of cost-sharing as Federal funding is phased out.

Program Organization and Staffing (Pages 55 to 63)

The Central Office AHEC staff is significantly understaffed and is, therefore, unable to properly administer the National AHEC Program. In addition, the Investigative Staff noted certain staffing imbalances among Divisions within BHM. This is attributable to (1) a very slow recentralization process and (2) a reluctance by BHM to internally realign staff resources.

The Department has complied with the Congressionally mandated recentralization and has transferred health manpower programs, but has not transferred staff to the Central Office, nor otherwise filled the recentralized positions. As a result, certain BHM components, such as the AHEC staff, are having difficulity administering the programs assigned.

BHM reported to the Investigative Staff that as of January 31, 1978--4 months after the effective date of Congressionally mandated recentralization, and almost 16 months after enactment of the law itself--only 5 regional office employees, or 3 percent, of the 180 health manpower positions being returned to the Central Office had been reassigned and were on-board in the Central Office. BHM does not expect to be able to complete the recentralization process until at least midsummer at the earliest.

BHM's stop-gap measure of utilizing detail personnel to fill the staffing void is a poor substitute for a timely recentralization process.

In May 1976, the U.S. Civil Service Commission (CSC) issued a report on its review of personnel management procedures and practices at HRA headquarters. The Investigative Staff noted that HRA had not taken adequate and timely corrective action on certain recommendations made by the Commission.

Recommendations

To improve personnel management and overall program administration, the Committee may wish to require the Secretary of HEW to:

(1) Expedite transfer of staff from the regional offices to the Central Office, and/or otherwise fill vacant positions, so that BHM can effectively administer the Department's health manpower programs.

(2) Review the policies and practices for assignment of personnel in BHM and HRA.

(3) Review BHM's policy regarding temporary detailing of regional office personnel to the Central Office.

(4) Expedite resolution of individual position classification cases and fully respond to the CSC findings.

Program Monitoring (Pages 64 to 69)

In general, the AHEC contracts received only cursory attention and the "careful technical surveillance" requirement of the AHEC cost-reimbursement contracts was not provided. Regional office personnel generally stated that during decentralization, they were understaffed and therefore were unable to properly monitor the AHEC contracts.

Due to a shortage of assigned staff, the Central Office AHEC staff has been unable to either monitor the original 11 AHEC's or provide sufficient technical assistance to the four medical schools awarded planning contracts for new AHEC's.

Coordination of AHEC with Related Federal Programs (Pages 70 to 75)

AHEC and a number of other HEW health manpower education programs, as well as several programs administered by the Veterans Administration (VA), are all designed to (a) improve geographic and specialty distribution and/or (b) improve the quality of the health manpower work force. Coordination of the AHEC Program with these other programs was informal and, in many cases, minimal or nonexistent. As a result, certain AHEC projects and related HEW and VA projects appeared to overlap in activities. Better coordination would have resulted in opportunities for improved program management, elimination of duplication of effort, reduced costs, and a more coordinated and unified Federal effort.

Recommendations

To develop a more unified and coordinated Federal approach to health manpower training, and to reduce costs, the Committee may wish to require:

(1) The Secretary of HEW to ensure that the AHEC Program and other BHM health manpower training programs are more effectively coordinated.

(2) The Office of Management and Budget to arrange for HEW and VA to enter into an Interagency Agreement to more effectively coordinate their respective health manpower training programs.

Program Evaluation (Pages 76 to 85)

HEW plans to significantly expand the AHEC Program over the next few years without first objectively determining whether the concept is a cost-effective and viable strategy to attack the problems of geographic and specialty maldistribution of health manpower.

HEW's past evaluation efforts have been of minimal value and have not "evaluated" the success of the program. Since no real evaluation had been performed on the National AHEC Program, Congress mandated, in PL 94-484, that HEW conduct such an evaluation and that a report be provided to the Congress by September 30, 1979.

BHM has experienced difficulty initiating the Congressionally-mandated evaluation of the AHEC Program and, as a result, did not anticipate being able to provide the Congress with a report until January 31, 1980--4 months after the reporting deadline specified in PL 94-484. However, after contacts by the Investigative Staff, the HRA Administrator stated that he intends to adjust the evaluation timetable to ensure that the Congressional reporting deadline of September 30, 1979, is met.

Furthermore, if the deliberations are intended to take place prior to October 1979, then even a reporting date of September 30, 1979, would mean that the HEW report would not be available for use by the Congress in the legislative cycle.

The Investigative Staff questioned the merit of HEW's AHEC evaluation strategy and, in particular, of planning to spend about $400,000 for an indepth AHEC evaluation, when the original 11 AHEC projects and the prestigious Carnegie Council is conducting an independent study on whether the AHEC Program is meeting its goals and objectives.

Recommendations

To ensure that the HEW report be available for use by the Congress in consideration of new authorities needed for FY 1981 funding, and to conserve Federal funds, the Investigative Staff recommends that the Committee may wish to:

(1) Reassess the HEW reporting date of September 30, 1979, and advise the Secretary of HEW of (a) a possible earlier reporting date in accordance with Congressional needs and (b) the importance of a timely report.

(2) Suggest to the Secretary of HEW that the Department explore the feasibility of utilizing the results of the Carnegie Council study and thereby reducing the magnitude of the HEW evaluation.

I. INTRODUCTION

A. Directive

By directive dated August 2, 1977, the Committee requested that the Surveys and Investigations Staff conduct a study of the Area Health Education Centers (AHEC) Program administered by the Department of Health, Education, and Welfare (HEW).

The particular areas of concern to the Committee were:

(1) Methods employed by the program in awarding contracts.

(2) Utilization of unexpended contract funds and its impact on subsequent year budgets.

(3) The extent of monitoring of contractors by central office and regional office personnel.

(4) The current amount of cost-sharing by State and local sources, and the future potential for shifting the funding of operational AHEC's to State and local sources.

(5) Utilization of program evaluation funds and the methods used in selecting evaluation contractors.

(6) How the results of the evaluation contracts were used in program management, short- and long-range planning, and drafting of legislative extensions.

(7) The amount of money spent annually by AHEC contractors on administration.

The Investigative Staff was also to address the question of whether or not the program was accomplishing its legislative objectives and to include recommendations for improving program management.

B. Scope of Inquiry

The majority of work at headquarters was performed in the Health Resources Administration (HRA) of the Public Health Service and one of its constituent organizations--the Bureau of Health Manpower (BHM). In addition, work was performed in other applicable organizational elements throughout the HEW Central Office. The Investigative Staff visited three HEW regional offices (Atlanta, Boston, and San Francisco), where meetings were held with HEW Regional Health Administrators, project officers, and contracting officers.

The Investigative Staff also performed work at 4 of the 11 medical schools and health science centers with operational AHEC projects and met or corresponded with representatives of the other 7 institutions. In addition, the Staff met with representatives of the four medical schools awarded planning contracts in September 1977 for new AHEC's.

Discussions were held with over 250 people, including medical school presidents, deans, and faculty; practicing physicians, nurses, and allied health personnel; medical, dental, and nursing students; local elected officials and community leaders; and other individuals associated with planning for and operation of AHEC sites.

HEW officials were interviewed including the Assistant Secretary for Health; a representative of the Deputy Assistant Secretary for Planning and Evaluation/Health; the Administrator and Deputy Administrator of HRA; the Associate Administrator for Planning, Evaluation and Legislation of HRA; the Director and Deputy Director of BHM; and the National Coordinator of the AHEC Program.

The Investigative Staff also held interviews with outside consultants hired to assist the Department in administering the AHEC Program and with representatives of the HEW National Advisory Council on Health Professions Education. Interviews were also held with officials of (1) selected State Health Systems agencies, (2) specific AHEC project advisory councils, (3) the Carnegie Commission, (4) the Veterans Administration, and (5) the Congressional Budget Office.

Finally, the Investigative Staff reviewed pertinent reports, legislation and documents relating to AHEC's.

II. FEDERAL INVOLVEMENT IN HEALTH MANPOWER

The Congress has declared that the availability of high-quality health care to all Americans is a national goal. For attainment of this goal, as early as 1956, PL 84-911, the Health Amendments Act, provided for graduate training of public health personnel. In the early 1960's various Federal laws were passed providing for health manpower support, including the Manpower Development and Training Act, 1962; the Health Professionals Educational Assistance Act, 1963, and its amendments of 1965; and the Health Manpower Act, 1968.

Of major importance was the passage of the Comprehensive Health Manpower Training Act of 1971 (PL 92-157) which, under Section 774(a), authorized Health Manpower Education Initiative Awards. AHEC's were funded in 1972 under this authority.

The Health Professions Educational Assistance Act of 1976 (PL 94-484), enacted on October 12, 1976, authorized a wide variety of Federal programs, including the continuation of AHEC's, to support the training of health professionals. (Appendix I lists the programs and amounts authorized under PL 94-484.) The Act amended and consolidated all HEW health manpower training programs into one law. In doing so, it specified the nature and kind of Federal support authorized for some 28 separate programs.

HEW support for health manpower training totaled approximately $5 billion during the 12 years between the time the program was first authorized and enactment of PL 94-484 in October 1976. In FY's 1977 and 1978 an additional $1 billion was available for health manpower. In addition, the President's budget provides $315 million for this purpose in FY 1979.

The Veterans Administration (VA), under authorization of PL 92-541, the Veterans Administration Medical School Assistance and Health Manpower Act of 1972, has made grants totaling about $400 million to support health manpower training. Other Federal departments have also funded health manpower training activities. These include the Departments of Defense, Justice, Labor, and Transportation.

In contrast to previous health manpower legislation, PL 94-484 does not emphasize increasing the number of physicians trained by medical schools. Instead, the Act primarily seems to be aimed at countering overspecialization and restoring balance in health professionals' training toward primary care (general internal medicine, family medicine, or general pediatrics) and at improving the geographic distribution of health professionals toward medically underserved areas.

Appendix II is a table which analyzes PL 94-484 by funding level and program objectives ranked in order of amount appropriated. Appendix III is a summary of major health manpower issues that emerged prior to PL 94-484.

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III. OVERVIEW OF THE AHEC PROGRAM

The purpose of the AHEC Program is to improve the accessibility to needed health services--through changes in the distribution of health manpower (both by specialty and by geography)--by means of (a) decentralization of health professions educational programs, (b) improvements in the professional environment, and (c) upgrading the skills of community-based nursing and allied health professionals.

The program began in 1972 when BHM awarded 5-year contracts, totaling $65 million, to 11 medical schools and health science centers to decentralize medical education and meet locally defined health manpower needs. At the end of the first 5 years, the program was providing health manpower training opportunities in 169 mostly rural counties in 13 States.

In September 1977, BHM awarded 1-year continuation contracts to the original 11 AHEC's. BHM also awarded contracts to four other medical schools for the planning of new AHEC's. BHM plans to continue the program and provide funds to support 22-30 AHEC's in any given year.

The AHEC approach addresses maldistribution through modifications in the health professions education and training programs. This approach is based on the assumption that changes in educational programs can reduce the degree of professional isolation and thereby provide effective incentives to encourage practitioners to locate and work in areas that currently have inadequate services.

A. Carnegie Commission Recommendations

The Carnegie Commission, in its 1970 report, Higher Education and the Nation's Health, called for a number of significant reforms in health manpower education and health care delivery, including the establishment of AHEC's. The Commission called particular attention to (1) a serious geographic maldistribution of health manpower in the Nation and (2) a decline in the percentage of primary-care physicians. The Commission noted that the ratio of physicians and dentists was much smaller in remote rural locations and densely populated inner cities than in other areas of the country. The Commission reported that, while the total number of physicians increased sharply between 1963 and 1970, the proportion engaged in primary practice declined from about 55 percent to 40 percent and, correspondingly, the proportion in specialized practice increased.

The President's 1971 Health Message advocated Federal support for the development of AHEC's. In addition, references to the Carnegie Commission recommendations were included in

the testimony on the health manpower bill under consideration in the Congress in 1971 and in Congressional reports and debates.

B. Program Initiation

The Comprehensive Health Manpower Training Act of 1971 (PL 92-157) established a program of Health Manpower Education Initiative Awards aimed at "improving the distribution, supply, quality, utilization and efficiency of health personnel and the health delivery system." Under this authority, the then Bureau of Health Manpower Education (predecessor of BHM) of the Public Health Service issued a "Request for Proposals" in June 1972 indicating the availability of Federal support for the establishment of AHEC's. Eighty-five institutions expressed interest, of which 27 were sent formal Request for Proposals. Of these 27, 11 AHEC contractors identified below were eventually selected, and funding began in September 1972.

West Virginia University Medical Center
Medical University of South Carolina
University of North Carolina
University of North Dakota
University of New Mexico
Tufts University School of Medicine
University of Missouri at Kansas City, School of Medicine
University of Minnesota
University of Texas Medical Branch, Galveston
University of Illinois
University of California at San Francisco
(with the UCLA School of Medicine)

Appendix IV shows the target areas served by these AHEC projects.

Federal aid for the 5-year period totaled about $65 million, or about two-thirds of overall program costs of about $100 million. Assistance to individual projects ranged from $2.7 million to $9.9 million.

In September 1977, BHM awarded new contracts to the 11 contractors for a sixth year of Federal support. BHM also awarded contracts to four additional medical schools for the planning and development of new AHEC's.

The FY 1978 appropriation for AHEC's was $17 million. Section 781 of PL 94-484, Health Professions Educational Assistance Act of 1976, authorized $20 million in FY 1978, $30 million in FY 1979, and $40 million in FY 1980 for the AHEC program. In addition, Section 802 of the Act authorized such additional sums as may be necessary in FYs 1978 and 1979 to continue payments to the existing 11 AHEC's.

C. Goals and Objectives

The goal of the individual AHEC projects is to develop a network of regional health manpower training centers (AHEC's). Each AHEC project is intended to be the focal point for the decentralization of the educational process for students in medicine, dentistry, pharmacy, and public health and for the regionalization of the educational process for (1) students in nursing and allied health, (2) primary-care residents, and (3) continuing education for health manpower of all types.

With these broad goals in mind, the specific objectives of the AHEC program can be viewed from the perspective of the three groups most affected by the program.

For students and medical residents it provides an enriched curriculum in primary care, exposure to community-based full-time faculty, and exposure to opportunities for community practice.

For practicing health professionals and nonprofessionals it offers an improved environment for practice through regionalized continuing education and through regular exposure to students and medical residents, and onsite educational opportunities for nurses and allied health professionals.

The community receives upgraded access to medical care through an established linkage between the AHEC and the health science center.

The following diagram is a conceptualization of how the AHEC model works to achieve program goals and objectives.

How The AHEC Model Works

D. Description of an AHEC

The key word in the AHEC system is linkage. The center is a system or an arrangement rather than a place; a system that links health service organizations and educational institutions in a way that serves the student, the practitioner, and the community.

The AHEC system works something like this: Money flows from the Federal Government to a medical school or a health science center. They in turn subcontract with one or more community teaching hospitals to serve as regional AHEC sites. The regional AHEC sites provide health manpower education programs in their geographical areas. The regional AHEC's also subcontract, or the health science center directly contracts, with smaller hospitals, other medical institutions, and professional associations located in the remote areas or in areas within the region where there is a shortage of health professionals. These secondary linkages foster the dissemination of the AHEC programs outward to the small hospitals and other health care activities which could not otherwise have access to these AHEC programs. The map on the following page shows, as an example, the primary and secondary health manpower education linkages for the South Carolina AHEC, which has developed into a statewide system.

Community hospitals chosen as AHEC's are those which already serve as regional health service referral centers. To become an AHEC, the hospital must agree to take on the additional responsibility for providing health manpower education to the smaller hospitals, community colleges, technical institutes, public health agencies, and practitioners within its defined region.

With these regional linkages, an AHEC builds the local capability needed to support undergraduate, graduate, and continuing education programs. There is a special emphasis on primary care physicians. However, training programs are also provided for dentists, nurses, nurse practitioners, and allied health personnel. Such training, it is hoped, will produce the traditional country doctor--but on a much more competent and supported level than his or her predecessors.

E. Other AHEC-Type Programs

Since the passage of the 1971 legislation, other Federal agencies as well as State, local, and private organizations have responded to the Carnegie Commission Report by supporting AHEC-type programs.

As of July 1975, BHM was supporting 11 AHEC projects; the VA, 8 AHEC-type projects; the Regional Medical Program (RMP) (administered by another bureau in HRA), 92 AHEC-type projects; and State, local, and private agencies were supporting 29 AHEC-type projects. Appendix V contains maps showing the geographical distribution of Federally funded AHEC and AHEC-type projects.

A brief discussion of the RMP and VA AHEC-type programs follows.

1. Regional Medical Program

RMP's were authorized in 1965 by amendments to the Health Professionals Educational Assistance Act of 1963 and received further funding under authorization of the Comprehensive Health Manpower Training Act of 1971 under the name Health Services/Education Activities (HS/EA). They were originally administered in the Bureau of Health Planning and Resources Development but were transferred to BHM in 1976.

The RMP's were intended to create a local and regional climate that would encourage voluntary cooperation among existing health institutions, individuals, and groups for the purpose of improving the quality, accessibility, and availability of health care. The RMP's were a type of AHEC but were "community based" in which grant awards were made to local consortia and hospitals.

At one time there were approximately 100 RMP's throughout the Nation, but the number has been reduced to about 30-35 since authorization for Federal funding expired in 1977.

Advocates of the RMP concept advised the Investigative Staff that RMP's significantly contributed to the development of health manpower programs and that a national evaluation should have been made of their effectiveness before Federal funding was terminated. They argue that RMP's were one type of AHEC on which the Federal Government expended large amounts of money but does not have the knowledge of benefits derived.

2. Veterans Administration AHEC's

Since 1972, VA has expended $5.2 million on eight AHEC projects separate and distinct from BHM's AHEC's. Three of the VA AHEC's were located in BHM AHEC areas--Asheville, North Carolina; Fresno, California; and Togus, Maine.

The Investigative Staff found that the VA withdrew its support for the Asheville and Fresno AHEC's to avoid a possible duplication of effort with the BHM projects. The VA has recently changed the designation of its AHEC Program to Cooperative Health (Manpower) Education Programs (CHEP's) so as not to be confused with BHM AHEC's.

Coordination between the BHM and VA programs is discussed in chapter IX of this report.

IV. CONTRACTING AND FUNDING

The 11 AHEC programs funded in 1972 were awarded 5-year incrementally funded contracts totaling about $100 million, with the Federal share totaling $65 million. In September 1977, just before the original contracts expired, BHM awarded 1-year contracts, totaling $14 million, for the continuation of the existing AHEC's. BHM, at that time, also awarded 1-year contracts, totaling $700,000, to four other medical schools for the planning of new AHEC's.

The Investigative Staff found that the BHM program staff and the HRA contracts office failed to properly schedule and staff the procurement and contract award cycle. This resulted in a very short proposal deadline, hasty proposal evaluations, and ineffective contract negotiation. In essence, there was a last-minute scramble to negotiate proposals and make contract awards for the 15 AHEC's by September 30, when the contracts for the 11 original AHEC's expired and when the FY 1977 funds had to be committed or deobligated and returned to the Treasury.

The 11 contractors had been allocated significantly less funds for FY 1978 (the sixth program year) than they had expected. In early 1977, they had been advised that although the original contracts had been considered "research and demonstration," the contracts for FY 1978 would be considered "training" contracts. As a result, indirect costs would now be limited to 8 percent of total direct costs, rather than to the institution's established indirect cost rate. Just prior to actual negotiations in September 1977 they were advised that no cost-sharing would be negotiated due to time constraints and, because of overall program budget considerations, the new contracts would be for 1 rather than the 2 years on which the proposals had been requested by BHM. Needless to say, during negotiations there was considerable hostility generated among the AHEC contractors. The process resulted in some loss of trust and confidence between BHM and the 11 medical schools and health science centers involved. The National AHEC Coordinator and project directors advised the Investigative Staff that a number of worthwhile program components had to be cut at the last minute, and that certain individuals working in the projects were terminated on very short notice.

The Investigative Staff believes that the "scramble" will occur in AHEC and other BHM and HRA programs at the end of the current fiscal year unless the Public Health Service (PHS) (the principal operating component of the Department over HRA) enforces the established requirements for procurement planning and implementation.

Information provided by BHM shows that throughout much of FY 1977, the National AHEC Coordinator was the only full-time professional staff member on the Central Office AHEC staff. Effective October 1, 1977, responsibility for program administration was transferred from the regional offices to the BHM Central Office. During the initial period following recentralization (October 1977-January 1978), the program operated at about 35 percent of authorized professional staff, and at such staffing levels the Central Office AHEC staff was unable to perform the initial procurement actions needed for completion of FY 1978 program funding.

A. Contracts for Original 11 AHEC's

The 11 AHEC programs funded in 1972 were awarded 5-year, incrementally funded contracts. The original contracts contained a scope of work and associated cost projects for each of the 5 years. The Government's total commitment (award), was the sum of these five annual cost projections.

The various regional offices, which were responsible for administering these contracts for the last 3 years, have viewed both the annual projections and the total commitment to the projects in different ways. Generally, however, the view has been that the total 5-year Governmental commitment was fixed, but that adjustments would be made in the annual workscopes and budgets, so long as the total price of the contract remained approximately the same. Most projects did, in fact, renegotiate the scope of work and budget with their regional office personnel prior to the third, fourth, and fifth year of activity. These contract modifications, however, did not significantly change the total amount of Federal funds committed to the projects.

1. Amounts Awarded

The following schedule shows a breakdown of the $65 million committed to the 11 AHEC's in 1972 and the actual amounts awarded to these projects over their 5-year existence.

Contractor	1972 Estimated Contract Amounts	Total Amount Awarded FYs 1973-1977	Increase or (Decrease) Over Estimated Contract Amount
Tufts----------	$ 4,861,944	$ 4,986,944	$125,000
West Virginia----	3,634,968	3,485,406	(149,562)
North Carolina---	8,563,734	8,961,567	397,833
South Carolina---	9,798,846	9,885,834	86,988
Illinois---------	9,724,056	9,724,056	0
Minnesota--------	3,406,364	3,406,359	(5)
New Mexico-------	4,725,075	5,301,144	576,069
Texas------------	5,830,965	5,740,115	(90,850)
Missouri---------	5,275,757	5,014,339	(261,418)
North Dakota-----	2,662,513	2,741,148	78,635
California-------	6,800,060	6,022,049	(778,011)
Total-------	$65,284,282	$65,268,961	$(15,321)

As shown in the above schedule, the West Virginia, Missouri, and California AHEC's received substantially less than the Federal share estimated in the original contracts.

2. Carryover of Unexpended Funds

Most projects got off to a slow start and did not spend all of the funds available during the first program year. As a result, over $4 million of the $9 million awarded remained unobligated and was then reprogrammed into FY 1974, the second program year.

There were three primary reasons for this carryover. First, BHM had given the projects a very short turnaround time for the AHEC proposals. As a result, planning for many of the specific programs within the projects had not been completed. Second, some of the institutions did not receive their signed contracts until January 1973, at which time the funding year was one-half over. Finally, the contracts did not recognize the need for a planning and startup period prior to full project implementation.

The projects likewise experienced problems in spending the money available to them in FYs 1975, 1976, and 1977 (program years two, three, and four).

BHM advised the Investigative Staff that $4.1 million was reprogrammed from FY 1973 to FY 1974, $3.5 million from FY 1974 to FY 1975, $3.3 million from FY 1975 to FY 1976, and, finally, $5.3 million from FY 1976 to FY 1977.

The reasons for the unexpended funds are many--implementation of particular activities were not feasible, the hiring of faculty and staff was delayed due to recruitment difficulties, or an activity was dropped because it was unsuccessful. These unexpended monies were generally "carried-over" to the following year and added to the sum considered to be available. In some cases the extra monies were used to implement new activities, either "one-time only" special projects or, more frequently, to expand the overall scope of the project in later years. In other instances an activity was simply postponed and took place on a delayed schedule, later in a project's development.

3. Cost-Sharing

The original 11 contracts awarded in 1972 provided that the Federal Government would contribute a total of $65 million for the AHEC projects and the contractors would provide at least an additional $23 million as negotiated cost-sharing. The cost-sharing provisions, however, were not standard for all 11 contracts, as shown below:

Contractor	Contracted Percent of Cost-Sharing
North Dakota	15% of total direct project costs
Minnesota	9-13% of total direct project costs
West Virginia	50% of total project costs
North Carolina	33 1/3% of total project costs
New Mexico	10.1-16.5% of total project costs

It is important to note that the cost-sharing column represents only negotiated cost-sharing amounts; i.e., the amounts required by the cost-sharing provisions of the contract. Most project officials advised the Investigative Staff that their actual cost-sharing substantially exceeded this amount.

4. Indirect Costs

Direct costs are those that can be identified specifically with the project or which can be directly assigned to the project relatively easily with a high degree of accuracy. Direct costs include such items as salaries, fringe benefits, travel, supplies, and consultant services. Indirect costs are those that have been incurred for common or joint objectives and, therefore, cannot be identified specifically with a particular project. At educational institutions such costs include (a) expenses incurred for the general executive and administrative offices of the institution and other expenses of a general character which do not relate solely to any major division of the institution; (b) expenses incurred by a central service organization for the operation, maintenance, preservation, and protec-

tion of the physical plant; and (c) expenses incurred in departmental administration.

Each of the 11 AHEC contracts provided that indirect costs incurred during the contracts would be reimbursed at rates established by a Negotiated Overhead Rate Agreement between the contractor and the HEW Regional Comptroller. These rates are negotiated in accordance with the authority set forth in OMB Circular A-88 and are for use on Federal grants and contracts.

The Investigative Staff noted that the indirect cost rates varied, as expected, among the 11 AHEC prime contractors and their subcontractors. The rates also varied depending on the program year involved. For example, the indirect cost rate for the Tufts University for FY 1976 was 42.9 percent of salaries and wages. The rate for one of the Tuft's subcontractors was 28.3 percent. The indirect cost rate for the University of North Carolina was 48.13 percent of salaries and wages.

The effect of the indirect costs on total project costs can be seen in the following example. Of the $8.6 million reimbursed to the South Carolina project as of August 1977, $1.4 million, or 16 percent, was for indirect costs.

5. Administrative Costs

BHM was requested to provide a schedule showing the amount of contract funds spent each year by each AHEC contractor and his subcontractors on administration (by category such as personnel administration, fringe benefits, indirect costs, other, total).

The Investigative Staff was subsequently advised that the information requested was not available in the Central Office or in the PHS regional offices, where the official files were maintained. Only a few of the budget proposals submitted by projects include information on administrative costs as separate from instructional costs, travel costs, etc. Moreover, the financial reporting forms used by BHM do not require this information, but generally contain broader categories such as "Salaries," "Other Direct Costs," "Travel," and "Student Support."

Administrative costs are particularly difficult to identify in this type of contract. Few projects had the luxury of sufficient funds for "purely" administrative staff. Rather, projects tended to take on multipurpose staff, "administrators" who also teach and have student-related responsibilities, and who may have significant responsibility for the development of a particular education program under the AHEC contract. Adding to the difficulty of such computations is the fact that personnel

costs and other project activities were not fully funded by AHEC alone. Even in those few instances in which the negotiated project budget breaks out projected administrative and other costs, the voucher system currently in use by BHM does not facilitate such accounting.

BHM provided the Investigative Staff with the following table on program administrative costs. The table was derived from contractor cost estimates which may not be fully accurate. The table thus only provides a general overview of the costs incurred for program administration.

ESTIMATED FEDERAL EXPENDITURES
FOR AHEC CONTRACT ADMINISTRATION a/
BY PROJECT, BY YEAR
($ in thousands)

AHEC Project	FY 1973	Percent	FY 1974	Percent	FY 1975	Percent	FY 1976	Percent	FY 1977	Percent
Tufts------	$126	25	$193	26	$253	24	$196	14	$171	11
W.Virginia-	22	14	120	22	256	25	192	26	271	20
N.Carolina-	122	15	574	34	498	28	511	24	470	21
S.Carolina-	103	12	259	13	272	12	363	15	374	12
Illinois---	156	38	285	25	392	17	356	16	479	17
Minnesota--	73	20	53	12	71	8	57	8	75	6
Texas------	70	28	120	11	104	7	113	9	144	8
New Mexico-	242	51	318	40	293	31	181	13	338	22
Missouri---	58	13	145	14	151	15	196	16	245	18
N.Dakota---	119b/	54	219b/	38	315b/	51	73	12	62	8
California-	132	25	226	18	241	17	229	16	283	18
Average Percent --		25		23		20		16		15

a/ Contract administration, for purposes of the above table, was defined to include only the costs of central or general contract administration and did not include the administrative costs of specific education programs.

b/ Due to a misunderstanding of the definition of categories used, some educational costs were included. Actual costs were less.

6. Analysis of Program Expenditures

The South Carolina AHEC provided the Investigative Staff with a detailed breakdown of program expenditures during FY 1977. The schedule on the following page shows that about 27 percent of the funds were spent on primary care medical education, 8 percent on undergraduate medical education, 8 percent on continuing and inservice education, 8 percent on minority programs, and 7 percent on library and audiovisual resources. Allied health, nursing, pharmacy, dental, and consumer education collectively received about 11 percent of the funds. Administration and operation, excluding indirect costs which are included in the individual program areas, totaled 26 percent of project expenditures, and other activities 5 percent.

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ANALYSIS OF PROGRAM EXPENDITURES FOR FY 1977
SOUTH CAROLINA AHEC

Program Area	State	Federal	Institutional	Total	Percent
		(in thousands)			
Administration and Operation	$236	$ 658	$ 298	$1,192	26
Primary Care Medical Education	242	676	345	1,263	27
Continuing and Inservice Education	62	207	109	378	8
Undergraduate Medical Education	109	175	78	362	8
Minority Programs	33	310	13	356	8
Library and Audiovisual Resources	53	196	69	318	7
Allied Health Education	29	131	24	184	4
Nursing Education	19	95	20	134	3
Dental Education	31	84	15	130	3
Communication and Transportation	18	76	8	102	2
Evaluation	13	42	12	67	1
Pharmacy Education	9	32	10	51	1
Team Approach	6	18	7	31	1
Retention of Health Professionals	8	21	2	31	1
Consumer Education	3	12	6	21	-
Total	$871	$2,733	$1,016	$4,620	100

Note: An additional $3.8 million in Family Practice State Funds has been expended in this program; however, it has not been included in this analysis because only specific AHEC dollars and specified cost-sharing dollars are accountable to HEW. Therefore, other program dollars likewise have been omitted. South Carolina AHEC officials believe that total project expenditures should be reported to HEW to properly reflect the magnitude of the program.

B. Continuation Contracts Awarded in September 1977

The Health Professions Educational Assistance Act of 1976 (PL 94-484 enacted October 12, 1976) added a new Section 781 to the Public Health Service Act, specifically authorizing appropriations for the support of AHEC's and setting forth new conditions of such programs. In addition, Section 802 of PL 94-484 specifically authorized the appropriation of "such sums as may be necessary" to continue payments to existing AHEC's for FYs 1978 and 1979, with the proviso that in FY 1979 the AHEC must provide satisfactory assurances that by the end of that fiscal year, the project will meet all the new requirements added by Section 781.

1. Project Directors Seek Information on BHM's Funding Plans

In December 1976 a national AHEC conference was held in Atlanta. At that time the project directors pressed for answers on when and how much money would be available for FY 1978. Would they receive their "current services" level of funding which, because of carryover funds, totaled $18-20 million? Would they receive less than that amount? Answers were not forthcoming. As a result, answers were sought from the Director of BHM.

For example, on December 13, 1976, Dr. Julius Krevans, Dean of the School of Medicine, University of California, San Francisco, wrote to the Director of BHM stating that it is absolutely essential that the university know within 3 months or so (by March 1977) what will be the conditions for continuing the project and roughly the number of dollars to be available at least for the next year. Dr. Krevans stated, in part:

> "The heart of the issue as we see it, is that these programs are educational programs tied to the calendar of the educational institutions in the Valley who receive much of the AHEC support. For example, if there is to be support of residency programs or if faculty supported through the AHEC contract are to be on board for the coming academic year, commitments have to be made well in advance of July of the current year. This has been possible to do up until now because of the continuity of the current 5 year contract, but now the uncertainty as to the future seriously threatens some of the most important programs, those which are central to the basic AHEC effort, and essential for the timely completion of what we have started."

In January 1977, the project directors felt that their questions on future funding were not going to be answered in a

timely manner by the Bureau. In addition, they had been advised that the Bureau was considering a major change in the contract mechanism and that this change would result in (a) 1-year training contracts rather than multiyear research and demonstration contracts, and (b) a revised method in computing the indirect costs allowed under the contracts.

The project directors advised the Investigative Staff that they discussed their concerns with appropriate Congressional representatives and, as a result, on February 9, 1977, Senators Cranston and Kennedy and Representative Paul Rogers wrote to the new Secretary of HEW regarding their concern for the continuation of funding of the AHEC's, as follows.

> "It has been brought to our attention that there is considerable uncertainty within the Bureau as to the size and the nature of this program in the next fiscal year, despite the clear intent expressed in the legislative history accompanying the Health Professions Educational Assistance Act of 1976 (P.L. 94-484) that the existing programs should be continued. * * * In addition, section 802 of P.L. 94-484 specifically authorizes the appropriation of 'such sums as may be necessary' to continue payments to existing AHECs for fiscal years 1978 and 1979.
>
> * * *
>
> "In addition--again despite the expressed Congressional intent--the AHECs have been advised that consideration is being given to a major change in the contract mechanism utilized in administering the program. This change would terminate the existing research and demonstration contracts and replace them with training contracts.
>
> "It is our understanding that under current HEW regulations such a change would have two important implications for the Area Health Education Center programs. Research and demonstration contracts can be made for multi-year periods, while training contracts, it is our understanding, are limited to one year only. The nature of AHEC programs, which to a sizeable extent include multi-year residency training programs as well as subcontracts with other educational institutions, requires the ability to make commitments on a multi-year basis.
>
> * * *
>
> "Another complicating factor is the need for the AHEC programs to operate on the basis of an academic fiscal year running from July 1 to June 30. It is our understanding that there is some question about the ability of HEW to give the AHEC's sufficient assurances of the probable

fiscal year 1978 awards prior to the first of July so that the AHECs can hire necessary faculty and make other necessary commitments to participating institutions consistent with the constraints of the academic fiscal year."

Two months later, on April 11, 1977, Secretary Califano replied to the letter from Senators Cranston and Kennedy and Representative Rogers. The Secretary stated that the existing 11 AHEC projects would be supported in FY 1978 subject to the availability of appropriations. Concerning the contracting mechanism, the Secretary stated that contracts would be awarded for 1 year with an option to renew for an additional year in FY 1978. It was recognized that the contractors would probably prefer incremental funding, but that the option to renew would signal an intent to continue support through FY 1979.

2. Limitation on Overhead Costs

The contracts awarded in September 1972 for the original 11 AHEC's provided that the contractors would be fully reimbursed for their indirect costs incurred during the contracts.

Subsequently, in May 1973, HEW published in the Federal Register a proposed procurement regulation which would limit indirect costs on training contracts with educational institutions and nonprofit organizations. The limitation established was 8 percent of the contractor's total allowable direct costs, or its allowable actual indirect costs, whichever is less.

The Investigative Staff found that the proposed regulation never became final in the Federal Register; however, the contents of the proposed regulation have been considered to be HEW policy. In that regard, HEW representatives stated that no changes were necessary as a result of publication in the Federal Register. Since the AHEC contracts fall within the definition of training contracts specified in the proposed regulation, they are therefore subject to the limitation on reimbursement of indirect costs.

3. FY 1978 Funding Requirements

The FY 1977 supplemental appropriation provided $14 million for AHEC's, while President Carter's FY 1978 budget requested $15.5 million for this purpose. According to the justification presented to the Congress, the $15.5 million would support 16 AHEC's--continuation of the original 11 AHEC's, continuation of 3 new AHEC's planned to be initially funded in FY 1977, and initial funding for 2 new centers in FY 1978. President Ford's budget had requested only $5.5 million, with no additional funding for the original 11 AHEC's.

President Carter's budget added funds for existing AHEC's as a result of PL 94-484, enacted in October 1976, which required such continued funding.

The Investigative Staff found that the House Subcommittee on Labor-HEW Appropriations had requested the Department to provide information on the level of funding necessary to continue the existing AHEC's in FY 1978 at their current (FY 1977) activity level. The Department, however, had difficulty providing the information, and the figures given differed from those provided by the project directors. For example, in response to a Subcommittee staff request of March 17, 1977, BHM indicated that $12.2 million would be required to continue funding for the original 11 AHEC's. On June 8, the continuation costs were amended to $10.8 million, with initial costs for three new projects reestimated to be $3.2 million.

The Subcommittee staff had information from the project directors that inadequate funds had been requested in FY 1978 for the AHEC's in existence, and it would require substantially more than $10.8 million to continue the 11 AHEC's in FY 1978. As a result, the staff requested PHS to review the information provided and were subsequently advised that the continuation costs in FY 1978 for the 11 AHEC's would amount to over $15 million, which was $4.2 million greater than the previous estimate.

In view of the above, on June 23, 1977, the Director, Office of Administrative Management, PHS, directed HRA to prepare certain financial information on current and future AHEC funding. The Director expressed concern over the Bureau's lack of financial information and the inaccurate cost figures provided. The Director stated, in part:

> "I am also concerned that we repeatedly reported misleading continuation costs to the Department and the Appropriations Subcommittee staff, while more accurate estimates have apparently been provided to others in the Congress outside of official channels. Such plays thwart the President's budget, embarrass us in front of the Department and the Congress, cause needless work for both departmental and Congressional staff, and cast doubt upon the accuracy of more conscientiously prepared submissions, including our Congressional justifications."

The Investigative Staff noted that there were several historical and procedural factors which complicated a determination of the actual annual expenditure rate for each AHEC. These factors included:

-- The impoundment of funds in FY 1973.

-- Contracting over a 5-year period (1972-1977) on an incremental basis.

-- Contract modifications which have varied in length from 6 to 24 months.

-- Carryover monies which have been substantial from year to year.

The Investigative Staff found that BHM's lack of adequate and reliable financial information on the AHEC projects was just one of the results of the Bureau's failure to adequately monitor the projects.

4. FY 1978 Appropriation

The House provided an additional $1.5 million to the President's budget and referred to a total of 18 AHEC's, or 4 new starts over the FY 1977 level. The Senate, in its Committee report, expressed concern that BHM had indicated that funds for the existing AHEC's would be sharply reduced, and that AHEC's were considered training activities, rather than developmental activities. Moreover, the Senate Committee directed that the current activity level of existing AHEC's be maintained, prior to funds being awarded to new projects.

The Conference Report on the FY 1978 Labor-HEW Appropriations Bill, dated July 26, 1977, endorsed the split of $14 million for continuations and $3 million for new starts, although neither specified the number of new starts. As will be described below, the rates of expenditures in FY 1977 by the original 11 AHEC projects were greater than that reported to the Subcommittee on Labor-HEW Appropriations and would not match the language provided in the Conference Report specifying $14 million for continuations.

5. BHM's Initial Funding Plan for FY 1978

The date of the Conference Report, July 26, was also the date that HRA responded to PHS' request of June 23. HRA responded by stating that they too shared the common concern with not having more precise reporting of AHEC continuation costs. HRA reported that the project directors perceived that their "current services" level was $18-20 million. The HEW regional contracting offices reported the level of funds available to the projects in FY 1977 (the fifth program year) to be $18.1 million ($10.8 million from the FY 1977 appropriation, $5.5 million from the FY 1976 continuing resolution but reprogrammed for FY 1977 expenditure, and $1.8 million from unexpended balances in FY 1976 and prior years).

BHM's position was that the "current services" level should be considered only the sum of the FY 1977 funds allotted to the regions ($10.8 million) and the FY 1976 appropriation intended for use in FY 1977 ($5.5 million) or $16.3 million. Since BHM had certain other program activities also to be supported from the FY 1978 AHEC appropriation, it was the Bureau's position that a level of approximately $15.1 to $15.7 million in FY 1978 would approximate the above "current services" level and would be consistent with the Congressional position to continue the necessary functions of the 11 AHEC's.

Language was included in the Conference Report for the FY 1978 appropriation which instructed that $17 million be divided, with $3 million for new starts and $14 million for existing projects. Based on information provided by BHM, it appeared to the Appropriations Committees that the $14 million would be sufficient for the existing 11 projects.

As previously noted, the Bureau had planned, in conformance with the President's budget and the appropriation, to fund three new AHEC's in FY 1977. This, however, had not yet been done.

In the face of a $17 million appropriation in FY 1978, and the initiation of three new starts in FY 1977, with subsequent FY 1978 and FY 1979 continuation costs, the trade-off was clearly between maintenance of the present effort with the original 11 AHEC's ($15.1-15.7 million), versus spreading the AHEC concept into other States.

The Bureau recognized that it had understated, to the Appropriations Committees, the FY 1977 expenditure levels of the 11 AHEC's and that, as a result, the Conference Report did not include sufficient funds for continuation of the original 11 AHEC's in FY 1978 at their "current services" level.

In view of the above, the Bureau planned to resolve the matter by terminating 1 of the existing 11 contracts on September 29 and then renewing it from otherwise uncommitted FY 1977 AHEC funds on September 30. This action would have had the effect of reducing the demand on FY 1978 funds and thereby enabled the 11 AHEC's to be funded at the $15.7 million level (BHM's "current services" figure). This would have been accomplished by funding 1 of the AHEC's at $1.9 million out of FY 1977 funds and funding the other 10 AHEC's with $13.8 million in FY 1978 funds.

Thus, as of the end of July 1977, BHM's funding plans for the Conference allowance of $17 million for FY 1978 was as follows:

Amount		Purpose
$13.8 million	----------	to fund 10 of the original AHEC's
1.5 million	----------	continuation costs for three AHEC's still to be initiated in FY 1977
1.2 million	----------	initiate four new AHEC's
.5 million	----------	program evaluation and technical assistance
$17.0 million		

BHM's funding plan thus provided (a) sufficient funds for the existing 11 AHEC's to meet what the Bureau considered as the projects' "current services" level, as well as (b) $2.7 million for new AHEC's.

6. Contracting Process

BHM sent out the Request for Proposals (RFP) for the continuation contracts on July 15. A short 30-day response period was given, which included the mailing periods for receipt and return of the RFP. Project directors advised the Investigative Staff their proposals were based on the projects' FY 1977 expenditure levels, an inflationary factor for FY 1978, and on the amount of funds they believed would be necessary to carry out new programs required by the new legislation. The 11 proposals totaled about $21 million.

The original contracts were being administered by the HEW regional offices. The continuation contracts, however, were to be negotiated by the Central Office in accordance with BHM's recentralization plans. The Investigative Staff noted that this recentralization of procurement activity resulted in problems which caused significant delays and severely impacted on the procurement process. In addition, because of BHM and HRA's failure to properly schedule its procurements throughout the year, the HRA contracts office had an extremely heavy workload, which forced the AHEC projects into being negotiated and awarded in the last 2 weeks of the fiscal year.

The Investigative Staff noted that there was a hasty and compressed proposal evaluation effort. As a result, not all of the concerns raised in the technical and business reviews of the proposals appeared to have been resolved.

For example, the North and South Carolina projects both proposed to continue their air transportation activities in support of their AHEC's. Regional office representatives reviewed the South Carolina proposal and suggested that continuation

of the project's air transportation activities be deleted from the scope of work and that the Contractor be required to submit a complete justification for the use or lease of project aircraft. The reviewers further suggested that the justification for project aircraft should be based upon program and economic advantages as opposed to ground or commercial air travel. The Investigative Staff noted, and BHM officials confirmed, that the justification was not obtained. The executed contract, however, required the project to "Continue to support the Med Air transportation program to provide the mobility necessary to support programs at the AHEC sites."

Likewise, the North Carolina project requested over $50,000 to pay the salaries of a full-time pilot, a part-time pilot, and a director of air transportation. The Medical Foundation of North Carolina, Inc., owned the five aircraft, and they were operated, on a nonprofit basis, by and primarily for the AHEC Program. Reviewers of the proposal questioned the utilization of private aircraft and suggested that "The operation of the private aircraft should be covered by an advance agreement if it is allowed in lieu of common carrier." The Investigative Staff noted that although a formal agreement was not prepared, the contract still provided the requested funds for the pilots and director of air transportation.

The Investigative Staff noted that the institutions were given 3 to 5 days' notice of the negotiation schedule. At that time, they were advised that only 1-year contracts would be negotiated, rather than 2-year proposals (1-year, with an option to renew) they had been asked for and submitted. Moreover, they were also asked to be prepared to reduce their FY 1978 budgets by at least 20 to 30 percent over the projected FY 1977 funding level and by up to 50 percent of the funding levels in their proposals.

During the negotiation process, the project directors were advised that no cost-sharing would be negotiated due, in part, to time constraints.

The Investigative Staff found that BHM allocated the FY 1978 funds in such a manner that each of the 11 AHEC contractors received at least 80 percent of its fifth-year budget as projected in the initial contracts awarded in September 1972. In that way, awards totaled about $14 million ($2.7 million from FY 1977 funds and $11.3 million from FY 1978 funds).

The schedule on the following page shows the FY 1978 contract awards and their relationship with the amounts originally projected for the fifth program year (FY 1978) and the amounts requested by the 11 projects.

FY 1978 FUNDING FOR ORIGINAL 11 AHEC'S

Project	FY 1977 Funding Estimated in Initial Contracts Awarded in 1972	Amount of Proposal for FY 1978	Funds Awarded for FY 1978	FY 1978 Award as Percent of 1972 Estimate of FY 1977 Funding
Tufts (Maine)----	$ 1,317,323	$ 1,637,000	$ 1,117,006	84%
West Virginia----	969,560	2,541,000	871,000	89%
North Carolina---	2,142,574	2,306,000	1,763,514	82%
South Carolina---	2,495,611	3,007,000	2,025,699	81%
Illinois---------	2,747,724*	2,649,000	2,037,312	74%*
New Mexico-------	1,335,596**	1,868,000	1,173,256	87%
Texas------------	1,285,859	1,621,000	1,117,498	86%
Missouri---------	1,083,705	1,590,000	909,891	83%
North Dakota-----	589,126	689,000	709,170***	120%
California-------	1,594,520	1,891,000	1,386,922	86%
Minnesota--------	796,225	1,539,000	839,324***	105%
Total-------	$16,357,823	$21,338,000	$13,950,592	

* Adjusted to reflect a 12-month period. Previous 11-month amount was $2,518,750, and award constituted 80 percent of that amount.

** Adjusted to reflect actual indirect cost rate, established in the second program year.

*** BHM provided additional funds to enable the project to broaden its limited scope of activities.

BHM funded 2 of the 11 AHEC's (North Carolina and Missouri), as well as 4 new AHEC's (rather than 3 as planned), out of otherwise uncommitted FY 1977 funds. The two AHEC projects received a total of $2.7 million. In addition, BHM utilized only $11.3 million under the 1978 Continuing Resolution (as opposed to $13.8 million as previously planned) for contract awards for the remaining AHEC projects.

This action resulted in the projects being funded at the $14 million level, which was the Conference Report figure but which was also significantly less than the "current services" level of $15.7 million.

The Investigative Staff inquired why the Bureau funded the 11 AHEC's at only the $14 million level when (a) BHM's funding plan as of the end of July 1977 provided that the original 11 AHEC's were to be funded at the $15.7 million level (1 AHEC forward funded), and (b) as a result of forward funding not 1 but 2 AHEC's, the Bureau had further reduced the demand on FY 1978 funds by an additional $800,000.

The Deputy Director, BHM, replied that the Bureau had subsequently changed its interpretation of what the Congress intended when it instructed that $17 million be divided, with $14 million for existing projects and $3 million for new starts. BHM's new interpretation was that "existing projects" in FY 1978 included both the original 11 AHEC's, as well as continuation costs of the FY 1977 new starts still to be initiated.

As a result of BHM's new interpretation of the legislation, continuation costs for the new starts would be assessed to the $14 million earmarked for "existing projects" rather than to the $3 million earmarked for "new starts."

7. Congressional Mandate for Revised Funding Plan

BHM officials subsequently met with representatives of the Senate Appropriations Committee staff to discuss their FY 1978 funding plans relative to the amount of funds available for the original 11 AHEC's. BHM officials advised the Investigative Staff that as a result of that meeting the Bureau agreed to provide an additional $2 million for the original 11 AHEC's, thereby bringing their FY 1978 funding level, as previously planned, up to their FY 1977 "current services" level.

The Senate Report (#95-564) for the FY 1978 Supplemental Appropriations Bill, dated October 28, 1977, directed that HEW prepare a new spending plan for the AHEC Program which, in HEW's judgment, meets the competing needs of the original 11 AHEC projects, the second program year for the new AHEC's, and new starts in FY 1978. The Report directed

that the new plan be presented to the House and Senate Appropriations Committees within 60 days following enactment of the Supplemental Appropriations Bill.

8. BHM's Revised Funding Plan

In response to the Senate Committee Report, a new spending plan was developed for the AHEC Program. The plan included additional awards of about $2 million to be made in March-April 1978, thereby providing a total of $16 million to the existing 11 AHEC's. BHM advised the Investigative Staff that it planned to allocate the additional $2 million to the projects in a manner which would bring each of them up to at least 95 percent of their fifth program year funding levels as estimated in the initial contracts awarded in September 1972.

The Investigative Staff questioned BHM's rationale for first cutting the proposals from $21 million to $14 million, and then planning, at midyear, to negotiate contract modifications to bring the total awards back up to the $16 million level. The Investigative Staff believes that such funding patterns have a disruptive effect on the continuity of project activities and result in unnecessary contract modifications. In that regard, project directors advised that it is counterproductive to terminate or cancel project activities (because of a reduction in Federal funding) and then reinstitute those activities for possibly only a 6-month period.

C. Contracts Awarded for New AHEC's

Section 781 of the Health Professions Educational Act of 1976 provided the authority for HEW to significantly expand and support the AHEC Program. This expanded direction was urged by the 1976 Carnegie Council Report, which reviewed health care progress since 1970 and made further recommendations concerning needed changes in health professions education.

1. Need for Urban AHEC's

The Investigative Staff found that the AHEC Program is making progress in its goal to recruit and retain health manpower in underserved areas, and as a result improve the quality of available health care. However, one aspect of AHEC development has not been achieved. There is an absence of AHEC's in urban areas. In its 1970 report, the Carnegie Commission clearly indicated the need for health professions education programs in underserved inner city areas. To date, AHEC development has focused on rural areas. The record shows that even private and State-supported decentralized health education programs have not had a major impact in urban areas.

Concern about the shortages of health manpower and inequitable distribution of primary care and specialist practitioners in the Nation's cities has been growing. The 1975 House of Representatives Committee Report on the Health Manpower Act of 1975 (#94-266, dated June 7, 1975) stated:

> "The only overall criticism . . . of the AHEC program to date is that none of the existing AHECs have been directed toward the health manpower problems of inner city urban areas. The Committee expects that a significant portion of AHECs developed under the new legislation will be designed to influence geographic distribution problems of these areas."

The Senate's Labor and Public Welfare Committee Report (#94-887, dated May 14, 1976) on the Health Professions Educational Assistance Act of 1976 contained similar language:

> "Finally, the Committee would note that all 11 Area Health Education Center programs established to date have emphasized the improvement of services in rural areas. While the Committee appreciates the need for improved services in rural areas, the Committee also believes there is a need for the establishment of AHEC programs which serve urban areas. This intent should be considered by the Department of HEW in making AHEC awards."

The record shows that unlike rural areas where health manpower resources are scattered and sometimes limited, access to health care in the inner city is more related to problems of financing, organization, coordination, and efficiency. Consequently, BHM believes that the emphasis of an urban AHEC should be on coordinating existing resources and maximizing their utilization.

2. Contracting Process

BHM's project solicitation, while authorized until the end of FY 1978 under Section 774(a) of the Public Health Service Act, was geared to the provisions of the new funding authorization in Section 781 of the Health Professions Educational Assistance Act of 1976. The solicitation stated that the initial award would be only for 1 year but that it is the intent of the Government to provide sustaining support for AHEC programs and the AHEC's they develop for a minimum of 3 years and a maximum of 5 years as follows:

Project's Program Year	Fiscal Year	Phase	Purpose
01	1978	I	Planning
02	1979	II	Development
03	1980	III	Operation
04	1981	III	Operation
05	1982	III	Operation

HRA solicited proposals from 51 medical schools. Twenty-five proposals were received. Seven proposals were deemed technically acceptable, and four were eventually funded.

The Investigative Staff noted that the contracting process for the 4 new AHEC's, like that for the 11 continuations, was quite unusual and not a normal contracting process. The Request for Proposals (RFP) were sent out in July and had only a 30-day turnaround time. The contracting office and BHM had not fully discussed the procurement. As a result, a single RFP went out for either a rural, urban, combination rural/urban, or statewide AHEC. In addition, the RFP failed to include award criteria. The contracts office advised the Investigative Staff that these mistakes never would have happened had the RFP included a statement that the awards would be made on the basis of cost and the technical merit of the proposal.

Because of the desire to fund the projects before September 30, and the heavy yearend workload in the contracts office, there was no real negotiation of the proposals. The Negotiation Summary shows that negotiations were conducted by telephone.

The Investigative Staff found that the "superior" proposal that received the highest technical rating was not funded. Instead, the marginal project receiving the lowest technical rating (of those deemed technically acceptable) was funded.

The ratings of the seven proposals deemed technically acceptable were as follows:

Institution	Rating	Funded	Type of AHEC
Albert Einstein	78.8%	--	Urban
University of Colorado	77.2	Funded	Rural/Urban
University of Maryland	72.0	Funded	Urban
University of Cincinnati	71.0	--	Statewide
University of Connecticut	69.8	--	Urban/Rural
Howard University	68.8	Funded	Urban
University of Pittsburgh	64.0	Funded	Urban

The Investigative Staff inquired why the "superior" proposal was not funded, while the two lowest technically rated proposals in the acceptable range were funded. The Investigative Staff was particularly interested because the University of Pittsburgh proposal received a three to two vote by the review panel, which made it marginally acceptable but still worthy of support. The HRA contracting officer stated that contracts for new AHEC's were awarded to the lowest bidders, within the limits of funds available for new AHEC's, and not on the basis of the technical ratings of the seven proposals, and other factors such as type of AHEC or geographic location of the project. He further stated that since the RFP failed to include the above-noted factors in the award criteria, and this was a competitive procurement, the contracts office had to either (a) award the contracts solely on the basis of cost or (b) cancel the RFP and issue a new one which stated that the awards would be made on the basis of the above-cited factors. Time, however, did not permit the issuance of a revised RFP.

The notices of award were not sent out until the last day of the fiscal year. Telegraphic notices were then given. As a result, the detailed scopes of work and the contracts were not executed until several months into the project year. For example, the HRA contracting officer did not sign-off on the Howard University contract until December 16, 1977, and the University of Maryland contract until January 12, 1978. The Investigative Staff believes that had BHM initiated the procurement action earlier in the fiscal year, and fully discussed the planned procurement with the HRA contracts office, the procurement could have been handled in an orderly fashion and in accordance with normal contracting policies and procedures.

3. Contract Awards and Cost-Sharing Provisions

Section 781 of PL 94-484 requires a minimum of 25 percent cost-sharing by the projects. The amount of the awards and the percentages of cost-sharing are as follows:

Institution	Government Share	Contractor's Share Amount	Contractor's Share Percent	Total
Univ. of Colorado----	$251,674	$239,890	49	$ 491,564
Univ. of Maryland----	185,921	152,116	45	338,037
Howard University----	132,329	68,170	34	200,499
Univ. of Pittsburgh--	129,272	44,715	26	173,987
Total----------	$699,196	$504,891		$1,204,087

The contracts are 1-year "planning" contracts for new AHEC's. As a result, they are not limited to the 8-percent

ceiling on indirect costs applicable to "training" contracts.

The Investigative Staff noted that the 8-percent limitation on indirect costs would apply after the planning phase is completed and the projects start to function as an AHEC and train health personnel. Under such circumstances and because funding under Section 781 requires a minimum of 25 percent cost-sharing by a project, HEW has ruled that if a contractor's indirect cost rate exceeds 8 percent (and most university rates are substantially above 8 percent), then the amount disallowed by applying the limitation may be counted toward meeting the cost-sharing requirement.

D. Problems Noted in HRA Procurement Planning

Each year HEW obtains nonpersonnel services, equipment, supplies, and construction costing about $7 billion. Nearly $2 billion of this is obtained by contracting; the remaining $5 billion is obtained through discretionary grants. About $550 million, or 25 percent, of the $2 billion in contracts is for HRA and other PHS activities.

On May 18, 1977, Secretary Califano issued a memorandum to Departmental personnel on actions required to correct major deficiencies in the HEW contracting and grant processes.

Secretary Califano stated that extensive review by his office and reports on procurement and grants made by the General Accounting Office, the HEW Audit Agency, HEW's Office of Grants and Procurement, and the Primary Operating Components of the Department themselves had revealed the following major deficiencies:

-- Failure to schedule procurement and grant awards.

-- Failure to protect the Government's interests in competitive procurement.

-- Failure to limit noncompetitive procurement.

-- Failure to ensure that contracts and grants are performed in all cases.

-- Favoritism, conflicts of interest, and subjectivity in the award of discretionary grants.

-- Inadequate price and cost analysis.

1. Failure to Schedule Procurement and Grant Awards

The Secretary directed that a specified plan of

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corrective action be put into immediate effect. In regard to the "failure to schedule procurement and grant awards," which the Investigative Staff noted in AHEC and other BHM and HRA procurements, the Secretary directed that schedules were to be developed for even distribution of procurements and discretionary grant awards throughout the fiscal year. In addition, reports were to be submitted on key indicators of performance.

The Investigative Staff noted that HRA's past experience was in awarding relatively few contracts during the first three quarters of the fiscal year and awarding the bulk of the contracts during the fourth quarter. Information provided shows that HRA awarded a total of 264 new contracts in FY 1977, but that 151, or 57 percent, were awarded in September, the last month of the fiscal year. Moreover, during the entire first 8 months of the fiscal year, only 41 contracts were awarded. In other words, 2 percent of the contracts were awarded during the first 4 months of the fiscal year, 13 percent during the second 4 months, and 85 percent of the contracts were awarded during the last 4 months of the fiscal year.

It is also noted that BHM's corrective action plan of August 1, 1977, stated that most of the Bureau's procurements had been in the fourth quarter and that the Bureau had a reputation of a "fourth quarter spender."

In a memorandum dated January 25, 1978, the HRA Associate Administrator for Operations and Management stated that HRA's revised procurement schedule for the remainder of the fiscal year clearly indicated that a disproportionate amount of work was again being pushed into the final quarter of the fiscal year. The following schedule shows HRA's plan for contract and discretionary grant awards for the remainder of FY 1978:

Fiscal Year Quarter	Number of Awards	Value
Contract Awards:		
First (Actual)	33	$ 12.4 million
Second	41	5.2 "
Third	52	8.6 "
Fourth	111	17.3 "
Discretionary Grant Awards:		
First (Actual)	12	$ 1.4 million
Second	376	43.8 "
Third	1,074	108.4 "
Fourth	311	42.0 "

The above schedule shows that there is a substantial variance in numbers of awards and total funds obligated for both grants and contracts in each quarter.

It is obvious that HRA's actions to date have not met the Department's mandate for an even distribution of contract and grant awards. In that regard, HRA contracts office officials agreed with the Investigative Staff's conclusion that there is a need to more evenly spread the contracting process over the fiscal year. Such action would permit more effective use of HRA personnel and would enhance actions required to correct other major deficiencies noted by the Secretary in the contracting process. In accordance with the Secretarial directive, the HRA contracts office is encouraging program staffs to initiate the procurement cycle earlier in the fiscal year.

2. Inadequate Price and Cost Analysis

HRA has reported that in the past, and especially during peak workload periods at the end of the fiscal year, the HRA contracts office was forced to request cost advisory personnel to perform an analysis of an offeror's business proposal concurrent with evaluations of his technical proposal by program personnel. As a result, cost advisory personnel were denied the opportunity to correlate other quantitative and qualitative findings related to unit prices, direct labor costs, indirect costs, etc.

The Investigative Staff noted that the concurrent review practice had to be followed for the AHEC contract proposals reviewed in August and September 1977. Otherwise, it would not have been possible for the contracts to be awarded by the beginning of the new fiscal year.

A better distribution of the contract workload throughout the fiscal year would permit HRA to provide cost advisory personnel with the results of evaluations of the technical proposals and, thereby, obtain more meaningful cost analyses of the offeror's business proposal.

E. Authority to Fund AHEC's with Grants

On February 3, 1978, the Federal Grant and Cooperative Agreement Act of 1977 (PL 95-224) was signed into law. The Act authorized agencies to use the grant or contract mechanism in those programs where the agency previously had the authority to make grants only or enter into contracts only. The Act also established a new type of funding mechanism--cooperative agreements--for use when the principal purpose of the funding is the same as for a grant but, unlike the grant, substantial involvement is anticipated between the executive agency and the funding recipient.

If, for example, BHM determines that a grant or cooperative agreement relationship would be preferable to the contract relationship for AHEC projects, the Department could award a grant or enter into a cooperative relationship, despite the fact that Section 781 of PL 94-484 authorizes contracts only.

Although AHEC's have been funded in the past by contracts, the Director of BHM believes that the grant or cooperative agreement may be preferable for the support of these programs. Accordingly, BHM is considering no longer funding AHEC's through the contract mechanism.

F. Observations and Conclusions

BHM program staff and the HRA contracts office failed to properly schedule and staff the AHEC contract award cycle. The Investigative Staff noted that this is a Departmentwide problem. The Secretary of HEW directed in May 1977 that corrective action be taken; however, HRA has not taken sufficient action to implement the Secretarial directive. As a result of the deficiencies in the contracting and grant process, there were too short proposal deadlines, hasty proposal evaluations, and ineffective contract negotiations in relation to AHEC contracts awarded in September 1977.

In addition, BHM and the HRA contracts office had not fully discussed the procurement, causing the contracts office to (1) issue a single request for proposals for different types of AHEC's, and (2) fail to specify award criteria in the request for proposals. As a result, contracts had to be awarded on the basis of cost alone, rather than on cost and technical merit of the proposal and other factors such as type of AHEC or geographic location of the project.

BHM awarded funds to the original 11 AHEC's for FY 1978 (program year six) primarily on the basis of costs projected for the fifth year in the original contracts awarded in September 1972, rather than on the basis of the merits of the technical proposals.

In addition, BHM underfunded the AHEC's and is now planning to provide about $2 million in supplemental awards to meet the legislative mandate of funding the projects in FY 1978 at their FY 1977 "current services" level.

BHM awarded AHEC contracts in September 1977 for a program year of October 1, 1977, through September 30, 1978 (Federal fiscal year), rather than in phase with the academic year (July 1 through June 30). Contracts in phase with the academic year enable AHEC's to hire necessary faculty and make other necessary commitments to participating institutions consistent with the constraints of their academic year. In addition, these last minute awards had rather serious consequences on program planning and development, faculty retention and residency selections.

G. Recommendations

To correct major deficiencies in HEW's contracting and grant processes and to improve administration of the AHEC Program, the Investigative Staff recommends that the Committee may wish to require the Secretary of HEW to:

(1) Ensure that HRA properly schedule and staff the procurement and contract award cycle.

(2) Ensure that BHM and HRA immediately initiate procurement actions required for completion of AHEC funding for FY 1978.

(3) Ensure that different requests for proposals be issued for new urban, rural, or Statewide AHEC's.

(4) Ensure that criteria for making awards for new AHEC's take into consideration, in addition to cost, such other factors as technical merit of the proposal and geographic location of the project.

(5) Consider awarding contracts for new AHEC's in phase with the academic year of July 1 through June 30, and with sufficient lead-time to enable medical schools to plan before the start of the contract period.

V. FUTURE FEDERAL FUNDING OF AHEC's

BHM provided the Investigative Staff with a forward funding plan for the AHEC Program. The plan projects FY 1979 and out-year costs of $17-$19 million for at least each of the next 6 fiscal years. These funds will support a range of 22-30 AHEC's in any given year. BHM has adopted the policy of decremental funding--new AHEC's are to be initiated as Federal support of existing AHEC's is gradually reduced.

A. Additional Funding for Original 11 AHEC's

Section 802 of PL 94-484 provided that for FY's 1978 and 1979, there are authorized to be appropriated such sums as may be necessary to continue payments to the original 11 AHEC's. Section 802 further provides that FY 1979 funding is contingent on the project providing assurances satisfactory to the Secretary that by September 30, 1979, the project meets certain requirements specified in the replacement Section 781.

Section 781 provides the authority for funding new AHEC's but in doing so requires the new AHEC's to meet certain requirements and carry out certain additional activities not imposed on the original 11 AHEC's.

As previously noted, the Bureau has awarded $14 million to the original 11 AHEC's for the current fiscal year. BHM intends to make supplemental awards of $2 million. The supplemental awards would bring each of the AHEC's up to at least 95 percent of their fifth program year funding levels estimated in the initial contracts awarded in September 1972.

In December 1977, BHM provided the Investigative Staff with a draft funding plan for AHEC's for FY's 1978-1984 that had been submitted to the Assistant Secretary for Management and Budget. As of mid-February 1978, the plan had not yet received Departmental approval and had not been submitted to OMB for its review. The plan showed the following funding for the original 11 AHEC's:

Fiscal Year	Funding Year	Amount
1978	06	$16 million a/
1979	07	14 million
1980	08	10 million
1981	09	5 million

a/ $2.7 million out of FY 1977 funds (2 AHEC's), $11.3 million out of FY 1978 funds (9 AHEC's), and proposed supplemental awards of $2.0 million.

Funding for FY's 1978-1979 would be made under Section 802. Funding for FY 1980 would be made under Section 781. Section 781 only authorizes appropriations for AHEC's through FY 1980. Therefore, funding in FY 1981 would require new legislative authority.

The next chapter of this report discusses the potential for shifting the funding of the original 11 AHEC's, as well as newly funded AHEC's, to State and local sources. In essence, the Investigative Staff found that certain projects will have difficulty in obtaining alternate funding sources to sustain the level of program activity developed with Federal financial assistance.

1. Section 781 Requirements

FY 1979 funding for the original 11 AHEC's is contingent upon their being able to assure BHM that, by September 30, 1979, they will meet the Section 781 requirements applicable to new AHEC's.

Section 781 requires expanded AHEC activities such as training in health education services and training of physician assistants and nurse practitioners.

Several project directors advised the Investigative Staff that they were concerned over the requirement in Section 781 that:

> "* * * no less than 10 percent of all undergraduate medical or osteopathic clinical education of the school will be conducted in an area health education center and at locations under the sponsorship of such center."

Section 781 requires the Secretary to develop and implement regulations establishing standards and criteria for the Section 781 AHEC's. These have not been promulgated

and announced. The Investigative Staff believes that it is improper for the Bureau to place the AHEC projects in the position of having to say whether or not they will meet the 10-percent requirement, without first knowing how the requirement will be defined. Projects could find that although they had made commitments to subcontractors and project personnel for FY 1979, Federal funding would not be provided because their assumptions on the definition of the 10-percent requirement were not compatible with the guidelines or regulations established by BHM.

BHM advised the Investigative Staff that the regulations establishing standards and criteria for the Section 781 AHEC's were expected to be completed and published in the Federal Register for public comment in about March 1978.

The 10-percent "clinical instruction" requirement appears to have two purposes: (a) to upgrade the educational and thus the health care resources in underserved areas, and (b) to expose students to health care problems in these areas and to interest them in the possibilities of practice in the rural areas. These are most worthwhile objectives.

However, the resources for clinical instruction are necessarily limited in the underserved areas--at least until they can be upgraded--and to expect a large medical school to give 10 percent of its clinical instruction, if it is broadly defined, in remote places where the resources simply do not exist, seems unrealistic.

For example, if HEW defines clinical training as the last 2 years of medical school, then 10 percent of the clinical education of a school with 70 students in each class would mean about 4 weeks of training for each of 140 students in the AHEC area each year, or about 560 person-weeks of training annually. For a school with 100 students in a class, the total personweeks of training in the AHEC area would be about 800.

The Investigative Staff was advised that some areas of potential AHEC development, and a few existing projects, may well be unable to meet the 10-percent training requirement, depending on its interpretation, because of lack of sufficient suitable clinical teaching resources in the area for the required number of students. A project director stated that the University of Mississippi, which has 300 third- and fourth-year students, is an example of a school that is considering establishing an AHEC, but may have difficulty in meeting the requirement for training undergraduate medical students.

Among existing projects, the University of New Mexico AHEC, serving the Navajo Nation and contiguous areas, will not be able to provide for the necessary training, largely because

of the lack of clinical resources in the area. The existing AHEC of the University of Texas Medical Branch (Galveston), with 200 third- and 200 fourth-year students, also is concerned about the impact of the requirement.

Likewise, the University of California, San Francisco, with 160 students in each class, is concerned about how the 10-percent requirement will be interpreted. The Project Director advised the Investigative Staff that the 10-percent requirement could be counterproductive if one wishes to encourage a large medical school to undertake an AHEC program in a remote area which is truly underserved.

The Investigative Staff believes that the 10-percent requirement is a good one but that it could be especially burdensome in the case of certain AHEC programs involving more than one medical school. The Howard University AHEC project, which is in the planning stage, is contemplated to be a consortium effort involving three medical schools/health science centers in the Washington, D.C., area--Howard, George Washington, and Georgetown. In such case, the teaching load in the inner city AHEC area could be very great.

In July 1977 HRA developed certain legislative proposals to facilitate implementation of PL 94-484. One of these proposals was to amend Section 781 to authorize the Secretary to waive the 10-percent requirement if the medical school demonstrates that noncompliance is due to a lack of suitable clinical facilities in the area served. The HRA Associate Administrator for Planning, Evaluation and Legislation advised the Investigative Staff in January 1978 that the proposal never went to OMB and that it was not under active consideration at the Departmental level.

The Investigative Staff believes that the HRA legislative proposal had merit and that it should be given consideration in any refinements of PL 94-484.

2. Special Provisions for New Mexico Project

The likelihood of the University of New Mexico AHEC project not meeting the Federal requirements for continuing funding under Section 802 for FY 1979 (the seventh program year) was anticipated in drafting PL 94-484. The Conference Report stated:

"The conferees recognize that the provisions of the new authority for Area Health Education Center programs are such that many existing area health education centers are not in compliance with them. In the view of the conferees, these centers have been

> given sufficient time under the provisions of the conference report to meet the new requirements. It may be, however, that in the case of the AHEC program located in New Mexico, the principal thrust of the program--the training of Indian people in health professions--can not be continued under the new provisions. If this becomes the case, then it is the intent of the conferees that the Secretary afford special consideration to the funding of the program under other provisions of law." (Underscoring added for emphasis.)

In a letter dated November 18, 1977, the Director of the New Mexico AHEC advised BHM (a) that it would not be possible for the University of New Mexico to meet the 10-percent requirement and (b) that it would be difficult to meet fully certain other requirements of Section 781.

The Director stated, for example, that the 10-percent requirement could not be met because acceptable clinical facilities and faculty will not exist in the New Mexico AHEC area (or in a conceivable expansion of that area) to provide the required amount of education without compromise of the present undergraduate medical curriculum.

In view of the above, the Investigative Staff discussed the matter with both BHM and New Mexico officials. BHM officials stated they were considering a plan under the FY 1979 budget request which involves the utilization of the authority under Section 788(d), Other Special Projects, for future support of the New Mexico program. Specifically, a request to reprogram $1,110,000 from the AHEC appropriation in FY 1979 to Section 788(d) would be made for the expressed purpose of supporting New Mexico's activities. BHM officials further stated that such a request would not affect the funding of the remaining AHEC projects and would be consistent with the conferees' intent.

New Mexico AHEC officials advised the Investigative Staff this approach is acceptable; however, there is concern that a plan be developed for funding after FY 1979. It is their contention that the intent of Congress within the Conference Report on PL 94-484 was to continue their activities as an AHEC. Furthermore, New Mexico AHEC officials pointed out that most of the activities of this AHEC are conducted within the boundaries of an Indian Reservation, which is generally viewed as a Federal responsibility.

B. BHM's Funding Plans for New AHEC's

Since the developmental and operational problems associated with the initiation of AHEC projects are complex and, in some cases, unique, BHM planned a phased program for new AHEC's. The first of three phases would be devoted to planning activities. The second phase would be developmental and would include limited training activities. The third and final phase would be the full operational level with the major thrust directed towards training activities and the transition to other sources of funding.

The RFP for the four new AHEC projects funded in September 1977 stated that BHM anticipated that the planning and developmental phases each would be 1 year in length and that in the third year of the contract--October 1, 1979, to September 30, 1980--the projects should have become fully operational. The RFP further stated that it is BHM's intent to fund the AHEC programs and the AHEC's they develop for a minimum of 3 years and a maximum of 5 years.

As previously noted, BHM developed a revised funding plan for the AHEC program. The plan no longer provided funding for a second program year for the FY 1977 starts. Instead, BHM planned to modify the contracts to extend the 1-year planning phase for an additional 3 months. The Investigative Staff noted that this was first discussed less than 2 months after the four contracts were negotiated and prior to the contracts even being signed. BHM representatives stated that this extension of the planning phase is contemplated to (1) permit a longer period of performance before judging the project's long-term viability and (2) more evenly distribute the workload of the limited Central Office AHEC staff.

The draft funding plan provided for 6 years of Federal financial support rather than for a maximum of 5 years as stated in the RFP. As for additional AHEC's, the BHM plan provides for 22 AHEC's by FY 1979 and 4 new AHEC's each year for the 5 years thereafter. Thus, by FY 1984, BHM envisions funding a total of 42 AHEC projects across the country.

The following draft funding plan is based on a planning assumption that the average year Federal cost per contract for AHEC's started in FY 1978 and later years would be $500,000 to $1.3 million, as follows:

Project's Program Year	Average Funding per Project
01	$ 500,000
02	700,000
03	1,000,000
04	1,300,000
05	1,000,000
06	700,000
07	-0-

BHM's approach, as demonstrated in the funding plan, is to gradually decrease funds for AHEC projects. In this way, new AHEC's are initiated as Federal support to existing AHEC's is gradually reduced. The Investigative Staff believes that it was never intended that the Federal Government support particular AHEC's indefinitely. Therefore, the Investigative Staff concurs with the BHM philosophy that once the AHEC organizations have had an opportunity to demonstrate their value to the area in which they are located, State and local financing must gradually replace the Federal support.

C. Observations and Conclusions

PL 94-484, enacted in October 1976 required the Secretary to develop and implement regulations establishing standards and criteria for AHEC's funded under Section 781 of the Act. Although 16 months have passed, these regulations have not been issued. As a result, the projects are forced to try to meet a 10-percent "clinical instruction" requirement without first knowing how the requirement will be defined.

The resources for clinical instruction are necessarily limited in the underserved areas--at least until they can be upgraded--and to expect a large medical school, or a consortium of medical schools, to give 10 percent of their clinical instruction in remote places where the resources simply do not exist, may prohibit certain medical schools or groups of medical schools from establishing AHEC's.

HEW did not make provisions for funding of the New Mexico project in FY 1979, as required by the Conference Report on PL 94-484. As a result, the Department is now planning to request authority to reprogram funds for FY 1979 from the AHEC appropriation to Section 788(d) for that purpose. In addition, HEW has not developed a long-range funding plan for the New Mexico AHEC.

D. Recommendations

The Investigative Staff recommends that the Committee may wish to require the Secretary of HEW to:

(1) Finalize and implement regulations establishing standards and criteria for the requirements of Section 781 of PL 94-484.

(2) Develop and provide the Committee with a plan for long-term funding of the New Mexico AHEC.

It is further recommended that the Committee consider taking action toward the enactment of legislation which would permit the Secretary of HEW to grant a waiver or postponement of the 10 percent "clinical instruction" requirement of Section 781 in areas that have a special need for an AHEC project but which lack suitable clinical facilities for teaching the necessary number of students.

VI. POTENTIAL FOR SHIFTING FUNDING OF AHEC'S TO STATE AND LOCAL SOURCES

In 1972, when the original 11 AHEC's were initiated, little was known regarding how long it would take to develop programs needed to meet the goals of the AHEC Program. Little was also known regarding the availability of alternate funding sources. Over the last 5 years, the projects developed at different paces, dependent on their magnitude, local support, administration, and other factors. Some AHEC's made concerted efforts to obtain additional funding sources, while others did not. Some had only a limited possibility for obtaining alternate funding.

The Investigative Staff found that the original 11 AHEC's most likely will have to reduce their scope of activities if Federal funding would terminate at the end of FY 1979 (the seventh year). BHM's draft funding plan provides for 2 additional years of Federal funding, at decreasing levels, which the Investigative Staff concluded is necessary to ensure that project activities continue while alternate funding sources are developed.

This chapter will discuss the duration of Federal funding, how BHM's contract provisions affect the projects' ability to obtain alternate sources of funding, and the capability of AHEC's to obtain long-term funding from State and local sources.

A. Duration of Federal Funding

Contracts for the original AHEC's were for a 5-year period. At that time a policy had not been developed regarding additional Federal financial support after the 5-year period.

Program officers in HEW regional offices stated that it was implied to the projects that Federal funding would continue after expiration of the 5-year contracts. In addition, the contracts provided for relatively level funding after the first year, with no provision for a phase-down of Federal funding and a corresponding increase in funding from State and local sources.

As a result, the projects perceived there would be Federal funding after the 5-year period, and possibly for an extended period of time. With some notable exceptions, the contractors had not made sufficient efforts to develop alternate funding sources by the end of the 5-year contract period. In fact, most of the AHEC project directors stated that the reduction in Federal funding for FY 1978 (the sixth program year) forced their projects to curtail certain activities.

As mentioned in a previous chapter, the basic structure for establishing AHEC's is the linkage from the medical school or health science center to the large regional hospitals, which in turn establish linkages with smaller rural hospitals. The Investigative Staff observed that when total funds for an AHEC project are reduced, it is the programs in the small rural hospitals which are first curtailed or discontinued.

The National AHEC Coordinator expressed the opinion that most of the original 11 AHEC's should be able to develop funding from State and local sources to continue their AHEC programs at the existing level of effort if Federal funding terminates, as planned, at the end of FY 1981 (the ninth year). The National AHEC Coordinator stated that although there has been speculation regarding what should be considered an "ideal" or "reasonable" Federal funding period for new AHEC's, he believes 6 years should be adequate. However, in his view, additional funding should be made for those AHEC's which initially did not have a base to build upon and which have not reached a level of development to enable them to be fully supported by State and local funding.

The Deputy Director, BHM, believes the Federal commitment to the AHEC Program, as with any special project commitment, is to experiment, initiate, develop, evaluate, and let the consumer judge the worthiness of the project. The Bureau has adopted the philosophy that a normal developmental/operational period worthy of Federal support is about 5 or 6 years. At that point there should be a willingness on the part of the State and the educational institution to allocate substantial resources to an AHEC project which they see as successfully meeting high priority local needs.

The Director of the Tufts/Maine AHEC believes that his project will require Federal funding for at least 10 and possibly 15 years. The Directors of the North and South Carolina projects stated that, in general, 10 years is a reasonable time frame to ensure that projects are viable when Federal funding is terminated. These directors stated their particular projects will continue operation but at reduced levels of effort should Federal funding cease after FY 1979.

As previously noted, BHM developed a long-range funding plan for the AHEC Program. The plan contemplated additional Federal funding of the original 11 AHEC's through FY 1981, or a total of 9 years. However, the plan provided for only 6 years of Federal funding for new AHEC's.

The Investigative Staff noted that the Bureau's draft funding plan is based on a policy of decremental funding, but does not require a corresponding increase in cost-sharing to ensure that the project's level of effort is maintained.

B. Impact of Contracting Provisions

The AHEC project directors advised that (1) a multiyear Federal financial commitment and (2) required cost-sharing provisions are mechanisms that aid in the development of alternate funding sources. Multiyear funding or other commitments, which specify levels and duration of Federal financial assistance, are desirable to both attract and retain high caliber staff and to provide the time necessary to develop viable programs. Likewise, contracts that would require increased cost-sharing over the duration of the contract would provide greater assurance that there is an established funding base when Federal support terminates.

While cost-sharing provisions were contained in the initial 5-year contracts for the 11 original AHEC's, this requirement was eliminated in the new contracts for a sixth year of funding (FY 1978). BHM eliminated cost-sharing because contracts were negotiated at the close of the fiscal year and there was insufficient time to negotiate the cost-sharing provisions. The Investigative Staff concluded, and BHM officials concurred, that this decision was detrimental to the ability of the AHEC projects' to obtain alternate funding.

BHM officials stated they plan to reinstitute cost-sharing in FY 1979 so that the original 11 AHEC's will come into compliance with Section 781, which requires a minimum of 25 percent cost-sharing by the projects. The Investigative Staff found that this switch from cost-sharing in the original contracts, to elimination of cost-sharing in the current contracts, and then reinstitution of cost-sharing in the contracts for FY 1979, had a detrimental effect on State and local participation. For example, the Director of the South Carolina AHEC stated that in order to foster the development of local funding sources, cost-sharing provisions were retained in this year's subcontracts with local hospitals and other participating institutions.

The contracts for FY 1978 contain a provision requiring each project to develop and implement a plan to identify and obtain alternate sources of funding for those contract activities that require long-term support beyond the performance period of the contract. In addition, the contracts specify that to the maximum extent possible, long-term activities developed under the contract should be planned or implemented with alternate sources of funding as an ultimate goal.

C. Capability of AHEC's to Obtain State and Local Funding

During discussions with AHEC project directors, the Investigative Staff received the impression that certain AHEC

projects are experiencing difficulty in obtaining State funding for continuation of long-term AHEC programs initiated with Federal support. In that regard, BHM statistical data shows that total financial support for health manpower training in all 50 States reached the level of $1.5 billion during fiscal year 1974 (the last year for which statistics have been tabulated) and that State support for health manpower training has increased in the past few years.

The Investigative Staff believes that the ability of individual AHEC projects to obtain State and local funding depends on a number of factors including:

-- the comprehensiveness and viability of the project.

-- whether the project encompasses all or a large percentage of the geographic area of the State.

-- the ability of the project to demonstrate its importance to the State government.

-- the amount of funding currently obtained from State and local sources.

-- the financial condition of the State.

-- the State commitment to medical education.

AHEC projects receive funds from a variety of sources including (1) private foundation funds, (2) hospital funds (including patient fees), (3) State and local funds, and (4) Federal funds (including AHEC). Funding from some of these sources appears to be of short duration (e.g., Federal grant funds and private foundation funds) and thus may not be available for support of long-term activities.

For instance, the Spartanburg General Hospital in the South Carolina AHEC had a budget of almost $2 million for its AHEC activities in 1977-1978, but only $391,000, or about 20 percent, was from the AHEC program. The following table shows the source and amounts of its funding:

Source of Funds	Amount	Percent
State	$763,000	38
Local	671,000	35
AHEC	391,000	20
Appalachian Regional Commission	92,000	4
BHM Family Practice Residency Grant	75,000	3

The Investigative Staff solicited the views of project directors concerning the capability of their particular AHEC's to obtain State and local funding in lieu of Federal funding.

The Director of the Tufts/Maine AHEC stated that there appears to be little potential for State funding of the AHEC in Maine. This is due to the State's low per capita income. In addition, the project only serves a portion of the State. The former Director of the Tufts/Maine AHEC agreed that State funding was unlikely, but was of the opinion that the AHEC would function with just foundation or local funds, albeit at a reduced level of performance.

California AHEC officials stated if Federal funding is terminated at the end of FY 1979, the level of activity achieved will not be able to be maintained. It is their opinion that, at the present time, the State does not have a sufficient commitment to medical education to assume funding of AHEC activities. In addition, the California AHEC, like the Tufts/ Maine AHEC, encompasses only a part of the State.

The Director of the Minnesota AHEC likewise stated that sufficient State and local funding probably will not be available to fully replace Federal funding if it terminates at the end of FY 1979. The AHEC is presently seeking alternate funding support for a number of its activities.

Two of the original 11 AHECs, North Carolina and South Carolina, have developed into statewide systems, receive substantial State funding, and are closest to the point at which Federal funding is no longer vital. For example, North Carolina's AHEC budget for FY 1978 is $15 million, of which 74 percent is from the State, 16 percent Federal (including AHEC), and 10 percent from local sources. The Director of the North Carolina AHEC indicated that the State has been advised that it will be asked to offset the Federal share of the AHEC Program upon completion of the Federal contract. The State has indicated its willingness to try to meet this request in a phased manner. As a result, the program is a line item in the State's appropriation to the University of North Carolina. Critical to this process of increased State involvement, according to the Director, is the need for a long-range Federal funding plan which can be coordinated with State biennial funding cycles which must be prepared 1 year in advance of each biennium.

The Director of the South Carolina AHEC expressed the opinion that the State is both capable and willing to assume funding of AHEC's, but that Federal funds would be needed for 2 or 3 more years while the State legislature is being convinced of the viability of the program. At the present time, the State provides about one-third of the funds for the statewide AHEC program.

D. Observations and Conclusions

If Federal funding for the original 11 AHEC's would terminate at the end of FY 1979, the projects would not have established sufficient alternate funding sources to maintain the existing level of effort. Therefore, BHM's draft funding plan, which provides for an additional 2 years of Federal funding after FY 1979, but at reduced levels, has merit.

BHM's draft funding plan is based on a phase-down of Federal support for AHEC's while they develop alternate funding sources. However, the plan does not include a requirement for corresponding increased levels of cost-sharing, to assure that project's level of effort is maintained.

The Investigative Staff believes that statewide AHEC's have the most potential for obtaining State funding for their programs after Federal funding terminates. Other smaller AHEC's, which cannot expand into statewide systems, may have more difficulty, since they may not have the ability to demonstrate their benefits on a statewide basis and must compete with other areas for State resources. These programs may continue at reduced activity levels or they may be forced to be phased out of existence upon termination of Federal funds. When programs are reduced, it appears that activities in the rural areas are discontinued first.

E. Recommendations

To ensure that AHEC activities do not terminate as Federal funding is phased out, and AHEC's develop alternate funding for those activities that require long-term financial support, the Investigative Staff recommends that the Committee consider requiring that future Federal funding of AHEC's include (a) a clear understanding on the duration of Federal funding and (b) provisions of increased amounts of cost-sharing as Federal funding is phased out.

VII. PROGRAM ORGANIZATION AND STAFFING

A. Organizational Evolvement of the AHEC Program

In late 1971 and early 1972, the AHEC Program was developed by the Manpower Initiatives Section of the Office of Special Programs, an adjunct of the Office of the Director in HRA's Bureau of Health Resources Development (predecessor to the Bureau of Health Manpower). The AHEC Program was placed in the Office of Special Programs and not in a categorical division (e.g., Dentistry, Nursing) due to its multidisciplinary and interdisciplinary nature.

At that time, interdisciplinary and health manpower training had become popular, and, since one of AHEC's objectives was to upgrade the quality of all health professions in the Nation, it was considered to be an interdisciplinary program.

By 1975, interest in the interdisciplinary approach had picked up momentum, and the Office of Interdisciplinary Programs (OIP) was established, with the AHEC Program becoming a major component. However, in November 1977, the AHEC staff was transferred to the Professional Education and Development Branch in the Division of Medicine.

The National AHEC Coordinator and several project directors expressed objection to this reorganization on the basis that (1) it downgraded the AHEC Program from a unit one level removed from the Director, BHM, to a unit two levels below the Director, and (2) its placement in the Division of Medicine would reduce the program's interdisciplinary focus.

The Director of BHM advised the Investigative Staff that the Bureau had no option but to abolish the Office of Interdisciplinary Programs in the HRA reorganization. Since PL 94-484 limited eligibility for AHEC programs to only schools of medicine or osteopathy, transfer of the program to the Division of Medicine (which is primarily concerned with physician training) was not illogical.

B. Decentralization of Program Administration

In July 1973, by Executive mandate, responsibility for administration of numerous Federal programs, AHEC included, was decentralized. Responsibility for allocation of AHEC funds remained at the Central Office, but functions such as monitoring AHEC projects and negotiating contract modifications and extensions became the responsibility of the regional offices.

Decentralization caused several problems relating to devloping a national AHEC effort. The AHEC files were sent to eight different regional offices. A former director of OIP advised the Investigative Staff that, in his opinion, the decentralization process was hastily carried out and resulted in chaos in most of the regional offices and, in many cases, crippled Central Office operations. Each AHEC project was different in size, work scope, geographic boundaries, and levels of funding. In addition to the new project officers in each of the regions, there were new contracting officers whose views and concepts of procurement regulations differed. These factors resulted in a fragmented approach to management of the AHEC Program and inconsistent contract administration.

Adding to the difficulties of the Central Office AHEC staff was the regional project officers' line of authority. The regional project officer reported through the Chief of the Regional Health Manpower Branch and the Director of the Division of Health Resources to the Regional Health Administrator. The Regional Health Administrator reported directly to the Assistant Secretary for Health. BHM and HRA were not included in the direct line of authority, and the National AHEC Coordinator could not direct regional office personnel to perform certain duties necessary for proper administration. For example, he could not directly obtain needed information regarding the amount of funds spent as of a given date by each project, although he was responsible for allocation of funds to the regional offices.

Upon decentralization of the program in 1973, it was determined by BHM administrators that most of the tasks concerned with AHEC would be accomplished in the regional offices, and the Central Office AHEC staff was reduced to only the National AHEC Coordinator. Although there was part-time clerical assistance, about 18 months passed until another professional was added to the AHEC staff. A full-time secretary was not assigned to the National AHEC Coordinator until February 1977.

Obviously, BHM officials did not have a proper understanding of the workload remaining in the Central Office and the complexity of the program. The Investigative Staff believes that had more staff been assigned to the program, some of the difficulties encountered could have been avoided.

C. Recentralization of Program Administration

PL 94-484, enacted in October 1976, directed that administration of health manpower programs be recentralized effective October 1, 1977. HEW is now in the process of changing staffing patterns and responsibilities, which it hopes to substantially complete by midsummer.

As a result of recentralization, the AHEC Program is again to be administered from the Central Office. In preparation for recentralization, the Central Office staff assumed the responsibility for negotiating 15 contracts awarded in September 1977.

As of mid-February 1978, the AHEC contract files for the original 11 AHEC's still had not been transferred to the Central Office. BHM officials stated that the files would not be transferred until the contracts are closed out. During visits to the regional offices, the Investigative Staff noted that the regional project officers and contract officers had been assigned to other duties, and no longer felt any responsibility for reviewing the remaining requests for reimbursements under the contracts.

BHM staffing data showed that the AHEC staff was authorized nine permanent full-time positions but that as of January 31, 1978, only two of these positions were filled. As a result, the National AHEC Coordinator was responsible for administering an expanding program with only 22 percent of authorized permanent full-time staff. The Deputy Director BHM pointed out that this apparent staffing imbalance is attributable to a slow recentralization process and difficulties encountered in internal realignment of staff resources.

The National AHEC Coordinator has repeatedly requested that additional staff be assigned to carryout the increased workload caused by recentralization. In this regard, the Deputy Director, BHM, advised the Investigative Staff that BHM Central Office staffs in general were experiencing difficulties in completing assigned work due to slow recentralization of staff, and that the AHEC staff was not unique in its need for staff resources.

D. Problems in HRA and BHM Staffing

1. Relocation of Personnel

BHM's Administrative Officer reported to the Investigative Staff that, as of January 31, 1978--4 months after the effective date of Congressionally mandated recentralization, and almost 16 months after enactment of the law itself--only 5 regional office employees, or 3 percent, of the 180 health manpower positions being returned to the Central Office had been reassigned and were on-board in the Central Office. Forty-eight other field office employees had accepted positions but had not yet relocated to the Central Office. The remaining 127 positions, or about 70 percent of those being recentralized, had not been filled.

BHM does not expect to be able to complete the recentralization process until at least midsummer at the earliest. This is certainly an excessive amount of time for recentralization.

2. Utilization of Detail Personnel

BHM has a policy of detailing personnel from the regional offices to assist the Central Office staff during peak workload periods. This policy has been expanded to somewhat fill the Central Office staffing void until the recentralization process is completed. The details generally last from 2 to 4 weeks.

The Investigative Staff noted, for example, that during the period March to December 1977, a total of eight persons were detailed to the Central Office for temporary assignments with the National AHEC Coordinator. According to the National AHEC Coordinator, six of the eight persons did not have a working knowledge of AHEC activities. As a result, these persons were of limited assistance to the Central Office staff.

BHM provided information showing that a total of 89 persons were detailed to the Central Office during the first 4 months since recentralization (October 1, 1977 - February 10, 1978). Total costs (less salaries) associated with these details amounted to $132,000.

3. Staffing Patterns

PHS officials advised that HRA had requested funding in the FY 1979 budget for new personnel positions in addition to the 180 positions returned from the regional offices. However, according to these officials, HRA had not adequately justified, on a quantitative workload basis, its need for the 180 positions being recentralized. As a result, PHS officials stated they were unable to honor HRA's request for the additional personnel.

PHS developed a Manpower Management Program (MMP) intended to be utilized for establishment of manpower ceilings, staffing requirements, and placement of personnel. The Investigative Staff reviewed certain MMP information prepared by BHM in May 1977 as a part of its Zero Base Budget (ZBB) submission for its FY 1979 budget. Regarding AHEC, BHM reported 6.63 man-years of effort would be required in FY 1977 (used as a base year) to accomplish the tasks assigned to the AHEC Central Office staff. However, BHM provided information regarding actual personnel assigned during FY 1977 which showed, based on MMP data, the AHEC staff was operating at less than 30 percent of manpower needed to conduct the program.

BHM officials advised that decisions regarding the assignment of staff are based upon "empirical judgment" and not on MMP or similar data.

In addition, certain staffing patterns were noted in BHM which indicate that there may be staffing imbalances among divisions. The BHM staffing summary dated January 31, 1978, shows, for example, that the Division of Medicine had 55 permanent full-time positions and was responsible for administering program activities, funded under the FY 1978 continuing resolution, totaling $182 million. In contrast, the Division of Dentistry, which administers programs totaling only $38 million for FY 1978, had an assigned staff of 72 permanent full-time positions.

Thus, the Division of Medicine was administering about four times the amount of funds administered by the Division of Dentistry, but with 24 percent less staff.

In sharper contrast, the AHEC staff was administering program activities totaling $17 million under the FY 1978 continuing resolution, but with only two permanent full-time employees. Thus, the AHEC staff was administering funds totaling about 44 percent of the funds administered by the Division of Dentistry, but with only 3 percent of the size of the Division of Dentistry staff.

The table on the following page shows staffing patterns and funds administered by various organizational components within BHM.

Organizational Component	Permanent Full-Time Staffing			Percent of Strength	Estimate FY 1978 a/ (In Millions)
	Ceiling	Assigned	Vacant		
Division of Nursing -------	80	72	8	90%	$ 92.5
Division of Dentistry -----	85	72	13	85%	38.5
Associated Health Professions ----------	67	40	27	60%	57.5
Division of Medicine (excluding AHEC) --------	83	53	30	63%	164.9
AHEC staff ----------	9	2	7	22%	17.0

a/ Activities requiring staff work by the organizational component, including appropriate share of capitation funds.

It is recognized that the above comparisons of staffing to funds administered are not precise indicators of workload; however, in general, they demonstrate apparent staffing imbalances within BHM. As previously noted, BHM is aware of these staffing imbalances but has indicated that the Bureau has experienced difficulties in internal realignment of staff resources.

The Investigative Staff was advised that the staffing of the Division of Medicine, as of January 31, 1978, and the number of vacancies, within 92 allocated positions, will necessitate assigning priorities to Division activities on its AHEC and other grant and contract programs in FY 1978. According to the Division Director, the principal activities which will have to be conducted, to the extent personnel resources are available, are, in order of importance, (a) preparation of regulations, requests for contracts, and applications materials, review of proposals and applications, and preparation of documents necessary for the obligation of appropriated funds; (b) filling of vacant positions; (c) monitoring of grantee and contractor performance; and (d) technical assistance and related activities. The Division Director further stated that to the extent personnel are not available, some of the above activities of relatively lower importance may not be performed in this fiscal year.

To conduct the full range of desirable activities, the Division of Medicine is requesting, and has requested in the past, individuals from the Bureau, other components within HRA, and regional office staffs to be temporarily assigned to the Division to assist in completing its work for FY 1978 or until the vacancies can be filled on a permanent basis. The Investigative Staff noted that the Division of Medicine is making an effort to fill all vacancies with permanent employees as soon as possible.

The Administrator of HRA stated that he had been unaware of any staffing imbalances in BHM and, in particular, of any "critical" situation caused by the number of unfilled positions in the AHEC office and Division of Medicine. The Director stated that he intended to personally review the matter and, if necessary, require staffing adjustments.

4. Civil Service Commission Findings

HRA has not taken adequate and timely corrective action on certain recommendations made by the U.S. Civil Service Commission (CSC) in May 1976 concerning HRA's personnel management procedures and practices. CSC conducted a review of personnel management at HRA headquarters and found:

"Vacancies at HRA are filled on a one-by-one basis, i.e., when someone leaves, the manager sends to the Personnel Office a request to fill the position, usually at the same grade at which it was vacated, and frequently has a candidate in mind for the position. There were few indications that vacant positions are reviewed for necessity or restructuring before being filled. In an agency like HRA, faced with severe problems resulting from reorganizations and legislative changes, this would seem to be a logical first step. Considerations should be given to the agency's overall staffing situation: does the workforce need to be expanded or reduced; what is the need for 'new blood' compared with the need for advancement and upward mobility opportunities for present employees; * * * "

* * * * * * *

"The idea of developing a comprehensive approach to staffing HRA's positions has not been acted upon. While the existing position management and classification problems are an impediment to a really effective staffing program (as they are to every other program), action could be initiated to review vacant positions, analyze work to develop career ladders and career programs, and to operate the merit promotion program in accordance with merit system principles."

The CSC Report recommended that corrective actions were required in HRA's management policies and practices. With regard to assignment of personnel, CSC stated:

"HRA should establish a position management system that can identify and deal with situations such as unneeded positions, overlapping duties and responsibilities, and excessive organizational fragmentation. HRA should exercise a central control over the creation of new positions to assure that they are needed and that the work cannot be done in existing positions."

The Investigative Staff was advised that as of February 15, 1978, HRA still had not resolved certain individual classification cases identified in the CSC report.

The Executive Summary of the CSC report is included as Appendix VI.

E. Observations and Conclusions

The Central Office AHEC staff is significantly understaffed and is, therefore, unable to properly administer the National AHEC Program. This is attributable to (1) a very slow recentralization process and (2) an apparent inability of BHM to internally realign staff resources.

The Investigative Staff concluded that the Department has complied with the Congressionally mandated recentralization of health manpower programs, but has not transferred staff to the Central Office nor otherwise filled the recentralized positions. As a result, certain BHM components, such as the AHEC staff, are having difficulty administering the programs assigned.

BHM's stop-gap measure of utilizing detail personnel to fill the staffing void is a poor substitute for a timely recentralization process.

There are staffing imbalances among Divisions within BHM, and an apparent reluctance on the part of BHM management to internally realign staff resources so that they are more evenly distributed in relation to workload.

Almost 2 years has elapsed since the CSC issued its report in May 1976 on HRA's personnel management procedures and practices, and HRA has not yet resolved all of the position classification cases identified by the Commission.

F. Recommendations

To improve personnel management and overall program administration, the Committee may wish to require the Secretary of HEW to:

(1) Expedite transfer of staff from the regional offices to the Central Office, and/or otherwise fill vacant positions, so that BHM can effectively administer the Department's health manpower programs.

(2) Review the policies and practices for assignment of personnel in BHM and HRA.

(3) Review BHM's policy regarding temporary detailing of regional office personnel to the Central Office.

(4) Expedite resolution of individual position classification cases and fully respond to the CSC findings.

VIII. PROGRAM MONITORING

Project monitoring can be defined as the assessment of managerial and operating efficiency and effectiveness of projects through periodic site visits and other management techniques. One of the primary objectives of monitoring is to ensure projects are adequately complying with established program guidelines, procedures, policies, and regulations. Another objective is to determine what technical assistance a project requires.

During the period 1973-1977, the administration of the AHEC and other BHM health manpower programs was decentralized. As a result, project monitoring responsibilities relative to the original 11 AHEC contracts were primarily vested with the PHS regional offices. The Central Office AHEC staff was responsible for monitoring the AHEC program on a national level and thus was required to monitor regional AHEC efforts.

As previously noted, the original 11 AHEC's were awarded 5-year "cost-reimbursement" contracts in 1972. Likewise, in September 1977, "cost-reimbursement" contracts were used for funding the 1-year follow-on contracts as well as the contracts for planning 4 new AHEC's. The Department published a guide for project officers on the negotiated contract process. The purpose of the guide was to highlight staff responsibilities and ensure sound contracting practices relative to negotiated procurements. The guide states the following concerning the monitoring of cost-reimbursement contracts such as those for the AHEC projects:

> "The cost-type contract requires careful technical surveillance, auditing of costs, and imposes a heavy administrative burden on both the Government and the contractor * * *. It is essential that the project officer monitor a contractor's progress closely, identifying potential problems that threaten his performance so that remedial measures may be taken by the contracting officer."

The Investigative Staff found that program monitoring activities generally have been minimal--both by the Central Office and the regional offices--due to higher priority activities.

Project monitoring is closely related to technical assistance. Therefore, because of an absence of routine project monitoring, problem areas or operating weaknesses may not be detected which call for the provision of specialized technical assistance to effect needed corrections or improvements.

Effective October 1, 1977, BHM recentralized the administration of most of its health manpower programs, including AHEC. As a result of a slow recentralization process, the Central Office AHEC staff has not yet expanded in size to enable it to carry out the monitoring responsibilities previously assigned to the Regional Offices.

A. Regional Office Site Visits

It was noted that the quality and frequency of regional office site visits to the original 11 AHEC projects varied depending on the initiative and workload of the assigned project and contracting officers. In general, the Investigative Staff found that the AHEC contracts received only cursory attention and the "careful technical surveillance" required of this type of contract did not exist.

Furthermore, the regional office staffs and contractors did not always ensure that claimed subcontract costs were reasonable and allowable or that projects were initiated on time and were being performed in accordance with contractual provisions. For example, there had been little monitoring of the Tufts/Maine AHEC project by the Boston Regional Office. The project officer involved stated that not more than 5 percent of his time was devoted to AHEC activities and that he did not attempt to "monitor" the project. He stated that due to the project involving numerous sites and a number of departments within the university, effective monitoring would have required a significant amount of time, something much more than his workload would permit. Likewise, the contracting officer stated that he too was overburdened and could only devote a minimum amount of time to monitoring of the contract.

The Atlanta Regional Office had responsibility for monitoring both the North Carolina and the South Carolina AHEC's. The Investigative Staff found that somewhat more attention had been given to the program than in Boston, but again responsibilities to other programs precluded adequate monitoring. Another problem in this region was a high turnover of AHEC project officers.

The HEW Audit Agency reviewed the administration of the California and New Mexico AHEC projects and noted that additional controls were needed to be implemented over the timeliness of and scope of projects, subcontractor expenditures and employment of consultants. For example, the Audit Agency reported in March 1975 that the University of California, San Francisco campus (which was the prime contractor for the San Joaquin Valley AHEC) needed to improve its management of the AHEC contract in order to accomplish the stated objectives.

The Audit Agency found that (1) many project activities were delayed or were not being performed in accordance with contractual provisions; (2) the University did not always ensure that claimed subcontract costs were reasonable, allocable, and allowable; and (3) the University needed to improve its procedures for employing consultants under the AHEC contract to assure that the services were necessary and the fees were reasonable.

The Investigative Staff believes that many of the deficiencies noted by the HEW Audit Agency could have been identified and corrected if the Regional Office staff had followed departmental guidelines and "closely" monitored the contract.

The Investigative Staff likewise noted certain ineligible costs and poor management practices which could have been identified had the projects been properly monitored. For example:

-- At the Richland Memorial Hospital in Columbia, South Carolina, AHEC funds were used to pay a portion of the salaries of all residents, and not just those in "primary care" specialties as specified in the AHEC contract.

-- The Tufts AHEC project provided over $20,000 in FY 1977 to the Consortium for Regional Medical Education, based at the Mid-Maine Medical Center in Waterville, Maine. The Consortium recognized that eventually physicians and hospitals would have to take over financial arrangements for the continuing education program developed with AHEC funds. The Consortium advised the Investigative Staff, however, that there didn't seem to be any immediate need to start asking participating physicians and hospitals to pay for the programs as long as AHEC funds were available.

B. Central Office Site Reviews

During the 4 years while the AHEC program was administered on a decentralized basis (1973-1977), the Central Office AHEC only infrequently visited the AHEC projects. For example, information provided by the National AHEC Coordinator shows that only 2 of the 11 projects were visited in FY 1977. The National AHEC Coordinator stated that a lack of travel funds at times precluded additional site visits by the Central Office staff.

Regional project officers stated that during the period of decentralization, they received little direction, assistance or advice from the Central Office AHEC staff. Shortly after decentralization, the Central Office issued a reference book to guide the Regional Office staffs in monitoring the AHEC contracts. The Investigative Staff found that the book was not

updated and, therefore, was of limited value to the project officers. Moreover, because of staff changes in the Regional Offices, several project officers stated that they were unaware that the reference book existed.

Effective October 1, 1977, BHM recentralized the administration of its health manpower programs, including AHEC. During the first 3 months after recentralization (October - December 1977), only one site visit was made by the Central Office AHEC staff and this visit was for the purpose of accompanying the Investigative Staff on one of its site visits.

The National AHEC Coordinator stated that he does not have a sufficient number of personnel on board to conduct site visits. He stated that as a result of recentralization and plans to award contracts for new AHEC's, BHM planned to increase the AHEC staff to a total of 7 professional staff members. In that regard, as of February 7, 1978, only one additional professional staff member had been assigned to the AHEC staff. As of that date, the professional staff consisted only of the National AHEC Coordinator, the staff member who was transferred to the Central Office, and a third part-time staff member.

The National AHEC Coordinator stated that the Director, Division of Medicine directed that no site visits be made by the AHEC staff until Requests for Contracts are completed for the remainder of this year's funding cycle. This process may not be completed until June 1978, depending on when additional Regional Office personnel are transferred to the AHEC staff.

C. Other Monitoring Methods

Together with site visits, BHM has other mechanisms to monitor the progress of the AHEC projects and to gain an overall understanding of whether the program is meeting its established goals and objectives. A brief discussion of these other monitoring methods follows.

1. Progress Reports

Progress reports are required to be submitted by the AHEC contractors, quarterly, annually, and at the end of the contract period. These reports describe both project accomplishments and technical and/or administrative problems encountered in carrying out the terms of the contracts. The final report is intended to be used as a technical reference document describing the activities and the results achieved during the contract period.

The Investigative Staff believes that these reports could be very useful documents; however, some regional office person-

nel stated that they merely filed the AHEC reports and, in some cases, copies were not even forwarded to the Central Office. Likewise, the Central Office AHEC staff stated that they only had the time to scan the reports.

2. AHEC Management Information System

An AHEC Management Information System (MIS) was designed in 1975 to provide readily accessible, specific information on the AHEC's. The MIS data was intended to assist BHM in responding to inquiries about specific program components and in evaluating the overall impact of the AHEC program on health manpower distribution.

AHEC project officials advised the Investigative Staff that the MIS data submitted each quarter is almost meaningless because (1) data on only the Federal portion and not total project expenditures are reported, and (2) reporting categories overlap, causing varying interpretations and thus unstandardized reporting. Moreover, preparation of the data is quite time consuming.

The project officials further stated that they had not received any sort of summarization or analysis of the data submitted. As a result, they lost interest in the MIS reporting.

The comments of the project officials were discussed with the National AHEC Coordinator who stated that the MIS had never been computerized and that he did not have the staff required to summarize, analyze and interpret the data submitted by the 11 AHEC projects. As a result, the data has not been used as intended.

3. Audits

Audits of only 2 of the 11 AHEC's had been conducted by the HEW Audit Agency. The Investigative Staff reviewed the two audit reports and found the reports to be of apparent good quality and, together with the on-site program reviews, to be a relatively effective means of ensuring both management and fiscal accountability in the AHEC program. However, since audits of only 2 of the 11 AHEC projects had been performed (one in 1974 and the other in 1975), both audits identified questionable financial and management practices, and follow-up audits or audits of the other 9 AHEC projects have not been performed, it appears HEW has not ensured proper fiscal accountability in the AHEC program through such audits.

A top HEW Audit Agency official indicated that it was virtually impossible to audit HEW grantees and contractors with any degree of regularity. He indicated that the HEW Audit Agency workload is substantially larger than the resources available to accommodate necessary audits. According to this official,

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the magnitude of the HEW audit workload, coupled with a relatively small audit staff, necessitated the establishment of audit priorities based on expected benefits of such audits. He indicated that the AHEC program had not been a priority program for audit simply because other HEW programs seemed to be experiencing more problems.

The Audit Agency official further advised that the Audit Agency is doing some special contract closing work this fiscal year and he would try to place the AHEC projects on the audit work schedule.

F. Observations and Conclusions

In general, the AHEC contracts received only cursory attention and the "careful technical surveillance" required of cost-reimbursement contracts was not provided because of a lack of managerial attention.

As discussed in the preceding chapter, because of a shortage of assigned staff, the Central Office AHEC staff is unable to either monitor the original 11 AHEC's or provide sufficient technical assistance to the four medical schools awarded planning contracts for new AHEC's.

The Investigative Staff believes that progress reports and MIS data have the potential for being effective tools for program management; however, if the information is not effectively utilized, it should not be required.

IX. COORDINATION OF AHEC WITH RELATED FEDERAL PROGRAMS

AHEC and a number of HEW's other health manpower education programs, as well as several programs administered by VA, are all designed to (a) improve geographic and specialty distribution and/or (b) improve the quality of the health manpower work force. Coordination of the AHEC Program with these other programs was informal and, in many cases, minimal or nonexistent. As a result, certain AHEC projects and related HEW and VA projects appeared to overlap in activities. Better coordination would have resulted in opportunities for improved program management, elimination of duplication of effort, reduced costs, and a more coordinated and unified Federal effort.

Appendix I lists the programs authorized by PL 94-484 and the specific objectives of each program. Three HEW programs--capitation grants, national health service corps scholarships, and family medicine and general practice of dentistry grants--all have the objective, as does AHEC, of improving the geographic and specialty distribution of health manpower. Likewise, interdisciplinary training, allied health projects, and other special projects have the objective, as does AHEC, of improving the quality of the health manpower workforce.

As for VA, it too funds AHEC projects. In addition, VA conducts a medical education program which includes grants for health manpower training.

A. HEW Programs

1. Grants for Graduate Training in Family Medicine

These grants provide funds for residencies for training physicians specializing in family practice. The program is administered by the BHM's Division of Medicine. Awards totaled about $40 million in FY 1977. Family practice medicine residencies are located in all of the AHEC areas visited by the Investigative Staff.

The Investigative Staff found that coordination had not been established between the AHEC Program and the Family Medicine Grant program. As a result, AHEC supported local programs for which funding had previously been made through Family Medicine Grants.

For example, in August 1977, the Natividad Medical Center in Salinas, California, was awarded a Family Medicine Grant for conducting a residency program for 18 doctors specializing in family practice medicine. One month later, in September 1977,

BHM awarded a contract to the California AHEC which likewise included funds for establishing the family practice residency program for 18 residents at the Natividad Medical Center.

Moreover, the program instructions for Family Medicine Grants stated "these grants are intended to assist in meeting the costs of the program, which cannot be met from other sources." The Director, Division of Medicine, stated that this is interpreted to mean that Family Medicine grants are "last dollar" funding, and no additional funding should be needed to support that particular program. Therefore, BHM officials agreed that the AHEC funds should not have been awarded for the Natividad family practice residency program after the program had already been "last dollar" funded by the Division of Medicine.

BHM officials agreed that these situations are most likely to occur when funds are awarded hastily and there is no coordination of programs. BHM officials stated that although previous AHEC contract proposals were not required to identify other sources of Federal funding for project activites, such a provision would be considered for future proposals.

2. National Health Service Corps (NHSC) Scholarships

NHSC scholarships are provided to medical students who accept an obligation to become a member of the NHSC and thereby practice in a health manpower shortage area. The program is administered by PHS's Health Services Administration. The funding for NHSC scholarships is $55 million under the FY 1978 continuing resolution.

Although the NHSC is a "medical service" function, as opposed to the "medical education" function of the AHEC's, both programs have related objectives. NHSC physicians are located in most of the AHEC areas, and AHEC activities establish a professional environment conducive to retention of NHSC physicians in shortage areas.

The National AHEC Coordinator stated the AHEC and NHSC Programs are not coordinated at the national level. The Investigative Staff did note, however, that at the local level NHSC physicians are encouraged to participate in AHEC-sponsored continuing education programs.

3. Special Projects

BHM's Division of Medicine has funded a number of special projects designed to develop decentralized medical education programs. These programs included:

-- The University of Washington Integrated Medical Education system, with programs in Washington, Alaska, Montana, and Idaho (WAMI Program).

-- Hahnemann Medical School at Wilkes College.

BHM officials responsible for administering these special projects stated they were aware of the AHEC Program but no effort was made to coordinate programs or exchange information. Likewise, the National AHEC Coordinator stated no coordination was established between AHEC and the special projects. The National AHEC Coordinator added, however, that higher priority work and staffing shortages precluded coordination activities.

B. Veterans Administration Programs

1. VA AHEC's

As previously noted, VA began funding eight community-based AHEC's in 1972. Program expenditures totaled $12.2 million for the 5-year period FY's 1972-1976, of which VA provided $5.2 million (42 percent); HEW $3.9 million (32 percent), largely from the Regional Medical Programs; and State, local, and other sources provided $3.1 million (26 percent).

In 1972, Joint Guidelines for coordination of VA AHEC's and BHM AHEC's were drafted; however, these were not finalized, and no formal coordination is now in effect. The National AHEC Coordinator and his counterpart at VA periodically meet to discuss their respective programs.

Three of the eight VA AHEC's--Asheville, North Carolina; Fresno, California; and Togus, Maine--were located in the same geographical areas as BHM AHEC's. VA has since discontinued funding its Asheville and Fresno AHEC's, due to possible duplication of effort and competition with BHM AHEC activities.

The Investigative Staff visited both the VA and BHM AHEC sites in the State of Maine. Although an indepth study was not made, it appeared the two projects were coordinated at the local level and did not overlap in activities.

In 1977, the VA reviewed its program and concluded that VA AHEC's were fulfilling the role assigned to them. As a result, the review committee recommended that five or six new VA AHEC's be established per year over the next 5 years. The VA AHEC Coordinator subsequently stated, however, that future funding plans provide for establishment of only two new AHEC's, and those not until FY 1980.

Previously, in 1976, VA had a private consulting firm evaluate the VA AHEC's. The evaluation, which cost $70,000,

showed that, on balance, the impact of the VA program had been favorable. The Investigative Staff noted the same contractor who conducted the VA AHEC evaluation--C. E. Pagan Associates, Inc.--was simultaneously conducting an evaluation of BHM AHEC's. Moreover, HEW had an interest in the VA AHEC's as it provided about one-third of the funding of the VA AHEC's during the period FY's 1972-1976. The Investigative Staff believes that opportunities for savings may have existed had these evaluations been conducted jointly.

In 1976, the Carnegie Council on Policy Studies in Higher Education (formerly known as the Carnegie Commission) recommended that, in the interest of good planning, the VA should not make separate determinations on the location of AHEC's and final authority for approval of allocation of Federal funds for the development of AHEC's should be centralized with the Secretary, HEW.

2. VA Medical Education Programs

As previously noted, VA is authorized to make grants for (a) establishment of new medical schools, (b) expansion and enrichment of undergraduate medical education, and (c) the training of health manpower.

The Carnegie Commission, in its 1970 report, concluded that an AHEC site would provide an existing medical school with the opportunity to expand its enrollment (by creating clinical education sites at the regional hospitals and in rural areas) and thus remove the pressure for establishment of new medical schools.

In that regard, although the Medical University of South Carolina, as an AHEC prime contractor, conducts such a decentralized medical education program in South Carolina, the VA, in 1974, awarded a $25 million grant to the University of South Carolina for establishment of a new medical school at Columbia, in affiliation with the Columbia VA hospital.

The Director of the South Carolina AHEC expressed the opinion that the statewide AHEC had the ability to provide additional clinical education sites, and, therefore, the existing medical school in the State could have increased its enrollment rather than having the State establish a new medical school.

The Investigative Staff believes this possible contradiction of efforts, and increased costs associated with development of a new medical school, may have been avoided by closer coordination between VA and HEW.

Activities of the BHM AHEC Program and the VA Medical Education Program, likewise, were both intiated in California. In 1975, the HEW regional office staff became aware that the University of California, San Francisco (UCSF) Medical Center had applied for an $18 million VA grant to increase the third and fourth year clinical rotations at Valley Medical Center in Fresno and to create a solid core of residents at the VA hospital in Fresno. HEW officials were of the opinion that some of these functions were already being accomplished with AHEC funds. HEW regional office representatives stated their inquiries concerning the VA grant were met with resentment by VA officials who seemed determined to make the grant whether or not it duplicated or overlapped with AHEC-funded activities. However, in order to prevent duplication, a plan was finally worked out whereby VA funds would be utilized to develop and assist undergraduate and graduate programs in medicine in cooperation with the Valley Medical Center and the VA hospital, and the AHEC would focus on the development of residency and clinical clerkship programs in rural areas. VA then, in July 1975, awarded a grant to UCSF totaling $8 million for an 8-year period.

The U.S. General Accounting Office (GAO) reviewed the VA Medical Education Grant Program and expects to issue a report to the Congress in several months. Audit work was performed at the VA hospital in Fresno and at a number of other locations across the country. GAO representatives stated they reviewed the impact of the VA Medical Education Program on the community but did not address the question of duplication of effort or coordination with other Federal programs.

The Investigative Staff ascertained there are certain efforts to coordinate the VA and HEW health manpower training programs at the national level. The Director of the Division of Medicine, BHM, sits on the review panel for VA medical education grants, and another HEW official reviews VA allied health grants to prevent duplication. Likewise, a VA official sits on the Division of Medicine review panel for its grants.

C. Observations and Conclusions

Coordination of the AHEC Program with other BHM health manpower programs is minimal. Likewise, more effective coordination between HEW and VA health manpower programs would avoid duplication of effort, provide opportunities for reduced costs, and ensure a more unified Federal approach.

Coordination of the BHM and VA AHEC Programs will become increasingly important in the future as both agencies plan to fund new AHEC's.

The Administrator of HRA agreed that it would be beneficial

if HEW entered into an Interagency Agreement with the VA for coordination of their respective health manpower programs. The Administrator added, however, that in his opinion such an agreement would more likely be facilitated if it were initiated by OMB, rather than by HEW.

D. Recommendations

To develop a more unified and coordinated Federal approach to health manpower training, and to reduce costs, the Committee may wish to require:

(1) The Secretary, HEW, to ensure that the AHEC Program and other BHM health manpower training programs are more effectively coordinated.

(2) The Office of Management and Budget to arrange for HEW and VA to enter into an Interagency Agreement to more effectively coordinate their respective health manpower training programs.

X. PROGRAM EVALUATION

Evaluation has been a managerial weakness in HRA's administration of the AHEC program. Since no real evaluation had been performed on the National AHEC Program, Congress mandated, in PL 94-484, that the Department conduct such an evaluation and that a report be provided to the Congress by September 30, 1979.

Although PL 94-484 was enacted in October 1976, and the Department was given 3 years to provide the Congress with a report, BHM's evaluation timetable showed that the evaluation would not be completed, as originally intended, in time for the Department to meet the September 30, 1979, reporting deadline.

PL 94-484 extended the authorizing legislation for the AHEC program through FY 1980. Thus, the Congressionally mandated evaluation was intended to be used in the legislative cycle needed to extend the program beyond FY 1980. Because of HRA's lack of timely initiation of the evaluation effort, and concern by the original 11 AHEC project directors that Congress should have both objective and subjective evaluation data on which to base future funding support of the program, the original 11 AHEC's requested the Carnegie Council to conduct such an evaluation. The Council agreed to sponsor and conduct a study and it is now underway independent of the BHM effort. The results will be presented to the Congress.

This chapter discusses past evaluation efforts of the AHEC program--the methods used in selecting evaluation contractors, the funds expended for these efforts, and a discussion of how the results have been used in program management, short- and long-range planning, and drafting legislative extensions. This chapter also discusses the actions taken by the Department to carry out the AHEC program evaluation mandated by the Congress.

A. Current Process

Program evaluation, generally speaking, is an assessment of the effectiveness or impact of an ongoing program in achieving its objectives, with appropriate reliance on the principles of research design to distinguish a program's effects from those of other forces working in a particular situation.

The Secretary of HEW is authorized by Section 513 of the Public Health Service Act to make funds available for program evaluation, either directly or by grants and contracts, in amounts not to exceed 1 percent of the appropriations made under the Acts authorizing establishment of the programs.

During the first 6 years of the AHEC program (FY's 1973-1978), about $82 million was appropriated for AHEC. As a result, about $820,000 has been set aside as Departmental "1 percent" evaluation funds.

Three AHEC evaluation-related projects have been funded to date using "1 percent" funds. The cost of these projects totaled about $400,000. One other evaluation-type contract, costing $11,000, was funded using program monies. In addition, BHM is currently receiving contract proposals for the Congressionally mandated evaluation of the National AHEC Program. The evaluation is estimated to cost $400,000.

By the time the study is completed and a report submitted to the Congress (estimated by BHM to be January 31, 1980), the Federal Government will have invested about $100 million in the AHEC program. The total cost of the evaluation efforts related to the national program should be approximately $800,000, somewhat less than 1 percent.

Evaluation has also been conducted at the individual AHEC project level. The 11 AHEC's have performed self-initiated evaluations of particular activities carried out by the projects using contract funds and not the Department's "1 percent" evaluation funds.

The Investigative Staff found that evaluation programs developed by the individual projects, and evaluation reports, were not routinely submitted to the National AHEC Coordinator. The Investigative Staff believes that had this been done, the Central Office AHEC staff could have summarized and disseminated these evaluation programs and reports for use by all 11 AHEC projects. In that way, each AHEC project could have received the benefits of overall evaluation efforts on the program.

The four previous evaluation-related efforts are summarized in the table on the following page and are described in greater detail below.

AHEC PROGRAM EVALUATION-RELATED EFFORTS

Date of Contract	Date of Report	Source of Funding	How Funded	Contractor	Amount of Contract Initial	Amount of Contract Final
4/73	8/73	1% Evaluation	Noncompetitive	Bio-Dynamics, Inc.	$ 26,109	$ 26,109
6/74	4/76	1% Evaluation	Competitive	Abt Associates	118,653	294,221
3/75	12/75	1% Evaluation	Noncompetitive	Applied Management Sciences, Inc.	36,158	73,137
6/76	9/77	Program Funds	Noncompetitive	C. E. Pagen Associates	11,000	11,000

B. Previous AHEC Evaluation-Related Projects

HRA has had four projects directly related to the development of an AHEC evaluation. However, none of these efforts "evaluated" the success of the program and, in that regard, the Deputy Administrator of HRA stated that the four projects were of minimum value. Nevertheless, the Department plans to significantly expand the program over the next few years without first objectively determining whether the AHEC concept is a cost-effective and viable strategy to attack the problems of geographic and specialty maldistribution of health manpower.

1. Bio-Dynamics, Inc.

The first effort, entitled National Area Health Education Center Program - External Assessment Design, was completed in August 1973. The contractor was selected by BHM's Evaluation Office from a list of contractors approved to perform short-term evaluation studies for the Public Health Service. The contract mechanism was a basic ordering agreement. (A basic ordering agreement is a written instrument of understanding executed between a procuring agency and a contractor which sets forth the negotiated contract clauses which shall be applicable to future procurements entered into between the parties during the time of the basic ordering agreement. Supplies and services may be ordered under the agreement only if it is determined at the time the order is placed that it is impracticable to obtain competition by formal advertising or negotiation for such supplies or services.)

No evaluation was actually conducted. This study produced an evaluation protocol that provided issue-oriented information for use by program management staff in assessing and reporting AHEC success. The protocol was not adopted by HRA for implementation. The Bio-Dynamics report made clear that there was was substantial lack of agreement between staffs of HRA and the local projects on the key goals for the program which should be the basis for an evaluation effort.

2. Abt Associates

From the materials developed by Bio-Dynamics and related materials, a request for proposals was developed to evaluate the National AHEC Program. A total of 14 organizations responded. An Advisory Group, composed of the project directors from the AHEC programs, assisted in the review process and concurred in the selection of the Abt Associates proposal. The contract to evaluate the National AHEC Program was awarded through a competitive procurement process to Abt Associates in June 1974 in the amount of $118,000. The original contract specified that the study should be a comprehensive

evaluation based upon measures of progress toward accomplishment of the National program goals.

Abt Associates found that the 11 projects did not have a uniform data base that would have been helpful in conducting an evaluation. Moreover, Abt Associates concluded that it was somewhat premature to assess impact for most of the project activities. As a result, the Abt Associates contract was modified in 1975 to simply provide a descriptive study of the program--to gather and organize detailed information about each of the 11 AHEC projects, to describe the projects individually, and to describe the National program in an aggregate fashion.

Because of the large number of target areas (26) and the resultant heavy field work requirements, plus the need to develop an automated data base, the original contract was extended for an additional 12 months and the price increased. The final contract amount was almost $300,000.

The Abt Associates study resulted in two types of reports--individual site reports on each project and an overall descriptive summary of the National AHEC program.

The Investigative Staff was advised by the Deputy Administrator of HRA and several AHEC project directors that they considered the ABT study to be a failure. Close to $300,000 was expended primarily to summarize project data that the projects themselves could have submitted to BHM.

The National AHEC Coordinator, however, stated that the study proved useful in a number of ways including (a) providing data on the first 3 years of program operations, (b) providing the initial basis for the development of a management information system, and (c) serving as a basis for the development of standardized evaluation and reporting requirements for new AHEC's.

3. Applied Management Sciences, Inc.

In March 1975, the Applied Management Sciences, Inc. (AMS) began work on a report entitled Assistance in the Designs of Evaluation of Program on Decentralized Health Professional Education. The contract was for $36,000. As in the case of the first evaluation contract with Bio-Dynamics, the AMS contract was awarded on a noncompetitive basis using a basic ordering agreement.

The contractor was to assist HRA in exploring ways to design evaluation of decentralized professional education programs in general. This study reviewed similar activities

supported by the Regional Medical Programs and the Veterans Administration as well as activities developed with local support.

The AMS contract was awarded after it was determined by HRA that the study by ABT Associates should be descriptive in nature and should provide a data base for future AHEC evaluation efforts. HRA also believed that it was important to have a group of experts review the issues of AHEC evaluation within the context of the larger focus of evaluating all of the major programs of decentralized/regionalized health professional education.

Subsequently, it was determined that there was a significant lack of available information in this evaluation area. Therefore, HRA decided to extend the contract and increase the total cost by $37,000 in order to commission approximately 20 original papers about various facets of decentralized/regionalized health professional education. The products of the AMS contract include summaries of group meetings, a final report by the contractor and 22 individual papers on various aspects of AHEC program development and evaluation.

4. C.E. Pagan Associates

An Evaluation Profile was developed through a noncompetitive contract with C.E. Pagan Associates, a minority small business concern. The profile was one of several program-related tasks included in this small business contract as authorized by Section 8(a) of the Small Business Act. BHM estimated that the portion of the contract associated with the profile was $11,000. Initial estimates and final costs were approximately the same and came from program funds.

This effort originally developed out of ideas generated at a meeting of local project evaluators, sponsored by HRA in the summer of 1975, to encourage sharing of evaluation approaches, results, and tools among the 11 local projects.

The report summarized the evaluation activities that had been or were being undertaken in each of the AHEC projects. It was intended that the report would (a) provide a profile of evaluation activities in the 11 AHEC projects, (b) assist the appropriate offices of HEW in developing a systematic and efficient approach for a National AHEC evaluation strategy and (c) improve communications among project evaluators in the development and/or refinement of their evaluation activities.

C. Current Evaluation Efforts

Section 802(b) of PL 94-484 requires the Department to determine the impact of the AHEC Program on (1) the distribution of

health manpower and (2) the access to and quality of health care in the areas in which AHEC projects are located. Section 802(o) requires the Secretary not later than September 30, 1979, to submit a report to the Congress on the results of this assessment.

1. BHM Evaluation

In December 1977, BHM advertized a Request for Proposals (RFP) in the Commerce Business Daily for the AHEC program evaluation. Costs estimated for the contract totaled $394,000 covering an 18-month period.

BHM anticipates a high response rate for a contract of this estimated magnitude, ranging from 30-40 percent of the 100 RFP's mailed. Proposals are due no later than February 20 and a contract is planned to be awarded about March 31, 1978.

Two major objectives have been established for the evaluation contract: (a) to develop and implement an impact evaluation on geographic and specialty distribution of health care services in AHEC target areas (i.e., program results and impact as measured against program goals), and (b) development of a methodology to assess the effects of AHEC activities on access to and quality of care in AHEC areas.

The questions or issues to be addressed in the evaluation, stated broadly, are as follows:

(a) Using the major Program goals as standards, do the results of the AHEC Program to date suggest that the Program should be continued or expanded in its present form, changed in substantial ways and continued at its current level, or discontinued (in an orderly fashion) in favor of other approaches to achieve these national objectives?

(b) Has there been a reasonable return to date on Federal dollars invested in terms of progress toward national objectives? If not, what changes in policy or program management practices might improve such an investment return?

(c) What are the common operating problems across the projects that hinder program operation? What are the sources and nature of these problems and what changes in operating policies and program management practices might facilitate improvement?

(d) What should be the next steps in continuing evaluations of the AHEC Program?

As previously noted, PL 94-484, enacted in October 1976, mandated that the Secretary submit a report to the Congress by September 30, 1979. Presumably, this reporting date was set so that the Congress could utilize the report in considering the enactment of new authorities for health manpower programs that will be needed for FY 1981 funding. (PL 94-484 authorities expire at the end of FY 1980.)

BHM provided the Investigative Staff with the following performance timetable which shows that the Department did not anticipate providing the report to the Congress until January 31, 1980--4 months after the reporting deadline specified in PL 94-484.

Date	Event
1978	
February 20	Proposal due date
March 31	Contract award (18-month performance period)
1979	
April 30	Contractor's preliminary report
September 30	Contractor's report submission date
October 17	Draft Congressional report to BHM
November 1	Report to HRA
December 1	Report to PHS
1980	
January 31	Report to Congress

BHM has encountered a series of difficulties in obtaining Departmental approvals for the evaluation contract. Initiation of the contract thus slipped; however, the initially planned 18-month contract performance period was not shortened to ensure that the reporting deadline would be met. The Investigative Staff believes that higher priority must be attached to this evaluation project if it is to be successful.

On February 14, 1978, the Investigative Staff discussed the BHM evaluation with the Administrator of HRA. He too expressconcern that about $400,000 was planned to be spent for an evaluation which may be of limited value to the Congress because of its programmed completion date. The Administrator stated that he intended to: (1) reevaluate the strategy of AHEC evaluation by contract, and (2) adjust the evaluation timetable to ensure that the Congressional reporting deadline of September 30, 1979, is met.

2. Carnegie Council Project

The Carnegie Council on Policy Studies in Higher Education (formerly referred to as the Carnegie Commission) is also in the process of developing a study of the AHEC projects.

The Carnegie Council agreed to conduct the study after being approached by the AHEC project directors. The project directors advised the Investigative Staff that they see a non-government evaluation as important to their future for both professional and funding purposes. They have reservations as to whether the Government will complete a study and concern for the timeliness of the HEW evaluation.

The Council plans to complete its study and issue a report in about December 1978. Costs will be borne by each project and the Carnegie Foundation will donate much of the needed services. Each project will contribute approximately $3,000 to defray project costs. The National AHEC Coordinator advised the Investigative Staff that he authorized the AHEC projects to utilize funds from their HEW AHEC contracts for that purpose.

D. Observations and Conclusions

HEW plans to significantly expand the AHEC Program over the next few years without first objectively determining whether the concept is a cost-effective and viable strategy to attack the problems of geographic and specialty maldistribution of health manpower.

HEW's past evaluation efforts have been of minimal value and have not "evaluated" the success of the program.

BHM has experienced difficulty initiating the Congressionally-mandated evaluation of the AHEC Program and, as a result, did not anticipate being able to provide the Congress with a report until January 31, 1980--4 months after the reporting deadline specified in PL 94-484. However, after contacts by the Investigative Staff, the HRA Administrator stated that he intends to adjust the AHEC evaluation timetable to ensure that the Congressional reporting deadline of September 30, 1979, is met.

It is difficult to understand why the planned 18-month contract performance period was not shortened to compensate for slippages in initiation of the evaluation and, thereby, ensure that the reporting deadline would be met. It remains to be seen whether the anticipated report will be received in time for any meaningful action by the Congress.

Furthermore, if the deliberations are intended to take place prior to October 1979, then even a reporting date of September 30, 1979, would mean that the HEW report would not be available for use by the Congress in the legislative cycle.

The Investigative Staff views as suspect the merit of HEW's AHEC evaluation strategy and, in particular, of planning to spend about $400,000 for an indepth AHEC evaluation, when the original 11 AHEC projects and the prestigious Carnegie Council is conducting an independent study on whether the AHEC Program is meeting its goals and objectives.

E. Recommendations

To ensure that the HEW Report be available for use by the Congress in consideration of new authorities needed for FY 1981 funding, and to conserve Federal funds, the Investigative Staff recommends that the Committee may wish to:

(1) Reassess the HEW reporting date of September 30, 1979, and advise the Secretary of HEW of (a) a possible earlier reporting date in accordance with Congressional needs and (b) the importance of a timely report.

(2) Direct the Secretary of HEW to explore the feasibility of utilizing the results of the Carnegie Council study and thereby reducing the magnitude of the HEW evaluation.

XI. ACCOMPLISHMENT OF PROGRAM GOALS AND OBJECTIVES

The AHEC concept is a viable one and the original 11 AHEC projects have shown signs of improving the accessibility to needed health services by (a) correcting the geographic and specialty maldistribution of physicians, and (b) improving the supply, quality and efficiency of health care personnel.

Individual AHEC projects have developed at different paces, and there are varying degrees of accomplishment among the 11 AHEC's. Objective and subjective indications of program accomplishments are as follows.

A. Objective Indications of Accomplishments

AHEC's were established as a vehicle to provide the structure and organization for the development and implementation of programs and activities to accomplish the goals of the legislation. Individual AHEC programs and activities were initiated commensurate with the three major thrusts of AHEC--physician and dentist training; training of other health professionals; and continuing education of health professionals.

1. Physician and Dentist Training

AHEC funds are used to help expand and strengthen residency programs at the regional AHEC community hospitals in family medicine, internal medicine, and pediatrics--the core specialties for primary care. In addition, the Investigative Staff found that AHEC extends support to establish or expand similar residencies to smaller rural hospitals in the region. Beyond this, the AHEC's were noted to introduce students from the medical school to rural medical practice through preceptorships and elective clinical clerkships offered to undergraduate medical students. AHEC's also provide support for dental clerkships and dental residencies.

The Investigative Staff found that certain physicians and dentists have located in underserved areas as a result of AHEC efforts. However, an insufficient amount of time has elapsed since the commencement of project operations to observe many actual practice location decisions. Through their decentralized medical education programs, AHEC's are introducing medical students and residents to local training settings, with the expectation that many will choose to establish their practices in rural settings.

The Investigative Staff found specific indicators of accomplishments in physician and dentist training during the

first 5 years of the program. Some representative examples are:

North Carolina AHEC

-- While the physician/population ratio in nonmetropolitan counties of the United States improved 4.4 percent, in North Carolina it improved 9.9 percent.

-- A statewide survey of physicians who have settled in North Carolina since 1972 showed that each year an increasing percentage list the AHEC Program as an important factor in choosing their practice site (in 1972, 8 percent, whereas in 1976 it was 39 percent).

-- About 24 percent of all clinical medical education is now conducted in remote sites from the university.

California AHEC

-- During the period of AHEC funding, the number of primary care residency positions has grown from 17 to 50 in the AHEC area, and a total of 215 residents have received training.

-- In 1975, the AHEC established a dental outreach program to the Firebaugh-Mendota Clinic, a rural area 50 miles from Fresno, under which 14 residents have received training.

South Carolina AHEC

-- The total number of physicians practicing in South Carolina had increased from 2,088 in 1972 to 2,757 in 1976.

North Dakota AHEC

-- As a result of AHEC, the university progressed from offering only a 2-year program in medical sciences to developing a medical school accredited to offer M.D. degrees. Eighty students have since received degrees.

-- Fifty-four residents are now training in 6 primary care residency programs, with at least 1 program located in each of the 4 AHEC regions of the State.

Texas AHEC

-- The number of physicians and dentists working in the AHEC area increased by 20 percent during the last 5 years, a possible result of AHEC effort.

Maine AHEC

-- The first two graduates of the residency program at Eastern Maine Medical Center are now practicing in rural areas--one in Kingfield, Maine, a rural town of 1,000 population, and another on Martha's Vineyard Island.

2. Nursing and Training of Allied Health Professionals

AHEC projects include nurse internships to prepare recently graduated nurses to assume responsibility in hospitals as well as specialized training for practicing nurses (such as intensive care). In allied health, AHEC contracts have provided support for the training of dental hygienists and dental laboratory technicians, the development of health care administration programs, training programs for medical assistants, and have made possible accredited training programs for respiratory therapists and radiologic technicians.

The training of nursing and allied health personnel is considered to be an important element of AHEC since it not only upgrades the quality of health care but contributes to the professional environment by making a community a more attractive place for practicing physicians and dentists.

Some representative accomplishments of the first 5 years of the AHEC program in the field of nursing and allied health training are:

Illinois AHEC

-- By the end of the 1975-76 program year, the Illinois AHEC was conducting 29 percent of all student allied health and nursing clinical experiences (16,000 student-days) through remote site locations in four AHEC regions.

Texas AHEC

-- Training was provided to 906 nursing students and 1,030 students in allied health. These programs contributed to the fact that the number of registered nurses increased by 43 percent and the number of allied health personnel increased 39 percent.

North Carolina AHEC

-- Sixty-four family nurse practitioners were trained to meet the need for additional health care providers and for more accessible primary care services.

3. Continuing Education

Continuing education is the third major thrust of AHEC, and, in this area, programs for physicians, dentists, nurses, and other allied health personnel have been developed or strengthened. Continuing medical education programs are one means to create a positive environment which will aid in attracting new physicians as well as retraining and upgrading the skills of those already in rural areas. These programs will increasingly become more relevant as States estabish continuing education requirements as a prerequisite to relicensure of health professionals.

Some representative examples of accomplishments in the continuing education area during the first 5 years are:

California AHEC

-- AHEC continuing education programs were attended by 3,903 dentists, dental hygienists, and dental assistants; 7,923 nurses; and 4,866 allied health professionals.

North Carolina AHEC

-- 3,294 continuing education programs were conducted and attended by health professionals in the fields of medicine, dentistry, allied health, nursing, pharmacy, and public health.

-- AHEC developed a long-range plan for a statewide network of learning resource centers to provide services to smaller hospitals in the State.

Missouri AHEC

-- During 1976, 2,056 dentists and dental assistants, and 2,445 practicing nurses attended AHEC continuing education programs.

B. Subjective Indications of Accomplishments

Although quantitative data highlight program activities and are indicators that the AHEC process is working and effective, there are more subtle, intangible benefits being derived from the program. The Investigative Staff observed that the existence of AHEC has tended to create an interdependency of the university, the regional hospitals, and the community, resulting in a spirit and belief that all segments can benefit from the AHEC Program.

The Investigative Staff believes the enthusiasm and dedication of the individuals associated with the AHEC Program are largely responsible for this success. The Investigative Staff

solicited the views of some of these personnel regarding the accomplishments of the program.

-- The Director of the Tufts/Maine AHEC stated:

"First and foremost, we of course hold the opinion that our program has thus far been successful in meeting the AHEC program's main objectives as expressed in the intent of the legislation. Specifically, we feel that we have succeeded in the decentralization of medical education from the health science center, represented by Tufts University School of Medicine, to rural Maine at the undergraduate, graduate, and continuing medical education levels.

"Based on this long term experience we at Tufts believe that the strategy of using education to make needed changes in our health care system has proven successful and should be continued as a long term national policy. We also believe that while as a general rule local problems are most effectively and efficiently solved locally, the complex nature of the problems of our health care system demand solutions that can only be achieved by partnerships between federal and local governments as well as by a combination of public and private resources."

-- The Director of the Illinois AHEC stated:

"We in Illinois have every reason to believe that the efforts of relocating educational experiences at places remote from the traditional Medical Center campus are making significant impacts on recruitment, training, and retention of health professionals in those geographic regional areas. The State of Illinois has been sufficiently convinced in the efficacy of this approach to invest approximately forty-eight million dollars in regionalization during the five-year AHEC contract. * * * The aggregate is a substantial commitment to geographically dispersed health professions education in the four areas of Illinois."

-- The Director of the Minnesota AHEC stated:

"* * * Professional education, particularly medical education, is a long-term process, and only with longitudinal follow-ups will we be able to ascertain whether individuals participating in AHEC activities are practicing in underserved areas. Evaluations to date indicate that students have expressed interest

in practicing in small towns, and that a fair number are starting to do so.

"We believe, as evidenced in our five-year Final Report, that the legislative objectives of AHEC have been met."

-- The Director of Medical Education at the VA hospital in Fresno, California, summed up the comments received from the local AHEC advisory council when he stated:

"I think the most important observation I can offer is that the existing AHECs represent 'living laboratories' applied to the solution of health professional education and, concomitantly, health services problems in rural regions. They are just reaching the stage of significant productivity; the relatively modest investments by the federal government in these programs are at the point of yielding high returns. The experience derived from the AHECs during the next 10-year period should provide a wealth of valuable and needed information of pertinence to all underserved regions of the nation.

"I should also point out that the AHECs were created to solve problems of health professional manpower and services in rural areas which are severe and have chronically and stubbornly resisted solution heretofore. One should not think that a program of relatively modest fiscal resources could accomplish the miracle of solving the problems in a limited time space of several years. The 'miracle' of the AHECs is that they now appear to represent an approach which may make more impressive inroads on the problems than any previously attempted. Their greatest strength appears to lie in their capacity, as an organizational entity, to catalyze community efforts and to integrate diverse and fragmented activities in focused common purpose."

-- The President of the Medical University of South Carolina, who was also instrumental in the establishment of AHEC's in Texas and New Mexico, stated:

"The monies which have been spent for the purposes identified under the general heading of Area Health Education Centers have, in my judgment, been some of the most accurately targeted and effectively spent federal dollars for the general purposes of making the

processes of the education of health professionals an integral part of the improving of health care."

C. Problems

Although the program has attained a measure of success, the Investigative Staff noted certain problem areas which should be addressed as the present AHEC's progress and new ones are developed.

The Investigative Staff noted decentralized medical education programs have costs not inherent to the traditional centralized mode. Medical schools and health science centers incur extraordinary costs in transporting students and faculty to and from the rural sites. The Investigative Staff noted some institutions have purchased or leased aircraft for this purpose. Physicians' time lost during travel is an additional cost factor. Additional costs involve living expenses for students on rotations at the rural sites.

As previously noted, there are possible long-range savings with the decentralized process, since fewer new medical schools and health science centers should be needed. North Dakota AHEC officials believe this is true and stated in their fifth-year report that $80 to $100 million was saved as a result of not developing a centralized university health science center. Conversely, the Investigative Staff noted that new medical schools were started in North and South Carolina, even though those States have successful and viable AHEC programs. The Investigative Staff believes long-range planning in the health manpower field could prevent these contradictions.

Another problem area noted by the Investigative Staff relates to the imbalance of funding within AHEC areas. A substantial portion of AHEC funds is being utilized in the larger regional hospitals and not reaching the more remote, rural areas. A director of a remote AHEC site pointed out, for example, that a reduction in Federal funding for the prime AHEC contractor in FY 1978 resulted in a budget reduction of 15 to 20 percent for the larger AHEC sites, while the small rural sites experienced a funding reduction of 50 to 70 percent.

Although Section 781 stipulates that "at least 75 percent of total funds provided to any school shall be expended by an area health education center program in the area health education center," the Investigative Staff believes this provision should be expanded to ensure that the larger and more influential regional AHEC sites do not receive a disproportionate share of the available AHEC funds.

Appendix I

HEALTH MANPOWER EDUCATION (PL 94-484) AUTHORIZATIONS, FY 1977-80 ($ Millions)

	FY'77	FY'78	FY'79	FY'80	78-80 Total
Capitation					
Medicine	133.7	124.2	131.7	139.4	395.3
Osteopathy		8.7	9.3	10.2	28.2
Dentistry		43.8	45.4	46.9	136.1
Veterinary Medicine	29.3	10.2	10.5	10.7	31.4
Optometry		3.2	3.3	3.3	9.8
Pharmacy		17.0	17.1	17.4	51.5
Podiatry		2.3	2.3	2.3	6.8
Public Health		9.7	10.5	11.1	31.3
Health Professions Special Projects					
Family Medicine Depts.	-	10.0	15.0	20.0	45.0
Family Medicine Residencies	39.0	45.0	45.0	50.0	140.0
Gen. Pediatrics/Internal Med.	10.0	15.0	20.0	25.0	60.0
Area Health Education Centers	-	20.0	30.0	40.0	90.0
Physician Asst./EFDA/Teams	-	25.0	30.0	35.0	90.0
Disadvantaged Assistance	-	20.0	20.0	20.0	60.0
Foreign Medical School Transfers	2.0	2.0	3.0	4.0	9.0
Occupational Health	5.0	5.0	8.0	10.0	23.0
General Special Projects	66.3	25.0	25.0	25.0	75.0
Medical School Planning	.4	-	-	-	-
Medical School Development	1.5	1.5	-	-	1.5
HMEIA	41.2	-	-	-	-
Emergency Medical Training (PL 94-573)	10.0	10.0	10.0	-	20.0
Construction					
Grants	103.0	40.0	40.0	40.0	120.0
Interest Subsidies	24.0	2.0	3.0	3.0	8.0
Student Assistance					
NHSC Scholarships	40.0	75.0	140.0	200.0	415.0
Insured Student Loans	-	1.5	-	-	1.5
Financial Need Scholarships	-	16.0	17.0	18.0	51.0
Student Loans	39.1	26.0	27.0	28.0	81.0
Lister Hill Scholarships	.1	.2	.2	.3	.7
Indian Health Scholarships (PL 94-437)		5.5	6.3	7.2	19.0
Allied Health					
Special Improvement	11.4	-	-	-	-
Special Projects	15.4	22.0	24.0	26.0	72.0
Traineeships	3.9	4.5	5.0	5.5	15.0
Full Utilization	.1	1.0	1.0	1.0	3.0
Public Health, Health Administration					
Special Projects	6.0	5.0	5.5	6.0	16.5
Public Health Traineeships	9.9	7.5	8.0	9.0	24.5
Formula Grants	6.4	(Replaced by Capitation)			
Health Administration Grants	-	3.2	3.5	3.8	10.5
Health Administration Traineeships	-	2.5	2.5	2.5	7.5
TOTAL HEALTH MANPOWER	$597.7	$609.5	$719.1	$820.5	$2,149.2

Note: Authorization totals do not reflect those programs with indefinite authorities.

Analysis of PL 94-484 by Funding Level and Program Objectives in Rank Order of Amount Appropriated

Order of funding rank	Title of program	Section of law	Funding[a] level (millions of dollars)	Objective of program: Achieve an adequate supply	Improve geographic and specialty distribution	Improve efficiency and utilization of health manpower	Improve quality of health manpower work force	Optimize opportunities for minorities and economically disadvantaged
1.	Capitation grants	770-772	144.0	x	x			
2.	National health service corps scholarships	751-756	55.0	x	x			
3.	Family medicine and general practice of dentistry	786	45.0	x	x			
4.	Direct loans to students in health profession schools	740-746	20.0	x				
5.	Area health education centers	761	17.0		x		x	
6.	Allied special health projects	796	16.5			x	x	
7.	Grants for training, traineeships, and fellowships in general internal medicine and general pediatrics	784	15.0	x				
8.	Educational assistance to persons from disadvantaged backgrounds	787	14.5					x
9.	Programs for physicians' assistants, expanded-function dental auxiliaries and dental team practice	783	13.1			x		

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10.	Traineeships for students in schools of public health	748	7.0	x				
11.	Emergency medical services training	789	6.0		x	x		
12.	Construction grants for teaching facilities	720	5.0	x	x			
13.	Scholarships for first-year students of exceptional financial need	758	5.0					x
14.	Public health training -- special projects	792	5.0	x				
15.	Interdisciplinary training	788(c)	3.5				x	
16.	Other special projects	788(d)	3.5				x	
17.	Assistance to institutions in financial distress	788(b)	3.0				x	
18.	Grants for graduate programs in health administration	791	3.0	x				
19.	Traineeships for advanced training of allied health personnel	797	3.0	x				
20.	Construction loan guarantees and interest subsidies	726	2.0	x				

Order of funding rank	Title of program	Section of law	Funding[a] level (millions of dollars)	Objective of program: Achieve an adequate supply	Improve geographic and specialty distribution	Improve efficiency and utilization of health manpower	Improve quality of health manpower for	Optimize opportunities for minorities and economically disadvantaged
21.	Start-up grants for educational institutions in health professions	788(a)	2.0		x			
22.	Education of U.S. students from foreign medical schools	782	2.0				x	
23.	Traineeships for students in other graduate programs	749	1.5	x				
24.	Educational assistance to disadvantaged persons in allied health training	798	0.5					x
25.	Insured loans to students in health professions	727-739	b	x				
26.	Lister Hill scholarships	759	0	x	x			
27.	Initial development of new medical schools	788(g)	0	x	x			
28.	Project grants for the establishment of departments of family medicine	780	0	x	x			

a. Conference Bill, fiscal year 1978
b. Sums needed to insure loans made.

SUMMARY OF MAJOR HEALTH MANPOWER ISSUES

During the 2 1/2 years of public debate preceding the enactment of PL 94-484, five major issues emerged:

-- The adequacy of the health manpower supply;

-- Its geographic distribution;

-- Its distribution by specialty;

-- Its quality, efficiency, and utilization; and

-- Access to health professions education.

The following is an overview of three of the major issues that emerged: (a) Adequacy of the health manpower supply, (b) its geographic distribution, and (c) its distribution by specialty.

A. Adequacy of Supply of Health Manpower

In the 1960's and early 1970's Federal aid to health professions education was for expansion of the capacities of medical and nursing schools. For example, the Senate, in May 1972, approved legislation which authorized the VA to plan 10 new medical schools to help alleviate the physician shortage.

BHM reports show that impetus for funds was based on a growing demand for services, rising tuition costs, and alarming predictions of physician shortages. The "50,000 physician shortage" was considered an accurate estimate of the personnel gap.

The impact of the Federal aid to health professions education in the 1960's and early 1970's was significant. From 1965 to 1972 there was more than a 50-percent increase to 13,000 first year places in the Nation's medical schools.

As the United States entered the decade of the 1970's, concerns about an inadequate supply of health manpower were slowly giving way to concerns about geographic and specialty maldistribution.

B. Geographic Distribution

During the late 1960's, the BHM began to recognize the maldistribution of health personnel by geographic area. This led to the 1965 loan forgiveness authorization for service

in a manpower shortage area and the formation in 1970 of the National Health Service Corps.

In his July 1973 Congressional testimony, Assistant Secretary for Health Edwards emphasized that for many Americans, health care was not accessible. The gap between the saturated and underserved areas was widening and would continue to grow unless Congress found a way to reverse the trend.

1. Capitation

BHM reports show that one school of thought was that training institutions should be required to motivate their students to practice in health manpower shortage areas. The theory was that exposure to shortage areas during training would influence certain students to establish a practice in a rural location.

As a result, the bills approved by the Senate in 1974, 1975, and 1976 required all schools receiving capitation support to set aside a certain percentage of class places for students agreeing to practice in shortage areas. In addition, HEW Secretary Matthews recommended a reduction in capitation funds for schools not meeting their goals. (Capitation is the Bureau's largest single program. Some $118 million was awarded in FY 1977 in health professions capitation grants--funds based primarily on student enrollment--to support educational programs of 293 schools.)

As enacted, PL 94-484 requires that schools of osteopathy, in order to receive capitation funds, must provide remote site training in ambulatory primary care for a minimum of 6 weeks. Schools of dentistry must have remote site training or an increase in enrollments to receive capitation funds.

2. Student Assistance

BHM reports show that the traditional vehicle for ensuring adequate geographic distribution of health personnel had been through loans and scholarships carrying a service obligation. However, these programs had not been very successful because the financial incentives had not been large enough to encourage students to repay loans through service. BHM therefore concluded that if loan amounts per year and total loan ceilings were raised, then students would be encouraged to repay the loans through obligated service in shortage areas.

In 1974, Senator Kennedy took a different approach to solving the problem of maldistribution of health personnel. His proposal, which was often called the "doctor draft," would have required all students whose education was even partially

subsidized by Federal funds (including capitation) to serve a minimum of 2 years in the National Health Service Corps (NHSC) or in private practice in a health manpower shortage area.

Every major legislative proposal debated from 1974 to 1976 contained both loan and scholarship provisions. The proposals differed from one another concerning deferral of the service obligation, penalties for failure to serve, length of obligated service, scholarship and loan amounts, and number of choices available to the student.

PL 94-484, as enacted in October 1976, combined loan-scholarship approaches. An NHSC scholarship was authorized with significant funding levels. The scholarship recipient must serve in the NHSC or establish a private practice in a health manpower shortage area (service on a year-for-year basis with a minimum of 2 years). The penalty for failure to serve is three times the scholarship amount plus interest, payable within 1 year. Incentives are available to those who complete obligated service and want to establish a private practice in a shortage area.

The direct health professions student loan was authorized to be continued and allows almost total repayment by serving in a shortage area. A new insured loan for health professions students was authorized. These loans, which may total $50,000 per student ($37,500 for pharmacy students), are repayable in cash, through service in the NHSC, or through private practice in a health manpower shortage area.

3. AHEC Program

Federal support for development of AHEC's came in 1972. AHEC's were considered a new initiative aimed at improving both the geographic and specialty distribution of health personnel in underserved areas. Subsequently, separate AHEC programs were developed by BHM and by the VA.

C. Specialty Distribution

In the 1960's, maldistribution of physicians by specialty was beginning to receive attention. In November 1972, Senator Kennedy addressed the annual convention of the American Association of Medical Colleges saying: "We do an excellent job of teaching physicians to take care of a few people and a poor job of educating physicians to take care of most people."

One of Senator Kennedy's concerns, shared by others, was the inadequate number of medical graduates specializing in primary care.

In 1973, Assistant Secretary for Health Edwards emphasized that there was a deficiency in the number of providers of primary care. The Department believed that expansion of primary care training should be required as a capitation condition and that the amount of the payments would be tied to the specialty choices of their graduates.

Starting in 1974, there were attempts to regulate the numbers of residency positions by medical specialty. Their aim was to increase the number of primary care specialty positions and reduce the number in specialties where there was an adequate supply.

1. Capitation

As previously noted, Congress views the capitation program as a method to ensure that a certain percentage of new doctors and dentists establish practices in shortage areas. The Congress views the capitation program as also being the appropriate vehicle for requiring institutions to increase their training in primary care and direct their students into primary care specialties. Therefore, PL 94-484 also ties capitation payments to increases in primary care training--medical schools must have specified percentages of filled first year residency positions in primary care. The percentage for FY 1978 is 35, for FY 1979 40 percent, and for FY 1980 50 percent.

The Act also requires schools of osteopathy for capitation funds to provide a minimum of 6 weeks of training in ambulatory primary care settings for all students.

Likewise, schools of dentistry must allocate 70 percent of their new first year residencies to general dentistry or pedodontics. These schools also have as an option the training of all students in ambulatory primary care settings for a minimum of 6 weeks.

2. Other Institutional Assistance

PL 94-484 also authorized several special project grant programs for primary care training. These are: Grants for the Establishment of Departments of Family Medicine, Grants for Training, Traineeships and Fellowships in General Internal Medicine and General Pediatrics, and the Family Medicine and General Practice of Dentistry Program.

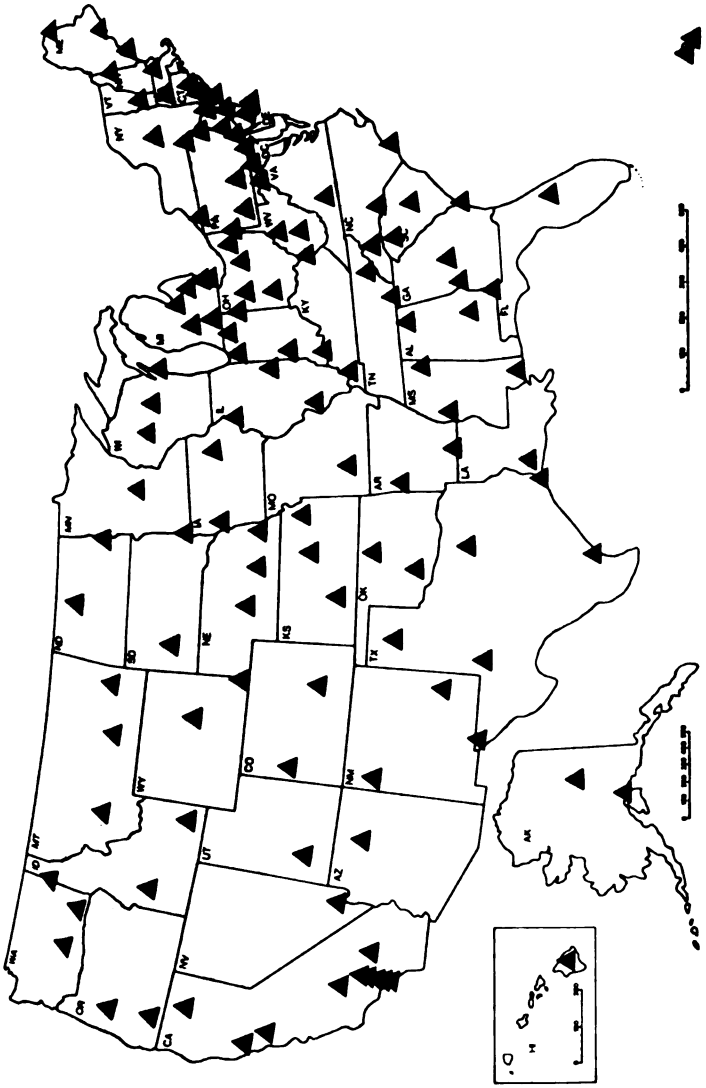
Appendix IV

Schedule of AHEC Projects and Target Areas Served

Contractor	Area Served
1. West Virginia University Medical Center ----------	Six county-area in Southern West Virginia (Kanawha, Boone, Clay, Lincoln, Putnam, and Roane Counties).
2. Medical University of South Carolina ----------	Statewide.
3. University of North Carolina ----------	Statewide.
4. University of North Dakota ----------	Statewide.
5. University of New Mexico ----------	Navajo Nation of four-corner area of Colorado, Utah, Arizona, and New Mexico.
6. Tufts University School of Medicine -------	Parts of the State of Maine.
7. University of Missouri at Kansas City, School of Medicine -------	Western Missouri (Including Kansas City, Springfield, and St. Joseph).
8. University of Minnesota ----------	Statewide.
9. University of Texas Medical Branch, Galveston ----	South Texas (16 counties in Corpus Christi, Rio Grande Valley and Laredo Areas) Central Texas (12 counties).
10. University of Illinois ----	Northern Illinois, Peoria, Urbana.
11. University of California at San Francisco ----------	Central San Joaquin Valley (Fresno) Central Coast (Salinas, Monterey) North Coast (Santa Rosa).

Appendix V
Page 1

▲ Carnegie Commission Suggested AHECs (1970)



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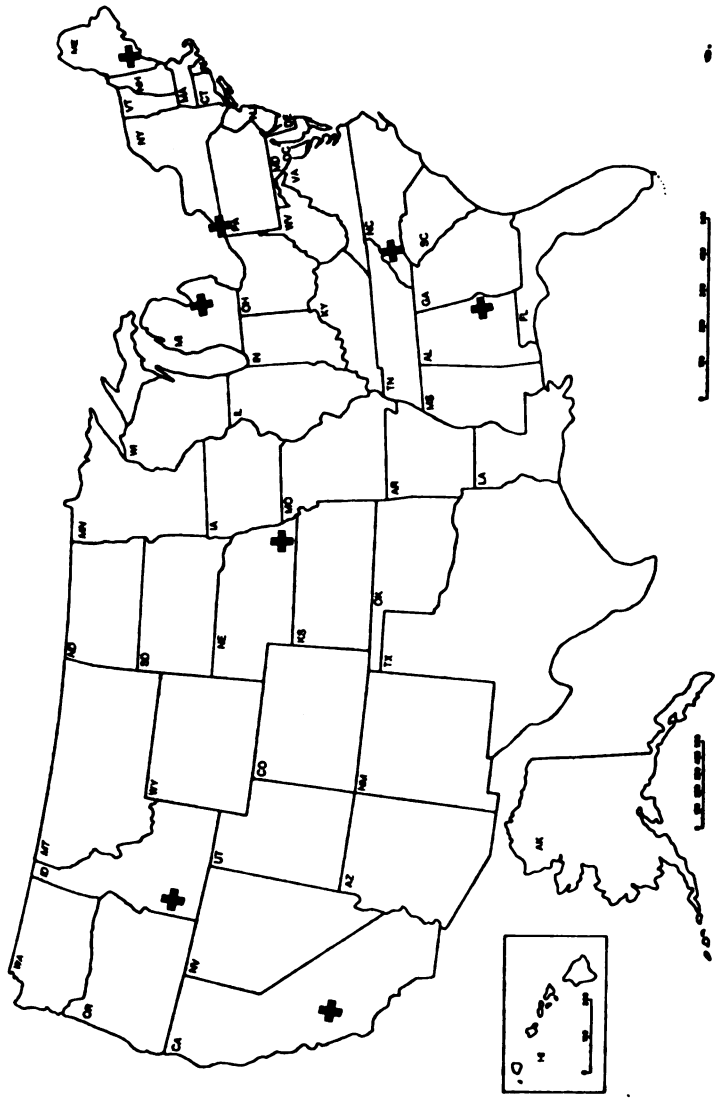

(Extract from a Report on Review of Personnel Management at the HEW HRA Headquarters, Prepared by U.S. Civil Service Commission, May 1976.)

EXECUTIVE SUMMARY

This is a summary of the principal findings and conclusions resulting from the Civil Service Commission review of personnel management at the Health Resources Administration (HRA) headquarters. A detailed discussion of these and other findings is contained in the body of the report.

To an outsider looking at HRA, it appears as a conglomerate connected only loosely and functioning in an uncoordinated fashion. Each Bureau and Center, and the Office of the Administrator, operate autonomously, performing their missions and maintaining sizable support staffs. Duplication of effort occurs not only between bureaus (which for some functions may be justifiable), but also within the individual bureaus. This situation is exemplified by inefficient fragmention of functions and excessive supervisory layering. Fragmentation becomes a problem when work is divided among more people than necessary to effectively accomplish the work; excessive supervisory layering exists when the supervisory and review processes are stacked up so that one layer merely reviews the work of the layer below and passes it on to the layer above without exercising any real decision-making authority or responsibility. This type of layering is also evident in a proliferation of division and branch level organizations, many with fewer than five people. To a large extent, HRA inherited these problems when it was formed. The primary cause of HRA's position management problems undoubtedly lies with successive reorganizations in which obsolete positions from abolished functions were absorbed intact and encumbered into the new organization. HEW has generally maintained a practice of no reduction-in-force, and this failure to follow appropriate personnel procedures in implementing reorganizations has resulted in people whose functions were abolished one or more reorganizations ago being placed at their existing grade levels in other organizations, further fragmenting existing work. Finding work for these people to do has caused organizational contortions which impact on position classification: splintering or fragmentation of work reduces the grade supporting duties in a given position. Extra supervisory layers reduce the amount of responsibility exercised at each level which tends to lower the grade of a given position. However, positions have not been reclassified to reflect the reduced scope of duties and responsibilities and, as a result, there is not a direct relationship between the duties performed by many employees and the pay they are receiving.

Because reorganizations were effected before classification work was completed, combined with a reluctance or inability to place employees properly through reduction-in-force procedures, an undetermined number of employees (managerial estimates range from 20-50%) have been on long term details or acting in supervisory capacities, sometimes for several years. Since these details were generally not made under appropriate procedures, employees view recipients of such assignments,

especially details to supervisory positions and positions with promotion potential, as the objects of favoritism and preselection at the time, and later when assignments are made permanent since details do provide people with experience which improves their competitive advantage when being considered for choice permanent assignments and promotions.

Poor work organization/position management, and misclassified - and unclassified - positions impact on other program areas as well.

- The EEO Program operates not as one program but as six: agency level, four bureaus and the Office of the Administrator. The Program thus has six different directors, six different Affirmative Action Plans, six different EEO Councils, and a multiplicity of goals, objectives and ways of achieving them. From an overall perspective, the EEO Program organization is characterized by fragmentation and duplication of efforts.

- Tradition for supervisory responsibility and accountability for employee performance has not been developed, and no systematic means has been established to insure that performance appraisals are done on an annual basis. When large numbers of employees are without accurate position descriptions and, in some cases, without substantive work to do, or are on details or "acting" for long periods of time, it is extremely difficult to evaluate fairly their performance against specific duties and responsibilities.

- The employee development and training functions are decentralized to the bureaus, centers and AO. There is virtually no coordination among the various bureau training people so they sometimes duplicate their efforts and rarely share resources or training opportunities with each other.

  Also, training appears to be approved for anyone who asks. A considerable amount of resources are being spent on training, but without the training being tied to improving employee performance or meeting agency staffing needs. Neither are executive development training plans based on systematic, objective analyses of employee performance deficiencies and program needs.

A more detailed discussion of these and other findings follows, along with required and recommended actions that we believe will foster necessary improvements in personnel management at HRA headquarters.

SUMMARY OF MAJOR HEALTH MANPOWER ISSUES

During the 2 1/2 years of public debate preceding the enactment of PL 94-484, five major issues emerged:

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-- Its geographic distribution;

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DEPARTMENT OF HEALTH EDUCATION AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON D.C. 20201

10 FEB 1978

The Honorable Daniel J. Flood
Chairman, Subcommittee on Labor/
Health, Education, and Welfare
Committee on Appropriations
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

The enclosed report on the current and future needs of genetic services is submitted in response to the committee's request on page 59 of House Report No. 95-381 on the fiscal year 1978 appropriation bill for the Departments of Labor and Health, Education, and Welfare.

In its report language the committee directed that the Assistant Secretary for Health determine current and future needs of genetic services, as defined under Title IV of the Health Research and Health Services Amendments of 1976. The report includes information related to activities intended to serve immediate needs as well as efforts to document future needs for genetic services.

We hope that this information fulfills the committee's requirements.

Sincerely yours,

Charles Miller
Acting Assistant Secretary
for Management and Budget

Enclosure

GENETIC DISEASES NATIONAL PLAN

I. Introduction

In developing a national plan for genetic diseases, there are three major factors which must be taken into consideration:

1. The National Heart, Lung, and Blood Institute, by an interagency agreement, will make $3.75 million available for the Sickle Cell Screening and Education Clinic program in FY 1978. These funds will be used by the Bureau of Community Health Services (BCHS) to provide support for approximately 20-24 Sickle Cell Screening and Education Clinics. A specific plan needs to be developed and implemented for integrating this program into a broader genetic diseases service program, while continuing to offer screening, education and counseling services to an additional 300,000 persons in the at-risk population.

2. The National Sickle Cell Anemia, Cooley's Anemia, Tay-Sachs, and Genetic Diseases Act, as authorized under P.L. 94-278, is a 3-year authorization which expires at the end of FY 1978. Plans need to reflect this factor as well as provide some foundation on which future programs could be built in the event that Congress elects to continue this activity in either its present or revised format.

3. The plan must reflect the intent of Congress by incorporating those special considerations specifically identified in legislative language and Committee Reports to the extent possible under the allowable time and dollar limitations.

II. Proposed Courses of Action

This plan is based on the availability of $4 million for genetic diseases in FY 1978 as suggested by the House-Senate Appropriations Conference Committee Report. This amount is in addition to the $3.75 million to be made available for the Sickle Cell Screening and Education Clinic program as described earlier. Proposed program actions are as follows:

1. Interagency Agreements

These funds will be used to support unique contributions of other Department of Health, Education, and Welfare constituent agencies to the implementation of the program. These are such agencies as Center for Disease Control (CDC),

in developing technical laboratory services, standards, proficiency testing and laboratory bench training. We will also explore the possible integration of the CDC pilot project which screens older pregnant women, as well as developing and stimulating screening and education programs in selected Public Health Services (PHS) facilities, services of the Indian Health Service, etc. In addition, we are exploring an agreement with the National Bureau of Standards to develop an operations research model for use in formulating state-wide area project plans.

2. Information and Education Services

A national program focusing on the development of education and information materials aimed at both service providers and the general public will be initiated, utilizing the contract mechanism and workshops designed to elicit input from national organizations focusing on specific diseases will be held.

3. Grant Programs for the Initiation and Development of State-wide Systems of Genetic Services

Grants will be awarded to appropriate entities based on competitive applications, in a national competition, to develop and implement State-wide or, if appropriate, regional systems of genetic services. Applications will be expected to show how these activities will be coordinated with existing health service systems and especially with the Maternal and Child Health programs supported under Title V of the Social Security Act. It is anticipated that 10-15 awards will be made initially based on quality of applications and characteristics of targeted populations.

Grantees will collect and document data on the number of persons in the targeted State, area or region, who are at risk for various genetic disorders and describe grantee priorities and methods for screening and education for specific diseases. Arrangements for the delivery of laboratory services and back-up support through State, area-wide or regional Genetic Service Centers will be included in applications.

4. Grants for Technical Assistance and Planning

Technical assistance and/or planning grants will be awarded to entities developing State-wide systems of genetic services, with particular emphasis on those which include target populations and service areas covered by existing contract Sickle Cell Screening and Education Clinics, in order to identify and initiate the development of effective linkages needed to assure the coordination of these clinic services with the State-wide system, and to facilitate the transition of these services from a contract to a grant mechanism of support.

5. Needs Assessment and Evaluation

Activities will include documentation of current and future needs of at risk populations, documentation of capacity in selected State-wide areas, collation of incidence, prevalence, and natural history of specific diseases covered by the Act. Two small pilot needs assessment studies at the State level have been initiated, one in Ohio ($10,000) and one in Hawaii ($9,500), which are expected to be completed by the end of February. In addition, an initial, modest national, needs-assessment study is being conducted at the Children's Hospital Medical Center in Boston and is expected to be completed by the end of January, and a needs assessment for Sickle Cell Disease is being conducted by the National Association for Sickle Cell Disease ($7,250).

6. Program Coordination

This program will be coordinated with other agencies and programs related to genetic diseases through the established PHS Genetics Coordinating Committee. Responsibility for Section 1106(a) of P.L. 94-278 ("the Secretary shall prepare and submit to the President for transmittal to the Congress on or before April 1 of each year a comprehensive report on the administration of this part") has been delegated to the National Institutes of Health and will be implementated by the Genetics Coordinsting Committee on which BCHS is represented. BCHS implementation of Section 1101 and 1105 and activities relating to this Act will be incorporated in the report through the Coordinating Committee.

7. Peer Review of Grant and Contract Programs

The Health Services Administration has objective review mechanisms in operation, and these will be utilized for this program.

For the grant programs under #3 above, a system of prior review and comment on these applications by the Regional Offices and CDC (in terms of coordination with other State-wide service plans and laboratory capability) will be instituted. A reader system of peer review utilizing selected experts in the field will be used, and comments on applications recommended for approval will be solicited from members of the Genetics Coordinating Committee.

III. Proposed Spending Plan

1.	Interagency Agreements	$ 260,000
2.	Information and Education Services	400,000
3.	Grants for State-wide Projects	2,240,000
4.	Grants for Technical Assistance and/or Planning	900,000
5.	Needs Assessment and Evaluation	200,000
	Total	$4,000,000

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON D C 20201

FEB 10 1978

The Honorable Daniel J. Flood
Chairman, Subcommittee on Labor-
Health, Education, and Welfare
House of Representatives
Washington, D.C. 20515

Dear Mr. Flood:

In its report on the Fiscal Year 1978 Appropriations for the Departments of Labor and Health, Education, and Welfare, the Committee on Appropriations requested the National Institute of Mental Health (NIMH), Alcohol, Drug Abuse and Mental Health Administration, to submit a report on the implementation of its new clinical training initiatves and the plan for evaluation.

The enclosed report has been prepared by the NIMH staff in response to this request and is respectfully submitted for your information and review.

Sincerely yours,

Charles Miller

Charles Miller
Acting Assistant Secretary
Management and Budget

Enclosure

Report on Implementation and Evaluation of NIMH Services Manpower Initiatives

Assistant Secretary for Health
Public Health Service
Department of Health, Education, and Welfare

December 1977

In considering the FY 1978 services manpower proposals of the National Institute of Mental Health (NIMH), the House Appropriations Committee stated: "It is expected that NIMH will give a high priority to those new directions including a concomitant and integral evaluation plan. The Committee requests a report from the Assistant Secretary for Health prior to the hearings on the 1979 budget, on the implementation of the above initiatives and on the plan for evaluation." 1/ In addition, the Senate Appropriations Committee made the following related request: "The Committee urges NIMH to develop procedures for monitoring the achievement of new objectives for the services manpower program and for the measurement of progress towards the actual redistribution of mental health manpower." 2/

This report summarizes progress in the implementation of the new initiatives and describes efforts to date in developing the evaluation plan. It has been prepared by an NIMH Work Group with representatives from the Office of Program Development and Analysis (the planning and evaluation office of NIMH), the Division of Manpower and Training Programs, the Division of Mental Health Service Programs, and the Division of Biometry and Epidemiology. This insures the involvement in the evaluation of those responsible for planning, implementing, and tracking the new initiatives so that the results can be fed back to key NIMH management.

I. Summary of the Major Features of the New NIMH Manpower Initiatives

The new initiatives are an outgrowth of an extensive and intensive review and assessment of NIMH clinical/services manpower training programs that occurred over a two-year period. They represent the most profound redirection of manpower policy and programs since the major reorganization of the Institute in 1966.

Shifts in the underlying principles and strategies for NIMH manpower training programs emphasize manpower development as a derivative of service needs and broadens the focus of related programs to include (in addition to training) such areas as: recruitment, utilization, distribution, credentialing, and evaluation.

The major overarching goal of the new NIMH services manpower program is to reduce the maldistribution of mental health manpower, with special emphasis on that segment of the mental health manpower universe influenced by NIMH support. To achieve this major goal, six derivative programmatic goals have been identified as contributing to more effective and efficient production and distribution of mental health manpower for service delivery. These goals are:

1/ House Report 95-381, page 47
2/ Senate Report 95-283, page 73

1. To educate or train mental health specialists for the provision of services to targeted unserved or underserved:

   geographic areas - rural, inner city, specific areas with unmet mental health needs;

   populations - minorities, children, youth, the aged, and other populations with special unmet mental health needs;

   public service facilities - including State and county mental hospitals, community-based agencies (especially CMHCs), and correctional agencies.

2. To promote collaborative and/or cooperative linkages between those institutions/agencies that educate or train mental health services manpower and those that comprise mental health services delivery systems.

3. To strengthen the capacity of State and sub-State mental health authorities to plan, implement, and evaluate systems for mental health services manpower development.

4. To develop a research and development capability for generating and disseminating nationally information and data on mental health services manpower development, especially in relation to manpower maldistribution and the related issues, i.e., recruitment and utilization.

5. To expand the capabilities of primary health care providers to appropriately deal with mental health problems of their patients with special reference to the unserved and underserved.

6. To increase the supply of minority manpower within the major mental health disciplines.

In line with the new program goals:

A. Mental Health Education Programs have been refocused to emphasize the preparation of mental health professional and paraprofessional personnel for practice in targeted areas of service need: underserved geographic areas; underserved populations such as minorities, the aged, and children; and understaffed public clinical facilities such as community mental health centers, State mental hospitals, correctional institutions, etc. Special attention is given to the preparation of primary health care providers to deal more effectively with the emotional problems or mental disorders of the patients under their care, and to increasing the numbers of minorities in the mental health professions.

B. The newly developed State Mental Health Manpower Development Program is designed to enable State mental health agencies and other appropriate State and sub-State entities to develop the capacity to plan, implement, and evaluate systems for mental health manpower development. Emphasis in this program is on developing State mental health manpower systems to facilitate more effective preparation, distribution, utilization, and retention of mental health personnel and, thus, improve the quality of services that are provided within the State and sub-State mental health jurisdictions.

C. The Mental Health Services Manpower Research and Development Program stresses the development of knowledge and technology needed to address national problems related to manpower development, and the dissemination and utilization of the knowledge and techniques produced through this effort. The program is designed to stimulate systematic studies of problems related to the: education and/or training of new and traditional categories of mental health service personnel; maldistribution of mental health manpower; and a broad range of problems related to manpower development in general--for example, the development of effective linkages between health service agencies and education/training institutions; manpower evaluation and credentialing; manpower needs assessment, planning, recruitment, etc.

II. Progress in Implementing the New NIMH Initiatives

A. Communications to the Field and Plans for the Review of Applications

On June 8, 1977, NIMH issued a nationwide announcement outlining the new directions and describing the mental health clinical/services manpower grant activities for FY 1978. September 15, 1977 was established as the deadline for the receipt of applications for the FY 1978 review and awards cycle. New and revised program guidelines were issued in July 1977. A significant number of applications have been submitted in all of the above program areas.

At this stage of the FY 1978 grants review cycle, we can roughly estimate a total of 450 to 500 applications in the Division of Manpower and Training Programs which handles the vast majority of the services manpower training and development programs. Between 60% and 70% of this estimated number list as their primary focus problems related to maldistribution of mental health manpower. Others deal more specifically with such areas as: the mental health training of non-psychiatric health personnel--mostly primary health care providers; increasing the numbers of minorities in the mental

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health disciplines; training for practice in community-based services--mostly CMHCs. A number of the projects focus training or educational approaches on two or more problem areas. For example, virtually all of the basic training programs in adult and child psychiatry are also focused on practice in CMHCs. Similarly, several projects addressed to geographic maldistribution include emphases on improving services to minority groups and/or the aged.

Included in the estimated totals above are applications from 33 States for grants to support State manpower development projects. At least 75% of these are requesting funds to improve their manpower planning for Statewide services. A major product of this planning will be more definitive information on the scope and characteristics of maldistribution of manpower within the State and in specific types of service settings, as well as improved organizational structures and processes for determining available options for resolving problems, establishing policy, and implementing these decisions.

Significant among the applications requesting support for mental health services manpower research and development are projects designed to: develop educational tools to assist primary health care providers in integrating mental health considerations into the management of patients with chronic health problems; identify factors affecting attrition and retention of mental health staff and the relationship between such factors and the quality of patient care; compare the effectiveness of alternative models for providing cross-cultural training to mental health personnel; develop and evaluate a model curriculum for evaluation training; and, study factors relating to the distribution of psychiatrists with respect to auspice of employment and geographic location. Others are focused on a broad range of problems such as: knowledge gains and clinical applications from continuing education programs; competency-based education and credentialing; models for identifying primary educational objectives and measuring outcomes with respect to a variety of mental health disciplines.

Reports of site visits will be useful in assessing the extent to which the applicant institutions and agencies are actually strengthening their capability and organizing staff, curricula, clinical practice, etc., in ways that will yield measurable results in fulfilling the program objectives. Criteria for making awards in FY 1978 will give priority to those projects of high scientific and technical merit that show the greatest promise for achieving NIMH new services manpower initiatives and, because maldistribution is a problem that cuts across all of these initiatives, relieving the problems of maldistribution.

The composition of the Initial Review Groups (IRGs) in the clinical services manpower areas has been altered as necessary to accommodate the new initiatives, and site visiting is in progress. IRG reviews will take place in January-February 1978, and reviews by the National Advisory Mental Health Council will be held in May 1978. Grant awards for projects reviewed during this cycle will have an effective start up date of July 1, 1978.

B. Strategy for Reorganizing the NIMH Division of Manpower and Training Programs

A comprehensive strategy to bring the structure and functions of the manpower and training programs into synchrony with the goals and objectives of the new initiatives has been developed. Phase one of the reorganization strategy provides an interim organization to permit the Institute to move ahead with the implementation of the new program components (State Mental Health Manpower Development and Mental Health Services Manpower Research and Development), to initiate shifts in the focus and priorities of the mental health services education programs, and to relate manpower and program planning, analysis, and evaluation activities more closely to the new initiatives. As of September 15, 1977, this phase of the reorganization strategy was initiated as follows:

1. The Vestermark Center and the Continuing Education Branch will be abolished and a Center for State Mental Health Manpower Development established.

2. The Experimental and Special Projects Branch will be converted into a Center for Mental Health Services Manpower Research and Development.

3. The Manpower and Analytic Studies Branch will be abolished and an Office for Manpower and Program Planning, Analysis, and Evaluation established.

During the first phase of reorganization, the present Branch structures of the professional and paraprofessional mental health services education programs remain unchanged. They are the: Psychiatry Education Branch, Psychology Education Branch, Psychiatric Nursing Education Branch, Social Work Education Branch, and the Paraprofessional Manpower Development Branch. Interdisciplinary and single (non-core) disciplinary projects are administered out of the Office of the Director. A mechanism has been developed to insure that the various components of this mental health services education cluster will work together in a more coordinated program effort. This is an interim arrangement pending a planning effort to determine the most effective model for organizing the mental health services education programs so that they will have maximum impact in insuring an adequate distribution and supply of well prepared mental

health personnel to correct major shortages in mental health services delivery.

Phase two of the reorganization strategy focuses primarily on the mental health services education programs and can only proceed upon the completion of the planning process which has already begun. This process is being coordinated out of the Office of the Director, NIMH, and will involve NIMH program managers, academic and professional constituencies, members of the National Advisory Mental Health Council, and staff from the Office of the new ADAMHA Administrator and the Assistant Secretary for Health. This planning activity will address disciplinary training in relation to a broad scope of issues pertaining to the new NIMH manpower policy, budget considerations, and targeted mental health service initiatives. Final decisions regarding the organization of the mental health services education cluster, then, will depend upon the careful consideration of a wide range of options developed through the planning process as well as the outcome of the work of the President's Commission on Mental Health.

C. Strategies for Improving the NIMH Manpower Analysis, Data Gathering, and Reporting Capabilities

NIMH has had a long standing need for a stronger data base to guide program development and evaluation and to meet the increasing demands for manpower information. Our efforts towards greater accountability in manpower programs require a stronger capability for program analysis, evaluation, and reporting than is currently operational. The increasing requests for reports and statistical information from the Congress, special task forces and commissions (e.g., the President's Commission on Mental Health), etc., combined with our internal needs to monitor and evaluate the new NIMH program initiatives, are overloading present capabilities. We are, therefore, taking immediate steps to reassess and strengthen our capability in this area.

1. A Committee on Manpower Information Needs and Resources has recently been appointed to assess NIMH manpower data needs and identify resources that will be required to meet these needs, and recommend alternatives for developing the required resources.

2. Several studies are currently under way or planned to augment the data that are presently available. These include:

   --A contract with the American Psychiatric Association that will produce information on the approximately 30,000 psychiatrists in the United States--both APA and non-APA members. Data will include education/training, work setting, professional activities and interests, credentials, geographic distribution by State, county, Standard Metropolitan Statistical Area, and where possible, mental health service catchment area. Report due December 1978.

--A contract with the National Association of Social Workers to design a study of the academic preparation, duties, functions, work settings, and other characteristics and qualifications of social workers who provide mental health services, both in mental health facilities and elsewhere. Data will include information related to the training needs and geographic distribution of social workers who perform mental health services. Report due March 1978.

--Similar contracts will be explored in the next fiscal year with the American Psychological Association and the American Nurses' Association. Studies to begin before September 1978.

--A contract to design methodology for assessing the manpower development capacity of States. After this methodology has been tested in several States, the findings will be reported back at a conference which will bring together key individuals concerned with mental health manpower development in those States. The design of this study will take into consideration the findings of a pilot survey of the State role in mental health education which will be completed shortly. The study will provide baseline data for assessing changes in State manpower development capacity resulting from the NIMH initiative in this area. Report due September 1978.

--A study which will describe the population of Foreign Medical Graduates (FMGs) in public mental hospitals, the characteristics of State mental hospitals that use varying numbers of FMGs, and the services currently provided by FMGs in these hospitals; further, the study will assess the impact in State mental hospitals expected to result from the new restrictions on the use of FMGs. Report due April 1978.

--A study addressing manpower maldistribution by attempting to identify those factors which influence personnel to locate in underserved areas. Report due February 1978.

--A study in a health maintenance organization (HMO) is assessing the validity of the diagnoses of mental disorders made by primary care physicians and will describe the specific services provided to patients with mental disorders. The data gathered in this and future studies will provide a firmer base for shaping the mental health position of the training provided to primary health care givers. Report due December 1978.

--The NIMH is working toward the development of a cooperative Federal/State statistical program. When it becomes operational, the data collection program for manpower information will be largely decentralized to the individual States which will collect more detailed and comprehensive information and forward selected data to the Federal level. This system is being developed in cooperation with the National Center for Health Statistics, Cooperative Health Statistics System. When implemented, this system will provide much more relevant data with much greater geographic specificity than is possible in a national reporting program. Planning effort ongoing.

--A major study is planned of the relationship of psychiatric training in community mental health to the future recruitment and retention of psychiatrists in this field of work. This study will help in understanding why some community mental health centers have little difficulty in filling their psychiatric positions while others experience considerable difficulty; what rewards and support systems are available in these CMHCs that are successful in recruiting psychiatrists but not in others. Study to begin before July 1978.

III. Progress in Developing the Plan for Monitoring and Evaluating the NIMH Clinical/Services Manpower Initiatives

In any comprehensive evaluation attention must be given to: (1) the definition of the program goal and objectives to be evaluated; (2) the development of measures for determining progress in the fulfillment of program objectives; (3) defining the kinds of data that will be required to identify and strengthen weak program elements to capitalize on those that are effective and to revise or drop those that are ineffective; (4) developing monitoring approaches and research projects that will be maximally effective in providing the required data and insuring valid and reliable measurement of program progress and impact; and (5) developing appropriate mechanisms for distributing and facilitating the utilization of evaluation results.

A NIMH Work Group for planning, implementing, and tracking the new manpower initiatives has been operational for several months. This group--composed of representatives from the Division of Manpower and Training Programs, the Division of Mental Health Service Programs, the Division of Biometry and Epidemiology, and the NIMH Office of Program Development and Analysis--has the major responsibility for developing the plan for monitoring and evaluating the NIMH manpower initiatives. Progress in implementing the new initiatives will be measured at periodic intervals over the next five years. In addition, assessments will be done of the outcome of this program and of its impact on the problem of maldistribution of mental health manpower.

This section of the report describes the current status of the evaluation planning effort. It is important to note that the plan is still evolving and will be modified as we progress towards a clearer conceptualization of the program goals, sharper definitions of specific program objectives, and further refinements of measurement criteria or approaches. It is anticipated that this effort to refine the plan will be completed by June 1978 although adjustments will continue to be made as the program is modified with experience.

A. Program Goals and Objectives

The evaluation plan is designed to monitor, assess and account for progress in implementing the goals of the new NIMH services manpower program which were described on page 1 of this report. Efforts are under way to develop clear objectives in order to measure progress in achieving the program goals. Figures 1 and 2 in Appendix A illustrate the current state of development of program objectives. As noted above, definitive objectives for all program goals will emerge from the planning effort by June 1978.

B. Measuring Progress in Fulfilling Program Goals and Objectives

As the objectives of the program are specified, approaches to measurement of progress are being developed. Appendix A illustrates the current state of these efforts.

A major problem associated with the development of measures is to determine the boundaries of NIMH impact on the overall mental health manpower universe. Such factors in development of the total mental health manpower pool as employment, utilization, deployment, etc., are influenced by factors outside the immediate control of the NIMH manpower initiative. We intend to identify such factors. However, the primary focus in the evaluation strategy will be on those individuals and institutions directly influenced by the impact of NIMH resources.

C. Defining Information Needs and Strategies

In an earlier section of this report we referred to a committee that has been appointed to assess NIMH manpower data needs, identify resources that will be required to meet these needs, and recommend alternatives for developing the required resources. The work of this committee will be closely linked to the evaluation planning activities. The need for baseline data against which to measure program impact is a high priority. The studies described under II. C., pages 6, 7, 8, will be augmented as necessary to provide a clearer assessment of the nature and scope of the maldistribution problems, and a sharper definition of "need areas." The recommendations of the newly appointed committee will instruct

the planning effort in this area. In the interim, however, steps are being taken to strengthen existing mechanisms for obtaining information that will facilitate the monitoring and short-term evaluation process. For example, the grant application packets are being reviewed and changes proposed that will strengthen our measures of project effectiveness in fulfilling specific program objectives. Program guidelines have been revised to elicit the kind of information in grant applications that will facilitate the evaluation process. For example, mental health education grant applicants are now instructed to include information relevant to plans for placing trainees in areas of need upon graduation, and mechanisms are being developed for eliciting information in the application that will enable us to assess: (1) progress in increasing the number of minorities in the mental health education programs; and (2) changes in the curricula, approaches, clinical practice, etc., that are necessary to enable trainees to provide services to underserved geographic areas, populations, public clinical facilities. Protocols for site visits have been strengthened so that this mechanism will yield the kinds of information needed for the comprehensive evaluation of the NIMH manpower initiatives.

D. Developing Monitoring and Research Strategies

Assessment of managerial and operational efficiency of the NIMH manpower program and its component projects will constitute a significant element in the formal organized evaluation plan. Appropriate mechanisms to improve reporting systems that can provide data useful to monitor the program and projects will be developed. A well planned, targeted research strategy is greatly needed to improve NIMH program evaluation capability. Such a strategy will be developed as part of the evaluation plan. The plan will also include a schedule and procedures for the timely review of the evaluation process, during which the work plans for expediting the process will be assessed and updated.

E. Developing Mechanisms for Dissemination and Utilization of Evaluation Results

NIMH will endeavor to strengthen the system for distributing evaluation results to insure that data relevant to program progress is available and can be utilized: in the budget preparation and legislative processes; at other levels of policy development; in the program management process; etc. The evaluation plan will include formal mechanisms for disseminating

evaluation results. These will include such devices as printed progress reports, scheduled briefing, news memoranda, written reports to policy makers and program managers, seminars, etc.

In Summary

NIMH is well along the way in implementing the new clinical/services manpower initiatives, and evaluation planning has been a concurrent process. The final product that will evolve from this process will be a well-thought-out, comprehensive evaluation plan to enable NIMH to track progress and evaluate the effectiveness of the new program strategy. This will, therefore, put NIMH in a position of being able to promptly and reliably account for its efforts in relation to the new services manpower initiative.

APPENDIX A

APPROACH TO MEASUREMENT OF PROGRESS

Efforts are under way to develop for each of the derivative goals of the services manpower initiatives, as described on pages 1 and 2 of this report, a sequence of logically structured, measurable objectives which relate short-term accomplishments to long-range goals. Objectives will be developed to track short-term, intermediate, and long-range progress. For each objective, approaches to measurement will also be developed.

The planning process for reorganizing the mental health services education programs (described on pages 5 and 6 of this report) will assist NIMH in determining what are realistic achievable objectives to: educate/train mental health specialists to provide services to underserved areas; develop collaborative and/or cooperative linkages between education/training institutions and mental health services delivery systems; and expand the mental health services capabilities of primary health care providers (goals 1, 2, and 5, respectively, as listed on page 2 of this report).

Some tentative general objectives are proposed for goals 1, 2, and 5 which are subject to revision and refinement pending the outcome of the NIMH planning activities, which should be completed by June 1978 (see Figure 1, pages 17, 18). More definitive objectives and measures have been developed for goals 3, 4, and 6. These are depicted in Figure 2 (pages 19, 20, and 21) and are described in further detail below.

GOAL 3

Strengthen the capacity of State and sub-State mental health authorities to plan, implement, and evaluate systems for mental health services manpower development.

Short-Term Objectives

A. Develop State Mental Health Manpower Development Program component and create an appropriate organizational entity for further development of this component and management of its operations.

Measure

Program component and Center for State Mental Health Manpower Development established.

B. Announce program nationally. Distribute guidelines. Generate applications through consultation and technical assistance, etc., to interested State and sub-State authorities.

Measure

Already achieved. See pages 3 and 4 of this report.

C. Complete review of grant applications and provide NIMH funding for at least 15 State or sub-State mental health authorities for manpower development in FY 1978.

Measure

More than 30 grant applications have been received and are being reviewed. It is anticipated that funds will be available to award grants to a sufficient number of high quality projects to achieve this objective.

Intermediate Objectives

A. Forty States with a designated official responsible for mental health manpower development by FY 1980.

Measure

Criteria will be developed which define "a designated official responsible for mental health manpower development." Such a person must be more than a figurehead or name on an organizational chart. State mental health plans will be reviewed in 1980 to measure progress toward this objective. Achievement will depend in part on direct NIMH grants to States for manpower development and in part from the indirect effects of highlighting for the field the relationship between planning for services and for manpower development.

B. Twenty-five States with an acceptable manpower development plan.

Measure

Criteria will be developed and used to judge the manpower development sections of State mental health plans submitted in FY 1980.

Long-Range Objectives

Twenty-five States with a functional manpower development system by FY 1983.

Measure

A contract is currently under way which will develop and test a methodology for assessing the manpower development capacity of States based on a conceptual formulation of a functioning manpower development system. This methodology will then be used in 1983 to assess progress towards this objective. It is recognized that the degree to which a manpower development system is actually functioning will depend primarily on State resources available.

GOAL 4

Develop an R&D capability for generating and disseminating nationally information and data on mental health manpower development, especially in relation to manpower maldistribution and the related issues of recruitment and utilization.

Short-Term Objectives

A. Develop Mental Health Manpower R&D Program component and create an appropriate organizational entity for further development of this component and management of its operations.

Measure

Program component and Center for Mental Health Services Manpower Research and Development established.

B. Announce program nationally. Distribute guidelines. Generate applications.

Measure

Already achieved. See pages 3 and 4 of this report.

C. Convene a conference to identify 10 priority areas as targets for mental health manpower R&D activities, especially in relation to maldistribution.

Measure

A conference is being planned for FY 1978 which will bring together leaders in the fields of mental health services manpower development with potential users of R&D products to identify priority areas for R&D activities.

Intermediate Objectives

A. Generate applications and provide funding for R&D activities in 10 top priority areas.

Measure

Funded grant applications will be reviewed in FY 1981 to assess the degree to which R&D projects have been generated and funded in areas targeted as top priority. Achievement of this objective will depend on the availability of adequate funds as well as the ability of the field to respond.

B. Disseminate 5 major R&D products in priority areas.

Measure

Dissemination is a critical part of any R&D program. Individual products in priority areas will be carefully evaluated in order to identify innovative models or approaches for further demonstration or intensive dissemination to promote utilization of these models in the field.

Long-Range Objectives

Have a functioning R&D system which identifies needs, develops solutions and disseminates them to appropriate users of mental health manpower knowledge--especially in relation to priority areas.

Measure

Criteria will be developed which define a functioning R&D system for mental health manpower development. The NIMH program will then be reviewed against these criteria in FY 1982. The degree to which the program is addressing priority areas will also be assessed.

GOAL 6

Increase the supply of minority manpower in the mental health disciplines.

Short-Term Objectives

A. Plan and initiate studies to quantitatively determine the current supply, distribution, and need of minority manpower in the mental health disciplines with special reference to underserved geographic areas, populations, and public mental health programs.

Measure

Studies are being planned to improve the data base with respect to supply, distribution, and need for mental health manpower. These studies will be designed to provide specific information with respect to minority mental health manpower.

B. Increase by 25% the number of training programs specifically targeted to the training of minority mental health professionals.

Measure

Training grants funded in FY 1977 will be reviewed to determine how many were specifically targeted to the training of minority mental health personnel. Grants funded in FY 1978 will then be monitored to measure the achievement of this objective.

Intermediate Objectives

A. Based on the data derived from short-term objective A. above, establish specific production targets for the training of minority mental health professionals.

Measure

Available data will be reviewed in FY 1979 in order to establish such production targets. These targets will be based on the need for minority mental health manpower and the number of minorities in the available pool for mental health training programs.

B. Develop a strategy for mental health career development for minorities with priority placed on those disciplines with fewest number of minorities, i.e., psychiatry.

Measure

Information on recruitment of minorities into mental health training programs will be reviewed in FY 1979 as a basis for developing the above strategy.

Long-Range Objectives

Strengthen and develop mechanisms to implement NIMH policy regarding increased participation of minorities in NIMH training programs.

Measure

The degree to which there has been increased participation of minorities in NIMH training programs will be assessed in 1982 for the period FY 1978-81. Recommendations will then be made for mechanisms to maintain or improve success in achieving such increased participation.

FIGURE 1
APPENDIX A

APPROACH TO MEASUREMENT OF PROGRESS

(Tentative General Objectives for Goals 1, 2, and 5)

GOAL	SHORT-TERM OBJECTIVES (FY 1978)	INTERMEDIATE OBJECTIVES (FY 1979-1982)	LONG-RANGE OBJECTIVES (FY 1983)
1. Educate/train mental health specialists to provide services in unserved areas.	Develop appropriate mechanisms for insuring that mental health education trainees are placed in needed areas upon completion of program.	Substantial number of funded projects to show high potential for mental health education, or commendable progress in, fulfilling this goal as determined by inclusion of acceptable plan for insuring appropriate placement of trainees in needed service areas upon completion of educational/training program.	Significant increases in the numbers of personnel, educated/trained in NIMH mental health education supported projects, who are providing services in underserved geographic areas, to underserved populations, and in publically supported underserved clinical facilities.
2. Promote collaborative and/or cooperative linkages between education/training institutions and mental health services systems.	Conduct NIMH sponsored workshops as facilitative mechanisms to bring together representatives of State and local mental health authorities, community mental health service providers, and training institutions to discuss methods for relating training to service needs.	A. Substantial number of funded Mental Health Services Education and State Manpower Development projects providing evidence of closer working relationships between educational institutions and service delivery systems. B. Develop explicit guidelines for developing formal linkages.	Substantial number of funded Mental Health Services Education and State Manpower Development projects to provide evidence of formal collaborative and/or cooperative linkages of training institutions with mental health service systems.

FIGURE 1
APPENDIX A

GOAL	SHORT-TERM OBJECTIVES (FY 1978)	INTERMEDIATE OBJECTIVES (FY 1979-1982)	LONG-RANGE OBJECTIVES (FY 1983)
5. Expand the capabilities of primary health care providers to appropriately deal with mental health problems of their patients with special reference to the underserved.	A. As a basis for future programming, identify the quantity and types of mental health problems seen and treatments provided in primary care settings, and describe the current division of responsibility between specialty mental health providers and general medical service providers. B. Pending availability of data from A. above, maintain in FY 1978 current level of funding of projects directed to basic and continuing education of primary care practitioners in mental health problems.	A. Assuming availability of data from survey identified as A. in short-term objective cell, expand volume of funded projects directed to basic or continuing education of primary care practitioners in mental health problems. B. Develop a methodology for assessing the effectiveness of mental health training of primary care practitioners. C. Begin assessment of effectiveness of mental health training of primary care practitioners.	A. Complete assessment of effectiveness of NIMH training of primary care practitioners. B. Begin dissemination of models of successful mental health training programs for primary care practitioners.

APPROACH TO MEASUREMENT OF PROGRESS

(Draft Definitive Objectives and Measures for Goals 3, 4, and 6)

GOAL	SHORT-TERM OBJECTIVES (FY 1978)	INTERMEDIATE OBJECTIVES (FY 1979-1982)	LONG-RANGE OBJECTIVES (FY 1983)
3. Strengthen the capacity of State and sub-State mental health authorities to plan, implement, and evaluate systems for mental health services manpower development.	A. Develop State Mental Health Manpower Development Program component* and create an appropriate organizational entity for further development of this component and management of its operations.** B. Announce program nationally. Distribute guidelines. Generate applications through consultation and technical assistance, etc. to interested State and sub-State authorities.* C. Complete review of grant applications and provide NIMH funding for at least 15 State or sub-State mental health authorities for manpower development in FY 1978. * Already achieved. ** In progress.	A. Forty States with a designated official responsible for mental health manpower development by FY 1980. B. Twenty-five States with an acceptable manpower development plan by FY 1980.	Twenty-five States with a functional manpower development system by FY 1983.

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FIGURE 2
APPENDIX A

GOAL	SHORT-TERM OBJECTIVES (FY 1978)	INTERMEDIATE OBJECTIVES (FY 1979-1982)	LONG-RANGE OBJECTIVES (FY 1983)
4. Develop an R&D capability for generating and disseminating nationally information and data on mental health manpower development, especially in relation to manpower maldistribution and the related issues of recruitment and utilization.	A. Develop Mental Health Manpower R&D Program component* and create an appropriate organizational entity for further development of this component and management of its operations.** B. Announce program nationally. Distribute guidelines. Generate applications.* C. Convene a conference to identify 10 priority areas as targets for mental health manpower R&D activities, especially in relation to maldistribution. * Already achieved. ** In progress.	A. Generate applications and provide funding for R&D activities in 10 top priority areas. B. Disseminate 5 major R&D products in priority areas.	Have a functioning R&D system which identifies needs, develops solutions and disseminates ~~them to~~ appropriate users of mental health manpower knowledge--especially in relation to priority areas.
6. Increase the supply of minority manpower in the mental health disciplines.	A. Plan and initiate studies to quantitatively determine the current supply, distribution, and need of minority manpower in the mental health disciplines with special reference to underserved	A. Based on the data derived from short-term objective A., establish specific production targets for the training of minority mental health professionals.	Strengthen and develop mechanisms to implement NIMH policy regarding increased participation of minorities in NIMH training programs.

FIGURE 2
APPENDIX A

GOAL	SHORT-TERM OBJECTIVES (FY 1978)	INTERMEDIATE OBJECTIVES (FY 1979-1982)	LONG-RANGE OBJECTIVES (FY 1983)
6. Continued	A. Continued geographic areas, populations, and public mental health programs. B. Increase by 25% the number of training programs specifically targeted to the training of minority mental health professionals.	B. Develop a strategy for mental health career development for minorities with priority placed on those disciplines with fewest number of minorities, i.e., psychiatry.	

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

DEC 2 1978

The Honorable Daniel J. Flood
Chairman, Subcommittee on Labor,
Health, Education, and Welfare
Appropriations Committee
House of Representatives
Washington, D.C. 20515

Dear Mr. Flood:

Enclosed is the report (No. 95-381:23) requested by your Subcommittee on plans for the expenditure of $1.5 million appropriated for the Office of the Health Information and Health Promotion (OHIHP), includin initial plans for the development of national goals and strategies to achieve those goals in prevention and health promotion. The Department is currently developing a prevention initiative through its Prevention Task Force. As the Task Force completes its work, these plans may be revised in keeping with prevention priorities identified for OHIHP and the Department. We will be pleased to keep you informed of these activities.

Sincerely yours,

Charles Miller
Deputy Assistant Secretary
for Financial Management

Enclosure

Office of Health Information and Health Promotion
(Report to the Senate Labor/HEW Appropriations Subcommittee by the Assistant Secretary for Health)

The Assistant Secretary for Health has taken the following actions to establish the Office of Health Information and Health Promotion as the focal point for the development of the Department's prevention initiatives:

- OHIHP has been organizationally placed in the Office of the Deputy Assistant Secretary for Health for Special Health Initiatives, an office recently formed to provide visibility for the Department's prevention activities;

- A major review of prevention activities in the Department has been undertaken by a Prevention Task Force in order to develop a comprehensive prevention strategy which will establish the priorities for OHIHP;

- OHIHP will be the focal point for the preparation of a Surgeon General's Report on Prevention which the Secretary has directed be drafted to develop national goals and strategies in prevention;

Within this new overall prevention effort and in collaboration with other Agencies, OHIHP will play a leadership role in identifying priorities and working to fill gaps in areas of opportunity and need, including:

- coordination of the wide variety of Agency programs which relate to prevention, preventive services, health promotion, health education and health information;

- coordination of Departmental activities in disease prevention and health promotion which are undertaken in concert with other governmental agencies, States, municipalities and voluntary organizations;

- advancement of our understanding of the development and alteration of lifestyle and behavioral factors affecting health (such as smoking, substance abuse, fitness, stress management), particularly common threads which may exist among such behaviors with special emphasis on children and adolescents;

- development of more effective interventions to help individuals achieve and maintain desired lifestyle changes, by applying knowledge gained through experience with existing interventions;

- expansion or development of prevention programs in priority areas not likely to be addressed by the Agencies in such areas as risk assessment and nutrition;

- initial development of the national information clearinghouse, beginning with a coordinated referral system among existing clearinghouses, and including the dissemination of information on the effectiveness of existing and emerging preventive interventions;

- working with individuals and groups in the public and private sectors to foster changes in social and environmental factors which influence individual lifestyle, including the development of more healthful products, and more healthful living and working environments.

OHIP will utilize its $1.5 million appropriation as "seed money" or incentive grant and contract programs of matching funds to stimulate Federal agency investment in high priority areas.

Specifically, the $1.5 million for FY 1978 will be used as indicated in the following chart:

Interim Plans for Use of FY 1978 Funds of the
Office of Health Information and Health Promotion

Epidemiology of Health Status and Health Promotion and Surveys of Public Knowledge, Attitudes, and Behavior (including reimbursable positions for the National Center for Health Statistics)	$300,000
Surgeon General's Report on Prevention	$400,000
Research and Demonstration Activities (emphasizing risk assessment, and planning for comprehensive prevention interventions in communities)	$350,000
Promotion of Healthful Lifestyles in Children (including primary prevention of smoking)	$250,000 (50,000)
Initial Development of National Information Clearinghouse (including coordinated referral system among existing clearinghouses and information resources, and dissemination of special reports and information on effectiveness of existing interventions)	$200,000

A detailed description of these activities follows.

- Epidemiology of health status and health promotion and surveys of public knowledge, attitudes and behaviors

  Activities in this category will be directed toward the accumulation of baseline data to provide for the identification of (a) health problem areas most amenable to change; (b) high-risk groups most susceptible to certain health problems; (c) trends which significantly impact health and which may be altered through preventive interventions (such as the rise in smoking among young women); (d) environmental factors impacting health, the effects of which may be mitigated by direct intervention or efforts to increase public awareness, etc. There will also be an assessment of current attitudes, knowledge, and practices (with regard to such health factors as exercise, smoking, eating habits/nutrition, alcohol consumption, drug use and abuse, coping and stress management, environmental health hazards, interactions among various aspects of lifestyle and environmental and social determinants of health, etc.).

  Such baseline data are essential in efforts to define the nature and scope of preventive and health promotional interventions to be implemented, and in measuring the ultimate impact of these activities. The design and implementation of the requisite surveys will be done in collaboration with the National Center for Health Statistics.

- Surgeon General's Report on Prevention

  A Surgeon General's Report on Prevention will be drafted, and the effort will be coordinated out of the Office of Health Information and Health Promotion. This report will review and assess the information currently available on disease prevention and health promotion, identify unmet needs in the area, address the process of establishing priorities, and suggest alternative strategies for a strengthened effort. Specific attention will be given to topics of particular importance, including nutrition, smoking, alcohol abuse, health risk appraisal, environmental health, and the delivery of private services.

  The work will be done by drawing on the best available expertise both within the Department and elsewhere, in States, municipalities, and academic settings.

- Research and Demonstration Activities

  To the extent that funds will permit, OHIHP will work with other Departmental components to develop and implement research and demonstration activities to expand upon currently existing evidence of the positive effects of health education and health

promotion activities. Examples of such activities include: community-wide interventions (similar to the Stanford Heart Disease Prevention Program), wellness programs for occupational settings, nutrition education, smoking cessation, etc.

The focus of these efforts will be on risk assessment and the development of comprehensive interventions to reduce risk and promote health.

- Promotion of Healthful Lifestyles in Children

Health habits begin to evolve in early childhood and progress throughout the physical and emotional maturation process. It is during this time, before patterns are firmly established, that promotion of healthful behavior can be most effective. OHIHP's work in this area will emphasize the building of decision-making skills applicable to health concerns relevant to young people, including smoking, eating habits, drug use and abuse, alcohol use, etc.

Specific activities will include collaborative work with the Office of Education to identify health education curricula strategies through demonstration programs; further testing and dissemination of existing educational methodologies, also through demonstrations; and development of strategies to reach children through mass media, community, and family. Coordination will also be undertaken with the Federal Trade Commission, the Federal Communications Commission and other agencies concerned with children's advertising in order to seek improvements in the influences of that advertising on children's health.

- **Initial Development of National Information Clearinghouse**

The OHIHP has begun to serve as a referral source among existing clearinghouses and information resources in both the public and private sectors. This is done by assessing the nature and degree of services provided by existing Departmental information resources. Included among these are formally established repositories for health information and educational materials, such as the National Library of Medicine, the National Clearinghouse for Smoking and Health, the Clearinghouse on the Handicapped, the National Clearinghouse on Mental Health, etc. This process has helped to identify areas where existing information services are not adequate, and has allowed OHIHP to act as a referral source in efficiently handling the vast variety of requests the Office receives.

The funding level proposed for this activity for 1978 will be devoted to the planning and development of a coordinated referral system among existing clearinghouses and referral resources. The system will consist of an automated memory and hard copy referral in OHIHP. Fiscal year 1978 activities will include:

(1) Consultation with information specialists.

(2) Design of the system.

(3) Investigation of equipment rental opportunities.

(4) Design of staffing plans.

The activities noted above may be altered somewhat as the Prevention Task Force completes its work in March and forwards its recommendations for priorities

Enclosed is a status report on activities of OHIHP which identifies some of the important aspects of prevention addressed by OHIHP since November 1976.

January 1978

Background Report on the Activities of the Office of Health Information and Health Promotion

BACKGROUND

The Office of Health Information and Health Promotion (OHIHP) was mandated to be established in the Office of the Assistant Secretary for Health, Department of Health, Education, and Welfare, by Title I of P.L. 94-317, the "National Consumer Health Information and Health Promotion Act of 1976." The Office was formally established in November 1976 to provide a focus for Federal health policy development, priority setting, and coordination of public and private sector efforts in the areas of prevention, preventive health services, health promotion, health information, and education of the public in the maintenance of personal and family health and in the appropriate use of the health care delivery system. Informing the public about new and/or controversial aspects of health and health care is an additional responsibility for OHIHP. A national information clearinghouse for the dissemination of information on all of these areas is also required to be established by this Office. A report to the President and the Congress on the areas covered by P.L. 94-317 is required by June 1978 and annually thereafter.

OBJECTIVES

The new impetus given to health information and health promotion activities as a result of the passage of P.L. 94-317 has increased the pressures for Departmental leadership in the development of consistent and complementary national policies throughout the Federal Government, and for the support of a wide range of programs and activities in these areas. The following principal objectives are to be accomplished in implementing this legislation:

- Formulate national goals and strategies with respect to health information and health promotion;
- Strengthen and expand the base of scientific knowledge concerning health information and health promotion (particularly, the environmental, occupational, social, and behavioral factors which influence health) and effective methods for conveying such information so that individuals can make more informed choices about health promoting behavior;
- Support new and innovative community programs, and research and evaluation related to such programs; and
- Increase the capability of the public to make more informed choices about those factors which are related to personal and family lifestyle and behavior, including their use of the health care system.

Preliminary Plans. Planning for the implementation of the National Consumer Health Information and Health Promotion Act provided an unusual challenge for several reasons. First, the scope of this legislation is so broad that nearly every PHS program and many of those administered by the Office of Education, the Office of Human Development, and Health Care Financing Administration fall within its purview. Thus, at a minimum, the plans should reflect a Department-wide perspective. Second, in order to be most effective, the implementation of Title I of P.L. 94-317 must be planned in such a way that it will complement programs and activities that are already under way within the Department without being restricted by them in setting future directions and priorities; these may, in fact, be quite different from those currently contemplated to individual programs and agencies. In addition, the development and enactment of this legislation has generated high expectations within both the public and private sectors for immediate accomplishments, expectations which already far exceed available resources. The initial task for OHIHP was to develop a reasonable set of objectives that struck a balance between fast-growing public demands and the relative paucity of resources allocated for prevention, health education, and related efforts in the Department.

Consultation with hundreds of individuals and groups interested in the broad mandate of P.L. 94-317 in the areas of prevention, preventive health services, health promotion, health education, and health information, preceded the development of OHIHP's preliminary plans. Preliminary plans for implementing Title I of this Act have been prepared and disseminated for review and comment within the Department.

A participatory planning process was the basis of the proposed OHIHP policy development strategy to include conferences, state-of-the-art papers, task forces and work groups -- combining consultants and Federal employees -- to help develop policies and set priorities for the Department. These activities are essential to future credibility of program efforts covering new and innovative approaches to health promotion and health education. Broad participation in the development of Federal health policy is always important, but is especially so in these sensitive areas involving significant questions about the role of the Federal Government in trying to influence health-related behavior directly or indirectly. Incentive grants and contracts are planned to stimulate Federal Agency program development in the high priority areas identified for health promotion and prevention. Plans and priorities which emerge from this process will be implemented through joint activities with existing agencies and programs as much as possible. OHIHP identified the following "health concerns" as principal areas of initial focus:

- smoking
- health of school aged persons
- personal risk assessment
- health concerns of the elderly (including opportunities for self care)
- family health (parenting, prenatal care, teenage pregnancy)

- [illegible]
- [illegible] management, coping behavior, etc.
- mental health
- [illegible] health [illegible] home, school, work site,
- accidents
- substance abuse (alcoholism, drug abuse, etc.)

During the first year of its existence, major activities of the Office were focused on:

- *Technical assistance.* The Office has already answered over 500 [illegible] telephone requests for information, [illegible] the design and development of prevention, health promotion, and health education programs across the full spectrum of settings, health and disease conditions, and regions of the country. Generally, the people making these requests are starting their activities with the [illegible] to know if anything else is being done in the same or related fields. Information has been disseminated on current research studies and their findings related to health promotion, prevention, and health education. Since many of the programs and projects, proposed or under way, lack an evaluation component, much of this technical consultation concerns ways to introduce and strengthen evaluation measures. To continue this dialogue with individuals and organizations interested in the work of the Office, a mailing list has been developed of over 500 individuals and groups thus far.

- *Clearinghouse activities.* Since existing resources do not permit the establishment of a traditional clearinghouse for all of the areas of P.L. 94-317, OHIHP has developed its information resources to serve as a referral source for other clearinghouses and information resources. OHIHP has identified resources which can contribute to the establishment of a national information clearinghouse, as mandated by P.L. 94-317. These include formally established repositories of health information and educational materials, such as the National Library of Medicine, the National Clearinghouse for Smoking and Health, the Clearinghouse on the Handicapped, the National Clearinghouses on Mental Health, Drug Abuse and Alcoholism Information, the National Health Planning Information Center, the National Clearinghouse on Family Planning Information, the private National Self-Help Clearinghouse. The intent has been to determine what kind of information currently is available through existing clearinghouses, how it is presented, to what extent it can be utilized to meet the growing public demand for more and better health information, and what additional information needs exist for clearinghouses and libraries to enhance their service role in this area. Community-based resources are also being analyzed which primarily serve other functions but which for many individuals and groups are principal sources of information related to health and medical care. The Office is continuing to meet with individuals performing other clearinghouse functions to identify resources which might collectively contribute to the national information clearinghouse required to be established by OHIHP under P.L. 94-317.

Health Information and Health
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• *Immunization policy and implementation.* The staff of OHIHP contributed to the development of the proposed Departmental statement on National Immunization Policy and the preceding First and Second National Immunization Conferences held in Bethesda, Maryland, in November 1976 and April 1977, respectively. OHIHP had primary responsibility for the public information and education aspects of the policy, including coordination with the PHS staff directly involved with the implementation of the childhood immunization campaign, and in the review of the contract proposals for the media aspects of the campaign. OHIHP proposed a school intervention designed to precede expanded community immunization efforts which would provide for experiential learning using a decisionmaking model for children and their parents. This is an effort to build understanding and a long-term commitment to immunization as an integral part of prevention and health promotion.

• *Study of the cost-effectiveness of prevention.* The OHIHP has begun research into the cost-effectiveness of various preventive interventions, to determine what conclusive evidence exists on the effectiveness and, preferably, the cost-effectiveness of preventive activities. The areas where such definitive information does not exist will help to determine priorities for further research and evaluation by OHIHP and the Agencies.

• *Adolescent pregnancy.* OHIHP staff contributed to the work of the Task Force on Teenage Pregnancy, convened by the Office of the Assistant Secretary for Planning and Evaluation to develop options and make recommendations to the Secretary for further Departmental action in this area. OHIHP developed a major option for the Task Force outlining what seemed to be the most appropriate educational strategy which would combine Departmental resources from various programs and agencies with emphasis on community organization, broad participation (including more than adolescents and their parents), and the integration of separate educational and informational activities into a total community-oriented intervention. Increased investment is also needed for research and evaluation related to (a) basic educational concepts and techniques which may be used with different groups of adolescents (depending on their age, social and cultural background, etc.) or other target audiences; and (b) the effectiveness of various educational approaches. Through participation in the Educational Strategies Work Group, effort was made to introduce some current and emerging views on factors affecting the outcome of health activities, to identify promising educational activities related to adolescent pregnancy, and to broaden the focus to address a wider range of health education needs of adolescents, of which sexuality is just one important area.

• *Smoking.* In May 1977, OHIHP, with input from the PHS agencies, developed a coordinated response to the Secretary describing PHS activities related to smoking and providing the best available estimates of Departmental expenditures on smoking-related activities, as well as the health and social costs of smoking, and a listing of possible future initiatives in this area. The Interim Director, OHIHP, chaired the

Educational and Public Awareness Work Group of the Secretary's Task Force on Smoking and OHIHP assumed principal responsibility, working with OE and the PHS agencies, for the development of the Education and Public Awareness component of the Departmental initiatives on smoking, recently announced by Secretary Califano.

• *National Guidelines.* Given the emphasis placed on prevention and health promotion in P.L. 93-641, the National Health Planning and Resources Development Act of 1974, OHIHP provided recommendations on the revision of the Guidelines, emphasizing the special importance of including prevention and health promotion considerations in long-range plans (specifically, Health Systems Plans) even where immediate implementation is not anticipated by the HSAs.

• *The health of school-aged children.* The Interim Director, OHIHP, along with the Office of Child Health Affairs represented OASH and delivered a paper at the May 1977 National Conference on School Health where recommendations were made for the overall planning and delivery of comprehensive school health programs. Since the conference, OHIHP has (1) participated in initial efforts to establish a PHS Task Force on School Health; (2) developed a series of recommendations for conducting a task force on the health of school-aged children; (3) convened a meeting of Departmental staff to discuss the school health curriculum project, one promising model supported by the Bureau of Health Education, CDC; (4) consulted other agencies both within and outside the Department (USDA, Justice, EPA, Labor, etc.) in coordinating activities to improve the health status of the school-aged population; (5) developed prevention and education strategies aimed at children and youth as components of health initiatives such as childhood immunization; and (6) consulted with school health experts on the role of OHIHP and DHEW's plans in promoting the health of school-aged persons. OHIHP is collaborating with the Office of Education which now has the lead agency designation for school health education and other school health activities.

• *Alcohol abuse.* The Interim Director, OHIHP, represents the OASH on the Federal Interagency Committee on Alcohol Abuse and Alcoholism. OHIHP has developed a paper on definitions of alcoholism and prevention goals for Federal activities for the Interagency Committee on Federal Activities for Alcohol Abuse and Alcoholism.

• *Laetrile.* The Office has provided consultation to the California and Indiana State Legislatures in their consideration of proposed legalization of laetrile.

• *Saccharin.* The Office is frequently called upon for advice about saccharin, and other controversial health policy issues. OHIHP was consulted by members and staff of the [illegible] on Saccharin both on problems

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[illegible]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

JAN 26 1978

The Honorable Daniel J. Flood
Chairman, Subcommittee on Labor-
Health, Education, and Welfare
Committee on Appropriations
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

The enclosed report on Home Health Programs is submitted in response to the Committee request in House Report No. 95-381, page 18, regarding the development of coordinated Health Services Administration, Administration on Aging, and Health Resources Administration training programs for Home Health Services personnel. This report includes information on program coordination through an interagency work group and home health activities planned for fiscal year 1978.

We hope that this information fulfills the Committee's requirements.

Sincerely yours,

Charles Miller
Acting Assistant Secretary for
Management and Budget

Enclosure

24-838 O - 78 - 33

Justification of Training Program of Home Health Services Personnel

Background

[illegible]

[illegible]

Program Justification

The administration of the Home Health Services Program, in the award of grants for the development and expansion of home health services nationwide, has been designed and operated to include a broad based representation from within the Department of Health, Education, and Welfare. The Bureau of Community Health Services (BCHS) formed a Home Health Interagency Work Group in January of [illegible]. This Interagency Work Group is composed of representatives from the Health Resources Administration, the Administration on Aging, the Health Care Financing Administration (HCFA), and the Office of the Assistant Secretary for Health. The Interagency Work Group was formed to assist the BCHS in the development of program policy and to play an active role in the administration of the grant program. For example, the Home Health Interagency Work Group forms the nucleus of a Joint Central and Regional Office Grant Review Committee which reviews applications for the award of Home Health Services Grants, as authorized under section [illegible](a). This Interagency Work Group has been successful in guiding the BCHS for the development and operation of the Home Health Services Grant Program in a manner which has allowed grant dollars to have the maximum impact on the development and expansion of home health services nationwide.

The BCHS intends to concentrate its training program effort during fiscal year [illegible] on upgrading the quality of care provided in Medicare Certified Home Health Agencies. This will be accomplished by the training of home health aides and the training of supervising nurses in rehabilitation

nursing techniques. The BCHS has requested and received from both the Administration on Aging and the Bureau of Health Manpower the appointment of persons to work with the Director of the Home Health Services Program. This interagency training group will carefully identify related programs in each agency and work to insure that supported activities are non-duplicative and that the best possible use is made of past experiences in the various programs.

It is anticipated that this HRA, AoA, and HSA coordinated program effort will lead to a maximum utilization of existing authorities and resources in the improvement of the quality of care provided by the nation's home health agencies.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

MAR 3 1978

The Honorable Daniel J. Flood
Chairman, Subcommittee on Labor-
Health, Education, and Welfare
Committee on Appropriations
House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

The enclosed report on Health Statistical Activities is submitted in response to the committee's request on page 53 of House Report No. 95-381 on the Fiscal Year 1978 Appropriation Bill for the Departments of Labor and Health, Education, and Welfare.

In its report language the committee requested that the report discuss the role and assigned responsibilities of the National Center for Health Statistics in reviewing and coordinating health statistical activities within the Department including the reimbursable work program and the relationship of the cooperative health statistics system to other health data systems.

We hope that this information fulfills the committee's requirements.

Sincerely yours,

Leonard D. Schaeffer
Assistant Secretary for
Management and Budget

Enclosure

Department of Health, Education, and Welfare

Report to Congress

as requested by

House Report No. 95-381

- nutrition/dietary habits
- mental health (stress management, coping behavior, etc.)
- dental health
- environmental health hazards (home, school, work site)
- accidents
- substance abuse (alcoholism, drug abuse, etc.)

During the first year of its existence, major activities of the Office have focused on:

- *Technical assistance.* The Office has already answered over 500 written requests and thousands of telephone requests for information, technical assistance in the design and development of prevention, health promotion, and health education programs across the full spectrum of settings, health and disease conditions, and regions of the country. Generally, the people making these requests are starting their activities with virtually no idea of anything else being done in the same or related fields. Information has been disseminated on current research studies and their findings related to health promotion, prevention, and health education. Since many of the programs and projects, proposed or under way, lack an evaluation component, much of this technical consultation concerns ways to introduce and strengthen evaluation measures. To continue this dialogue with individuals and organizations interested in the work of the Office, a mailing list has been developed of over 600 individuals and groups thus far.

- *Clearinghouse activities.* Since existing resources do not permit the establishment of a traditional clearinghouse for all of the areas of P.L. 94-317, OHIHP has developed its information resources to serve as a referral source for other clearinghouses and information resources. OHIHP has identified resources which can contribute to the establishment of a national information clearinghouse, as mandated by P.L. 94-317. These include formally established repositories of health information and educational materials, such as the National Library of Medicine, the National Clearinghouse for Smoking and Health, the Clearinghouse on the Handicapped, the National Clearinghouses on Mental Health, Drug Abuse and Alcoholism Information, the National Health Planning Information Center, the National Clearinghouse on Family Planning Information, the private National Self-Help Clearinghouse. The intent has been to determine what kind of information currently is available through existing clearinghouses, how it is presented, to what extent it can be utilized to meet the growing public demand for more and better health information, and what additional information needs exist for clearinghouses and libraries to enhance their service role in this area. Community-based resources are also being analyzed which primarily serve other functions but which for many individuals and groups are principal sources of information related to health and medical care. The Office is continuing to meet with individuals performing other clearinghouse functions to identify resources which might collectively contribute to the national information clearinghouse required to be established by OHIHP under P.L. 94-317.

• *Health highlights.* The Office of Health Information and Health Promotion, in conjunction with PHS agency staff and an outside consultant, has prepared a "Health Highlights" publication. The purpose of this volume is to present basic health status information (including both positive and negative trends) in a manner easily understood by the public, and to highlight new information on emerging trends of potential importance to health status and health policy.

• *Nutrition.* Discussions have been held between the staff of the Office of Health Information and Health Promotion and representatives from the nutrition community, including professional organizations such as the Society for Nutrition Education, the Nutrition Consortium, the Food and Nutrition Board, the Center for Science in the Public Interest, the American Dietetics Association, as well as the Giant Food Nutrition Labelling Committee to expand the dialogue on prudent dietary practices related to health and to elicit their views on nutrition needs nationally, activities which should be strengthened or initiated in this field, and priorities to be pursued. The Office developed a matrix in nutrition to demonstrate how various strategies and settings can be effectively combined and the range of activities that could be developed in any given area by various kinds of organizations. This draft matrix has been very favorably received by nutrition groups. This matrix will continue to be developed as additional information is received. The refinement of the concept of personal risk assessment has been an important component of the application of the concept of prudent dietary practices given the current state of scientific knowledge. OHIHP has also been developing the concept of a voluntary code for broadcast advertising of food products directed mainly at children, and has consulted informally with representatives of media, advertisers, other Federal Agencies, and public interest groups.

• *Risk assessment and health hazard appraisals.* One area that has received special attention by the Office is the increasing popularity of health hazard appraisal as a technique for health and risk assessment. This technique of computer analysis of the probability of reduced life expectancy has great potential for promoting concepts of wellness and the relation of lifestyle to risk factors. However, the technique is now hampered by several important deficiencies. First among these is the absence of certain critical information from the various assessment forms, particularly information on nutrition/diet, socioeconomic status, workplace/work situation, and life stress/life change assessment. Another shortcoming of most risk assessment techniques stems from the limited utility of available mortality projections, particularly as a tool for motivating young people to adopt more healthful behavior early in life. The Interim Director of OHIHP gave the opening paper on these issues at the annual meeting of the Society for Preventive Medicine in September.

• *Immunization policy and initiatives.* The staff of OHIHP contributed to the development of the proposed Departmental statement on National Immunization Policy and the preceding First and Second National Immunization Conferences held in Bethesda, Maryland, in November 1976 and April 1977, respectively. OHIHP had primary responsibility for the public information and education aspects of the policy, including coordination with the PHS staff directly involved with the implementation of the childhood immunization campaign, and in the review of the contract proposals for the media aspects of the campaign. OHIHP proposed a school intervention designed to precede expanded community immunization efforts which would provide for experiential learning using a decisionmaking model for children and their parents. This is an effort to build understanding and a long-term commitment to immunization as an integral part of prevention and health promotion.

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• *Laetrile.* The Office has provided consultation to the California and Indiana State Legislatures in their consideration of proposed legalization of laetrile.

• *Saccharin.* The Office is frequently called upon for advice about saccharin, and other controversial health policy issues. OHIHP was consulted by members and staff of the CPC Panel on Saccharin both on problems

of explaining to the public the basis for extrapolating animal data to human populations, and on the special requirements of the Delaney clause which mandates a different regulatory process for food additives than is available for other known health hazards such as cigarette smoking.

• *Insurance/Health Care/EWDs.* Under Section 1705(b) of P.L. 94-317, the Department is required to conduct a study of the coverage of health education services and preventive health services under public and private insurance programs. The Office has discussed this requirement with Blue Cross, the Insurance Council of America, and the National Center for Health Education. Section 1704(4) requires the development of models and standards for insurance carriers and the public on health insurance and prepaid health plans, and the dissemination of information on the costs and coverage of health insurance to enable the public to make comparisons of the costs and benefits of such insurance and health plans. For FY 1978, the Office planned to have a work group address these questions and to publish a volume, similar to "Health Highlights 1976-1977," to make such information readily accessible to the public.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

JAN 26 1978

The Honorable Daniel J. Flood
Chairman, Subcommittee on Labor-
Health, Education, and Welfare
Committee on Appropriations
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

The enclosed report on Home Health Programs is submitted in response to the Committee request in House Report No. 95-381, page 18, regarding the development of coordinated Health Services Administration, Administration on Aging, and Health Resources Administration training programs for Home Health Services personnel. This report includes information on program coordination through an interagency work group and home health activities planned for fiscal year 1978.

We hope that this information fulfills the Committee's requirements.

Sincerely yours,

Charles Miller
Acting Assistant Secretary for
Management and Budget

Enclosure

24-838 O - 78 - 33

Coordination of Training Programs for Home Health Services Personnel

Background

Public Law 94-63, Section 602(b) authorized funds in fiscal year 1976 for the award of grants to train professional and paraprofessional personnel to provide home health services as defined in Section 1861(m) of the Social Security Act. The authorization was extended for fiscal year 1977 by Public Law 94-460. However, monies were never appropriated in either of these fiscal year appropriations. Public Law 95-83 extends the training authority of Section 602(b) through fiscal year 1978.

The House Committee on Appropriations, Report No. 95-381 (Page 18) states that the Committee expects the training program to be developed in close collaboration with the Health Resources Administration (HRA) and the Administration on Aging (AoA).

Program Coordination

The administration of the Home Health Services Program, in the award of grants for the development and expansion of Home Health Services 602(a) Funds, has been designed and operated to include a broad based representation from within the Department of Health, Education, and Welfare. The Bureau of Community Health Services (BCHS) formed a Home Health Interagency Work Group in January of 1976. This Interagency Work Group is composed of representatives from the Health Resources Administration, the Administration on Aging, the Health Care Financing Administration, (HCFA), and the Office of the Assistant Secretary for Health. The Interagency Work Group was formed to assist the BCHS in the development of program policy and to play an active role in the administration of the grant program. For example, the Home Health Interagency Work Group forms the nucleus of a Joint Central and Regional Office Grant Review Committee which reviews applications for the award of Home Health Services Grants, as authorized under section 602(a). This Interagency Work Group has been successful in guiding the BCHS for the development and operation of the Home Health Services Grant Program in a manner which has allowed grant dollars to have had maximum impact on the development and expansion of home health services nationwide.

The BCHS intends to concentrate its training program effort during fiscal year 1978 on upgrading the quality of care provided in Medicare Certified Home Health Agencies. This will be accomplished by the training of home health aides and the training of supervising nurses in rehabilitation

nursing techniques. The BCHS has requested and received from both the Administration on Aging and the Bureau of Health Manpower the appointment of persons to work with the Director of the Home Health Services Program. This interagency training group will carefully identify related programs in each agency and work to insure that supported activities are non-duplicative and that the best possible use is made of past experiences in the various programs.

It is anticipated that this HRA, AoA, and HSA coordinated program effort will lead to a maximum utilization of existing authorities and resources in the improvement of the quality of care provided by the nation's home health agencies.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

MAR 3 1978

The Honorable Daniel J. Flood
Chairman, Subcommittee on Labor-
Health, Education, and Welfare
Committee on Appropriations
House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

The enclosed report on Health Statistical Activities is submitted in response to the committee's request on page 53 of House Report No. 95-381 on the Fiscal Year 1978 Appropriation Bill for the Departments of Labor and Health, Education, and Welfare.

In its report language the committee requested that the report discuss the role and assigned responsibilities of the National Center for Health Statistics in reviewing and coordinating health statistical activities within the Department including the reimbursable work program and the relationship of the cooperative health statistics system to other health data systems.

We hope that this information fulfills the committee's requirements.

Sincerely yours,

Leonard D. Schaeffer
Assistant Secretary for
Management and Budget

Enclosure

Department of Health, Education, and Welfare

Report to Congress

as requested by

House Report No. 95-381

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J. Data Collection and Analysis Under P.L. 93-641) (DHEW Publication No. HRA 76-637)

Background

Report No. 95-381 of the Committee on Appropriations that accompanied the Departments of Labor and Health, Education and Welfare, and Related Agencies Appropriations Bill, 1978 requires the Secretary to submit a report by February 1, 1978 on coordination of health statistics activities within the Department and on the role and assigned responsibilities of the National Center for Health Statistics in reviewing and coordinating health statistical activities within the Department (Tab A). Specific activities to be included in the report are:

1. The reimbursable work program of the Center.
2. The relationship of the Cooperative Health Statistics System to other health data systems within the Department.

This report describes the past developments and present arrangements within the Department to achieve the objectives cited by the Committee on Appropriations.

Introduction

The development of a uniform, coordinated, and responsive health information system capable of satisfying the multiple needs for data at national and subnational levels, including the assessment of the impact of policy decisions, represents one of the most significant challenges to this Administration. The field of health statistics has grown vigorously and rapidly as each new piece of legislation has generated reporting systems often related to those already in existence. The demands upon the medical community and the public in general have increased substantially while the resultant health information is inconsistent and leaves many gaps for the effective administration of health programs.

Despite considerable improvement in recent years, problems of coordination and fragmentation of health data activities are still evident. In the short time this Administration has had to study this problem, we have taken a number of major steps towards resolving the issues so that the National Center for Health Statistics (NCHS) will function as the focal agency in the Public Health Service for coordinating collection of health statistics. Among these are a major reorganization within the Public Health Service (PHS); the establishment of a PHS committee for coordination of Health Statistics systems to be chaired by the Director, NCHS; continued emphasis on the NCHS Cooperative Health Statistics System (CHSS) as a high priority data effort of the Department; and, increased support for the NCHS Reimbursable Work Program.

In the following sections we will review the progress to date, identify some of the present problems, and proposed next steps for solutions.

Previous Developments

A. Legislation

The primary legislative authority for coordinating the health statistical activities derives from P.L. 93-353, "Health Services Research, and Health Statistics and Medical Libraries Act of 1974" (Tab B) as follows:

> "Sec. 304(c) The Secretary shall coordinate all health services research, evaluation, demonstration, and health statistical activities undertaken and supported through units of the Department of Health, Education, and Welfare. To the maximum extent feasible, such coordination shall be carried out through the National Center for Health Services Research and the National Center for Health Statistics."
>
> "Section. 306(d) To insure comparability and reliability of health statistics, the Secretary shall, through the Center, provide adequate technical assistance to assist State and local jurisdictions in the development of model laws dealing with issues of confidentiality and comparability of data."
>
> "Sec. 306(e) The Secretary shall (1) assist State and local health agencies, and Federal agencies involved in matters relating to health, in the design and implementation of a cooperative system for producing comparable and uniform health information and statistics at the Federal, State, and

local levels; (2) coordinate the activities of such Federal agencies respecting the design and implementation of such cooperative system; (3) undertake and support (by grant or contract) research, development, demonstrations, and evaluations respecting such cooperative system; (4) provide the Federal share of the data collection costs under such system; and, (5) review statistical activities of the Department of Health, Education, and Welfare to assure that they are consistent with such cooperative system."

Other legislation that strengthen the role of the National Center for Health Statistics in coordinating health statistical activities within the Public Health Service are as follows:

The National Health Planning and Resources Development Act of 1974, P.L. 93-641, Sec. 1513(b) "In carrying out this paragraph, the agency shall to the maximum extent practicable use existing data (including data developed under Federal health programs) and coordinate its activities with the cooperative system provided for under Section 306(e)." (Tab C)

The Health Professions Educational Assistance Act of 1976, P.L. 94-484, Sec. 793(a) "The Secretary shall, in coordination with the National Center for Health Statistics (established

under Section 306), continuously develop, publish, and disseminate on a nationwide basis statistics and other information respecting public and community Health personnel, ..." (Tab D)

Also, from the same Act:

"Sec. 702(b) In addition, the Secretary shall, in coordination with the National Center for Health Statistics (established under Section 306 of the Public Health Service Act), develop, publish, and disseminate on a nationwide basis a report containing statistics and other information respecting allied health personnel..."

More recently the Medicare-Medicaid Anti-Fraud and Abuse Amendments, P.L. 95-142, (Tab E) being implemented by Health Care Financing Administration states:

"Sec. 1121(a) The uniform reporting system for a type of health services facility or organization shall provide for appropriate variation in the application of the system to different classes of facilities or organizations within that type and shall be established, to the extent practicable, consistent with the cooperative system for producing comparable and uniform health information and statistics described in Section 306(e)(1) of the Public Health Service Act."

B. Delegations of Authority

The authority for coordinating the gathering of health statistics activities within the Public Health Service as cited in P.L. 93-353 was delegated by the Assistant Secretary for Health to the Health Resources Administration (HRA) on August 28, 1975 and redelegated by HRA to the National Center for Health Statistics on October 15, 1975. (HRA Delegation No. 25) (Tab F)

The authorities cited under P.L. 94-484, Sections 793 and 702 were delegated to the Center on July 25, 1977 by HRA Delegation No. 43. (Tab G)

Additionally, authority for coordination, other than that cited in P.L. 94-484, was given the Center by delegating the following subsections of Section 708 of P.L. 94-484:

Subsections 708(a) and 708(b)(1) providing for the establishment of a program to collect, compile, and analyze general purpose data on health professions personnel, including the uniform professions data reporting system.

Subsection 708(b)(3) to award data collection grants and contracts to the States.

Subsections 708(e) and 708(g) dealing wit
confidentiality; and, technical assistanc
were also delegated to the Center.

The authorities cited in P.L. 93-641 were dele
by a memorandum from the Administrator, Healt
dated April 2, 1975 (Tab H) which states:

"To effectively carry out the responsibi
legislation (P.L. 93-353 and P.L. 93-641
health planning initiatives, the Health
assigns managerial authority for all data
National Center for Health Statistics."

C. Inter-Bureau Agreements, and Advisory Committe

1. One of the prime mechanisms for accomplis
legislation and delegated authority is to
agreements, memoranda of understanding, o
the involved bureaus and administrations
statistical activities that will be coord
has the lead responsibility, establish a
target dates, and provide for certain on-
improve communications and coordination.
that the Center has with other PHS compon

The relationships between the NCHS and the Bureau of Health Planning and Resources Development (BHPRD) to carry out the duties prescribed in P.L. 93-641 were defined in a formal policy statement issued December 10, 1975 (DHEW Publication No. HRA 76-637) entitled "Data Collection and Analysis Under P.L. 93-641: BHPRD-NCHS Data Work Program." (Tab I) Key policies enunciated in this document that relate to statistical coordination are: (1) The health planning data will not be produced by a unique data system, but will be, to the maximum extent possible, derived from other data systems; (2) The Cooperative Health Statistics System will be a principal source for the health planning data; (3) HRA assigned managerial responsibilities for the design, development and operation of these health data systems to the NCHS; and, (4) all activities related to health planning data will be carried out collaboratively by the two organizations, which have developed a Memorandum of Understanding. Continuity in these working arrangements is preserved by frequent meetings of a working group that includes the directors of NCHS and BHPRD.

2. Another primary mechanism for coordinating health statistical activities is the United States National Committee on Vital and Health Statistics (USNCVHS) established by P.L. 93-353, Sec. 306(i). This committee is the principal external advisory

group to the Secretary on all matters relating to health statistics. The Office of Statistical Policy, OHPRS, OASH, provides executive secretariat services while the management staff support to the Committee and its technical consultant panels is provided by NCHS.

Among the Committee functions specified in law, the following are particularly relevant for coordinating Departmental health information systems by assisting and advising the Secretary:

> "...to determine, approve, and revise the terms, definitions, classifications, and guidelines for assessing health status and health services, their distribution and costs..."
>
> "with respect to the design of and approval of health statistical and health information systems concerned with the collection, processing, and tabulation of health statistics within the Department of Health, Education and Welfare."
>
> "...to make proposals for improvement of the Nation's health statistics and health information systems."

At present the USNCVHS and its technical consultant panels are developing for the Department's consideration minimum basic data sets for hospital care, health facilities, health manpower, long-term care, and ambulatory care. The use of uniform minimum data sets and definitions can go a long way towards improving

comparability of data collected by various programs as part of both general purpose and programmatic statistical activities. Their use would also facilitate interprogram linkages and comparisons.

3. Within the Department, the Health Data Advisory Committee (formerly the Health Data Policy Committee) will continue to serve as the primary mechanism for coordinating the development of health statistics activities in the Department and for advising the Secretary on cross-cutting policies and priorities relating to current long range health data needs and in the development and modification of data policy objectives.

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Current Problems

Realistically, despite legislative and administrative support, the objective of a coordinated national, uniform system of health statistics has not been met. For instance, the area of ambulatory care abounds with separate reporting systems for maternal care, infant care, child care, family planning, venereal diseases, chronic diseases, and many others using different definitions of encounters, services, and patient characteristics. Many of these require reporting from the same facilities on the same visit.

The area of hospital utilization statistics also includes several disparate systems--Medicare, Medicaid, Professional Standards Review Organizations, and NCHS, as well as smaller systems run by the Indian Health Service, the Veterans Administration, the Department of Defense, and other agencies. The situation is very similar when we look at reporting for categorical disease programs.

This situation has resulted from a variety of factors. Within the Department, the organization and decisionmaking structure of health statistics activities is decentralized. Nearly all agencies in the Department engage in health statistics activities in the planning, management, monitoring and evaluation of a wide variety of health programs. Many of these statistical activities are essential for the ongoing day-to-day operations of specific programs.

Clearly, there is need for an organizational analysis in the Department to (1) examine and delineate roles, responsibilities, and relationships of the various agencies and offices of the Department engaging in general purpose or program-specific health data activities including an analysis of the various functional and organizational statements and delegations of authorities; (2) examine the roles and appropriate interrelationships among the various advisory bodies for health statistics within and outside the Department, and (3) examine and delineate roles, responsibilities, and relationships among the several Departmental organizations engaged in Federal-State-local arrangements for health data.

Such an analysis should identify inconsistencies, overlap of function and other problem areas and could recommend formal and informal mechanisms for remedying identified problems.

Steps Toward Resolution

In recognition of these problems, the Administration has taken several steps to move towards resolving them:

A. Reorganization

The recent reorganization of the Office of the Assistant Secretary for Health reflects the importance placed by this Administration on health statistical policy and coordination of health statistical activities (Federal Register, December 2, 1977). This reorganization established under the Assistant Secretary for Health the position of the Deputy Assistant Secretary for Health Policy, Research, and Statistics.

One of the objectives of the reorganization is the creation of a central locus within the Public Health Service for the development and coordination of health data and statistical policy and standards as well as for the operational coordination of statistical activities in the programs and agencies of the Public Health Service.

To achieve this objective, two steps have been taken:

(1) The National Center for Health Statistics and the National Center for Health Services Research were transferred from the Health Resources Administration to the Office of the Assistant Secretary for Health, reporting directly to the Deputy Assistant Secretary for Health Policy, Research and Statistics.

In addition to its role as the focal agency for collection, analysis, and dissemination of national statistics on vital events and health statistics, and fostering research, consultation, and training programs in international statistics, the NCHS has responsibility for (a) coordinating the overall health statistical activities of the programs and agencies of PHS and providing technical assistance in the planning, management, and evaluation of statistical programs of PHS; (b) maintaining operational liaison with statistical units of other health agencies, public and private, and providing technical assistance within the limitations of staff resources; (c) administering the Cooperative Health Statistics System; (d) participating in the development of national health statistics policy with other Federal agencies; (e) administering the Reimbursable Work Program; and (f) in its role as the government's principal general purpose health statistics organization, providing the Assistant Secretary for Health with consultation and advice on statistical matters.

(2) Also established within the Office of Health Policy, Research, and Statistics is the Office of Statistical Policy, reporting directly to the Deputy Assistant Secretary. This office (a) serves as the PHS focal point for coordinating all health data and statistical policy; (b) coordinates all matters regarding PHS health data policy standardization; (c) provides leadership and staff support to the DHEW Health Data Advisory Committee on the identification

of intermediate and long-range health data needs and in the development and modification of health data policy; (d) serves as statistical policy liaison with all components of PHS and other health related organizations; (e) reviews all PHS statistical and data gathering plans; (f) provides policy oversight for clearance and inventorying of public use reports; and (g) provides an Executive Secretary and staff support for the U.S. National Committee on Vital and Health Statistics.

This reorganization creates a whole set of new relationships that will require some time before they are functioning fully and smoothly.

B. Reimbursable Work Program

In recent years, the main emphasis of the reorganization of Federal statistical activities has been the reduction of the number of agencies engaged in data collection by designating one statistical agency for each broad functional area. As part of this effort, a Reimbursable Work Program was established in NCHS in 1976 for the purposes of collecting and/or analyzing health data for other Federal programs. These services are provided primarily to other PHS agencies, other DHEW components, and other Federal agencies as resources permit. This program is designed to:

(1) promote coordination and cooperation among Federal programs with similar data needs;

(2) reduce duplication of efforts;

(3) reduce reporting burden on respondents;

(4) promote the use of uniform definitions and classifications;

(5) promote uniform standards for quality control;

(6) efficiently utilize the numerous data bases presently in existence.

The present personnel ceiling of thirty-four positions for this program has limited the amount of service that can be offered, but to date over twelve agreements have been entered into with a wide array of agencies such as the Environmental Protection Agency; the Food and Drug Administration; Bureau of Health Planning and Resources Development, HRA; National Institutes of Health; and other Federal agencies.

C. Cooperative Health Statistics System

The Cooperative Health Statistics System (CHSS) is designed to establish a coalition among the various levels of government--Federal, State, and local--providing for the collection of data by the level of government that is best equipped to do it and then sharing information with the other levels. The purpose of the System is to unify the often fragmented, uncoordinated, and duplicative efforts in the health

statistics area to create a unified national system that will yield useful data for the nation as a whole as well as for States and local communities. This cooperative system brings to the health field the kind of highly comprehensive statistical effort already sponsored by the Federal government in economics, labor, and agriculture. Federal programs concerned with statistics on health and health affairs--located primarily in PHS--have largely been limited to the broad data required for national purposes.

The historical model for such a cooperative system is the national vital registration system which has long provided a setting for cooperative efforts between the Federal, State, and local governments and has for decades produced complete, accurate, and comparable data for natality and mortality. This program remains the only annual series of health statistics which cover all events in every jurisdiction and are used widely by numerous public and private agencies. Similar results, in the long run may be achievable for statistics on health care facilities, health manpower, hospital care, long-term care, and ambulatory care. These five areas together with vital statistics and the health interview survey program make up the seven components of the CHSS. This system is currently in various stages of development and operation. The original legislative authority for the CHSS is contained in P.L. 91-515, Section 305(b) enacted in October 1970, which was expanded in P.L. 93-353, Section 306(e). The research

and development phase was instituted in late 1971 under the auspices of the National Center for Health Services Research and Development in close collaboration with NCHS. In 1973, the administrative responsibility for this program was transferred to NCHS and the first operational contracts for the vital statistics component were negotiated with four States. Since that small beginning, the CHSS has grown very rapidly to where it has at least one component funded in forty-four (44) States, the District of Columbia, and Puerto Rico. Twenty-nine (29) of these States and Puerto Rico are funded for two or more components.

The CHSS has grown rapidly in large part to the wide acceptance it has gained among the States as the most practical means of acquiring and sharing data. This Administration has given it a high priority. Moreover, we are currently assessing alternative modes of operation of CHSS and where appropriate seeking ways for other units in the Department to assist in funding of the CHSS contracts with States for various components.

D. Minimum Basic Data Sets

The term "minimum basic data set" refers to the concept of a small core of data items considered useful by the major providers and users in a particular area of statistics. Each data element has a uniform, standard definition to assure comparability among data systems.

While this concept is critical for the development of the CHSS, it is discussed apart from that since the value and use of minimum data sets go beyond the limits of CHSS. The implementation of prescribed data sets is one of the key mechanisms for attaining comparability of health statistics within the Department. For example, many programs are collecting data on ambulatory care visits--maternal and child health, venereal disease, emergency rooms, dental care, to name a few--but each program defines for itself what is to be considered a visit, the data on facility and patient characteristics, patient symptoms and/or diagnoses, treatment or services provided, or outcomes. As a result, comparable and comprehensive data are not available for comprehensive health planning, program development, and evaluation that is critical for establishing national health policies.

The Departmental Health Data Advisory Committee is the central body to provide leadership in advising the Secretary on Departmentwide policy and procedures concerning the establishment, implementation, and periodic review of and organizational locus for the promulgation of uniform minimum data sets in the Department.

Ideally, minimum data sets should be developed in a manner that assures the opportunity for input from all interested parties, public and private, and promotes the acceptance of the data set for actual use.

Although it is unlikely that the content of these data sets will require frequent changes, they should be reviewed, and modified if necessary, every 5-10 years.

As stated earlier, at present the U.S. National Committee on Vital and Health Statistics and the technical consultant panels associated with it are working on minimum basic data sets for hospital care, health facilities, health manpower, long-term care, and ambulatory care. The NCHS has provided technical staff support to these technical consultant panels and plans to conduct pilot and evaluation studies on the data sets.

E. Operational Coordination by NCHS

1. Clearance under the Federal Reports Act

Project clearance for the Public Health Service is now centralized within the Office of the Assistant Secretary for Health (OASH) with the Office of Statistical Policy (OSP) having the responsibility for review and approval of all data collection plans and projects. As part of the President's directive to reduce reporting burden on the public, the NCHS is responsible for determining for all statistical activities within the PHS whether the desired data are already available. In addition, NCHS provides the PHS clearance officer with authoritative advice on technical merits of the project and as necessary provides technical assistance to the programs.

2. Health Statistics Plan

The National Center for Health Statistics has provided staff support to the Office of Statistical Policy in the preparation of the Departmentwide health statistics plans for the past two years and the PHS plan for the current year presently under preparation. This effort includes a survey of ongoing statistical programs; identification of areas of duplication and data gaps; identification of technical problem areas; and, necessary next steps toward a uniform national health information system. NCHS will continue to assist and advise the OSP in a major way in the design and development of the future iterations of the health statistics plans for the Department.

3. Classification of Diseases

In 1976, the NCHS was designated by the World Health Organization as the WHO Center for Classification of Diseases in North America. As such, one of its functions is the development and issuance of a modification of the current ninth revision of the International Classification of Diseases (ICD-9-CM) for use in the United States for morbidity coding. The Center will coordinate the efforts of various national organizations to convert all users, including every hospital, to this classification system starting January 1, 1979. This will replace the two previously used classifications thus removing a serious obstacle to comparable health data that has existed up to now.

4. Statistical Standards

Within the PHS the OSP serves as the PHS focal point for coordinating statistical policy and standards and the NCHS serves as the principal agency for the technical development, maintenance, and promulgation of health statistical standards. This includes minimum basic data sets, definitions of health data items, classification and coding systems, quality control, geocoding, data collection, processing, and analysis methodology. As part of this function, NCHS will develop a series of package surveys for use by HSAs and others in collecting and analyzing small area data.

5. Confidentiality, Privacy, and Freedom of Information

Within the PHS, NCHS will provide technical assistance in implementing certain aspects of the policies regarding protection of confidentiality of individually identifiable data. In particular, this includes standards regarding level of aggregation needed to preserve confidentiality in statistical tabulations and combinations of personal characteristics that could serve as personal identifiers. NCHS will develop, refine, and promulgate model State laws to assist them with problems of confidentiality, privacy, and freedome of information.

6. Inter-Departmental Agreements

Continuing working relationships and coordination between NCHS and the Bureau of Health Manpower in jointly implementing the data provisions of P.L. 94-484 are maintained by an inter-bureau coordinating committee. This committee has been meeting for nearly

two years and has drafted mutually agreed upon short and long term data collection plans. The major unresolved issues still remaining relate to the level of expenditure for each activity and the sources of funding.

To implement the provisions of Section 19, P.L. 95-142, PHS and Health Care Financing Administration staff are currently preparing a draft memorandum of understanding to spell out areas of joint interest, types of coordination needed, and mechanisms to develop and maintain shared data systems. Particular attention will be given to the Cooperative Health Statistics System and the relation of Medicaid, Medicare, and PSRO statistical and billing systems to it.

The Director, NCHS and the Director, Center for Disease Control, together with their respective staffs, are discussing ways and means to better work cooperatively in areas of joint data needs. There has already been an agreement reached on collecting abortion statistics using the vital statistics component of the Cooperative Health Statistics System.

A memorandum of understanding between NCHS and the National Institute of Mental Health has been developed recently which clarifies the roles and responsibilities of the agencies for (1) meeting the needs for mental health statistics at the national, State, and local levels, and (2) the support activities provided to States and local agencies

participating with the Federal government in mental health statistics programs. Important areas covered by the agreement are: the NIMH has the responsibility for defining and meeting national mental health data needs; the NIMH agrees to work in cooperation with the CHSS to meet common data needs at the national, State, and local levels; NCHS and NIMH will work jointly in establishing minimum data sets for mental health; NCHS and NIMH will jointly fund a technical consultant panel of the USNCVHS to recommend the structure and content of mental health statistics; and, there will be a NIMH-NCHS Inter-Bureau Committee to maintain close coordination.

SUMMARY

In summary, the Administration has recently undertaken a number of specific steps to more vigorously develop a coordinated, uniform system of health statistics both within the Department and throughout the Nation. We expect that these and future efforts to facilitate coordination will more clearly delineate roles, responsibilities, and relationships of the various agencies engaged in the collection and analysis of health data.

OCT

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH
WASHINGTON, D.C. 20201

The Honorable Daniel J. Flood
Chairman, Subcommittee on
Labor-Health, Education, and Welfare
Committee on Appropriations
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

In House Report 95-381 on the Preventive Health Services Appropriation, the Committee requested a report on progress made by the health delivery programs to screen for lead poisoning and on efforts of the U.S. Public Health Service to coordinate its lead based paint program with the health care delivery programs of HEW as well as those of other Federal agencies.

The enclosed report is submitted as requested.

Sincerely yours,

Julius B. Richmond

Julius B. Richmond, M.D.
Assistant Secretary for Health

Enclosure

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE

REPORT TO THE HOUSE APPROPRIATIONS COMMITTEE ON PROGRESS AND COORDINATION OF CHILDHOOD LEAD POISONING PREVENTION ACTIVITIES

Introduction

The House Report on the Fiscal Year 1978 Labor-HEW Appropriation Bill contains the following passage:

> The Committee continues to be impressed with the progress being made by the Center for Disease Control in assisting the other health service and health financing programs of the Department to incorporate routine lead screening as an integral part of the delivery of health care. The Committee strongly encourages the Center for Disease Control to continue working closely with the community health centers, the maternal and child health program, migrant health, medicaid and other health programs to achieve full implementation of screening programs to detect elevated blood lead levels. The Committee will expect another report from the Assistant Secretary for Health to be submitted by February 1, 1978, on the progress made by the health delivery programs to screen for lead poisoning and on the efforts of the U.S. Public Health Service to coordinate its lead-based paint program with other Federal agencies.

Background

Childhood lead poisoning is a significant health problem which can result in mental retardation, hyperactivity, and slowed learning ability, whether or not the child develops symptoms. These dysfunctions deprive the child of the chance to achieve full genetic potential; society also loses the benefit of that potential. The National Bureau of Standards has estimated that approximately 600,000 children, ages 1-5, suffer from undue lead absorption.

The widespread use of lead has resulted in the permeation of this contaminant through food and water supplies, in the atmosphere, and, in general, throughout the total living environment. This has resulted in a continuing lead

insult to every individual in our society. However, for children the single most significant source of lead is lead-based paint. It has been estimated that over 30 million dwelling units have been contaminated with lead source. As these paint films deteriorate, the risk of lead poisoning increases. All children under 6 years of age who reside in older, deteriorating housing are at highest risk. Young children are particularly vulnerable since the brain is undergoing rapid development.

In the last report, routine screening of all children ages 1 through 5 in this country was felt to be "neither appropriate nor justified" due to the cost of the screening test and the low prevalence in some areas. This situation has now changed, since a technologic breakthrough has resulted in the development of the dedicated hematofluorometer by Bell Laboratories for erythrocyte protoporphyrin (EP) determinations. This instrument allows the test to be performed for less than $.10 in consumable supplies. The test reflects the metabolic effects of lead, and is not subject to contamination. It is also sensitive to iron deficiency and the other porphyrias. The EP test allows multipurpose screening at an analytical cost below that of the traditional screening procedures for these conditions. Routine screening for undue lead absorption is now economically feasible in all areas of the country, including those with a low incidence of that condition.

Community Level

Since the inception of the Childhood Lead-Based Paint Poisoning Prevention Program in 1972, 83 projects have been supported in communities with a

documented high incidence of undue lead absorption. These community projects serve as a focal point of expertise providing community outreach, health education, medical and environmental services necessary for the proper care of the child identified with undue lead absorption. These projects have reported screening approximately 1.8 million children since the inception of the grant program and have identified 121,000 with undue lead absorption.

However, it is only through coordination of all health and environmental resources that the high incidence of childhood undue lead absorption can be reduced. All of the Childhood Lead-Based Paint Poisoning Prevention Projects have established a working relationship with the other pediatric health programs within their communities. These other programs include Maternal and Child Health (MCH); Neighborhood Health Centers; Women, Infants and Children (WIC); Early and Periodic Screening, Diagnosis and Treatment (EPSDT); Community Health Centers; Rural Health; and Children and Youth. With the use of the EP test for screening, approximately 18,400 children have been referred to these other pediatric programs by the projects for care of iron deficiency. Since the initiation of the program, over 19,000 children have been referred to the projects for pediatric and environmental followup for undue lead absorption. The number of cross referrals has increased to approximately 7,900 per quarter. Through the community outreach activities of the Lead-Based Paint Poisoning Prevention Projects, many children not already in the health care delivery system have been placed under care. It is through technology transfer, such as the development and utilization of the hematofluorometer, the increase

of medical expertise, local community awareness, and outreach that progress can now be made toward the goal of screening all children under the age of 6 in project communities.

State Level

It is on the State level that many major decisions are made regarding the specific types of services to be provided by the programs on the community level. Traditionally, the States have not included routine screening for undue lead absorption as a part of their pediatric programs. The State program directors' perception of the magnitude and distribution of the childhood lead poisoning problem, coupled with the high cost of screening with the blood lead test, has retarded implementation of routine screening. State laboratory capabilities were limited and environmental lead hazard detection procedures were primitive. Coordination between State and local agencies regarding the provision of lead poisoning prevention services has been extremely poor. The specialized services and expertise necessary for proper care of children identified with undue lead absorption has generally not been fully developed in the States. The large urban communities and their childhood lead poisoning prevention projects were left to develop the necessary program resources. However, it is now readily apparent that childhood undue lead absorption is not an exclusive problem of the big cities.

The Childhood Lead-Based Paint Poisoning Prevention Act (P.L. 91-695, as amended by P.L. 93-151 and P.L. 94-317) prohibits grants to State agencies to conduct childhood lead poisoning prevention programs except under special circumstances and restrictions in the Federal legislative authority limit CDC assistance. Without a coordinator to focus diverse specialities and

and programs on the problem, attempts to achieve full integration of lead poisoning prevention services can meet with only marginal success.

The Center for Disease Control has continued activities and developed new initiatives designed to directly assist State pediatric programs to incorporate lead poisoning prevention services into their operations:

1. Meetings have been held with all childhood lead poisoning prevention program directors to reemphasize the need for full integration of lead poisoning prevention services into the ongoing pediatric health care systems in their communities. The project directors have also been requested to provide assistance where appropriate to the State agencies.

2. Directors of many of the other pediatric programs and their staffs have attended the Childhood Lead-Based Paint Poisoning Prevention Program Regional meetings for mutual exchange of ideas and operational technology.

3. Blood lead proficiency testing services are provided monthly to 100 laboratories in 42 States, the District of Columbia, and Puerto Rico to assure quality blood lead analysis. In fiscal year 1975, approximately 55 percent of the participating laboratories demonstrated proficiency; this increased to over 80 percent by the end of fiscal year 1976. The majority of these laboratories provide services to other pediatric health

programs. Of the 43 laboratories which perform blood analyses for the Childhood Lead-Based Paint Poisoning Prevention Projects, 98 percent have demonstrated their proficiency through monthly testing.

4. A monthly EP testing analysis program has also been established for 90 laboratories in 35 States and the District of Columbia. The latest reports indicate increasing competency in specimen analysis.

5. Tentative agreement has been reached with the EPSDT Program on reporting definitions for undue lead absorption. This will enchance the interchange of statistical data and will enable CDC and EPSDT to direct programmatic assistance to the States with the greatest need.

6. The EPSDT Program has issued a statement on undue lead absorption to all of their program directors and advisory committees (Tab A). This statement was also distributed by the Maternal and Child Health Program. In all, approximately 4,400 individuals received a copy of the statement and a CDC publication, entitled "Increased Lead Absorption and Lead Poisoning in Young Children," March 1975. This CDC publication has now been distributed to approximately 30,000 individuals in the United States.

7. Periodic meetings have been held with the National EPSDT Program to discuss mutual program issues. Work plans have been developed by EPSDT to intensify routine screening for undue lead absorption in State EPSDT programs. Members of the EPSDT staff have been briefed on the medical and environmental aspects of lead poisoning prevention. Plans are being developed for a presentation on childhood lead poisoning to the State EPSDT program directors.

8. Program representatives of EPSDT and MCH have accompanied CDC staff on site visits to selected State agencies. Additional joint consultations are planned.

9. The Center for Disease Control has developed a training situation for environmental and epidemiologic personnel from State and local agencies. Individuals participating in this training experience will receive a practical orientation in current lead poisoning epidemiology, hazard identification, and reduction methods. This activity will increase the level of lead poisoning epidemiological and environmental expertise.

10. The Department of Housing and Urban Development (HUD) is developing and evaluating new technology to facilitate lead hazard reduction.

11. New X-ray fluorescent analyzers have been developed under contract with HUD that increase the capability of the environmental epidemiologist to identify lead hazards. As these instruments become available on the State and local levels, improvement in hazard identification is expected to occur. The major limiting factor in implementation of the new XRF is the acquisition of resources for acquiring the instrument.

12. The Center for Disease Control is currently evaluating the potential in several States for developing State-wide lead-based paint poisoning prevention programs utilizing existing resources. This activity will involve development of management information systems, model ordinances, logistical support systems, physician education, and environmental epidemiologic expertise. When this program is full operational in several States, it can serve as a model for other States to follow. An example of the results of this effort is shown in Attachment 1.

13. A series of meetings were held with the participants of the CDC Nutritional Surveillance Program during which the EP test was discussed. As a result, several State programs have acquired the hematofluorometers for use in detecting iron deficiency. Since the test also screens for undue lead absorption, consultation is being provided to ensure that children with positive

EP results also receive tests for blood lead levels and that proper pediatric and environmental services are provided.

14. The Center for Disease Control has continued to provide problem identification services to requesting State and local agencies. This activity makes available expertise to assist the communities in the rational planning process for developing a lead poisoning prevention program.

15. The Childhood Lead Poisoning Prevention Demonstration Model Program developed by HUD in concert with CDC is now fully operational. This program will provide a practical orientation in the most current technologies and operational methodologies necessary to provide comprehensive services to children identified with undue lead absorption. As needs are identified on the State and local levels, individuals will be invited to visit the program. This activity will increase the level of lead poisoning expertise in the other pediatric programs and will emphasize the need for the coordinated delivery of medical and environmental services.

16. The Center for Disease Control has recognized that screening services for undue lead absorption require an intensive effort. Consequently, CDC plans to develop a training program

for outreach and community health workers. The Childhood Lead-
effective community outreach methodologies which are
appropriate to all pediatric health programs.

The Center for Disease Control will continue to provide assistance to the other pediatric health programs on the Federal, State, and local levels in incorporating routine lead poisoning prevention services into the program operations. Where health programs provide pediatric services for undue lead absorption, funds appropriated under the Lead-Based Paint Poisoning Prevention Act should be used to coordinate community outreach services, case holding, and environmental lead hazard identification and reduction services. In the other federally funded health care programs there are generally no provisions for environmental lead hazard identification and reduction services. The availability of screening services is superfluous in the absence of effective community outreach, case holding, and environmental control activities. The Center for Disease Control will continue to assist other programs as requested in developing all the necessary components and procedures necessary for an effective lead poisoning prevention program.

STATE OF CALIFORNIA - HEALTH AND WELFARE AGENCY
DEPARTMENT OF HEALTH
714 P STREET
SACRAMENTO CALIFORNIA 95814
(916) 322-2950

ATTACHMENT 1

July 18, 1977

TO: County Health Officers
Child Health and Disability Prevention Directors/Deputy Directors
Regional Center Directors
Maternal and Child Health Directors
Crippled Children's Services Directors
Local Directors of Environmental Health
State Hospital Executive Directors
Directors of Nursing

The Department of Health has been granted authority to undertake a two year program which will indicate the health and demographic nature and magnitude of the hazard environmental lead poses to the children of California and which will put in place a mechanism to afford continuing adequate protection of children against the adverse effects of lead on their physical and mental health and development. The Department is undertaking this initiative in response to the findings of three CDC-funded lead screening projects in Alameda, Contra Costa and Los Angeles Counties. Those findings indicate that, contrary to prevalent opinion, children with excessive lead burdens do reside in some areas of California. In addition there are some residents of State Hospitals who exhibit the same condition.

Overt lead poisoning with attendant encephalitis, seizures and severe neurological deficits does not appear to be a significant problem. However, children with an excessive lead burden (blood lead greater than 30) have been discovered at a rate of 3.6 percent in Contra Costa, 8.1 percent in Alameda, and a startling 22.7 percent in Los Angeles. These data represent findings in over 1,200 children screened in each county in certain high risk census tracts through August 1, 1976.

An excessive blood lead level in "asymptomatic" children is thought by many experts in the field to be closely related to school and behavior problems, learning disabilities, hyperkinesis and the constellation of symptoms termed "minimal brain dysfunction". The causal relationship has not been unequivocally established but a large amount of circumstantial evidence has been accumulated and reported in the literature.

The advent of the erythrocyte protoporphryn (E.P.) screening test has been a major breakthrough making possible simple rapid detection of children at risk for excessive lead burden. Elevated E.P. is found in children with iron deficiency and frank anemia as well as in lead burdened children so any program using this method will uncover children with these conditions as well. Follow-up blood lead and hematocrit determinations are necessary to confirm the diagnosis.

Literature is included which more fully discusses the points made above.

The Department is seeking a cooperative effort at the County level with Child Health Programs to focus on this problem.

The purpose of this letter is to solicit your participation in this effort to determine the extent of the "lead problem" in California.

If you are interested, I would appreciate a response to this letter by August 19, 1977. A member of the State Childhood Lead Program team will then arrange a meeting with you to discuss the program in greater detail.

Please send your response to Bernice Robertson, State Department of Health, Maternal and Child Health Branch, 2151 Berkeley Way, Annex 4, Berkeley, CA 94704.

Sincerely,

Edward P. Melia, M.D., Chief
Maternal and Child Health
Services Section

Siegrid Centerwall, M.D., Chief
Child Health and Disability Prevention
Program Branch

Don Bowling, Chief
DD Hospital Services Section

Rita Evans, Chief
Regional Centers Section DD

Esmond Smith, M.D., Chief
Crippled Children's Service Section

Attachments
EM:BR:vs

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
Health Care Financing Administration
Washington, D. C. 20201

INFORMATION MEMORANDUM
IM-77-32 (MSA)
June 9, 1977

TO : STATE AGENCIES ADMINISTERING MEDICAL ASSISTANCE PROGRAMS

SUBJECT: New Technology available in the Screening and Detection of Lead Poisoning and EPSDT

CONTENT: This information transmittal was jointly developed by the Division of Early and Periodic Screening, Diagnosis and Treatment (EPSDT) and the Division of Environmental Health Services of the Center for Disease Control (CDC) to provide our endorsement of available new technology for the detection of lead poisoning among the EPSDT population.

We encourage your exploration of the ideas presented here and hope they will generate productive discussions between the responsible agencies.

The Problems

All children should be considered at risk for lead exposure since all individuals receive varying degrees of exposure to lead in their daily life. The impact of excessive lead exposure to children 1 through 5 years of life can and does have serious and largely irreversible effects on the development of the central nervous system. It may vary from severe brain damage to relatively mild neurologic disability and hyperactivity at lower levels of exposure. Undue lead absorption may also result in toxic effects on the kidneys as well as bone marrow with associated impairment of blood cell formation. Childhood lead poisoning costs money for long term institutional care and increases public assistance expenditures.

Risk

Most of the children with undue lead absorption do not have overt symptoms of the disease. The problem can only be detected by screening the child for the disease. Children who live in, or frequently visit, poorly maintained housing units constructed prior to the 1960's, are at greatest risk of the disease. Unfortunately, the majority of the children served by the EPSDT Program are in this high risk group.

New Technology

Screening for undue lead absorption has been recommended in A Guide to Screening for the Early and Periodic Screening, Diagnosis, and Treatment Program Under Medicaid. Since its publication, there have been considerable advances in technology and information relating to undue lead absorption. In the past, screening, using blood and lead determinations, was recommended as the primary detection tool. Recently, however, a series of instruments have been developed to allow a program to perform erythrocyte protoporphyrin (EP) determinations at the provider site or in a centrally located laboratory. This test not only provides an indicator of the metabolic effects of undue lead absorption, but also can be used in determining if a child is anemic due to iron deficiency. These instruments, called "hematoflurometers" are relatively inexpensive, require only a few drops of blood, and optically analyze the specimen in less than 10 seconds. The EP is not subject to contamination as is the micro blood lead test. If the EP is negative (less than _60 ug/dl whole blood), the program can rule out iron deficiency and undue lead absorption. If, however, the test results are above _60 ug/dl, then the child should be fully evaluated for iron deficiency anemia and undue lead absorption. With these advantages and low cost per specimen analyzed, the erythrocyte protoporphyrin test would appear to be more desirable as a primary screening test and will result in significant long term savings to the EPSDT Program.

Recommendations

In light of the data we have reviewed from EPSDT programs and the CDC data, it is obvious that programs which look for children with undue lead absorption, find children requiring medical attention. In order to determine how much of a problem there is in the 1 through 5 years of age group, each State program should plan to include lead testing procedures in their screening requirement so that each child is tested at least once. The providers should carefully review the yield from the testing to determine if the lead test should continue on a periodic basis as determined by the percentage of children found to have lead problems.

The Center for Disease Control, Environmental Health Services Division, has released a statement entitled "Undue Lead Absorption and Lead Poisoning in Young Children", March 1975, which describes the current recommendation for screening and pediatric care for children with a lead problem. Note that children with a blood level of _30ug/dl and EP _60ug/dl are considered to have undue lead absorption and require medical care. The CDC statement (attached) discusses the interpretation of test results in detail and has served as a guide to many of our providers in the management of children with lead problems.

Screening Eligibles

When screening eligibles on a county or city wide basis, at least 10 percent but not less than 100 children of the EPSDT eligible children screened ages 1 through 5 should be tested for undue lead absorption as an indicator of the magnitude of the lead problem within that group. The specimens collected during the testing phase should be processed by a laboratory with known technical competence in this field as was described in "The Guide for State Title XIX Directors for Assurance of Laboratory Quality Performance in Lead Poisoning Prevention Programs", released May 1975 and distributed to State Medicaid Directors. If a program has a yield of less than 3 percent positive, the lead screening test should probably not be performed on a periodic basis but utilized on a selective basis only. In counties where there are less than 100 eligibles we suggest that all children be tested initially.

Should you have questions relating to the screening for undue lead absorption or the medical and environment management of children, the following individuals should be able to assist you:

State Health Officer
Director, State Laboratory
Regional Consultant
Director, Division of Prevention, Regional Office
Director, Environmental Health Services Division,
Center for Disease Control

INQUIRIES TO: Regional Commissioners

Paul A. Williams
Commissioner
Medical Services Administration

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

30 JAN 1978

The Honorable Daniel J. Flood
Chairman, Subcommittee on Labor-
Health, Education, and Welfare
Committee on Appropriations
House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

The enclosed report on the Hemophilia Diagnosis and Treatment Program is submitted in response to the Committee's request on page 17 of House Report No. 95-381 on the fiscal year 1978 appropriation bill for the Departments of Labor and Health, Education and Welfare.

In its report language, the Committee stated that it expected a report from the Assistant Secretary for Health on the Department's program for reducing the cost of hemophilia treatment as well as expanding the availability of sufficient plasma products for hemophiliacs. The report includes information on program coordination with the National Heart, Lung, and Blood Institute, National Institutes of Health, and describes actions which have been taken to increase services for hemophiliacs and to identify financial barriers to care.

We hope this information fulfills the Committee's requirements.

Sincerely yours,

Charles Miller
Acting Assistant Secretary
for Management and Budget

Enclosure

HEMOPHILIA DIAGNOSIS AND TREATMENT
PROGRESS REPORT

Background

This report is related to the Committee's concern t
attention is being given to reducing the cost of tr
hemophilia patient. The Federal program authorized
was implemented late in fiscal year 1976 with the f
mophilia diagnosis and treatment centers designed t
ficantly the scope and quality of services to hemop
grants were made to applicants who already were con
hemophilia treatment programs. The additional fund
able through the grants provided resources needed t
lized health care services, and generally upgrade t
quality of services.

Approaches to the Problems of Costs

The improvement in the service delivery capacity of
not self-evidently address the problem of the cost
tient. However, there is considerable evidence to
tention that a program of comprehensive care, chara
treatment, counseling, education, outreach and self
contributes significantly to the health status of t
tient, stablizes his condition, reduces the inciden
dic medical intervention and enables him to have su
necessary, to further reduce complications which re
ment. From this perspective, the funding of center
of a significant decrease in costs to the patient a
ability to function in society.

Peter Levine, M.D., who is currently the Director o
supported Center in Worcester, Massachusetts, compu
tients over a three-year period and found a reducti
in total health care costs to the patient, from $5,
$3,511 in 1973. 1/ The decrease was attributed to
tions in total costs relating to emergency room and
While it is true that the Levine study had as its p
reductions brought about by the utilization of home
treatment, this does not detract from the observati
sive care helps reduce costs because home care acti
major elements of care which the Federal program is
the provision of additional funds to the Centers.

1/ David P. Agle, M.D., Editor, Mental Health Servi
hensive Care of the Hemophiliac, page 50, 1977.

by Judy Haverstick, RN., and M. Elaine Eyster, M.D., at the workshop on Mental Health Aspects of Hemophilia Care, it is stated in the introduction that the administration of the clotting factor at home by the patient himself produces stunning decreases in work and school absenteeism, in days hospitalized and in the number of visits to physicians. Overall costs of health care are reduced by half. 2/

It should be noted that the hemophilia treatment community does point out that the change from hospital or center to home-based therapy introduces new difficulties, such as anxiety on the patients' part, which cannot be overlooked. It is anticipated that a study initiated by the Bureau of Community Health Services this fiscal year will provide critically needed data relevant to the effect of comprehensive care as a significant factor in reducing patient costs.

Of the estimated 14,000 hemophiliacs in this country, approximately 2,500 or 18 percent will have received services in the 21 centers by the close of FY 1978. Staff of the Bureau of Community Health Services, have, in addition to assuring effective implementation of the program, initiated several actions which impact on the problem of costs to the patient. These actions include:

1. Coordination with the National Heart, Lung, and Blood Institute on an extensive study by Booze-Allen and Hamilton of the supply and demand relationships involved in the fractionation of blood products required by hemophiliacs. This study, which was completed in April 1977, resulted in the conclusion that the supply was more than equal to the demand. The study also provided a much needed realistic estimate of the hemophilia population and the degrees of severity of the disease in that population. The assessment of the fractionation industry and the supply of products needed, indicated that the answer to the problem of the costs of blood products to hemophiliacs could not be resolved through Federal supplementation of the fractionation industry to increase supply.

2. The National Institute for Advanced Studies (NIAS), has been secured as a contractor to assess various aspects of the federally-funded hemophilia treatment centers over the course of this fiscal year. The study which NIAS is doing has been carefully structured to address the critical problems which are recognized as urgently requiring resolution. Although the major emphasis is on the impact which Federal funding has had on the effective diagnosis and treatment of hemophiliacs, the evaluation study will involve investigation and

2/ Ibid, page 57.

documentation of the costs of care to the patients and their families, the extent to which insurance companies and other third-party reimbursement mechanisms provide financial coverage, and the costs to the patients of blood products used in infusion therapy. Where possible, NIAS will identify those treatment modalities utilized by centers which are proven to be both medically sound and cost effective. It is hoped that such findings will enable the program to institute changes in those centers which are not utilizing the cost-effective procedures evidenced in others.

Recently the American Red Cross has engaged with Bureau staff in discussions regarding their proposal to make low-cost Antihemophilic Factor Blood Coagulation Factor VIII (AHF) concentrate available to hemophiliacs through both federally and non-federally supported centers. The Red Cross has available about 20-25 million units of AHF concentrate which it intends to make available for treatment at a cost of $.055 per unit which is about one half the usual cost. The Red Cross proposal appropriately describes the planned action as a pilot study because it will include data gathering and analysis activity designed to measure the impact of the availability of low-cost concentrate on the patient's utilization of the products he needs.

The Bureau has endorsed the draft Red Cross proposal and views it as a significant step. The results of the pilot study will assist the Red Cross in determining whether or not it should finance the construction of its own blood fractionation plant at an estimated cost of $25-40 million, an action which obviously requires careful deliberation and highlights the critical nature of the study. To insure the effective coordination of the Red Cross and NIAS studies, the Bureau has initiated meetings with representatives of both organizations. Through this mechanism all concerned parties will be kept informed about each other's activities, and the work of the centers will not be hindered due to excessive data reporting requirements and site visits. Duplication of effort will be avoided or kept to a minimum. It is anticipated that the Red Cross pilot study, the results of which will be made available to the Bureau of Community Health Services, and the NIAS study, will provide a great deal of information on problem areas relating to hemophiliac care including the costs of care to patients and their families.

As previously indicated, the Booze-Allen and Hamilton study identified a national hemophiliac population of about 14,000 with about 50 percent suffering from the moderate and mild forms. In the many discussions which have been held regarding program planning and implementation it has been noted that another study has been initiated by the Marketing

Research Bureau in Newport Beach, California, and that this particular study will be completed early in 1978. In the interim, the Booze-Allen statistics are the most current and reliable ones of which we are aware. The testimony which was made to the Congressional Committee prior to the enactment of P.L. 94-63 which authorized the Federal hemophilia program, indicated that a sound regimen of replacement therapy would cost approximately $5,000 to $6,000 per year per patient. An estimate based on approximately 14,000 hemophiliac cases shows the aggregate cost of providing such regimens of therapy to be between $70 and $84 million annually.

Health care expenditures of this magnitude are quite significant and investigation of various avenues of cost reduction and cost control will continue. In the interim, Federal staff will continue to work closely with funded centers and to draw upon the knowledge and expertise of the National Heart, Lung, and Blood Institute, the National Hemophilia Foundation, the Red Cross, and the State Crippled Children's services programs all of whom have exhibited willingness to provide the maximum degree of assistance and support possible.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

6 JAN 1978

The Honorable Daniel J. Flood
Chairman, Subcommittee on Labor-
Health, Education, and Welfare
Committee on Appropriations
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

In response to your request that the National Heart, Lung, and Blood Institute conduct a study on the state-of-the-art in Cooley's Anemia (Thalassemia) research and treatment, I am sending a report of what has been accomplished to date.

To be completely responsive to your request the Institute must conduct rather comprehensive surveys which will take longer than the specified year to complete. However, the Institute plans to send an analysis of the available data to you in March of 1978.

The Department shares your concern that the NHLBI assure a concerted effort toward understanding this disease and will keep you informed of our progress.

Sincerely yours,

Charles Miller
Acting Assistant Secretary for
Management and Budget

Enclosure

PROGRESS REPORT

Cooley's Anemia Research and Treatment

Current Status - The staff of the NHLBI, with a representative from the NIAMDD, has investigated the availability of materials related to the aforementioned mandate and suggests the following approaches for fulfilling that mandate.

(a) "a comprehensive study of the epidemiology of the disease": The intent is to investigate the occurrence of the homozygous thalassemia. Thalassemia major is not a "reportable" disease, the populations in which the disease occurs is not sharply defined, and summaries of hospital records are not often helpful because such data usually mention total number of admissions and discharges without accounting for multiple admissions and discharges. Consequently, there is a lack of documented information about the incidence of thalassemia major in the population. Most experienced hematologists in geographic areas where there are significant Greek and Italian populations agree with the estimate of less than 5,000 cases of thalassemia major in this country. Nevertheless, there are not statistical data to support this perception, even though the opinion may be based on many years of experience in medical centers where it is possible to treat thalassemia major. (Since the disease is so severe, these patients are treated in hospitals where there are appropriate hematologic capabilities and services). The NHLBI therefore proposes to sample pediatric hematology centers in areas where there are populations of Italian and Greek ancestry. This portion of the task would probably require longer than the specified year for completion. The NHLBI is aware of a recently completed, privately supported (pharmaceutical industry) survey of the incidence of thalassemia major in the United States, the results of which we may be able to obtain for use in the report which is to be transmitted to the Congress. The results of the survey sponsored by the NHLBI would be transmitted separately when completed.

(b) "an evaluation of the public and private resources (including trained personnel) for diagnosis, screening, and research on Cooley's Anemia": On the basis of our knowledge of the development of this "congressional initiative" related to Cooley's Anemia, we would propose to implement the stated charge by including, in the aforementioned sampling of hematology centers, a survey of the availability of medical manpower and laboratory technicians and facilities; the capabilities for genetic counseling, and an evaluation of the social, economic, and psychological impact of the disease on the patients and their families.

(c) "a survey of past and present research towards the end of developing a plan for the most productive future research and treatment areas": To satisfy the requirement for "a survey of past and present research," the NHLBI proposes to solicit a major review of the field.

The "plan for the most productive future research and treatment areas" would be developed by a task force that would advise the NHLBI in all areas of the mandated charge.

Summary

The NHLBI proposes to fulfill its congressionally mandated responsiblities in Cooley's Anemia research and treatment by convening a task force of appropriate scientists and lay representatives who would be given the charge to (a) develop a plan for ascertaining the magnitude of the problem of Cooley's Anemia as a public health problem, which would be done through a survey of pediatric medical centers in areas where the affected patient population is most obvious, and (b) survey the state of the science in research pertaining to Cooley's Anemia and advise on the implementation and evaluation of such research. Before the proposed task force would be assembled, however, representatives of the NHLBI would meet with representatives of the Cooley's Anemia Blood and Research Foundation for Children and The Science and Health Communications Group, present this proposed plan for their information, and solicit their comments.

8/17/77

Preliminary Report

ASSESSMENT OF COOLEY'S ANEMIA RESEARCH AND TREATMENT

March 3, 1978

Division of Blood Diseases and Resources
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

March 3, 1978

Honorable Daniel J. Flood
Chairman, Subcommittee on Labor,
Health, Education, and Welfare
Committee on Appropriations
House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The expression of Congressional interest in the status of research and treatment relating to Cooley's anemia prompted the convening of an ad hoc group of consultants by the Division of Blood Diseases and Resources of the National Heart, Lung, and Blood Institute. The consultants held their first meeting in October 1977 and two others have been held since that time. Because they wish to provide the Congress with a broad view of Cooley's anemia, they have not only set out to study readily available information, but they have also initiated several data collection and analysis efforts. Some of the efforts will not be completed for several months. This preliminary report has been prepared expressly to provide the Congress with an early indication of the goals and methods of the studies and of the consultants' progress toward meeting those goals.

Because Cooley's anemia is complex both in its research and in its patient care dimensions, experts in a wide array of disciplines and interests were sought. Ten consultants are serving currently: four hematologists who are specialists in the care of children, two basic research scientists, a population geneticist, a social worker, a nurse, a parent of a child with Cooley's anemia, and a physician with extensive experience in screening and genetic counseling.

The consultants took their direction from the language of the Report of the House Committee on Appropriations (95th Congress):

> "The Committee is convinced that Cooley's anemia (Thalassemia), a uniformly fatal disease suffered by children whose ancestors once inhabited the Mediterranean area, deserves priority attention.

The Committee therefore directs that a study be undertaken and completed within the next year on the state of the art in Cooley's anemia research and treatment. This study should include a comprehensive study of the epidemiology of the disease, an evaluation of the public and private resources (including trained personnel) for diagnosis, screening, and research of Cooley's anemia, and a survey of past and present research towards the end of developing a plan for the most productive future research and treatment areas."

In response to the directive, the consultants identified six tasks:

1) Review of the state of the art of research in the field;

2) Development of practical standards for clinical services;

3) Ascertainment of the dimensions of Cooley's anemia in the United States;

4) Survey of facilities where Cooley's anemia is treated;

5) Study of the impact of the disease on patients and their families; and

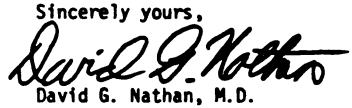
6) Recommendations for future approaches to research and to improving the care available to patients based on an evaluation of the results from the other study tasks.

The consultants wish to draw special attention to their choice of methods for these efforts. For each task a range of methods was considered. Each approach was discussed in terms of the time and cost of implementation and its relative value in relation to other possibilities. In every instance the consultants are satisfied that the chosen approach will provide them adequate information from which to develop their recommendations, and that it will allow them to complete the study tasks within the limits of time and money. The specific methods are described in the individual sections of this report.

The first two tasks, those pertaining to research and standards of clinical care, do not require as long a time period to collect the needed information; thus, these tasks are nearer completion than the others.

The study group intends to complete its work within six to eight months, barring difficulties often associated with such data collection efforts, and to have a full report ready for the Congress before the budget hearings are conducted in 1979. The consultants want the Congress to know how very pleased they are to be part of this important undertaking, and they wish to assure the Congress of their continuing commitment to its goals.

Sincerely yours,



David G. Nathan, M.D.
Chairman

CONSULTANTS TO THE COOLEY'S ANEMIA STUDY

David G. Nathan, M.D. (Chairman)
Robert A. Stranahan Professor of Pediatrics
Harvard Medical School
Chief, Division of Hematology and Oncology
Children's Hospital Medical Center
Pediatrician-in-Chief, Sidney Farber Cancer Center
Boston, Massachusetts

W. French Anderson, M.D.
Chief, Molecular Hematology Branch
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, Maryland

Joseph P. Giusti, Ph.D.
Associate Professor of Education
School of Education
Director, Beaver Campus
The Pennsylvania State University
Monaca, Pennsylvania

Joseph H. Graziano, Ph.D.
Assistant Professor of Pediatrics and Pharmacology
Cornell University Medical College
New York, New York

Rose M. Greenwood, R.N., B.S.N.
Head Nurse, Hematology Clinic
Children's Hospital of Michigan
Detroit, Michigan

George R. Honig, M.D., Ph.D.
Professor of Pediatrics
Northwestern University Medical School
Director, Division of Hematology
Children's Memorial Hospital
Chicago, Illinois

Howard A. Pearson, M.D.
Professor and Chairman
Department of Pediatrics
Yale University School of Medicine
Chief of Service
Yale-New Haven Hospital
New Haven, Connecticut

Peter T. Rowley, M.D.
Professor of Medicine, Pediatrics, Genetics and Microbiology
University of Rochester School of Medicine
Rochester, New York

Donald L. Rucknagel, M.D.
Professor of Human Genetics and Internal Medicine
University of Michigan School of Medicine
Ann Arbor, Michigan

Nancy J. Steficek, M.S.W.
Department of Social Work
Children's Hospital of Philadelphia
Philadelphia, Pennsylvania

Wolf W. Zuelzer, M.D.
Director, Division of Blood Diseases and Resources
Bethesda, Maryland

STAFF, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

John B. Dunbar, D.M.D., Dr.P.H.
Project Officer, PEC
Division of Blood Diseases and Resources

John B. Lyons, M.P.A.
Administrative Officer
Division of Blood Diseases and Resources

Thomas J. Thom
Statistician
Division of Heart and Vascular Disease

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INTRODUCTION

Thalassemia major, or Cooley's anemia, is a severe, inherited blood disorder seen largely in persons of Greek, Italian, and Oriental ancestry, and to a lesser extent, in Blacks and Jews. The disorder begins shortly after birth. The red blood cells that normally carry the pigment hemoglobin are destroyed by the body because the hemoglobin within each cell is inadequate. This inadequate production is the result of defective hemoglobin genes. The result is severe anemia, a life-long dependence on blood transfusion, and death usually before the third decade of life. In areas of the world, such as parts of Greece and Italy, where the abnormal gene frequency is high, the disease is a major drain on medical resources. Fortunately, the disease is not widely prevalent in the United States because there is sufficient outmarriage by members of the ethnic groups in which the Cooley's anemia gene is concentrated. Yet the disease is devastating to the patients and families who are afflicted.

In addition to the obvious motivation of biomedical research efforts to reduce human suffering, it is important to recognize how much this relatively small group of patients contributes to the knowledge of human biology and to innovative approaches to blood replacement therapy. Research in thalassemia has led to fundamental knowledge about the control of gene expression in man. This information is now being brought to bear in studies of several common disorders of abnormal gene function, including diabetes and cancer. The approaches to treatment of Cooley's anemia with blood transfusion and iron chelation therapy, and future considerations of gene replacement and bone marrow transplantation, all will contribute to understanding and treating more common, better known diseases. Thus,

a small group of patients with an unfortunate genetic abnormality provide medical investigators a vital resource for information that will one day be used to benefit the entire population. It is both appropriate and significant, therefore, to develop the means of optimal management for this group of patients who have contributed so much to the advance of medical science and to the public.

Organization of the Preliminary Report

The consultants have identified six tasks to be completed for the final report to the Congress of their study of Cooley's anemia. This preliminary report presents the status of each undertaking, some of which are in the data collection phase. Each task is described in a separate section of the report, as described below, except the sixth task which is to recommend to the Congress future approaches for research and care. An appendix presents a table of research support for Cooley's anemia.

- Task One: To review the state of the art of research in the field. A brief history of basic and clinical research describes scientific events that have led to the current understanding of the disease and that imply avenues for future investigation. In the final report, the research story will be further updated and documented.
- Task Two: To develop practical standards for clinical services. Comprehensive guidelines for all aspects of treatment are presented, based on current research. In the final report, if more definitive data are available, these standards will be updated.

- Task Three: To ascertain the dimensions of Cooley's anemia in the United States. Approaches are presented for determining the prevalence of the disease by direct enumeration and the frequency of the gene by estimation.
- Task Four: To survey facilities where Cooley's anemia is treated. The survey method is described that will be used to collect data about current standards of treatment in those facilities where most patients are cared for.
- Task Five: To study the impact of the disease on patients and their families. Those afflicted with Cooley's anemia suffer long-term social, psychological, and financial burdens. Interviews will be conducted to ascertain the dimensions of these sensitive issues.

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A REVIEW OF RESEARCH IN THE FIELD OF COOLEY'S ANEMIA

INTRODUCTION

Cooley's anemia and other disorders of hemoglobin synthesis have been studied in greater depth than any other genetic disease, and progress in research on these disorders is sufficiently advanced so that in time, it could yield practical applications.

Cooley's anemia (beta thalassemia) lends itself to fundamental investigation at the molecular level for three reasons. First, it is a disease of the red blood cells, and blood cells can be obtained easily from a patient. Second, the red blood cells make primarily one protein, hemoglobin, while most other cells synthesize many different proteins; thus, problems in the production of hemoglobin can be easily recognized and are not masked by the synthesis of other proteins. Third, the precursor red blood cell differentiates into a unique cell, the reticulocyte. This cell has lost its nucleus and is essentially a bag of protein-synthesizing machinery making the one product, hemoglobin. All other cells have a nucleus and are, therefore, much more complex to study. Many of the clues to the defective mechanism of protein synthesis in Cooley's anemia have come through the study of the reticulocyte in human blood.

Because the implications of research findings at the very basic molecular-genetic level are so vital and widespread, basic research on Cooley's anemia and related disorders has always been supported.

Since 1973, support for clinical research has begun to increase somewhat. During the past 20 years, research progress in the area has been so significant that science is now on the verge of even greater advances in basic research. With Cooley's anemia and related hemoglobin disorders, it may well be possible in the future to correct the gene defect and therefore to cure the disease, and not merely ameliorate the patient's condition. Many findings that have resulted from molecular research in this disease are so fundamental that they are applicable to research in other diseases. Therefore, continued research in Cooley's anemia is worthy of support on a scientific basis in addition to its importance as a fatal and tragic genetic disease with hardships on individuals and their families.

HISTORICAL DEVELOPMENT OF BASIC RESEARCH

Hemoglobin Background

Research on Cooley's anemia has drawn on the wealth of knowledge about the structure and function of hemoglobin and its biochemical characteristics. Hemoglobin is one of the best studied of all proteins and, therefore, more is understood about it than many other proteins; over 200 mutant hemoglobin types have been "sequenced" and studied functionally. This fundamental knowledge provides a great advantage to research in the field of thalassemia.

A second advantage in thalassemia research is that a good background of knowledge is available in hemoglobin genetics. The arrangement of the globin genes on the chromosomes and their crossover potentials have been described. Different genetic mechanisms of mutation can be correlated with different disease patterns.

The term "molecular disease" was first applied to hemoglobin disorders by Linus Pauling in the late 1940's in his study of sickle cell hemoglobin. The importance of Pauling's research was the concept that a change in the protein could produce a disease. Although sickle cell anemia differs from thalassemia in that the defect in the former is in the molecular structure of the hemoglobin molecule rather than in its amount, the concept stimulated others to begin thinking about thalassemia as a molecular disease.

Research in Cooley's Anemia

Characteristics of Cooley's Anemia. Thalassemia is characterized by a quantitative defect in the synthesis of the protein hemoglobin, although qualitatively, such hemoglobin as is synthesized is normal. The hemoglobin molecule is composed of two alpha and two beta chains and thalassemia is a defect in one of those chains. In beta thalassemia, the defect is in the beta chains. The homozygous form has either no beta or only a small amount of beta globin; the heterozygous form has about half the normal amount. Cooley's anemia, specifically, is the homozygous form of beta thalassemia. Children with this defect are unable to make their own blood cells in a useable form (i.e., with complete alpha and beta hemoglobin chains) and must receive transfusions from an early age on for the rest of their lives.

The clinical manifestations of Cooley's anemia can be understood in terms of the body's response to the deficiency of beta globin chains in the red blood cells. When the beta chains are insufficient, the alpha globin

precipitates within the cell into masses called inclusion bodies. The inclusion bodies make the red blood cells unstable and, as they pass through the circulatory system, they are identified as defective cells and are destroyed. This process compounds the disease state because not only is the amount of hemoglobin produced insufficient, but also the life of the red blood cell itself is greatly reduced. The bone marrow is constantly producing new red blood cells to replace the destroyed cells, but these new cells are removed sooner than normal. Consequently, children with Cooley's anemia have serious bone defects in which bones are abnormally large and weak from the expanded, hyperactive marrow. For example, a patient's face may develop a mongoloid appearance.

An important advance in research was the development of a method for measuring the amounts of alpha and beta globin chains made in the red blood cell. This was achieved in the late 1950's with the development of the technique of carboxymethyl cellulose chromatography. Whole blood (which contains the reticulocytes) from a patient is incubated with a radioactive amino acid. The radioactivity is incorporated into the hemoglobin that is made in the reticulocytes, and the total number of globin chains can be determined by the chromatography technique. This method demonstrated the insufficient amount of beta globin chains in Cooley's anemia and it became clear that the defect in this disease must be in the regulatory mechanisms that control the amount of hemoglobin synthesis rather than in the structure of the hemoglobin protein itself.

This hypothesis that Cooley's anemia is a regulatory mutation has become a classic model and it has stimulated considerable thought about the mechanism of other genetic diseases.

Advances in Cooley's Anemia Research Through Molecular Biology

Early Work. After the measurement of alpha and beta globins, the first major breakthrough in Cooley's anemia research occurred in the mid 1960's when thalassemic material was first used in molecular biology studies. Reticulocytes from normal and thalassemic patients were fractionated into ribosomes and a supernatant of all other components. The thalassemic ribosomes were incubated with the normal supernatant and the normal ribosomes with the thalassemic supernatant. These experiments demonstrated that the defect in thalassemia is in the polysome fraction. At that time, messenger RNA had not yet been isolated from the ribosomes.

Cell-free Protein Synthesizing Systems. A second breakthrough in basic science was made in the late 1960's when cell-free systems were developed for synthesizing new and complete hemoglobin protein outside the cell. Previous research had established methods for isolating and fractionating the cell, but new protein could not be synthesized in a cell-free system in a test tube. The key to synthesizing new protein was isolating stable protein initiation factors from intact cells and using them in the cell-free system. With an active cell-free protein synthesizing system it was possible to synthesize enough new protein to demonstrate the defect. Protein initiation factors were added to thalassemic ribosomes to reproduce exactly what the intact cell would do, that is, the alpha chains were made in normal amounts but the number of beta chains was very low. This cell-free system, first used for Cooley's anemia, has since been applied to the study of a number of human proteins.

Messenger RNA. The first messenger RNA isolated was for hemoglobin in mouse and rabbits. The first human messenger RNA, a milestone in

research, was obtained from a patient with Cooley's anemia: isolated messenger RNA from human thalassemic cells was introduced into cell-free protein synthesizing systems and the molecular defect in Cooley's anemia was exactly reproduced. This proved that the defect is in the messenger RNA. That discovery has led to the finding of messenger RNA for a whole range of human and animal proteins, for example, collagen, albumin, lens crystallin, and preparathyroid.

Complementary DNA (cDNA): A Genetic Probe for mRNA and DNA. Knowing that the defect is in the mRNA, researchers next had to quantify mRNA and determine if the defect is in the amount of mRNA. That was accomplished by obtaining a probe (complementary DNA) which could exactly recognize the mRNA. Complementary DNA is made by synthesizing the exact complement of the mRNA. This is done by incubating mRNA with a specific enzyme (RNA-directed DNA polymerase), which makes the cDNA from simple substrates. By using cDNA it was possible to demonstrate that the most common form of Cooley's anemia had too little beta globin mRNA and that this deficiency, therefore, is the molecular cause of the disease. The cDNA technique was also used to map the hemoglobin genes on the human chromosomes: the alpha globin gene is on chromosome 16 and the beta globin gene on 11. In alpha thalassemia the alpha globin gene is deleted; in beta thalassemia, Cooley's anemia, the gene is present but the beta globin mRNA is not made.

Complementary DNA was first obtained for studying globin and was first applied to thalassemia; now the technique is being used in many areas of genetic research. So far, thalassemia is the only human disease whose cause is established to be a regulatory mutation; undoubtedly, however, many other genetic diseases are caused by regulatory mutations.

The techniques and results obtained from thalassemia research are being used to study a wide range of genetic syndromes.

Recombinant DNA. Cloning of mammalian genes was a major breakthrough with wide-ranging implications and is now being applied to Cooley's anemia research. Mouse and rabbit hemoglobin genes were among the first to be cloned by the new techniques of recombinant DNA, and globin genes were the first human genes to be cloned. At present, the NIH Guidelines for Recombinant DNA Research have put severe limitations on human gene research and work has been greatly slowed. Nonetheless, the potential benefit for patients is very high.

Already, normal human alpha, beta, and gamma globin genes are being sequenced to determine their exact structure; and, once that is achieved, the DNA of patients with thalassemia can be sequenced and compared with the normal sequences for the globin genes. In this way it should be possible to determine the precise nature of the mutations that produce the disease. With this knowledge, it might very well be possible to construct a "corrected" gene which could be given to a patient and thus cure the basic genetic defect.

Hemoglobin Gene Switching

An area of research that is potentially important in preventing or reversing Cooley's anemia and other diseases involving hemoglobin, but which has little knowledge accumulated to proceed from, is the hemoglobin gene switching that occurs at the birth of an infant. While in utero, the fetus has blood whose hemoglobin is composed primarily of gamma chains rather than beta chains. At birth there is a switch to

the gene that makes adult hemoglobin (with beta chains). The adult can use fetal hemoglobin almost as efficiently as normal adult hemoglobin.

If scientists could understand the mechanism that causes the switching, they might also be able to develop a technique for (1) intervening and preventing the switch or (2) reversing the switch once it has occurred. The basic mechanism of how the gene switching occurs is not yet known; however, study is underway on animal models.

FUTURE APPROACHES IN BASIC RESEARCH TO THE PROBLEMS OF COOLEY'S ANEMIA

Gene Replacement Therapy

Research in recombinant DNA has brought scientists to the verge of understanding the mechanisms which ultimately may make gene replacement therapy possible. Understanding gene expression in animals and humans is prerequisite to accomplishing this goal. It will probably be necessary to identify and understand the controlling regions of DNA and the regulatory factors that control the rate, amount, and type of transcription that occur in the cell. At present, neither the controlling regions of the DNA nor the regulatory factors are identified; however, once they are identified, cell-free (and intact cell) systems for studying the control of mRNA synthesis can be developed.

A reasonable sequence of research advances that might ultimately lead to gene replacement therapy is as follows. First, the normal globin gene with the correct controlling regions linked to it would be obtained by molecular cloning techniques. To this normal gene would be attached the correct sequences which would allow the gene to insert itself into the correct place in the genome. Once the globin gene with controlling regions and insertion sequences was available, animals with thalassemia

would be treated with the controlled gene. If the animals were cured, they and their offspring would be followed to be certain that no detrimental side effects result. After successful animal treatment, the final step would be genetic engineering in human patients.

Replacement of Adult Hemoglobin with Fetal Hemoglobin

Theoretically, adult hemoglobin could be replaced by gene switching or by infusing or transplanting marrow cells. Both areas require extensive fundamental research. The development of the erythroid cell must be understood; that is, its evolution from a stem cell to a mature red blood cell through the action of erythropoietin (and possibly other hormones) must be explained. Erythropoietin is the hormone that stimulates the production of red blood cells. Successful gene switching should be accomplished first in cell culture, next in appropriate animal models, and finally in human patients.

For bone marrow transplantation to be feasible in a patient with thalassemia or a hemoglobin disorder, scientists must understand the immune mechanisms that would allow transplanting normal bone marrow stem cells reliably without incurring the problem of graft versus host reactions.

Reduction of Hemolysis

In Cooley's anemia, the inclusion bodies of the alpha globin and the subsequent destruction, or hemolysis, of blood cells result from the fact that there is more alpha than beta globin. If the imbalance between these two could be eliminated, either by reducing the alpha globin or increasing the beta globin, the cells should survive for a full 120 days and the blood-producing system would compensate for any deficiency of

hemoglobin by making enough cells to bring the oxygen-carrying capactiy of the blood up to normal. Conceivably, a drug might be developed that would ameliorate the imbalance. Another possibility is proteolysis of the excess alpha globin chains. If there were a specific enzyme, for example, that could be activated to dissolve the alpha inclusions, an effective treatment might follow.

CLINICAL RESEARCH IN COOLEY'S ANEMIA

In 1925 Cooley identified the syndrome that defines Cooley's anemia. Blood transfusions were given to babies with Cooley's anemia, and they survived. These were the beginnings of treatment for the disease and of improved therapy through clinical research.

Transfusions

Blood transfusions every two to six weeks has been the standard therapy for Cooley's anemia. The transfusions provide normal blood, composed of cells with ages from 1 to 120 days. As the youngest blood cells grow old and die, new cells must be transfused into the system. Unfortunately, blood transfusions are accompanied by iron. Thus, this survival therapy is complicated by iron buildup which eventually destroys the body's organs and results in death.

Clinical research, therefore, has focused on the type of transfusion regimen that is best for the patient. Until the late 1960's, patients were usually put on a low regimen of transfusion. Whereas hemoglobin levels in normal pre-adolescent children are in the range of 11-13 gm/dl, in Cooley's anemia patients hemoglobin was transfused only up to 9 or 10 gm/dl and then

allowed to drop to 5, 6, or 7 gm/dl. The side effects of this regimen were physical weakness, hyperactive bone marrow, and an attempt by the body to get more iron by absorption from the gastrointestinal tract.

During the late 1950's and the 1960's, a "hypertransfusion" regimen was tried in which hemoglobin was raised to 12 to 14 gm/dl and allowed to drop only to 8, 9, or 10 gm/dl before it was replaced. In this way, the body's stimulus to keep the bone marrow active is greatly reduced. The result is a marked improvement in general well-being, physical strength, growth, and normal bone structure. By the early 1970's, the data were solid enough to convince clinicians of the effectiveness of the hypertransfusion regimen. Currently, a "supertransfusion" regimen in which the hemoglobin is never allowed to drop below 12 is being evaluated. With the hemoglobin always maintained in the normal range, the bone marrow is almost completely inactive.

Other improvements have been made in blood transfusions in general--frozen blood, packed cells, washed cells low in white blood cells to reduce transfusion reactions, and other techniques to reduce reactions to blood transfusions. Current research projects are aimed at providing transfusions with only young red blood cells which have a relatively long survival in the body.

Iron Chelation

After the use of blood transfusions, the next major breakthrough in clinical research was the development of iron chelation therapy. The drug desferrioxamine extracts excess iron from the body. Desferrioxamine was not widely used because it is expensive and is administered daily and intramuscularly (a painful injection), and because doses were not high enough to draw out large amounts of iron. As a direct result of the Cooley's Anemia Control Act of 1972, however, research in iron chelation

therapy was intensified. Not only was the use of desferrioxamine re-evaluated but also a major push was initiated to develop new, more effective iron chelators. It soon became clear that high doses of desferrioxamine could be given intramuscularly and that this dosage resulted in significant excretion of excess iron. In 1977 the Food and Drug Administration approved relabelling desferrioxamine to allow its use for the removal of iron in chronically iron-overloaded patients. However, desferrioxamine is active in the blood for only an hour or two; therefore, by administering it subcutaneously over the entire day by means of a small, light, portable pump, the effectiveness of a given dose of desferrioxamine can be greatly increased. Efforts are now underway to obtain the Food and Drug Administration's approval for subcutaneous administration of the drug. The goal now is to develop either an oral drug or an iron chelator that can be stored in a depot from which a supply will be diffused over a long period of time without injections.

An adjunct to the increased research effort in iron chelation therapy is the increased interest in iron metabolism. A clearer understanding of absorption, storage, and mobilization of iron may provide the knowledge needed for new agents.

Clinical Management

In patients with Cooley's anemia, the spleen enlarges enormously and eventually must be removed. Definitive guidelines for splenectomy, based on transfusion requirements, have now been developed. After splenectomy, patients have an increased susceptibility for serious infections. To eliminate these risks, effective vaccines continue to be sought. A pneumococcal vaccine already is available.

A major problem for patients with Cooley's anemia is cardiac dysfuction due to iron overload. New diagnostic techniques such as echocardiography are currently being used to monitor cardiac function more accurately.

Screening and Counseling Techniques

Improved techniques for screening populations for Cooley's anemia and its traits have been developed. In addition, methods of counseling patients and their families have improved.

Prenatal Diagnosis

Prenatal diagnosis of Cooley's anemia can now be accomplished by incubating fetal blood cells obtained by amniocentesis with labelled amino acids and then separating the labelled globin chains by carboxymethyl cellulose chromatography. New and more effective methods are being sought; the goal is to detect the expression of globin genes in amniotic cells in tissue culture. It might be possible to predict the type and degree of hemoglobin abnormality that the unborn patient will incur by examining the globin genes in his amniotic cells.

FUTURE APPROACHES IN CLINICAL RESEARCH

Clinical research should continue in all the directions discussed above: an oral iron chelator or a depot agent should be developed; improved blood transfusion techniques and blood products to reduce or replace transfusions should be developed--for example, therapy might consist of an oxygen-carrying product and iron-rich transfusions could be reduced; research should proceed into the feasibility of transplanting bone marrow; and prenatal diagnosis and screening techniques should be improved.

STANDARDS FOR CLINICAL CARE

INTRODUCTION

The quality of life and the life span of patients with Cooley's anemia are greatly influenced by the quality of clinical care administered. Some standards for clinical care for patients with Cooley's anemia have been established through research and experience; others are in a formative phase, requiring more time and research to prove or disprove their validity. In their final report to Congress, the consultants for the Cooley's anemia study plan to describe acceptable standards for high-quality care, based on a review of the most recent data and developments. Meanwhile, summarized below are those standards generally accepted by specialists in the field, though not necessarily practiced everywhere.

STANDARDS FOR THERAPY

Standards for appropriate transfusion criteria, need for removal of the spleen, chelation therapy, and other aspects of therapy are summarized in the following sections. For more extensive background details, two recent review articles are available.[1-2]

Hemoglobin Concentration

Adequate blood transfusion therapy produces the following benefits in patients with Cooley's anemia:[1-4]

- Reduced erythroid expansion of the bone marrow, thereby preventing the facial deformities otherwise associated with the disease.

- Thickening of the bone cortex, which reduces the incidence of broken bones.
- Improved growth and development.
- A subjective sense of general well-being.
- A normal level of activity.
- Delayed onset of hypersplenism with the corresponding need for removal of the spleen.

Because patients with Cooley's anemia usually die of complications of iron-overload, clinicians have been reluctant to "hypertransfuse," that is, to maintain hemoglobin levels in a normal to near-normal range. However, evidence dates back to 1964 that hypertransfusion significantly benefits patients with Cooley's anemia, and it is now generally agreed that the pretransfusion hemoglobin concentration should not be allowed to fall below 10 gm/dl.[1-4] Besides the benefits listed above, maintaining hemoglobin above 10 grams seems to reduce absorption of iron from the intestinal tract. Compared to earlier, low transfusion regimens, maintaining hemoglobin levels above 10 gm/dl does not significantly increase the iron-overload, but it does susbstantially improve the patient's quality of life.

Indications for Splenectomy

The spleen appears to function as a sink for excess iron, thereby preventing early damage to the liver, and should be left intact as long as possible. Hypertransfusion therapy delays the development of hypersplenism (a condition in which the spleen destroys blood cells and becomes enlarged)

and the need for removing the spleen; however, when hypersplenism does occur, the spleen should be removed.

The "transfusion quotient," which is the patient's observed blood consumption (ml/kg/yr) divided by the expected blood consumption for the transfusion scheme, expresses the increase in blood requirement due to the presence of the spleen. An increase in the transfusion quotient is good evidence of hypersplenism even in patients who have no other clinical signs of hypersplenism. Another criterion for removing the spleen is an increased need for more frequent transfusions.

Patients with Cooley's anemia have an enhanced risk of fatal infection after splenectomy,[5] caused by streptococci, pneumococci, or Haemophilius influenzae type B. One approved pneumococcal vaccine is now available that seems effective in children two years old or older; it is recommended for children who have had splenectomies. It is not known if the antibiotics used prophylactically in the past will be necessary after use of the pneumococcal vaccine.

Chelation Therapy

The long-term trials of desferrioxamine (Desferal(R), Ciba-Geigy) have shown that daily intramuscular injections of desferrioxamine in conjunction with an intravenous injection of desferrioxamine at the time of transfusion significantly reduce the incidence of certain secondary complications of iron-overload;[6] however, there is no definitive evidence that the lethal cardiac consequences of iron-overload can be prevented by intramuscular desferrioxamine.

Desferrioxamine administered subcutaneously by a pump is currently being tested; preliminary reports indicate that it may be more effective than the intramuscular desferrioxamine,[7,8] but more investigation is needed before conclusions can be drawn.

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Though the only effective drug now available and approved by the Food and Drug Administration, desferrioxamine is considered by the consultants to be a temporary approach because (1) the cost* is high and constitutes a heavy financial burden to most afflicted families, (2) administering the drug is time-consuming and painful for the patient, and (3) the psychological effects can be severe. Ultimately, the goal is to develop an oral drug that would eliminate the physical and emotional hardships of chelation therapy and would reduce the cost. Pending further developments, desferrioxamine is part of the total therapy recommended.

Vitamin Supplementation

Patients with iron-overload use large amounts of vitamin C because of iron-catalyzed oxidation of the vitamin. The finding that vitamin C supplementation for patients with ascorbate-depleted iron-overload increases the iron excretion effect of desferrioxamine[9,10] has led to widespread use of the vitamin (500-1000 mg/day) for patients with Cooley's anemia. However, ascorbic acid in high doses is potentially toxic in patients with iron-overload,[11,12] and cardiac arrhythmias have been associated with the administration of 500-1000 mg/day.[13,14] In one study, patients maintained on a daily multivitamin with only 100 mg of vitamin C showed no signs of ascorbate depletion, and response to desferrioxamine was good; therefore, there may be no reason for using higher doses of vitamin C. Under no circumstances should patients with iron-overload receive high doses of ascorbic acid without chelation therapy.

*Chelation therapy costs at least several thousand dollars a year; the cost of the drug is in addition to the cost of clinical personnel required to administer the drug.

Good nutrition through a balanced diet adequate in all vitamins should be encouraged. Folic acid supplementation is probably not necessary if a hypertransfusion regimen is used. Any form of iron supplement should be strictly avoided by patients with Cooley's anemia.

Periodic Examination of Patients with Cooley's Anemia

A patient with a chronic disease and on long-term therapy should receive a thorough examination periodically. Particularly since patients with Cooley's anemia suffer serious cardiac, endocrine, and hepatic complications because of the accumulation of iron in those tissues, the examination should include tests for cardiac, pancreatic, and hepatic functions to detect the secondary complications of Cooley's anemia. Most patients eventually develop heart conditions, often compounded by diabetes mellitus, adrenal insufficiency, and liver failure. Most of these patients ultimately die of chronic congestive cardiac failure.

Psychological and Psychiatric Support

Cooley's anemia, like other chronic life-threatening illnesses, produces serious psychological burdens for the afflicted child, the parents, and the siblings. Blood transfusions every two to four weeks throughout life remind families of the frailty of the child's life. Consequently, the child is often overprotected. The responses of the child and the family to the disease often include denial, anxiety, anger, guilt, self-doubt, depression, and fear of death.(15)

Such responses may be reduced by supportive therapy. The physician should straightforwardly discuss the diagnosis and complications as they arise. Group discussions among the physician and several families of afflicted children may help improve the patient's ability to cope.

Specialized psychological or psychiatric assistance is sometimes required not only for the child but also for other family members.

The emotional hardship to the family is often complicated by the financial burden of constant medical attention. The financial aspect of the problem is becoming more important now that effective chelation therapy is available but may be financially inaccessible to most families.

STANDARDS FOR SERVICES

Although the primary genetic defect in Cooley's anemia involves the blood, the secondary problems associated with the disease encompass a wide range of medical and social disciplines. The provision of blood transfusions is only one step in therapy; Cooley's anemia requires specialized, comprehensive care from a variety of trained personnel.

Facilities should be available to provide appropriate diagnostic testing for Cooley's anemia and for the trait. Families at risk should be informed of the possibility of receiving prenatal testing for the presence of Cooley's anemia. Those families wanting this option should be referred to a center where the procedure is done.

Once the disease is diagnosed, comprehensive care ideally should be provided by a single physician. If the primary physician is not personally familiar with the complex issues of Cooley's anemia and its therapy, he or she should be able to consult with a pediatric or an adult hematologist who is familiar with all aspects of the disease. The primary care physician should also have access to specialists in cardiology and endocrinology because of the life-threatening complications of Cooley's anemia in these areas. The physician should either be capable of providing genetic counseling or should refer the family for consultation. The primary physician

should be located near the home of the patient to facilitate regular and emergency visits.

Other professionals may be required for orthopedic, orthodontic, and surgical problems. Often, too, psychological or psychiatric support will be needed by the afflicted child or family members and specialized assistance from a social worker may be required to help the family deal with the financial burden.

Patients requiring repeated blood transfusions are at risk of serious, sometimes fatal, reactions. It is essential, therefore, that good blood banking services and facilities be available that are capable of furnishing such special preparations as may be needed. For example, the availability of frozen, washed, red blood cells is important in the management of such patients. Because insurance coverage frequently does not pay for out-patient costs, some hospitals admit patients for blood transfusions. Health-related costs would be reduced by the recognition of this disease as a special entity which can be dealt with on a "day-hospital" basis.

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STATUS REPORT ON THE TASK TO ASCERTAIN THE DIMENSIONS OF COOLEY'S ANEMIA IN THE UNITED STATES

Frequencies of the thalassemia trait in certain other countries are of interest to the consultants because they provide an upper limit for frequencies likely to be encountered in the United States. The following table lists estimates of the percentage of persons by country having the trait (thalassemia minor or the heterozygous state):

Frequency of Beta Thalassemia Heterozygotes in Selected Countries

Country	Percentage	Reference
Italy		
Sicily	4.2	1
Rome	2.3	2
Ferrara	20.0	2
Greece	7.7	3
Peloponnesus	6.6	3
Cyprus	0-10.6	4
Turkey	1.7	5
China	3.0	6
Thailand	3.0	7
India		
Bengal	4.0	6

Trait frequencies in corresponding ethnic groups in this country would be smaller because of gene dilution over time through outmarriage.

Cooley's anemia occurs in one-fourth of children born to parents who both have the trait. Thus, the condition is comparatively rare. In addition, as already noted, its occurrence is limited to certain ethnic populations. Also, families and individuals belonging to these at-risk

ethnic groups live in all parts of the nation, and their numbers vary greatly from one location to another. This particular combination of demographic features complicates the estimation process. As a result, Cooley's anemia does not lend itself to standard sampling and estimating techniques.

Even though a precise measure of the condition's occurrence would be extremely difficult to establish, the consultants are developing an approach which they believe will provide an adequate and useful estimate. Because Cooley's anemia is such a severe disorder, it is not likely to go undiagnosed; furthermore, afflicted children require not only constant medical care but also a kind of specialized attention available in major pediatric hematology treatment centers. Because the great majority of Cooley's anemia patients are receiving care in such facilities, it is anticipated that a direct survey of the centers will provide a good estimate of the overall magnitude of the problem. Additional methods have been chosen to supplement and validate this primary method.

The overall strategy can be summarized as follows:

1. Direct survey

   a. As noted above, the principal approach will be a direct survey of major pediatric hematology treatment centers.

   b. A survey of practicing pediatricians and hematologists has been undertaken to identify those few patients not being treated in major centers.

   c. Another measure is the number of deaths recorded by the National

Center for Health Statistics. The consultants will derive mortality data from these records for the past five years. Unfortunately the records may not always reflect Cooley's anemia as cause of death. A secondary complication, such as cardiac failure, may be reported as the immediate cause. Therefore, these numbers may underestimate the mortality.

2. Indirect calculation

To provide a check on the direct approach, existing data on the trait frequency (heterozygous state) established for known ethnic populations in this country can be used. By making certain statistical assumptions, the occurrence of Cooley's anemia (homozygous state) can be calculated and the result applied to national ethnic population totals.

3. A sentinel state

To further assess the possibility of error in the direct surveys, the consultants are contemplating the in-depth study of one state, such as Pennsylvania. Acording to the 1970 decennial census, Pennsylvanians of Italian ancestry constituted approximately 10% of Italian-Americans estimated for the nation overall. Over 5% of people of Greek ancestry, according to the same source, were residents of that state. Two approaches are under discussion: (1) Appropriate records of third-party payers could be assessed to learn the number of affected individuals. (2) The consultants also plan to establish contact with hospitals providing primary and secondary care levels as well as those providing the entire range of specialized medical services (tertiary care level). In some instances, it

will be necessary to seek the help of hospital medical staff to assure that only Cooley's anemia, not thalassemia minor, is recorded.

Two uses would be made of the state data: They would be compared to those of the direct surveys for that state to ascertain whether approximately the same number of patients were detected by both surveys, and the number of cases would then be statistically compared to the number of persons of Italian and Greek ancestry counted in the 1970 census. An estimate of the total number of persons with Cooley's anemia could then be extrapolated to the national census figures. Admittedly, a number of assumptions are implicit in this approach, but it is a possible means of circumventing the complicated statistical problem of defining ethnic ancestry.

The consultants believe that these approaches, taken together, will provide them with data of an order of magnitude consistent with the task goals. They are confident that the results will provide a sound basis for analysis and for their subsequent recommendations to the Congress.

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STATUS REPORT ON THE TASK TO SURVEY TREATMENT FACILITIES

The consultants have undertaken the task to survey facilities used by patients with Cooley's anemia for treatment and to develop a critique of those facilities with recommendations for improvements.

The specific elements of the treatment facilities to be examined include the following:

1. The number of trained personnel available and their level of training and experience.
2. The availability and quality of appropriate diagnostic services.
3. The forms of treatment used, their accessibility to the patient, and the extent to which the total health care needs of the patient are being met.
4. The availability of blood and blood components that are required for care of the Cooley's anemia patient.
5. The sources of financial support for the Cooley's anemia treatment program.
6. The relationship, if any, of clinical and nonclinical research to the patient care program.

A data collection instrument is currently being designed. It will be directed to individuals with principal responsibility for treatment programs at facilities used by patients with Cooley's anemia. The instrument

will be designed to assess the nature and quality of services provided to Cooley's anemia patients in a variety of different treatment settings, ranging from large university and hospital settings to small out-patient settings. Completion of the questionnaire may involve a search of patient records. Thus the determination of the designated respondent in each facility will be an especially important aspect of the study design.

Experts in survey methods will assist in designing and conducting the study. They will design the structure and format of the survey instrument in a manner that will ensure that questions will be understood, will be easily tabulated and analyzed, and will not constitute an undue burden of time on facilities staff. The primary responsibility for the substantive content of the instrument will necessarily lie with the consultants.

When the data from this survey have been collected and tabulated, the consultants will review them as a basis for recommendations to the Congress.

STATUS REPORT ON THE TASK TO STUDY IMPACT ON PATIENTS AND FAMILIES

To determine the impact of Cooley's anemia on patients and their families, the consultants will conduct a study of a sample of families of patients with Cooley's anemia with respect to four areas: financial, social, educational, and psychological. Each aspect potentially has a direct effect on the patient's medical course. Data will be collected by means of a questionnaire designed for a personal interview with a parent or guardian of the patient with Cooley's anemia. The length of the interview is not expected to exceed 30 minutes. The approval of hospital clinical investigation committees will be gained before the questionnaire is administered.

Survey design experts are working with the consultants to specify the topics to be included in the interview. Aspects being considered tentatively include the following:

1. Identifying Information: Family composition; socioeconomic status including occupational data; religion; and ethnic origin.
2. Financial Impact: Assessment of overall cost involved for the family of a patient with Cooley's anemia; medical insurance coverage; and availability of and need for federal, state, and local aid.
3. Social/Psychological Impact: Effects on psychological quality of life including effects on marital and family relationships;

effects on patient's development of interpersonal skills, such as peer relationships, and educational progress.

4. Treatment Facilities: Availability of facilities and parents' evaluation of treatment facilities.

5. Availability of Additional Support Systems: Investigation of the availability and perceived value of various sources of information about Cooley's anemia, including physicians, other parents of Cooley's patients, and literature; respondents' views about what other sources of information, counseling, or other forms of support should be made available.

The questionnaire will be pretested in a major metropolitan area. During the pretest, all field procedures and field materials will be tested, and interviewers will uncover subtle problems, particularly with question wording, parents' willingness to respond, and respondents' reactions to the interview situation. The pretest evaluation results will be used to resolve potential problems.

Assistance will also be sought from survey methods experts in conducting the interviews. Once the information has been received and tabulated, the consultants will interpret the results in the form of recommendations to the Congress.

APPENDIX

NATIONAL INSTITUTES OF HEALTH SUPPORT OF RESEARCH RELATING TO COOLEY'S ANEMIA IN FISCAL YEAR 1977

National Institutes of Health		Amount Encumbered[1] (thousands of dollars)
National Heart, Lung, and Blood Institute		$3,751[2]
Intramural	$2,048[2]	
Extramural	1,703	
National Institute of Arthritis, Metabolism, and Digestive Diseases		3,496[3]
National Institute of General Medical Sciences		611
National Institute of Allergy and Infectious Diseases		50
TOTAL		$7,908

[1] Figures include both direct and indirect costs.

[2] Figures include $100,000 set aside for the study of Cooley's anemia begun in FY 1978.

[3] Figure includes $35,000 estimated support for an intramural project aimed at developing a new technique for early diagnosis of Cooley's anemia.

EXTRAMURAL RESEARCH PROJECTS RELATING TO COOLEY'S ANEMIA

SUPPORTED BY THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE IN FISCAL YEAR 1977

HEMOGLOBIN

Project Number	Principal Investigator	Institution	Title of Project	Amount Encumbered ($1,000's)
RO1 HL 02558-20	Walter A. Schroeder	California Institute of Technology	Structure-Function Relationships in the Heme Proteins	$122
RO1 HL 02799-20	Samuel Charache	Johns Hopkins University	Study of Abnormal Hemoglobins	151
RO1 HL 0516816-16	Titus Huisman	Medical College of Georgia	Inhomogeneity of Hemoglobin Types	131
RO1 HL 05791-17	Ruth E. Benesch	Columbia University	Structure and Function of Hemoglobins	43
RO1 HL 15026-11	Kirby D. Smith	Johns Hopkins University	Quantitative Control of Protein Synthesis	73
RO1 HL 16654-05	Thomas G. Gabuzda	Lankenau Hospital, Philadelphia	Regulation in Developing Erythroid Cells	63
RO1 HL 16927-04	Franklin H. Bunn	Peter Bent Brigham Hospital	Structure and Function of Normal & Abnormal Hemoglobin	95
RO1 HL 17710-03	Corrado Baglioni	State University of New York, Albany	Selective Replication of Hemoglobin Genes	81
RO1 HL 20074-01	Walter G. Niehaus	Virginia Polytechnic Institute	Structure and Function of Amidinated Human Hemoglobin	39
RO1 HL 20905-01	David J. Weatherall	Radcliffe Infirmary, Oxford, England	Synthesis of Fetal Hemoglobin in Human Erythroid Cells	$ 56

(THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE - Continued)

HEMOGLOBIN

Project Number	Principal Investigator	Institution	Title of Project	Amount Encumbered ($1,000's)
RO1 HL 20912-01	Raymond A. Popp	Oakridge National Laboratory	Control of Non-A-Chain Synthesis in Thalassemic Mice	$ 57
RO1 HL 20922-01	Bernard G. Forget	Yale University	Control of Human Fetal Hemoglobin Synthesis	56
RO1 HL 20928-01	Lee-Nien Chan	University of Connecticut	Regulation of Hemoglobin Synthesis in Chick Embryos	56
RO1 HL 20939-01	John Lee	University of of Texas	Regulation of Fetal Hemoglobin Synthesis in Humans	30
R23 HL 21438-01	Stuart H. Orkin	Children's Hospital Medical Center, Boston	Expression of Human Globin in Thalassemia	30
RO1 HL 21831-04	Winston A. Salser	University of California, Los Angeles	Determining Sequences for Hemoglobin Messenger RNA	71
RO1 HL 18163-03	Bernard Goldstein	New York University	Red Cell Membrane Effects Due to Oxidizing Agents	$ 12*

*This figure is only that part of the total project award judged to be directly related to Cooley's anemia.

(THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE - Continued)

IRON

Project Number	Principal Investigator	Institution	Title of Project	Amount Encumbered (1,000's)
R01 HL 06242-17	Clement A. Finch	University of Washington	Kinetic Studies of the Blood	$ 35*
R01 HL 11511-09	Irving Listowsky	Albert Einstein College of Medicine	Structure of Ferritin and Its Role in Iron Metabolism	22*
R01 HL 20141-01	Daniel C. Harris	University of California, Davis	Biochemical Approaches to Management of Iron Overload	40

Note: All the following five programs are concerned with research aimed at improving the clinical management of Cooley's anemia. The overall effort was undertaken upon the initiative of the National Heart, Lung, and Blood Institute.

R01 HL 19898-02	Denis R. Miller	Cornell University	-	94
R01 HL 19946-02	Sergio Piomelli	New York University	-	58
R01 HL 19961-02	Howard A. Pearson	Yale University	-	94
R01 HL 20000-02	David G. Nathan	Children's Hospital, Boston	-	86
R01 HL 20016-02	Anthony Cerami	Rockefeller University	-	$108

*This figure is only that part of the total project award judged to be directly related to Cooley's anemia.

EXTRAMURAL RESEARCH PROJECTS RELATING TO COOLEY'S ANEMIA

SUPPORTED BY THE NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES IN FISCAL YEAR 1977

HEMOGLOBIN

Project Number	Principal Investigator	Institution	Title of Project	Amount Encumbered ($1,000's)
2 RO1 AM 00780-27	Rose G. Schneider	University of Texas, Galveston	Hemoglobin Variants in Relation to Disease	$ 71
2 RO1 AM 08154-13	John F. Bertles	St. Luke's Hospital Center, New York City	Genetic Control of Hemoglobin Synthesis	101
2 RO1 AM 09274-13	Sergio Piomelli	New York University	Mechanism of Red Cell Aging-Hemolytic Anemias	86
2 RO1 AM 09805-10	Prawase Wasi	Mahidol University, Bangkok, Thailand	Thalassemias, Hemoglobinopathies and Related Problems	20
5 RO1 AM 12401-11	Ronald F. Rieder	State University of New York, Brooklyn	Protein Synthesis in Erythroid Precursors	96
5 RO1 AM 13431-11	Edward R. Burka	Jefferson Medical College	Mechanisms in Hemoglobin Synthesis and Destruction	97
5 RO1 AM 13532-09	Michael L. Freedman	New York University	Control of Polyribosomes in Human Reticulocytes	43
5 RO1 AM 13983-08	Haig H. Kazazian, Jr.	Johns Hopkins University	The Genetic Control of Hemoglobin	87
2 RO1 AM 14923-06	Michael D. Garrick	State University of New York, Buffalo	Studies on Hemoglobin: Biosynthesis and Genetics	60
2 RO1 AM 153222-12	David G. Nathan	Children's Hospital, Boston	Lysis of Red Cells by Hemoglobin and Membrane Disease	$198

(THE NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES - Continued)

HEMOGLOBIN

Project Number	Principal Investigator	Institution	Title of Project	Amount Encumbered ($1,000's)
5 R01 AM 15770-09	Fumito C. Taketa	Medical College of Wisconsin, Milwaukee	Structure and Function of Hemoglobin	$ 48
5 R01 AM 16272-06	Irving M. London	Massachusetts Institute of Technology	Regulation of Hemoglobin Synthesis and Hematopoiesis	114
5 R01 AM 16666-05	Yuet W. Kan	University of California, San Francisco	Study of Abnormal Hemoglobin Synthesis	109
2 R01 AM 16691-06	Elias Schwartz	Children's Hospital, Philadelphia	Heme and Globin Synthesis in Infants and Children	93
3 R01 AM 16846-03S1	Albert S. Braverman	New York Medical College	Beta Thalassemia: Excess Alpha Chain Kinetics	35
5 R01 AM 16847-05	Peter T. Rowley	University of Rochester	Control of Hemoglobin Synthesis	60
5 R01 AM 17348-05	Helen M. Ranney	University of California, San Diego	Studies of the Properties of Hemoglobin	119
2 R01 AM 17850-04	Richard T. Jones	University of Oregon	Hemoglobin: Structure, Function, and Genetic Control	85
5 R01 AM 18065-03	Phillip Pulsinelli	University of Pittsburgh	Structural Basis of Regulatory Function in Hemoglobin	55
5 R01 AM 18507-02	Arthur L. Beaudet	Baylor College of Medicine	Regulation of Hemoglobin Biosynthesis	$ 35

HEMOGLOBIN

Project Number	Principal Investigator	Institution	Title of Project	Amount Encumbered ($1,000's)
2 R01 AM 19046-02	George Honig	Children's Memorial Hospital, Chicago	Regulation of Hemoglobin Synthesis	$ 58
5 R01 AM 19482-02	Bernard G. Forget	Yale University	Molecular Biology of Human Hemoglobin Synthesis	108
1 R01 AM 20119-01	Jerry B. Lingrel	University of Cincinnati	Mechanism of the Switch from Fetal to Adult Hemoglobin	66
1 R01 AM 20120-01	Oliver Smithies	University of Wisconsin	DNA Controlling the Synthesis of Human HbF and HbA	135
5 R01 AM 21386-02	Robert H. Broyles	University of Oklahoma, Oklahoma City	Differentiation of Red Blood Cells In Vitro	$ 22

IRON

5 R01 AM 12381-10	Goetz W. Richter	Rochester University	Iron in Cell Pathology	$ 80
2 R01 AM 12386-10	Paul D. Saltman	University of California, San Diego	Studies of Biological Transport Mechanisms	125
5 R01 AM 15056-07	Philip Aisen	Albert Einstein College of Medicine	Iron-binding Proteins and Control of Iron Metabolism	129
5 R01 AM 16577-05	Elmer B. Brown	Washington University	Mammalian Iron Metabolism	$ 82

IRON

Project Number	Principal Investigator	Institution	Title of Project	Amount Encumbered ($1,000's)
5 R01 AM 17146-04	John B. Neilands	University of California, Berkeley	Chelates for Cooley's Anemia	$ 51
5 R01 AM 17327-04	Manfred Steiner	Memorial Hospital, Pawtucket	Studies on Erythroleukemia and Sideroblastic Anemia	33
2 R01 AM 17775-04	James W. Drysdale	Tufts University	Mammalian Isoferritins: Structure and Metabolism	108
5 R01 AM 18329-03	Ursula Muller-Eberhard	Scripps Clinic and Research Foundation, La Jolla	Distribution of Iron and Heme by Proteins	132
5 R01 AM 18550-02	Lewis R. Weintraub	Boston University	Iron Metabolism	99
5 R01 AM 18894-02	Anthony Cerami	Rockefeller University	The Identification of New Iron Chelating Drugs	55
5 R01 AM 19424-02	John A. Edwards	State University of New York, Buffalo	Inherited Abnormalities of Iron and Globin Metabolism	32
5 R01 AM 19466-02	Stanley F. Porter	Eastern Virginia Medical School, Norfolk	Studies of Iron Loading in Sickle Cell Disease	36
1 R01 AM 20148-01	Richard W. Topham	University of Richmond	Physiological Significance of Ferroxidase-II	31
1 R01 AM 20207-01	Richard G. Lee	University of Utah	Studies in Copper and Iron Metabolism	196
1 R01 AM 20251-01	Elizabeth C. Theil	North Carolina State University	Developmental Regulation of Red Cell Ferriton Content	$ 48

(THE NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES - Continued)

IRON

Project Number	Principal Investigator	Institution	Title of Project	Amount Encumbered ($1,000's)
1 R01 AM 20452-01	William H. Rastetter	Massachusetts Institute of Technology	Chelation-Antibiotics/ Treatment of Iron Overload	$ 46
N01-AM-4-2224	Richard Palmer	Duke University	Chelating Agents for Iron Overload*	4
N01-AM-4-2225	Colin G. Pitt	Research Triangle Institute, Research Triangle Park, North Carolina	" "	42
N01-AM-5-2202	Robert Grady	Rockefeller University	" "	65
N01-AM-5-2212	Edward Gralla	Mason Research Institute, Worcester, Massachusetts	" "	9
N01-AM-7-2232	Arthur Martell	Texas A&M Research Foundation	" "	46
N01-AM-7-2223	William Crosby	Scripps Clinic & Research Foundation, La Jolla	" "	$ 10

*This project and the five following it are concerned with research aimed at improving the clinical management of Cooley's anemia. The overall effort was undertaken upon the initiative of the National Institute of Arthritis, Metabolism, and Digestive Diseases.

EXTRAMURAL RESEARCH PROJECTS RELATING TO COOLEY'S ANEMIA

SUPPORTED BY THE NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES IN FISCAL YEAR 1977

Project Number	Principal Investigator	Institution	Title of Project	Amount Encumbered* ($1,000's)
PO1 GM 14552	Paul A. Marks	Columbia University	Normal/Abnormal Cell Multi-Disciplinary Study	$167
P50 GM 15253	Arno G. Motulsky	University of Washington	Center for Inherited Diseases	148
PO1 GM 15419	Myron Levine	University of Michigan	Program Project in Cellular and Biochemical Genetics	133
P50 GM 17702	Jarvis E. Seegmiller	University of California, La Jolla	Human Biochemical Genetics Program	52
P50 GM 20124	Leon E. Rosenberg	Yale University	A Center for Human Genetics and Inherited Diseases	57
RO1 GM 23143	Arthur Bank	Columbia University	Isolation and Characterization of Human Globin Genes	$ 54

*These figures are only parts of total project grants judged to be related to Cooley's anemia.

EXTRAMURAL RESEARCH PROJECTS RELATING TO COOLEY'S ANEMIA

SUPPORTED BY THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES IN FISCAL YEAR 1977

Project Number	Principal Investigator	Institution	Title of Project	Amount Encumbered* ($1,000's)
R07 AI 10051	Albert Rudnick	University of California, San Francisco	International Center for Medical Research	$ 50*

*This figure is only that part of the total project award judged to be directly related to Cooley's anemia.

JAN 6 1978

The Honorable Daniel J. Flood
Chairman, Subcommittee on Labor-
Health, Education, and Welfare
Committee on Appropriations
House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

In the Report on the 1977 Appropriation Bill the Committee directed that a study be conducted on the "state-of-the-art" of cystic fibrosis research and treatment within the Public Health Service. An interim report on the status of that study is enclosed.

The National Institute of Arthritis, Metabolism and Digestive Diseases and the National Heart, Lung and Blood Institute are funding a contract jointly with the Cystic Fibrosis Foundation to conduct this study. The Contract will be completed next February and the final report will be submitted to you in the early Spring of 1978 as requested.

Sincerely yours,

/s/ Charles Miller

Charles Miller
Acting Assistant Secretary
for Management and Budget

Enclosure

PROGRESS REPORT

Cystic Fibrosis Foundation Contract
(Jointly Entered Into By NHLBI and NIAMDD)

Current Status - A comprehensive study is now being carried out by the Cystic Fibrosis Foundation for the NIH which would define accurately the current state-of-the-art in research and clinical care in cystic fibrosis and which would develop data helpful for defining current research opportunities and for projection of future directions. This study is financed by a $290,000 contract funded in equal parts by the NIAMDD and NHLBI.

This comprehensive study began in February 1977 (the contract was signed on January 28, 1977) and has been actively under way ever since. A comprehensive report is expected to be submitted to the NIH by February 1978.

Considering the complex nature of cystic fibrosis and the broad scope of the goals of the study, the data gathering and subsequent evaluation involved is, perforce, extremely complex. In addition to very substantial literature searches and other surveys involving ongoing research activities and clinical cystic fibrosis centers, a broad spectrum of committees of experts, and their deliberations and evaluations, is involved. We are pleased to report that some of the most knowledgeable scientists in the field of cystic fibrosis have been recruited into the study and are actively engaged in it, in addition to a broad spectrum of scientists in related areas and particularly in the basic scientific disciplines that underlie most inherited metabolic diseases -- so that novel viewpoints and new directions will be introduced into the ongoing deliberations.

Throughout this effort, there has been close liaison between the principal investigator and the staff of this project and NIAMDD/NHLBI NIH staff. This study is now at its half-way point. According to current indications the Cystic Fibrosis Foundation will probably be able to finish this task by the allotted time. Subsequently, the NIH will submit this report to the Congress.

8/17/77

TRAINING OF ENVIRONMENTAL HEALTH SCIENTISTS -- THE ROLE OF PRIVATE ENTERPRISE

I. Introduction

The Second Supplemental Appropriation Act for Fiscal Year 1977 included $2 million for the National Institute of Environmental Health Sciences (NIEHS) to increase research training in the fields of environmental toxicology, environmental pathology, and environmental epidemiology. This supplement was in response to the recognized demand for scientists to undertake the research efforts prescribed in the Toxic Substances Control Act (TSCA) and other national legislative initiatives intended to promote the regulation of agents in the environment potentially hazardous to human health.

In its report accompanying the bill, the House Appropriations Committee suggested that there was an appropriate role for industry in the training of these scientists, especially in toxicology, because many of these individuals would be employed in industrial settings and engaged in studies on the toxicity of substances in connection with their production and marketing.

Although approximately one-third of the scientific manpower which NIEHS research training programs expect to produce will be employed in the private sector, it must be remembered that their job opportunities are being created in response to public policy priorities--specifically the evaluation and control of human health hazards. Because of the state of science the degree of sophistication and creativity required for applied science activities responding to environmental health problems is similar to that required to

conduct basic investigations intended to improve the state of science and to increase the science base dealing with environmental health problems. Although industrial organizations have a significant interest in the growth of the manpower pool available to them to conduct research and to meet newly imposed legal requirements, in the past there have been no appropriate mechanisms, traditions, or incentives for the private sector to participate in the support of training and research education in the same manner in which the National Institutes of Health has traditionally participated. As a result of the House Appropriations Committee's suggestion, NIEHS has assessed the willingness and capability of the private sector to participate in research training. Because of existing incentives and cost-benefit structures, NIEHS has found that there are certain needs which cannot be met by industry, although industry can participate significantly in enhancing and promoting research training through closer interaction with academic institutions.

II. The State of Science

At the outset it should be recognized that the science base pertaining to environmental health problems is quite shallow. Research of this nature is based upon the premise that human diseases and disorders can be caused by exposure to chemical and physical agents which either occur naturally in the human environment or are introduced as a result of human enterprise. Although the first research associating chronic disease to exposure to an environmental agent was done in 1775; systematic attention to the concept that these exposures may adversely affect a person's health without being manifested in acute disease episodes is only two decades old. The approaches

of classical biomedical science to these problems have been found to be generally inadequate. It has been necessary to develop a broad range of new research methodology in order to adequately study health problems related to long-term, low-level exposure to toxic agents, assess the toxicity of various agents at low dose levels or in combination with a wide variety of additional factors, measure minute levels of these agents in human or animal tissues, and extrapolate data derived from tests on animals to the human situation. This task of building a science base is far from complete, and it is the major responsibility of NIEHS.

Although our level of knowledge is far from complete, there are sufficient data to presume adverse health effects from long-term, low-level exposures to toxic substances. On the basis of this evidence, various decisions have been made to rapidly apply what information is available to the control of human exposure to these substances. This has resulted in a situation requiring application of the science base at an early stage in its development. This application has been, to a major extent, in the field of toxicity testing. However the testing of chemicals and other agents for toxicity is still not a fully developed science. Many testing techniques are not transferable or routine, and a considerable level of scientific judgment, and broad knowledge is required to plan and develop tests, and to interpret the results.

Environmental health research is pursued in a variety of organizational settings ranging from academic institutions including both universities and medical schools, through public research agencies such as NIH, public regulatory agencies such as the Environmental Protection Agency and the Food and

Drug Administration, commercial laboratories, and the research laboratories of manufacturing firms.

The research enterprise can be subdivided into two major functions. The first is the basic research which augments the science base in environmental health research and which provides the basic methodologic and research tools. These studies can be and are being carried out in all of the settings noted above; however, they tend to concentrate in academia and the public research agencies. Basic studies are being done by environmental health scientists who have prepared for a research career.

The second general activity is the conduct of testing for the evaluation of the safety of chemicals and other agents. The purpose of this activity is the generation of conclusive results regarding the toxicity or relative safety of agents. To carry this out, test protocols must be designed, difficult and complex experiments involving large numbers of animals must be executed, and a vast amount of data must be reduced, analyzed and interpreted. Because so little basic information is available, there are few currently useful procedures and protocols which can be used in conducting toxicity tests. Therefore scientific judgment and creativity are needed to carry out these programs. Testing programs are also carried out by the full range of institutions noted above, but tend to be concentrated in public regulatory agencies, and commercial and industrial laboratories.

In summary, there is no "routine" toxicity testing at this time. The planning, development, conduct, and interpretation of test programs are still the purview of highly trained environmental toxicologists. Therefore, these scientists must be competent and creative investigators in order to participate

fully in scientific activity extending the science base, and in scientific activity carrying out toxicity testing; and training and preparation for both endeavors must be identical.

III. The Manpower Requirement

The shortage of trained environmental health scientists has been widely discussed and documented. A portion of the report of the Second Task Force for Research Planning in Environmental Health Science was specifically devoted to manpower needs and research training opportunities. Information available to the Task Force indicated that only 25 percent of the available job openings for environmental toxicologists in 1976 could be filled that year by qualified scientists ready to enter the job market. NIEHS has no information which would indicate that this situation has drastically changed. Indeed, recruiting efforts for in-house positions at NIEHS and contact with the Environmental Protection Agency and the Food and Drug Administration indicate that the availability of qualified candidates for this type of activity has not improved. Within the coming year, NIEHS will launch a major effort to systematically assess the total need for environmental health scientists and to project the alterations and changes in the manpower requirement over the coming five years. The results of this study will assist NIEHS in the development and implementation of sound program plans and establishment of funding priorities for the support of individual fellowships and institutional training programs. Until these data are available, we believe that the current short-fall is of sufficient magnitude that there is little danger of overproducing qualified scientists for the range of work opportunities available.

There are also a number of mechanisms which can be used to increase the number of environmental health scientists being trained. The first mechanism is the organization of academic training programs, such as the Environmental Health Science Centers, including both predoctoral and post-doctoral training, in academic settings where environmental health research is of the highest quality. The second mechanism is the strengthening of existing research training programs of demonstrated potential so that they can increase the number of people being trained, and improve the quality of training. The third mechanism is the support of individuals' training related to the problems of environmental health at the predoctoral level--both training leading to the award of the Ph.D. degree and other degrees of relevance, such as the Doctor of Public Health for environmental epidemiologists. The fourth mechanism is the provision of postdoctoral fellowships for junior scientists whose classical predoctoral training was in fields allied to problems of environmental health but not specifically directed toward these problems. Such fields include pharmacology, pharmacokinetics, biochemistry, physiology, and statistics. Postdoctoral training exposes the trainee to the magnitude and complexities of environmental health problems and with broader data and information related to these problems than were available in their classical predoctoral education. A final mechanism is the re-training of established scientists with research careers in allied fields. This training is intended to prepare mature scientists to cope with the different scope and scale of research problems by exposing them to the type of problems encountered in environmental health research, especially toxicology, and prepare them to understand and integrate information in environmental health science with the already sound scientific background they have.

Among all of these mechanisms the common factor is that training for research in environmental health requires a considerable investment of time and effort on the part of the trainee, and a major commitment to environmental health research and to providing the setting for good research training on the part of the academic institution where the training takes place. Training for an environmental health research career is therefore a long-term activity requiring a great deal of time to produce results.

IV. The Role of Industry in Training and Education

The manpower requirement in environmental health science is one which must be met by long-term basic science education and training programs. The private sector has no history, background, or traditional interest in organizing or supporting these types of programs.

An industrial firm is organized for the complementary purposes of maximizing return on invested capital and producing of goods and services of economic value. The profit and production incentives drive an industrial firm to minimize costs and to seek early returns on investments. There has traditionally been no history of industrial support of long-term training and education. Training and education in industrial settings has traditionally been focused on a firm's immediate needs. It has involved training employees for specific roles and responsibilities and has generally been tied to a tangible benefit.

Support of education by industrial organizations has generally been indirectly through foundations, research grants or contracts for varying degrees of targeted activity, or endowments for faculty posts or for construc-

tion of teaching and research facilities at academic institutions. Firms or industries have generally coped with manpower shortages by these indirect contributions, or through market mechanisms such as increasing salary levels to attract qualified people, rather than through the support of long-term training or education.

As industry responds to the requirements of the TSCA, a number of specific efforts have emerged, and germane programs have expanded. These efforts are intended principally to meet the needs of a single firm or organization and not as components of a coherent private sector manpower development program. The Chemical Industry Institute of Toxicology (CIIT) currently sponsors several classical fellowships at academic institutions for training in toxicology and will soon begin to take on postdoctoral trainees in its laboratories. The CIIT will also participate in a consortium arrangement in the Research Triangle Park area, including nearby universities, commercial firms, and Federal laboratories (including NIEHS). A fairly extensive lecture series in toxicology, emphasizing industrial concerns, will be included in the consortium's program. The Dow Chemical Company has excellent facilities for toxicological research. These facilities are also utilized for training of postdoctoral fellows. Fellows participate in Dow's toxicity research for a period of two years and remain "free agents" with regard to future employment. Several chemical and commercial testing firms are also setting up residency programs for the training of safety evaluation experts. For example, the International Research and Development Corporation and Hercules, Inc. will offer two postdoctoral internships to individuals who will gain a broad exposure to methods of product safety evaluation. This kind of industrial

experience may also be written into institutional research training proposals from academic departments seeking NIEHS support. NIEHS is encouraging such experiences for trainees. Monsanto, Stauffer, and other firms are beginning the construction of corporate toxicological research and testing facilities. These laboratories will initially increase the need for trained people, but in the longer term, should provide additional facilities for training of industrial toxicologists.

Industry is encouraged to participate in NIEHS-sponsored training programs by providing instructors, laboratory space, and research problems for trainees at neighboring universities; and also by offering cooperative residency programs as described above.

Finally, arguments have been made that a factor in the large variation between laboratories' results in rather simple toxicological tests on apparently identical materials is due to differences in operations, procedures and technician training. Industry may, therefore, play a major role in supporting programs to develop standardized laboratory procedures and train technicians to implement these procedures. Several universities are interested in training toxicologists at the MSc. and BSc. levels for these purposes.

Although there are opportunities for collaboration with the private sector in research manpower training; and although the private sector can be expected to buttress academic institutions in traditional ways; it is clear that the public interest in creating a pool of research talent competent in the environmental health sciences is greater than the interest of any single firm or industry.

V. NIEHS Attempts at Collaboration

The National Institute of Environmental Health Sciences has been generally cognizant of the relatively broad job market for trained scientists in the environmental health field as compared to that which other biomedical research institutes must consider. NIEHS has also been cognizant of the interest of industry in the employment of these scientists; and the potential for industry to play a role in enhancing academic training programs. However, in view of the high degree of interchangeability between the commercial/industrial job market and the academic/scientific job market, and the long term of most training options, industrial interest in supporting extensive training efforts in academic institutions has been found to be very limited.

In collaboration with the Conservation Foundation, NIEHS has initiated a dialogue with components of the private sector--chemical manufacturing industries and commercial testing laboratories--and public regulatory agencies, where significant numbers of work opportunities exist for environmental health scientists. The initial purpose of this dialogue was to explore opportunities for industrial participation in training. It is obvious from the first of these meetings held last September that the private sector does not perceive a significant role in the support of general training. The private sector is willing to continue to support training on a limited basis.

An initial option which has been discussed is increased interchange between industry and academia, and industry and public regulatory agencies. Predoctoral practicums can be arranged in industrial laboratories by academic institutions. Exchange of faculty and senior staff should be encouraged, and consultant relationships established which would expose academic departments

and training programs to "real world" problems. Interchange between industry and public regulatory agencies would, of necessity, have to be on a rather guarded basis. However at the level of targeted research and development programs, significant benefit to the scientific and technical expertise of the staff of both the public agencies and industrial firms might be realized through staff exchange.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

JAN 28 1978

The Honorable Daniel J. Flood
Chairman, Subcommittee on Labor/
Health, Education, and Welfare
Committee on Appropriations
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

The enclosed report is submitted by the National Heart, Lung, and Blood Institute in response to the Committee's request on page 28 of House Report No. 95-381 on the Fiscal Year 1978 Appropriation Bill for the Department of Health, Education, and Welfare.

In the report language the Committee indicated that it would expect status reports on the clinical trial designed to determine whether or not chronic treatment of heart attack survivors with anti-arrhythmic drugs can reduce the incidence of sudden deaths and the clinical trial to test the effect of the administration of corticosteroids in infantile respiratory distress syndrome (Hyaline Membrane Disease).

Sincerely yours,

Donald Fredrickson

Donald S. Fredrickson, M.D.
Director

Enclosures

Status of an NHLBI Clinical Trial on Anti-arrhythmic Drugs: Beta Blocker Heart Attack Trial (BHAT)

Coronary heart disease and its complications account for over 600,000 deaths in the United States each year. Moreover, 300,000 of these deaths are sudden. Survivors of a documented myocardial infarction are recognized as having a high risk of dying relative to the general population. Serious arrhythmias, occurring with or without evidence of new infarction, are a common cause of death in this population. There is some evidence, but not conclusive evidence, to show that so-called beta blocking agents, which block the sympathetic nervous activity thought to be involved in precipitating sudden death, may prevent or retard complications of coronary heart disease such as serious arrhythmias. The result would be a decrease in mortality and morbidity due to the major cause of death in the United States.

The Institute has undertaken a major clinical trial of the effect of beta blocking agents on the secondary prevention of coronary heart disease. Some 4,200 men and women, aged 30-69 with one or more documented myocardial infarctions, will be enrolled in the study. The trial will be conducted in 33 centers across the United States with recruitment of patients to begin in June 1978 and extend through June 1980. The follow-up period will extend from July 1980 through June 1982 with final data analysis to be completed in December 1983. The detailed trial protocol is now under development and will be reviewed by the Director, NHLBI, before implementation.

Status of an NHLBI Clinical Trial: Neonatal Respiratory Distress Syndrome

Neonatal Respiratory Distress Syndrome (RDS) is one of the leading causes of disability and death in the newborn. In the United States approximately 10% of all infants are premature and each year about 50,000 cases of neonatal respiratory distress syndrome occur. Hospital costs average $5,000 per patient with an average stay of 23 days. Extensive studies on animal models have demonstrated that antenatal administration of synthetic and natural corticosteroids accelerates lung maturation and significantly diminishes the occurence of neonatal respiratory distress syndrome. Some evidence exists which reports a lower expected incidence of neonatal RDS when betamethasone is given to mothers for at least 24 hours after the onset of premature labor, not later than the thirty-second week of gestation. Although a variety of conditions in newborn infants have been treated over the past twenty years with steroids without adverse effects, investigation is needed on the short-term effects of corticosteroids on neonate and mother, and on the long-term effects on the infant.

The Institute has launched a clinical trial to evaluate the efficacy of neonatal steroid therapy in the prevention of neonatal respiratory distress syndrome. The trial will evaluate, as well, the short-term effects on the mothers and the long-term (18-month) effects on the infants. Dexamethasone, a synthetic corticosteroid, is to be administered to the mother 24-72 hours before parturition in this double-blind clinical trial. The 300 patients and 300 controls are now being admitted into the study by five collaborating institutions. Patients will be followed through June 1980 and that data analysis will continue through December 1980.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

MAR 6 1978

The Honorable Daniel J. Flood
Chairman, Subcommittee on Labor,
Health, Education, and Welfare
Appropriations Committee
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

On page 94 of House Report No. 95-381, the Committee on Appropriations notes that funds are available for university-affiliated facilities for the developmentally disabled under two separate HEW programs: grants for the developmentally disabled and maternal and child health. The attached report is submitted, as directed, to describe the interrelationship of these programs.

We hope that this information fulfills the Committee's requirements.

Sincerely yours,

Leonard D. Schaeffer
Assistant Secretary for
Management and Budget

Report to the House Appropriations Committee Describing the Interrelationship of Human Development Services (HDS) Funding for University-Affiliated Facilities (UAFs) and of Maternal and Child Health (MCH) Funding

This report briefly describes the separate programs which fund the university-affiliated facilities: Maternal and Child Health and Developmental Disabilities and the interrelationship of these programs.

The elements of the comparison include:

1. Authority
2. Operation and Administration
3. Use of Funds
4. Activities Funded
5. UAFs by region
6. Interagency Coordination

1. Authorization

A. The Developmental Disabilities Office, Office of Human Development Services (DDO/HDS)

In 1963, P. L. 88-164 authorized project grants for the construction of university-affiliated facilities for the mentally retarded. The law also stipulated that this space had to be used for not less than twenty years after completion of construction for the research purposes for which it was constructed.

In 1976, P. L. 94-103, Part B, Section 121(a) authorized DDO/HDS to make grants to assist in the operation and administration of university-affiliated facilities.

Section 121(a)2 authorizes DDO/HDS to initiate feasibility studies for satellite centers which would extend services and training programs of the present UAFs. $250,000 was the maximum amount appropriated for this activity in 1977. Nine studies began October 1, 1977.

Section 125 authorizes renovation or modernization of buildings used by the UAFs and buildings to be used as satellite centers. This section has received no appropriation.

In addition to those sections of the Act noted above which specifically relate to UAFs, the DD Office has encouraged UAFs to compete for grants administered under other parts of the Act. For example, Part D, Section 145, "Special Projects," makes monies

available to UAFs to furnish training and technical assistance in special areas such as legal advocacy, respite care, training of state DD council members, and demonstrations of services to those over 21 years of age.

UAFs have also competed and obtained grants for Projects of National Significance (Section 145.E). These include 5 projects which are studying the state of the are in serving the aging/aged developmentally disabled, a training center for manager/administrators of DD facilities, and a UAF data base.

State DD councils utilizing State formula grant funds under P.L. 94-103, Section 132 also have made small special purpose grants available to UAFs for such activities as state manpower studies.

B. Maternal and Child Health (MCH)

The major part of Maternal and Child Health's (MCH) support for UAFs is derived from Section 511 of Title V of the Social Security Act.

This section is not limited to UAFs but also authorizes grants to institutions of higher learning for training personnel for health and related services for mothers and children, particularly children with mental retardation or multiple handicaps. Additional support for the UAF program is provided from Section 503 and 504 of Title V which authorizes grants to State Agencies administering the MCH and Crippled Children's programs and to institutions of higher learning for projects of regional or national significance. Section 511, which was originally Section 516, P.L. 89-97, of the Social Security Administration Act of 1965 was intended primarily for assistance in staffing the Health Services component of the UAFs being constructed at the time under P.L. 88-164.

2. Operation/Administration of Programs

A. DDO/OHDS

The DDO central office makes regional allotments, develops guidelines for use of the monies, and monitors regional office operations of this program.

B. MCH

In accordance with the rules and regulations published under 45 CFR Part 51a, MCH direct grants for UAFs are administered by the Central Office. Review of continuations and renewals is carried out by an interagency committee, composed of: DDO, MCH, BEH, NICHD, and AAUAP representatives.

This activity has been a rather recent innovation (approximately 1 year). The committee now meets monthly to discuss applications as well as share ideas regarding issuances, policies, and operational details that affect the agencies involved. These meetings have been exceedingly productive in bringing the parts of this program closer together.

3. Use of Funds

A. DDO/OHDS

Funds authorized for assisting the operation and administration of UAFs has enabled the UAFs to fund staffing positions such as:

Directors and Deputy Directors

Secretaries

Coordinators of Training

Coordinators of Services

Coordinators of Research

Computer Personnel

Librarians

No funds are utilized for direct trainers or direct service personnel.

Monies can be used for travel and equipment providing that it is limited to those personnel and types of equipment that relate to the administration and operation of the UAFs.

B. Maternal and Child Health (MCH)

Funds authorized and appropriated under Section 511 of Title V are utilized to support care health professionals, health profession trainees, clinical services, and related [illegible] services. Support has been limited to those units based in Medical Centers and having the capacity to train leadership personnel of the major health components in the interdisciplinary approach to handicapped retarded individuals. Part of the training is conducted through the provision of clinical services to the multi-handicapped with priority being given to pre-school children. Except

in those programs having separately funded but related clinical services grants, the number of persons being served in a given UAF program is largely determined by the program's training requirements.

Activities Funded

A. DDO

Again it must be stressed that DDO/OHDS funds are not used to directly serve or train individuals; they are utilized to expedite the work of the training personnel or to enable the service providers to more effectively or efficiently do their work.

Administrators, coordinators, and support personnel funded by DDO are only indirectly responsible for the numbers of trained or served by a given UAF.

B. MCH

During the past year over 400 long-term trainees were supported by MCH stipends in the following areas:

Clinical Psychology	75
Speech and Audiology	61
Medicine	60
Social Work	114
Pediotondics	17
Public Health Nursing	17
Occupational Therapy	30
Physical Therapy	19
Nutrition	7
Biochemistry	8

MCH has no available data on service-related activities.

5. Listing of UAFs funded by DDO and MCH in FY 1976

	FY 1976 Support	
	DDO	MCH
University of Alabama Birmingham, Alabama	TA - 35,074 $220,368	$ 826,085
University of California Irvine, California	50,000 32,526	-
University of California Los Angeles, California	1,500 137,311	408,111
Children's Hospital Los Angeles, California	3,170 75,000	843,218
University of Colorado Denver, Colorado	100,000	381,619
University of Miami Miami, Florida	17,537 114,614	940,000
Department of Human Resources Atlanta, Georgia	73,654 231,128	-
Georgetown University Washington, D.C.	23,365 98,613	604,490
Indiana University Bloomington, Indiana	36,482 192,437	-
University of Iowa Iowa City, Iowa	16,482 73,816	-
University of Kentucky Lexington, Kentucky	51,884 19,182	-
Louisiana State University Baton Rouge, Louisiana	21,775 75,000	-
John F. Kennedy Institute Baltimore, Maryland	22,040 [illegible]	2,415,275
Children's Hospital Boston, Massachusetts	26,140 122,440	561,118

	FY 1976 Support	
	DMO	MCH
Walter E. Fernald State School	$ 25,000	
Waltham, Massachusetts	106,583	$752,927
University of Michigan	25,000	
Ann Arbor, Michigan	133,573	600,000
University of Kansas	65,031	
Lawrence, Kansas	291,239	-
Department of Mental Health	17,537	
Jackson, Mississippi	74,888	-
St. Louis University	14,249	
St. Louis, Missouri	63,812	-
University of Missouri	33,810	-
Columbia, Missouri		
University of Nebraska	32,593	-
Lincoln, Nebraska	112,158	
Kean College	16,747	-
Union, New Jersey	75,000	
Albert Einstein College	16,747	-
Bronx, New York	75,000	
New York Medical College	49,946	
Valhalla, New York	223,674	956,092
University of North Carolina	17,537	
Chapel Hill, North Carolina	89,953	630,366
University of Cincinnati	27,073	
Cincinnati, Ohio	100,000	915,755
Ohio State University	33,744	
Columbus, Ohio	134,974	606,874
University of Oregon	27,564	-
Eugene, Oregon	79,293	

	FY 1976 Support	
	DDO	MCH
University of Oregon	$ 27,563	
Portland, Oregon	77,112	$689,965
Temple University	25,200	-
Philadelphia, Pennsylvania	59,377	
University of South Carolina	17,537	-
Columbia, South Carolina	116,666	
University of South Dakota		
Vermillion, South Dakota	28,340	-
University of Tennessee		
Memphis, Tennessee	166,643	933,177
Utah State University	49,420	-
Logan, Utah	92,985	
University of Washington	27,563	
Seattle, Washington	213,906	996,935
West Virginia University	26,110	
Morgantown, West Virginia	29,562	-
University of Wisconsin	27,736	
Madison, Wisconsin	110,947	532,620
Texas Technical University (Study)		
Lubbock, Texas	22,500	-
	4,250,000	
TQ	949,000	

6. Interagency Coordination

DDO and MCH have historically operated programs for the UAFs in relative isolation from one another. Each agency knew the funding limitations of the other and neither allowed funds to be used in a duplicative fashion.

Recently, however, the two agencies have been pursuing a closer working relationship and an Interagency Committee is currently in the process of developing performance standards for all UAFs.

The standards will include appropriate measures for:

interdisciplinary training,

service,

research,

operations and administration;

as well as outreach consultation and technical assistance activities. This committee has agreed that quality control with the use of these standards will be a mutual responsibility of all agencies making resources available to the UAFs.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

REPORT ON ACTIVITIES IN

AGING

A REPORT TO THE

HOUSE COMMITTEE ON APPROPRIATIONS

FEBRUARY, 1978

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
ACTIVITIES SERVING OLDER AMERICANS
DURING 1977

In response to the many social, health, economic, education, and other needs of the Nation's elderly, a wide range of programs serving this age group were administered during 1977 by various agencies throughout the Department of Health, Education, and Welfare. This report begins with a tabular summary of actual and expected annual expenditures for activities on behalf of older Americans of each HEW agency which performs functions relating to this segment of the population. This is followed by narrative descriptions of these activities, in the following order:

I. Office of Human Development Services

- A. Administration on Aging
- B. Administration for Public Services
- C. Rehabilitation Services Administration

II. Social Security Administration

III. Public Health Service

- A. National Institute on Aging
- B. National Institute of Mental Health
- C. Health Resources Administration
- D. Health Services Administration
- E. Office of Assistant Secretary for Health

IV. Health Care Financing Administration

- A. Medicaid
- B. Medicare

V. Education Programs

- A. Public Library Services
- B. Adult Education
- C. University Community Service and Continuing Education
- D. Fund for the Improvement of Postsecondary Education

VI. Office of the Inspector General, HEW

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Funds for Programs on Aging [1]

(in thousands of dollars [1])

I. Office of Human Development	1976 Actual	TQ Actual	1977 Actual	1978 Actual	1979 [2] Estimate
A. Administration on Aging					
Title II, National Clearing house on the Aging	None [3]	None [3]	None [3]	2,000	2,000
Title II, Federal Council on the Aging	575	150	585	450	450
Title III, Area Planning and Social Services Programs	93,000	31,250	122,000	153,000	153,000
Title III, Planning, Coordination, Evaluation and Administration of State Plans	17,035	4,250	17,000	19,000	19,000
Title III, Model Projects	13,800	2,500	12,000	15,000	15,000
Title IV-A, Training	10,000	4,000	14,200	17,000	17,000
Title IV-B, Research and Demonstrations	8,000	2,000	8,500	8,500	8,500
Title IV-C, Multidisciplinary Centers of Gerontology	1,000	1,000	3,800	3,800	3,800
Title V, Multipurpose Senior Centers	0	5,000	20,000	40,000	40,000
Title VII, Nutrition Program for the Elderly	125,000	31,250	203,525	250,000	287,000

1. All amounts in this tabulation are stated in thousands of dollars, except those relating to Social Security Administration and Health Care Financing Administration programs, which are stated in millions of dollars.

2. All figures in the 1979 column are budget estimates.

3. The Clearing house during these years was funded with salary and expense money of the Department of Health, Education, and Welfare.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Funds for Programs on Aging /1

(in thousands of dollars)

I. Office of Human Development (Continued)

	1976 Actual	TQ Actual	1977 Actual	1978 Actual	1979 Estimate
B. Administration for /2 Public Services	299,000	77,000	318,000	318,000	315,000
C. Rehabilitation Services Administration /3					
Basic State Grants	14,406	3,600	14,806	15,970 /4	17,280
Innovation and Expansion	340	75.4	340	340	376
Facility Improvement	138	5.632	145.08	144	144
Special Projects	350	0	488.7	769	1,200
Training	12.3	5.411	15.250	15.250	22.614

/1. All amounts are stated in thousands of dollars, except those relating to Social Security Administration and Health Care Financing Administration programs, which are stated in millions of dollars.

/2. All APS figures are based upon estimates of the percentage of APS funds which relate to the elderly.

/3. All RSA data applies to rehabilitants 65 years of age and over.

/4. All RSA figures in this column are estimates for current fiscal year.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Funds for Programs on Aging

(in millions of dollars)

	1976 Actual	TQ Actual	1977 Actual	1978 Estimate	1979 Estimate
II. Social Security Administration					
Benefit payments to persons age 65 and over from social security trust funds:					
Disability Insurance benefits (dependents)....	$33	$9	$39	$43	$48
Retirement and survivors' insurance benefits.....	49,301	13,445	56,613	63,147	70,236
Hospital insurance benefits 1/.....	11,026	2,754	--	--	--
Supplementary medical insurance benefits 1/....	3,970	1,046	--	--	--
Sub-total, benefit payments to persons age 65 and over from social security trust funds 1/.....	64,330	17,254	56,652	63,190	70,284
Payments to persons age 65 and over from Federal funds:					
Supplemental Security Income payments.....	1,810	452	1,734	1,864	1,526
Special benefits for disabled coal miners.....	645	164	662	699	736

1/ The Medicare activity was transferred to the Health Care Financing Administration (HCFA) in 1977. Data shown for 1977, 1978, and 1979 do not include Medicare payments from the Hospital Insurance and Supplementary Medical Insurance Trust Funds, which are stated under IV. Health Care Financing Administration.

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE

Funds for Programs on Aging
(in millions of dollars)

II. Social Security Administration (continued)

	1976 Actual	TQ Actual	1977 Actual	1978 Estimate	1979 Estimate
Assistant Payments	-----	------	2	2	2
Refugee Assistance Payments	-----	------	32	30	22
Subtotal, payments to persons age 65 and over from Federal funds	2,455	616	2,430	2,595	2,286
Grand Total, Social Security Administration	$66,785	$17,870	$59,082	$65,785	$72,570

Funds for Programs on Aging
(in thousands of dollars)

III. Public Health Service	1975 Actual	1976 Actual	1977 Actual	1978 Estimate	1979 Estimate
A. National Institutes of Health					
1. National Institute on Aging 1/	N.A.	$19,221	$29,879	$37,000	$37,910
B. Alchol, Drugs Abuse Mental Health:					
1. National Institute of Mental Health 2/	4,438	5,340	6,242	6,907	9,290
C. Health Resources Administration					
1. Health Planning and Resources	50,986	108,156 3/	18,901	29,831	13,298
2. Bureau of Health Manpower	2,455	314 4/	1,019	963	714
Total, PHS	$ 57,879	$133,031	$ 56,041	$74,701	$ 61,212

1/ Obligations for Transition Quarter are $4,004.
2/ Obligations for Transition Quarter are $681.
3/ Includes $47,704 obligated in Transition Quarter.
4/ Includes obligations for Transition Quarter.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Funds for Programs on Aging
(in millions of dollars)

	FY 1976	TQ	FY 1977	FY 1978	FY 1979
IV. Health Care Financing Administration					
A. Medicaid [1]	3,254.705	920.252	3,487.092	3,898.450	4,181.096
B. Hospital Insurance Benefits	[2] ---	[2] ---	13,296	15,531	18,093
C. Supplementary Medical Insurance Benefits	[2] ---	[2] ---	4,987	5,941	7,019

Funds for Programs on Aging
(in thousands of dollars)

	1975 Actual	1976 Actual	1977 Actual	1978 Estimate	1979 Estimate
V. Education Programs					
A. Public Library Services [3]	2,415	1,836 [4]	1,800	1,800	1,800
B. Adult Education [3]	5,630	2,700 [5]	7,150 [5]	8,050 [5]	8,050 [5]
C. University Community Services and Continuing Education [3]	1,326	1,121	1,325 [5]	1,600 [5]	None
D. Fund for the Improvement of Postsecondary Education	347		296	--- [7]	--- [7]
VI. Office of the Inspector General, HEW	[6] ---	[6] ---	--- [7]	--- [7]	--- [7]

1/ Estimate of portion of total expenditures for this program which relate to older persons.
2/ Expenditures under these programs which were made before they were transferred to Health Care Financing Administration appear under II. Social Security Administration.
3/ Office of Education Program.
4/ The decrease in Federal dollars expended for services to older Americans does not represent decreased efforts in this area. Rather, it demonstrates greater willingness on the part of States and localities to provide these services from their own funds, using a minimum of Federal assistance. In the last year, this trend toward increased local expenditures and decreased Federal funding has been noted and is reflected in the actual and estimate figures above.
5/ Estimate -- based upon the percentage of adults receiving services under this program who are aged 65 and over.
6/ Fiscal periods before establishment of the Office of the Inspector General.
7/ No reliable estimate can be made regarding funds allocable to aging program activities.

I. OFFICE OF HUMAN DEVELOPMENT SERVICES

A. ADMINISTRATION ON AGING

Introduction

The Older Americans Act of 1965 mandated the establishment of the Administration on Aging, now located within the Office of Human Development Services, Department of Health, Education, and Welfare. The Administration on Aging was created to serve as the Federal focal point and advocate for the concerns of the nation's older persons and to foster coordination and increased commitment of Federal resources to the field of aging. We are in a transitional period in as much as we are changing from a "young" society to an older society. At the turn of the century only 4% of our population was over 65, while today it is 10%. By the year 2030 it will be between 17% and 20% and even higher in some communities. An increasing proportion of the elderly will be over 75. In 1977, 38% of the elderly population was over 75 years of age. By the year 2000 this number is expected to increase to 43%. Current data indicates that between 4 and 4.5 million older persons may need assistance in order to continue to live independently in their own communities. At least 18% of older persons are limited in their mobility because of chronic conditions. Recent estimates show that half of the elderly living alone had incomes under $3,000, while 1/3 of older families had incomes less than $6,000. Among elderly whites, one of every seven was poor, while over 1/3 of elderly blacks were below the poverty level. To serve these needs the Administration on Aging focuses special concern on the poor, disabled, minority and socially isolated elderly.

Title I of the Older Americans Act declares the following ten national objectives for Older Americans:

1. Adequate Income
2. Best Possible Physical and Mental Health
3. Suitable Housing
4. Full Restorative Services
5. Employment Opportunity
6. Right to Retirement
7. Involvement in Society
8. Community Services
9. Research Benefits
10. Freedom and Independence

In February of 1977, the Administration on Aging formulated four new long-range goals which guide the Agency in seeking to meet these objectives for older Americans. These goals are:

I: To increase the number of older persons who receive needed services, with particular attention paid to low-income and minority older persons.

II: To increase Federal resources used to serve the needs of older persons.

III: To modify public and private policies to promote achievement of the objectives for older persons identified in Title I of the Older Americans Act.

IV: To promote increased involvement of Americans of all ages to solve the problems of older persons.

The need to provide for assistance to the growing number of older persons is a National priority. AoA serves to meet this need in two ways. First,through advocacy, AoA encourages others to assume a share of this responsibility. Second, AoA provides assistance where others cannot. In order to accomplish this, AoA has supported the development of a Network of State and Area Agencies on Aging. This network is encouraging communities to design and implement comprehensive and coordinated service systems to serve the needs of older persons.

Organization of the Administration on Aging

To carry out its mandates, the Administration on Aging has been organized in the following manner: (1) the Office of the Commissioner on Aging; (2) the Office of Planning and Evaluation; (3) the Office of State and Community Programs; (4) the Office of Research, Demonstrations and Manpower Resources; (5) the National Clearinghouse on Aging; (6) the Field Liaison Staff; and (7) ten Regional Offices on Aging.

The Office of Planning and Evaluation (OPE) serves as the focal point in the Administration on Aging for forward 5-year planning, policy analysis, legislation, budget formulation, and evaluation. It conducts policy analyses of program issues affecting AoA and programs for the aging, formulates the budget, develops and updates AoA's 5-year forward plan, prepares AoA's annual reports to the President and Congress, develops and carries out program evaluation for AoA, develops legislative proposals, and identifies and reports on policy issues regarding proposed legislation and regulations which will affect the elderly.

The Office of State and Community Programs (OSCP) has major responsibility for development and assessment of the State and Community Programs on Aging (Title III), the Multipurpose Senior Centers Program

(Title V) and the Nutrition Program for the Elderly (Title VII). In addition, OSCP develops regulations, policies, and guidelines for use

by State and Area Agencies on Aging, Nutrition Project Agencies and, where appropriate, Senior Centers; develops optional models and disseminates "best practice" suggestions for use by the Regional Offices, State Agencies on Aging, Area Agencies on Aging and Nutrition Project Agencies; develops and monitors, in cooperation with other AoA units, management information and reporting systems which provide information to facilitate planning and program adjustment for management efficiency at all organizational levels; and carries out other related functions.

AoA's Office of Research, Demonstrations and Manpower Resources has lead responsibility as a focal point for coordination of research on aging by Federal agencies; provides the chairman and secretariat services to the Interagency Task Force on Aging Research; develops policy, supports projects and monitors progress of research, demonstration, and manpower resources programs under Title IV of the Older Americans Act and the Model Projects program authorized by Section 308 of the Act; and carries out other functions supportive of AoA's mandate to provide national leadership and expertise in encouraging new knowledge and upgrading competencies in the field of aging.

AoA's National Clearinghouse on the Aging serves as the focal point within the Federal Government for the collection, analysis, and dissemination of information related to the needs and problems of older persons, and, wherever possible, develops and coordinates programs with other offices and agencies to fill gaps in information in the field of aging; develops policy for information and referral services; provides technical assistance for State Agencies on Aging in the development of information and referral services; provides the chairman of, and secretariat services for the Interagency Task Force on Information and Referral, and to the Federal Task Force on Statistics; produces a variety of professional and lay publications and audiovisual material on aging; publishes AGING magazine; develops special information campaigns; responds to letters and telephone inquiries; and performs other related functions in the area of public information.

AoA's Field Liaison Staff assists Regional Offices in keeping informed of continuing developments relative to the objectives and programs of the Administration on Aging; identifies difficulties being encountered by Regional Offices in carrying out their duties and responsibilities; ascertains the degree of further assistance required from AoA Headquarters to ensure that Regional Offices achieve national and operational planning objectives; and provides other related assistance to Regional Office staff.

Regional Offices on Aging are located in the ten HEW Regional Offices. Each is headed by a Director, whose function is to represent, and act for the Commissioner in serving as a Regional Office focal point on

programs and problems concerning older persons and in providing leadership and advocacy to carry out the responsibilities of the Administration on Aging as set forth in the Older Americans Act. In performing its functions, the Regional Office of Aging works directly with the State Agency on Aging, and through the State Agency, with the Governor's immediate staff in each State in the Region in developing the State's programs on aging.

Building Comprehensive and Coordinated Service Delivery Systems through the Network of State and Area Agencies on Aging

A National Network on Aging has been put in place during FY '74, 75 and 76 to respond to the Older Americans Act Comprehensive Services Amendments of 1973. In addition to the pre-existing 56 State Agencies on Aging, 1/ there were at the end of FY 1977 556 Area Agencies on Aging located in 612 planning and service areas 2/ which cover 92% of the Nation's older persons. In addition 1,047 Nutrition Project Agencies were operating 9,166 sites serving meals five days a week and providing support services.

For the past two fiscal years the Administration on Aging's operational plans have focussed on providing policy and process tools. The purpose has been to build the capacity of the National Network on Aging to foster the development of a comprehensive, coordinated system of quality services for older persons in each planning and service area in the Nation; and to have each State and Area Agency on Aging function as a focal point on aging for its jurisdiction.

The network agencies have established connecting links with many of the wide range of other agencies and organizations whose efforts and resources are, or should be, directed to helping meet the needs of older persons. The linkages are beginning to pay off in the expansion of services to older persons and the coordination of these services so that they are more accessible and effective.

During 1977 AoA determined that it was then appropriate to shift concern from building the network to achievement of expansions and improvements in service delivery systems through this network.

1/ Includes the 50 States plus American Samoa, Guam, Puerto Rico, the Trust Territory of the Pacific Islands, the Virgin Islands, and the District of Columbia.

2/ An additional 14 new Area Agencies are proposed by the end of FY '78.

Title III: Coordinated, Comprehensive Service System for the Elderly

State Agencies: Under Title III, $17 million in Federal funds were available in FY 1977 for State Agency administrative activities through formula grants to each State with an approved annual State Plan on Aging. Title III grants pay up to 75% of the cost of staffing and operating the State Agency on Aging to:

- Identify the needs and problems of older people
- Establish priorities for State and Area Planning
- Mobilize resources to carry out program plans
- Negotiate interagency cooperative agreements to expand and coordinate services
- Provide leadership and technical assistance to Area Agencies on Aging
- Fund, monitor, and provide training and technical assistance to Title III, V and VII grantees.

Area Agencies on Aging: States awarded $122 million in Title III grants to pay part of the cost of the operations of Area Agencies on Aging and for the funding of Social Services by such agencies or by the State Agency where no Area Agency exists. Area Agencies on Aging are responsible for developing an annual plan which seeks to foster a comprehensive and coordinated system of services for older persons, with special emphasis on the needs of the low-income, minorities and impaired elderly. Area Agencies on Aging are public or private non-profit agencies, designated by the State Agencies on Aging to:

- Serve as the focal point and advocate on aging for a State-designated planning and service area, identifying the needs and problems of older people in the area, establishing goals and priorities, mobilizing resources from other public and private agencies to meet needs, and negotiating interagency cooperative agreements to expand and coordinate services.

Area Planning and Social Services funds are available at different matching ratios for three types of use:

- Maximum of 15% available for the administration of the Area Agencies, at a Federal matching rate of up to 75%.
- Up to 75% Federal matching share for services which are not provided as part of an area plan approved by the State agency. A maximum of 20% of the State allotment is available for non-area plan services.
- The remainder is available for the purchase of services for the welfare of older persons at a Federal matching rate of up to 90% for services which are part of an area agency annual plan.

Pooling Resources to Increase Services: At the end of FY 1977 State and Area Agencies had increased the amount of total dollars pooled from other public and private sources: 1/

FY 1975	$122,541,000
FY 1976	$215,190,000
FY 1977	$440,403,806

This increase of $225,213,806 results in additional resources to expand the level of services provided to increasing numbers of older persons.

Sources of pooled funds	Amount	%
local government	$86,563,441	20%
State appropriated	$43,234,764	10%
Other Federal	$310,605,601	70%

1/ Other than Title III and Title VII Resources

Title III Services: Title III of the Older Americans Act places emphasis on the purchase of priority services (listed below). The proportion of service funding from $77,292,737 during FY 1977 was as follows:

Title III Services

Type of Service	%
. Transportation	20%
. In-home Services	23%
. Information and Referral	11%
. Legal and Other Counseling	5%
. Home Repair	6%
. Escort	2%
. Outreach	7%
. All Other Services	26%
Total	100%

In 1977 an estimated 11,217,067 person units of service were provided to elderly persons 1/ under area plans approved by State Agencies. Of these, 23% were minority and 48% low income 2/. They received the following services:

1/ Duplicated count, total served with all funds - represents an increase of 5,140,067 from FY 1976.

2/ Low income definition is based on Department of Commerce, Bureau of the Census - poverty threshold 1976 estimates and established by each State.

Persons Units of Service Provided by Title III

3/

Type of Service	Number of Person Units of Service
Transportation	2,451,610
Home Services	486,529
Legal & Other Counseling	198,369
Repair and Renovation	777,892
Information and Referral	3,171,946
Escort	289,754
Outreach	1,430,966
All Other Services	3,110,001
	11,217,067

Involving the Elderly: Area Agencies on Aging are committed to involving older persons in programs that serve the elderly. Area Agencies have fulfilled this responsibility through the significant employment and meaningful use of older volunteers in Area Agency activities.

Older Persons and Area Agencies on Aging

Paid Staff	
60 years or older	1,507
Volunteer Staff	
60 years or older	25,571

3/ Number served under Title III funds. Some older persons received more than one person unit of service each.

Title VII - Nutrition Program

The Nutrition Program authorized by Title VII of the Older Americans Act, as amended, began operations in FY 1973. Under this program $225 million 1/ in Federal funds were available for formula grants to State Agencies on Aging to establish and maintain community based Nutrition Program projects. These projects manage nutrition sites which provide low-cost, hot nutritious meals, primarily in congregate settings, and provide support services as needed to persons 60 years of age and over and their spouses. Many projects also furnish home-delivered meals to the homebound.

Each project must provide at least one hot meal per day, five or more days per week, all year long. The projects provide those supportive services needed to facilitate participation in the program. Such services include outreach, transportation, and escort services. In addition, projects are encouraged to offer other supportive services such as health and welfare, education and counseling, information and referral services, shopping assistance, and recreational services.

The U.S. Department of Agriculture also provides commodity and product support to the Nutrition Program, for which Section 707 of the Older Americans Act provided a minimum level of 25 cents per meal for FY '77. The actual contribution was 27 1/4 cents per meal.

The purpose of the Nutrition Program is to encourage and assist communities in significantly supplementing the nutritional and social needs of older persons who do not eat adequately for one or more of the following reasons:

- They can not afford an adequate diet
- They lack the skills to select and prepare well-balanced meals

1/ Actual appropriation was $203,525,000. Due to a FY 1973 Title VII appropriation of $100 million on the last day of FY 1973 which Congress directed AoA to use as "carry-over" funds during the course of several years to increase the operating level of the program over the appropriated level. This situation ended at the end of FY 1977 when all such carry-over funds had been obligated by the State Agencies on Aging.

- Their capacity to cook and shop independently is impaired
- They suffer from the depressive effects of isolation and lack incentive to prepare and eat a meal alone.

During Fiscal Year 1977 the number of nutrition projects increased from 845 to 1,047. The number of meal sites increased from 6,672 to 9,166.

Summary: Title VII Nutrition Program

	FY 1976	FY 1977	Change
1) Total Meals Served	64,273,000	101,091,000	+36,818,000
2) Average Number of Meals Served Daily	247,000	388,000	+141,000
3) Estimated Number of Different Persons Served	1,723,000	2,854,755	+1,131,755
4) Average Cost of Meal (food and preparation)	$1.63	$1.73	+$.10
Average Total Program Cost of Meal	$2.25	$2.46	+$.21
5) Percent Home Delivered Meals	14%	15%	+1%
6) Percent Expended on Supporting Social Services	11%	14%	+3%
7) Percent Minority	21%	22%	+1%
8) Percent Low-Income	62%	67%	+5%
9) USDA Commodities	$10,500,000	$14,615,853	+$4,115,853

The Title VII program complements Title III which focuses on the development of comprehensive, coordinated service delivery systems designed to meet the needs of older persons. Nutrition services and related support services are vital components of such systems.

Title V: Multipurpose Senior Centers

A Multipurpose Senior Center ideally means a community facility for the organization and provision of a broad range of health, social, educational and other services for older persons. Title V sections 501-505 authorize the Commissioner to make grants or contracts to units of general purpose local government or other public or private non-profit agencies or organizations for the purpose of acquiring, altering, or renovating existing facilities to serve as multipurpose senior centers. In order to assure that Title V supported multipurpose senior center facilities are integrated with the comprehensive and coordinated service systems established under Titles III and VII of the Older Americans Act, priority is being given to applications from State Agencies on Aging in award of funds.

The program was funded for the first time during the 1976 Transition Quarter. A total of 549 grant awards were made from the $5 million appropriated to initiate the program. A total of 49 Statewide grants and 22 individual grants were awarded in Fiscal Year 1977 from an appropriation of $20 million. These grants were awarded at the close of the fiscal year. States are in the process of awarding subgrants or contracts within each State.

The Nursing Home Ombudsman Program

The purpose of the Nursing Home Ombudsman Program is to enable State Agencies to develop a process at the local or area level which is responsive to complaints made by or on behalf of the elderly in nursing homes and to work in a variety of ways to improve the quality of care and quality of life of nursing home patients.

In October, 1977 nursing home ombudsman grants totalling $1,000,126 were awarded to State Agencies on Aging in 46 States, Puerto Rico and the District of Columbia. The only two States not participating in the Ombudsman Program are Oklahoma and Wyoming, neither of which applied for funding.

During the second year of funding (1976-77), many significant accomplishments were made by the State programs. State legislation mandating nursing home ombudsman services was passed and became effective in Connecticut, South Carolina, New Jersey and Nevada. The Connecticut law establishes the ombudsman office in the State Office on Aging and provides for five Regional Offices throughout the State.

In addition to working for the passage of ombudsman legislation, Ombudsman Developmental Specialists have been involved in shaping legislation and new regulations covering a variety of long term care issues. These include provisions which would strengthen existing

nursing home standards, bring boarding homes under State regulation, guarantee patients' rights, assure an adequate number of beds for Medicaid patients, provide protective services for older people along with the establishment of criminal penalties for adult abuse, protect patients' personal funds, mandate unannounced inspections of care facilities, and provide more services to enable older persons to delay or prevent institutionalization.

LEGAL SERVICES PROGRAM

In Fiscal Year 1977, the Legal Services Program provided $1,125,000 in model project funds on a formula grant basis to support the establishment of a legal services development project in each State agency on aging. The program provides support for a legal services development specialist in each State. The objectives of the program include:

(1) Working with Area Agencies on Aging in order to help them design legal services programs for older persons;

(2) Assisting, working through Area Agencies on Aging, legal services corporation offices and/or legal aid programs to expand services and outreach efforts to eligible elderly clients;

(3) Assisting Area Agencies on Aging in involving the private bar in increasing legal representation to older people;

(4) Stimulating law schools and other educational institutions to provide research, law related training, and/or direct client services to the elderly;

(5) Designing and coordinating through State and Area Agencies on Aging legal and aging training programs for State and Area Agency staff and grantees, paralegals, lawyers, and older persons.

The legal services development specialists are also working closely with the State Bar Associations to encourage the inclusion of the legal problems of the elderly in State conferences. On the national level, Legal Research and Services for the Elderly, an AoA grantee, is working with the American Bar Association in the development of an Elderly Law Section of the Bar. The Administration on Aging sponsored a three-day conference in the summer of 1977 for legal services development specialists from States throughout the country. These development specialists were thoroughly exposed to workshops and materials relating to the legal concerns and problems of the elderly.

Supporting Achievement of the National Objectives and AoA Goals

TITLE IV, PART A: MANPOWER AND TRAINING

This part of the Older Americans Act authorizes the Commissioner to award grants to public or non-profit agencies, organizations or institutions, including State Agencies on Aging, and to enter into contracts for training projects. The purpose of this program is to increase the number of adequately trained personnel in the field of aging so as to improve the quality of services to older people.

CAREER TRAINING

The Administration on Aging supports training programs at institutions of higher education that will provide students with the necessary gerontology knowledge and skills to enable them to serve the nation's elderly in their chosen career or profession.

Through the career development program, students are prepared for employment at baccalaureate, masters, and doctorate levels in such areas as:

(1) State and Federal program planning and administration;

(2) Community development and coordination;

(3) Administration of retirement homes and homes for the aged;

(4) Senior center direction;

(5) Teaching and research; and

(6) Serving older people through adult education, architectural design, counseling, law, library service, recreation and other relevant fields.

During the 1976-77 academic year $6.3 million supported 77 grant awards at 68 colleges and universities in 36 States. Approximately 15,000 students were enrolled in courses and programs in aging. 801 students (240 minority) received financial assistance as part of FY 1976 Career Training Awards through universities. In addition over 400 students were supported in the summer institute program sponsored by the University of Southern California.

University Multidisciplinary Development

At the close of FY 1977, $6.5 million was awarded on a national competitive basis to educational institutions to support activities relative to career training in aging. This included: Fifty-eight awards ($6 million) were made for "Development Support for Career Training in Aging" with the program emphasis on multidisciplinary efforts of the grantee institutions; and twenty awards ($500,000) for "Planning Grants for Institutions of Higher Education" to assist in the organization and development of institution-wide faculty capability in the gerontology field.

IN-SERVICE TRAINING

The Administration on Aging continued its grant awards to each State Agency on Aging for the support of training to meet priority in-service needs identified in each State. Although the awards were made during FY 1976 they were used during FY 1977. A total of $6.0 million supported in-service training in such areas as gerontology, information and referral, nutrition, program management and analysis, planning and outreach. More than 130,000 persons now in the field of aging were trained as a result of these programs. At the close of FY 1977, $6,000,000 was awarded in new grants to State agencies on aging to support in-service training activities during FY 1978.

MANPOWER DEVELOPMENT

The Administration on Aging, together with the Bureau of Labor Statistics, Department of Labor, has continued to develop information on manpower needs in the field of aging.

Activities conducted included:

- the development and distribution of vocational guidance information on professional careers in the field of aging for young people enrolled in high schools, vocational and technical schools, colleges and universities.
- assessment of social work manpower in the field of aging.
- assessment of Agency on Aging manpower needs.
- study of the aging content of ongoing surveys.
- update on manpower needs in the nursing home industry.

- assessment of Agency on Aging manpower needs.

- study of the aging content of ongoing surveys.

- update on manpower needs in the nursing home industry.

Documents referring to these studies will be made available through the National Clearinghouse on Aging during the early part of Fiscal Year 1978.

Other Manpower and Training Activities - Other significant accomplishments in the area of training and manpower are:

- o continued support of clearinghouse on available in-service and other training materials (Duke University, Durham, N.C.)

- o design of model program for training senior center personnel (National Council on Aging, Washington, D.C.)

- o curriculum and materials development of videotape cassettes and instructional materials which could be used in training State, area and other Network personnel (University of Maryland, College Park, Md.)

- o project to train trainers to develop self help groups for older persons in areas of health care, safety and consumer affairs (City University of New York, N.Y.)

- o manpower development projects in specific areas

  - training for lay advocates, law students and lawyers in law and aging

  - curriculum development and training in health related fields

  - sensitizing professionals to needs and concerns of minority older persons.

TITLE IV, PART B: RESEARCH AND DEMONSTRATIONS

The research and demonstrations program [$8,500,000] supports projects which expand knowledge in a wide variety of subject areas that are critical to the Network's development and improvement of programs to promote a comprehensive system of services and benefits for older

persons. Research program initiatives are designed to increase the Federal sector capacity to realize the national objectives stated in Title I of the Older Americans Act, as amended. (See Introduction)

Research to Improve Service Delivery Systems

Sixty-two Title IV-B awards ($5,703,951) support new and continuing projects in response to growing service needs of increasing numbers of older persons. In FY 1977 a major effort was undertaken to develop a research strategy involving the information needs of Federal, State and sub-State administrators, planners and local service providers in dealing with barriers to development of comprehensive service delivery systems. Research projects were solicited in response to the following five strategy areas:

- o The needs of older persons which may cause them to require services
- o Alternative ways of meeting the needs of older persons other than public provision of services
- o Social, political, and economic conditions which influence how the needs of older persons are met
- o How services are now being provided for older persons
- o The role of State and Area Agencies on Aging in providing services to older persons.

Policy Research in Support of Achievement of Title I Objectives

During FY 1977, seven new and continuing awards were made to support projects on research which contribute to the Federal capacity to realize the national objectives of the Older Americans Act ($942,067). Five projects were awarded to identify issues in the policy areas of income, housing, employment, community services and health. This first phase in developing a policy research agenda related to achieving national objectives was completed in Spring 1977.

The second phase has now been initiated to develop a policy research agenda based on the findings of the initial issue studies. This phase will continue through FY 1978 and is expected to form the basis for a large segment of the FY 1978 and FY 1979 IV-B research program.

Dissertation Research

Twenty awards of $5,000 each were made during FY 1977 to support dissertation research in the field of aging.

New Initiatives

The Administration on Aging launched a major initiative in 1977 to increase the Federal resources allocated for research on minority elderly and to encourage the conduct of such research by minority researchers. AoA organized two workshop conferences during the Winter of 1977 where minority researchers and Federal officials who fund research on aging came together to discuss ways to increase the amount of such research. As its part in this effort, AoA committed itself to set aside at least 15% of new start funds for minority research projects and did meet this goal in FY 1977 IV-B funding.

TITLE IV, PART C: MULTIDISCIPLINARY CENTERS OF GERONTOLOGY

Funds are made available through project grants to public and private non-profit agencies, organizations, and institutions for the purpose of establishing or supporting multidisciplinary centers of gerontology to fulfill the following functions:

- o recruit and train personnel at the professional and sub-professional levels;
- o conduct basic and applied research on work, leisure, and education of older people, living arrangements of older people, the economics of aging, and other related areas;
- o provide consultation to public and voluntary organizations with respect to the needs of older people and in planning and developing services for them;
- o serve as repositories of information and knowledge with respect to the areas for which it conducts basic and applied research;
- o stimulate the incorporation of information on aging into the teaching of biological, behavioral, and social sciences in colleges or universities;

- help to develop training programs on aging in schools of social work, public health, health care administration, education, and in other such schools at colleges and universities; and

- create opportunities for innovative, multidisciplinary efforts in training, research, and demonstration projects.

Under the Title IV-C Multidisciplinary Center of Gerontology program, grants are made under two different categories:

(1) developmental grants to support the establishment of multidisciplinary centers, or alternatively to assist recently established institutes on aging in realizing their potential for becoming Multidisciplinary Centers of Gerontology;

(2) operational grants to already well established multidisciplinary centers of gerontology to expand and strengthen their activities consistent with the provisions of Title IV-C.

In FY 1977, the $3,800,000 appropriated for the Title IV-C program was used by the Administration to fund second-year continuation costs of those center projects initiated in FY 1976 and the transition quarter, and to make 23 new grants. Of the new awards, there were 8 operational grants to well established centers and 15 developmental grants to establish center programs. With the exception of one operational grant to a free standing geriatric center, all FY 1977 new awards were made to institutions of higher learning. As with the awards made in the previous fiscal year, new grants covered a two year project period.

TITLE III: MODEL PROJECTS

Model projects are designed to increase the effectiveness of the National Network on Aging in improving and expanding services for older persons by testing and initiating new services and innovative approaches.

During FY 1977 Model Projects initiatives were funded at $14,700,000 in twelve priority areas.

Model Projects

Priority Areas	# Projects	$
Housing	9	758,433
Continuing Education	2	119,635
Retirement and Pre-Retirement	9	794,806
Special Services to Mentally and Physically Handicapped	7	744,912
Ombudsman Services	49	381,582
Improved Services to Under-Served Populations	8	722,884
Senior Ambulatory Care Day Centers	2	324,238
Legal Services	61	2,540,880
Communications Media	2	2,311,860
Organization Development	9	1,800,659
Elderly Disaster Victims	5	148,834

Examples of Projects by Priority Area

1. Housing and Living Arrangements

The City of New Haven, Connecticut is developing and testing ways of involving the elderly in neighborhood preservation and revitalization.

A project in Roxbury, Massachusetts is developing a model in the involvement of older persons in the development and design of a major housing complex.

2. Continuing Education

Washington Center for the Study of Services developed a unique approach to consumer education by providing evaluative information on service providers of home maintenance, health services, financial services, etc.

3. Retirement Preparation/Employment

AoA and the Environmental Protection Agency are engaging in a joint effort to improve the environment and increase employment opportunities for older persons. The Senior Environmental Employment Program is designed to demonstrate ways older Americans may be employed in jobs which improve and protect the environment and which provide alternatives to forced retirement.

4. Special Services for the Physically and Mentally Impaired

New York City Department of Aging, the Community Service Society and Bellevue Hospital Geriatric Unit established a Friendship Center designed to serve the community's mentally impaired or at risk elderly, many of whom are non or limited English speaking. The demonstration provides a basis for planning programs to enable these older persons to continue functioning within the community.

5. Improved Services to Underserved Populations

(low-income, minorities, Indian, limited English speaking and rural elderly)

Several grants have been made to Indian tribes and organizations to developed service delivery systems for elderly Indians previously underserved. A major

effort by the national Indian Council on Aging, supported by a Model Projects grant, is developing policies and initiatives, nationwide, to improve access for elderly Indians to the whole spectrum of Federal, State and local resources.

6. Disaster Assistance for Older Americans

A set-aside of $250,000 in Model Projects funds was authorized for Presidentially declared disasters. Older victims of disasters have fewer resources to start over again and are often less aggressive in seeking help. Model Project funds are encouraging increased involvement of the aging network in generating emergency food and shelter, and in assisting older persons to get loans and in restoring older victims' life styles when disasters occur. Two such projects have been jointly funded by the Administration on Aging and the Federal Disaster Assistance Administration.

7. Senior Ambulatory Day Care Centers

Demonstration projects are defining the role of the adult day care center and determining the place of this emerging level of care on the long term care service delivery continuum. The On Lok Senior Health Services in San Francisco is providing the nation a unique model of the multi-cultural social/health services day care center for the frail elderly. A demonstration of two different models of day care programs under single management is being conducted by the Lockport Senior Citizens Centre, Inc., Lockport, New York.

In addition, model projects awards supported the following demonstrations of national importance:

- Six Statewide models of comprehensive home services involving multiple State agencies are being tested for adoption in other States under the auspices of the National Council of Homemaker Home-Health Aide Services, Inc. These models accommodate the need for both occasional and sustained health, social and other services in the home.

- Crime prevention projects were started in six cities funded jointly with the Department of Housing and Urban Development, Community Services Administration, and the Law Enforcement Assistance Administration.

- Organizational development support was provided national organizations in the field of aging to increase their capacity, e.g., National Association of State Units on Aging; National Asssociation of Area Agencies on Aging; National Center on the Black Aged; Asociacion Nacional Pro Personas Mayores; National Indian Council on Aging.

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TITLE II: NATIONAL CLEARINGHOUSE FOR THE AGING

The National Clearinghouse for the Aging is charged with the collection, analysis and dissemination of information about older people and their needs. During FY 1977, the Clearinghouse continued to expand its activities in the areas of public information, statistical analysis, public inquiries, publications distribution, and information referral policy.

Service Center for Aging Information: The National Clearinghouse for the Aging major initiative in FY 1977 was the development of the Service Center for Aging Information (SCAN). The purpose of SCAN is to expand access to the knowledge base related to the aging field, and to make that information readily available. SCAN is an automated bibliographic information system designed to facilitate utilization of the growing body of gerontological literature and research findings. The implementation of the SCAN system, which is to be completed in phases, is scheduled for FY'78 and FY'79. The National Clearinghouse for the Aging will manage and administer the information system by establishing policies and guidelines that will be carried out under contract.

This system is modeled after the Educational Resources Information Center (ERIC) established by the National Institute of Education. The SCAN system will consist of three decentralized resource centers which will be responsible for collecting, indexing and abstracting reports of journal literature within their respective topic areas. Organization of the centers will be along disciplinary lines to cover three major areas: bio-medical, behavioral - social science, and social practice.

Public Information: Public information activities concentrated on providing support for the Network of public and private agencies working for and with older persons and on increasing public awareness of the circumstances, needs and contributions of the older population.

Aging Magazine entered its 27th year of publication publishing news of innovative developments in the field of gerontology, proposed programs, legislation and reports of studies in the field.

Publications: The National Clearinghouse for the Aging issued several publications produced by staff or other AoA offices, grantees and contractors. Some of the most significant are as follows:

- o A National Directory of Education Programs in Gerontology— Information on gerontological activities of 1,275 colleges and universities in the United States.

- o Evaluative Research on Social Programs for the Elderly--Report of a seminar on Evaluative Research sponsored by the Committee on Research and Development Gerontological Society.

- o Facts About Older Americans, 1977--A statistical profile of older Americans and their geographic distribution.

- o The second of a series of AoA Occasional Papers in Gerontology covering Manpower Needs in the Field of Aging: Homemaker-Home Health Aides Services.

- o Older Americans Act of 1965, as Amended--A new compilation incorporating the 1975 amendments.

- o Ombudsman for Nursing Homes-Structure and Process, Second Edition--A manual for the practitioner.

- o National Clearinghouse on Aging THESAURUS--2nd Edition. A basic structure and guide to the acquisition, indexing, and retrieval of material related to the field of aging.

- o Congregate Housing for Older People - An Urgent Need, A Growing Demand. Selected papers from the First National Conference on Congregate Housing for Older People conducted by the International Center for Social Gerontology.

- o Three of a series of 7 Handbooks for State and Area Agencies in Program Development: Multi-Purpose Senior Centers; Legal Services for the Elderly; Homemaker and Home-Health Services.

- o Comprehensive Inventory and Analysis of Federally Supported Research on Aging, 1966-75 (microfiche edition)

- o Fact Sheets describing Federal resources in areas of transportation, nutrition, employment and voluntary services.

Statistical Publications

- o Statistical Reports on Older Americans - Report No. 3: Social Economic and Health Data for the American Indian Population

- o American [illegible] Population 55 years of Age and Older: Geograp[illegible]ribution 1970

- o Facts About Older Americans: 1977

- Income and Poverty Among the Elderly: 1974
- Statistical Memo No. 34 "BLS Retired Couples Budgets: Autumn 1975
- Asian and Pacific Island Americans 60+ - 1970
- Social and Economic Characteristics of Elderly Asian and Pacific Island Americans
- Estimates of the U.S. population 60 and 65+ by State, counties, and planning and service areas.

Increasing Public Awareness:

- Continued distribution of "Don't Stop the Music," an AoA supported film which discusses problems of aging and ways in which communities can help. The film was seen by approximately 67,169 people in FY 1977.
- Development and distribution to State and area agencies on aging of an Information Kit to promote "Over Easy", a new public television program funded in part by AoA.

Statistical Analysis: During FY 1977 a number of publications were completed and statistical information for professionals in the field of aging was prepared. The Statistical Analysis staff also responded to 400 written requests and a similar number of phone requests for demographic, socio-economic and health and other statistical information about the older population.

Information and Referral Policy: During FY'77 the Administration on Aging reaffirmed its commitment to "information and referral services" as a top priority for the National Network on Aging.

Two I&R documents were published Information and Referral: How To Do It; and Information and Referral Services: Research Findings. These two documents are reports of AoA supported research and demonstration projects designed to increase the knowledge base regarding information and referral service delivery.

TECHNICAL ASSISTANCE

Capacity strengthening initiatives during the past year addressed a wide range of areas. The Administration on Aging developed and issued in June a technical assistance handbook for use by the network. This handbook is to be used to improve equal employment practices, to increase the capabilities of State and local agencies in awarding grants and contracts to minority agencies or organizations, and to increase services to low income and minority persons.

The Administration on Aging also contracted for the development of seven technical assistance handbooks designed to guide State and Area Agencies in developing and strengthening the following priority services for older persons:

- information and referral
- legal
- nursing home ombudsman
- homemaker and home health
- senior centers
- employment
- residential repair and renovation

These handbooks, which will be available to State and Area Agencies in early calendar 1978, include information on the importance of the service to older persons, service definitions, alternative service models, and the role of State and Area Agencies in service development. Handbooks for transportation and nutrition services have already been disseminated to the aging network.

During FY 1977 a number of technical assistance memoranda were also disseminated to the Network, covering such subjects as:

o Establishing and financing Adult Day Care Services

o Senior Center organization and management

- o Insurance coverage issues affecting volunteers and older employees who provide transportation for older persons

- o Providing services to older persons with no fixed addresses

- o Program Information for Nutrition Project Management

EVALUATION

During FY 1977, AoA continued work on two major evaluation studies of the Title III Area Planning and Social Services Program and the Title VII Nutrition Program for the Elderly. Preliminary findings from both studies are outlined below.

During FY 1977 evaluation projects were also completed on information and referral and the first year of the implementation of Title XX. A description of their major findings is included. Finally, two new evaluations were begun. These are an evaluation of Title IV-A career training and the use and effectiveness of interagency agreements at the Federal, State and local levels.

Preliminary findings of the Longitudinal Evaluation of the Nutrition Program

Highlights of the recent findings of the Longitudinal Evaluation of the Nutrition Program include the following:

- Proportionally, the Nutrition Program is drawing significantly more low income and minority elderly than is found in the general elderly population and nonparticipant comparison group.

- Twenty-seven percent (27%) of elderly participants in the program are minority compared with eight percent (8%) in the general elderly populations (based on Census Data), and seven percent (7%) in the non-participant comparison group.

- Sixty-eight percent (68%) of participants report an income below $4,000 a year compared with 22% for the general elderly population and 47% for the nonparticipant comparison group.

- More than 50% of all program participants live alone while only about 1/4 of all elderly in the U.S. live alone.

Summary of Evaluation of I&R Services for Older Persons

Overall, the I&Rs designated by State and Area Agencies on Aging visited were meeting AoA minimum requirements for I&R and were also meeting a number of the long-range goals. In general, I&Rs were were making an effort to provide the best quality I&R services they could within the limits of their resources. There were some exceptions, but generally the findings were positive.

Highlights of the findings are:

Services Provided:

- Most I&Rs connected older persons with service providers who could meet their needs.
- Most I&R's were already providing follow-up, escort and transportation services.
- The majority of I&Rs were meeting publicity requirements and providing outreach services.

Quality of Services:

- Resource files were generally comprehensive in their listing of available resources for older persons.
- A high level of planning and coordination activity was reported by a majority of I&Rs.
- The majority of I&Rs were meeting the confidentiality requirement to keep personal information on users in locked files.

Cost and Quantity of Services:

- The average cost per inquiry was $4.60, with a range of less than $1.00 to more than $20.00.
- On the average, one inquiry was received by the I&R annually for every nine older persons in the area served.

First-Year Evaluation of the Implementation of Title XX

Administration for Public Services Regional Offices and Title XX State agency staff perceptions of the role of State and Area Agencies on Aging in the first year of Title XX were as follows:

- Specifically, the majority of State Agencies on Aging have been more active or influential in the making of social services decisions than they were prior to Title XX.

- Overall, the Area Agencies were seen as having been less active or influential than State Agencies. However, Area Agencies in 18 States were seen as more active during the first year of Title XX than they had been before. Among the most frequent actions in this regard were:

  (1) Development of Cooperative Agreements

  (2) Participation in Title XX Advisory Councils

  (3) Exchange of Plans and Needs Assessment Material

  (4) Review and Comment on Comprehensive Annual Service Plans

      - Attendance at public hearings

      - Negotiating of purchase of service agreements

- Generally, where State and Area Agencies were perceived as being active in the Title XX process, the Aging were seen as benefiting from Title XX. Some example of results of State and area agency on aging involvement:

  (1) Raising eligibility levels for aging persons and/or services to the aging

  (2) Adjustment in States' fee policies

  (3) Elimination of barriers to aging services

  (4) Expansion of services to the aging

relation to the amount of Title XX services going to older

States, the percent of Title XX services to aged SSI
ts is below the percent of aged in the population.
States, it is half or lower. However, 7.2% of all
social services go to aged SSI recipients.

4 top ranked services in terms of expenditures
tle XX, only 5 show major expenditures going to
rsons as SSI recipients. These are homemaker,
ealth related, home management and transporta-
vices.

protective services show a low percent of expenditures
ged recipients. However, both are available to the
population without regard to income.

and foster care also show a low percent of expenditure
ged recipients.

States, the percent of Title XX services to SSI aged
s is equal to or slightly higher than the percentage of
he State's population.

States are "at ceiling", there is substantial opportunity
nd Area Agencies to increase the amount of Title XX services
der persons by such activities as:

nvolved in the State budget process, since governors
latures have the power to reallocate social services

ng substate planning.

taff to the Title XX agency to participate in Title XX
committees, planning groups, and to conduct needs assess-

of the Title IV-A Career Training Program in Aging

an evaluation project, to be completed in July, 1978, was
to meet the following objectives:

1. to determine whether students who have received support under the career training program are, in fact, able to obtain jobs in the field of aging.

2. to determine how universities decide on the level, type, and recipients of student support and the factors involved in the decision-making process.

3. to determine characteristics of students enrolled in AoA supported programs and whether the characteristics of students receiving AoA support differ from those not receiving AoA support.

4. to determine the extent of faculty and institutional involvement in the field of aging at those universities receiving AoA support and, to the degree possible, the relationship of this involvement to the existence of AoA support.

5. to determine the relationship between the AoA supported training programs and the National Aging Network at all levels.

Evaluation of the Use and Effectiveness of Interagency Agreements at the State Level

An evaluation contract was awarded to evaluate the use of interagency agreements at the State level as tools to increase coordination among State Agencies and to measure the outcomes of specific interagency agreements.

The evaluation is being expanded to include an analysis of Federal and Area Agreements. Area Agencies will be involved. The formal interagency agreements within all the States will be analyzed, looking at such factors as parties involved, objectives ,and steps to be taken to accomplish these objectives. This analysis will be presented in an independent report.

ADVOCACY AND COORDINATION

FEDERAL COUNCIL ON THE AGING

History:

The Federal Council on the Aging was created by Congress under the 1973 amendments to the Older Americans Act for the purpose of advising the President, the Secretary of the Department of Health, Education, and Welfare, the Commissioner on Aging and the Congress on matters relating to the special needs of older Americans. The Secretariat for the Federal Council on the Aging is housed in the Administration on Aging for administrative purposes.

The Council is composed of 15 citizen members appointed by the President for three-year terms and is chaired by a member designated by the President. The Present Chairman of the Council, has also been designated by President Carter as his Counsellor on Aging. The Secretary of the Department of Health, Education, and Welfare and the Commissioner on Aging are ex-officio members. Ten members of the Council are themselves older persons. They and the other members are drawn from older Americans, national organizations with an interest in aging, business, labor, and the general public, as called for in the law.

Advocacy:

In fulfillment of its mission of advocacy for the elderly, the Council has made a number of recommendations to the Executive and Legislative branches of Government. Aside from specific projects on health manpower, minority elderly, assets, and the frail elderly, the Council is concerned with and monitors major legislative and administrative initiatives in such areas as Social Security financing, welfare reform, mandatory retirement, national health care, long-term care, Older Americans Act, and Title XX.

A recent Council study on "The Interrelationships of Benefit Programs" examined the negative effect that one or more programs may have on an older person's eligibility for benefits from other programs. As a result of the findings of this study, the FCA commissioned a study on the treatment of assets and asset income in determining eligibility for income-conditioned benefit programs. This study

is being conducted by the Institute for Research on Poverty at the University of Wisconsin. Technical papers were published in late 1977, presenting a range of policy options to the Council as the basis for recommendations to the President and the Congress on a national policy for treatment of assets.

The FCA continued to develop recommendations for services to the "frail elderly". These oldest of older Americans are seen as a a sub-group within the aging population who should have an entitlement to case assessment and case management for them to cope with daily living. This social support would be complementary to income maintenance, shelter, and health benefits.

To assure that the special needs of the elderly are fully considered as the Nation debates the role of the Federal Government in providing better health care for its people, the Council has adopted "Principles for National Health Care and the Elderly." The FCA advocates inclusion of the elderly in any Federal initiative to improve health care and urges the development of a national health policy emphasizing the maintenance of health, treatment of illness, and care of the sick, rather than merely focusing on a method of financing.

The Older Americans Act mandates the Council to inform the public about the problems and needs of the aging. The Council carries this out through broad distribution of its reports and publications. In early 1977 a periodic "status report" was initiated to provide the field of aging with a summary of major actions of the Council taken in connection with its quarterly meetings.

INTERAGENCY AGREEMENTS

In its role as the Federal focal point for action to benefit older Americans AoA works to mobilize and coordinate existing Federal resources to meet the service needs of older persons. In this capacity AoA has negotiated and signed 23 working agreements with

Federal Agencies. During Fiscal Year 1977, AoA negotiated six new intra and inter departmental agreements, concerned with health services, nutrition services, crime prevention, legal services, disaster assistance, and educational opportunities. Other agreements previously negotiated include Information and Referral Services, Title XX services, Medicaid, housing, rehabilitation services, transportation, energy, and public health services. There are 320 State level interagency agreements currently in effect.

These agreements serve to focus the attention of the Federal agencies involved on the service needs and concerns of the elderly. The agreements call for specific actions which commit the Federal agency to using its leadership and technical assistance capacity to focus the attention on meeting the needs of older persons. Inter-agency agreements contribute to and support the goals of the National Network on Aging in its effort to establish comprehensive coordinated service systems on the community level to realize the objectives of the Older Americans Act.

OTHER FEDERAL COORDINATION ACTIVITIES

Besides the negotiation and implementation of interagency agreements, the Administration on Aging was engaged in other Federal coordination activities during FY 1977.

Federal Regional Councils - The Federal Regional Councils (FRCs) have established committees on aging which include representation from departments and agencies with programs that impact on the elderly. These committees serve to identify and ameliorate program coordination problems and to assist State and local officials to improve programs which affect older persons. Some of the committees also include voluntary organizations such as the American Red Cross, the American Association of Retired Persons and others. Examples of FRC activities include the following:

- providing technical assistance to Area Agencies on Aging in developing effective program coordination and in developing interdepartmental agreements
- conducting joint meetings with Federal program personnel and State Government counterparts
- publishing Regional Newsletters with information about programs for the elderly
- developing and distributing directories of Federal services for the elderly
- working with Indian Tribes on problems of program coordination involving Federal and State resources.

Federal Executive Boards - The Federal Executive Boards are organized in 26 major metropolitan areas. Membership consists of the highest ranking Federal officials in each city. Under AoA assistance the FEBs have been involved in helping area agencies on aging establish adequate Information and Referral sources for the elderly. In addition, program efforts have been directed toward making the Federal agencies themselves more responsive to calls from the elderly. Some FEBs are giving Federal employees orientation in the characteristics

of the elderly in order to promote better communication. Programs address fuel and energy, crime prevention, and other problems of older persons. Directories of local services for the elderly have been updated and distributed. Efforts have been made to unify and publicize Information and Referral numbers. The FEB's also focused on problems of residents in nursing homes.

Federal Inter-Agency Task Force for Research on Aging

As in past years, AoA exercised its leadership role in the Federal Inter-Agency Task Force for Research on Aging. The Task Force serves as a coordinating body for Federal Agencies which fund research related to the aging. In a previous project under the sponsorship of the Task Force, AoA funded the development of a nine volume Inventory of Federally Sponsored Research on Aging, 1965-1975. During FY 1977, AoA funded a contract for dissemination of the Inventory to the State and Area Agencies and major research centers.

The Interdepartmental Task Force on Information and Referral

The Interdepartmental Task Force on Information and Referral has continued to meet and is currently concentrating on two major objectives of the I&R Agreement: (1) to extend and coordinate efforts of participating departments and agencies in information and referral; and (2) to encourage their counterparts in States and communities to cooperate in making information and referral services immediately available to older people. In FY'77 the Interdepartmental I&R Task Force developed and published a brochure entitled I&R GUIDE which identifies and describes the five building blocks which are essential to the delivery of effective information and referral services. Another publication, soon to be printed, is the first annual report of I&R activities of the agencies which comprise the Interdepartmental Task Force.

The Interdepartmental Task Force on Statistics-Working Group on Aging

The Interdepartmental Task Force on Statistics sponsored by AoA has prepared a draft copy of the Inventory of Statistical Programs on the Elderly. This document will contain descriptions of all Federal statistical programs in which age is collected as a data item, the purpose of the survey, limitations of the data, the level of geography at which the data are collected and tabulated, the publications in which the results of the tabulation can be found, and so forth. The final document can then serve as a data resource to coordinate and improve the collection of data on the elderly and to develop and provide special tabulations.

SPECIAL PROJECTS

AoA Role in Disaster Planning

Continuing to build on previous experiences in the area of disaster planning and follow-up, the Administration on Aging was able to make additional progress toward enhancing the capacity of the National Network on Aging to respond to needs of elderly disaster victims.

The booklet "Planning for the Elderly in Natural Disaster," produced under a grant from the Administration on Aging, as an outgrowth of the first National Conference on Disasters and the Elderly held in Omaha, Nebraska, in 1976, was distributed to the National Network on Aging along with a technical assistance memorandum in March, 1977. The memorandum was a sequel to the planning document and the Administration on Aging's Memorandum of Understanding issued the previous September. In addition to spelling out the responsibilities of the various components of the National Network on Aging, the memorandum included a sample Regional Office/State Agency on Aging agreement on disasters, a sample State Agency on Aging instruction to all of the State and sub-State agencies involved in disasters, and a sample section of an Area Agency on Aging plan covering disaster activities. Based on this material several Regions have held training sessions for State Agency on Aging staffs, and a number of States have held training sessions for aging personnel in their States. The Federal Disaster Assistance Administration has assisted in the training.

The Administration on Aging has continued to work with State and Area Agencies in individual disasters. AoA Field Liaison Staff and Regional Office staffs provided substantial assistance to a number of States during the severe winter. For example, in the Presidentially declared disaster in the Buffalo, N.Y., area, AoA gave extensive help, including a $119,655 Model Project grant designed to develop information on severe weather assistance to older persons and establish a county-by-county Statewide disaster assistance program for the elderly as a model for the network on aging. As a follow-up to this winter effort, older persons were encouraged to respond to the invitation of the Energy Policy and Planning Office to comment on hardships and economic problems caused by the severe weather. A subsequent report on the public's response noted the substantial number of comments received from older persons.

The Administration on Aging provided considerable disaster assistance throughout the year. The following examples are only a few of the many Network efforts. The Administration on Aging was likewise involved with staffs in Regions III and IV in the April flooding in Appalachia. In Region VII staff worked with the State Agency and affected Area Agencies to meet the needs of elderly victims when a series of tornadoes hit Missouri.

The State of Hawaii's County of Hawaii Office of Aging evacuated older persons from the town of Kalapana, when they were endangered by the lava flow from a potentially destructive volcanic eruption on the island of Hawaii. The threat lasted for six days and the elderly and their possessions were removed from the area and assisted by the aging program.

When older persons in large numbers suffered losses as the result of the July 20 flood in Johnstown, Pennsylvania, the Federal Coordinating Officer for the Federal Disaster Assistance Administration called on the aging network at all levels to work closely with his office.

The House Select Committee on Aging held the first hearing on the issue of "Weather Disasters and the Elderly" on June 29, 1977 concentrating their interest on the 1975 Omaha tornado, the 1976-7 Buffalo blizzard, and the 1977 spring Appalachian states floods and the cooperative efforts of the Administration on Aging and the Federal Disaster Assistance Administration. The Commissioner was one of the principal witnesses.

Physical Fitness for the Elderly

As the result of successful demonstration programs in physical fitness for older persons conducted in 1976, the National Association for Human Development was funded by the Administration on Aging for a nation-wide program. In most instances headquarters and Regional Office staff worked with the National Association for Human Development and the President's Council on Physical Fitness and Sports to bring together the network on aging and the practitioners in health, physical education and recreation to develop cooperative programs at the community level. Nearly all State Agencies on Aging, including Hawaii, were involved in the training programs aimed at involving older persons in physical fitness programs in Title VII nutrition projects, senior centers, public housing, homes for the elderly, and other congregate settings.

Direct Deposit Program

The Department of the Treasury requested technical assistance from the Administration on Aging in intensifying its efforts to encourage recipients of Federal checks to have them deposited directly in their personal bank accounts, because of the large number of older persons receiving checks from Social Security as beneficiaries and through the Supplemental Security Income Program, Railroad retirement, Civil Service Commission annuities, and Veterans Administration. AoA headquarters and Regional Office staffs worked with Treasury staff on the development of training materials, on the testing of the training, and then on training all Regional Office staffs, who in turn trained State Agency on Aging staffs. The State staffs then trained Area Agency and Title VII project staffs in the direct deposit program so they could present the information to older persons. AoA also worked with Treasury in the involvement of other Departments and agencies with access to groups of older persons in the Regional training programs. It is expected that the direct deposit program will provide some degree of protection to older persons who are preyed upon at the time when Federal checks are delivered by mail.

Experience Exchange

At the Commissioner's request the Field Liaison Staff investigated the possibilities of developing a program for exchanging experiences and expertise within the National Network on Aging. The Area Agencies on Aging had requested in-depth information on innovative programs which had been developed to the point where they might be replicated without trial and error. The program developed as the result of the study consisting of monthly informational sheets called "Experience Exchange." Each issue was devoted to a single subject, reported on one or more innovative experiences, and provided information on available literature and the availability of a person or persons with expertise. Subjects covered were: health fairs, employment, aging and blindness, mental health care and aging, fire safety for the elderly, cardiopulmonary resuscitation/Heimlich maneuver, elderly deaf and burglar proofing of residences. Response from the network was positive with numerous requests for materials and for sharing of expertise. Based on the response, a decision was made by the Commissioner to include the "Experience Exchange" in AGING magazine.

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Over Easy

"Over Easy" is America's first daily television series for older persons. It is designed to provide entertainment, information of special interest, and examples of projects involving the elderly. AoA, the Corporation for Public Broadcasting, and the American Association of Retired Persons funded KQED-TV in San Francisco to produce two "Over Easy" pilot programs. They were broadcast in September on 240 public broadcasting stations, and received high marks from older persons, the public-at-large, and agencies responsible for serving older people. The series is being broadcast in prime time hours Monday through Friday by most local PBS stations.

"Over Easy" is the culmination of three years of planning. The producers, with the assistance of a content advisory committee made up of well known experts in gerontology, researched the field of aging to determine what the problems are, how older persons feel about themselves and their lifestyles and what progress is being made because of programs at the national, State and local level. With Hugh Downs, formerly of the "Today Show," as host, "Over Easy" explores the widest variety of topics of interest to older people. Each half hour program uses a magazine variety format to report on subjects such as housing, transportation, nutrition, health and medicine, money management, consumerism, legal rights and other concerns of older people.

Goals of the "Over Easy" series include fostering positive attitudes about aging in the society as a whole, but especially among those growing older. The producers want to dispell myths and stereotypes about older persons and the aging process. Hopefully "Over Easy" will stimulate interest in the needs, concerns and aspirations of the growing number of older persons. Also it will bring millions of older persons into contact with information and services that are designed to improve their living conditions. It should be a new resource for serving older persons.

White House Conference on Handicapped Individuals

The White House Conference on Handicapped Individuals took place May 23-27, 1977. The Conference brought together 3700 people from every State and territory. These delegates were designated to represent the concerns of more than 35 million Americans with mental or physical disabilities. The Conference provided the first opportunity for persons with handicaps to speak up in their own interest and vote for recommendations which present approaches to the problems that directly affect their lives.

Prior to the Conference, members of the Administration on Aging staff who had been members of the staff of the White House Conference on Aging in 1971, provided considerable assistance to the Office of Human Development in preliminary plans for the White House Conference on Handicapped Individuals. AoA provided State Agencies on Aging with background information so they could work with State Conference Directors in the involvement of older persons in sections relevant to the needs of the handicapped aged.

The important findings of the Conference have been documented in the form of recommendations, resolutions and a summary of the proceedings. The mission of the Conference was:

- to stimulate a national assessment of problems faced by individuals with mental or physical handicaps,
- to generate a national awareness of those problems,
- to develop recommendations for legislative and administrative actions which help handicapped individuals live independently, with dignity and integrated into community life.

In April 1977, just prior to the White House Conference, final DHEW regulations were signed implementing Section 504 of the Rehabilitation Act of 1973. Section 504 prohibits discrimination against handicapped persons in programs and activities which receive Federal funds. As a result of the White House Conference and Section 504, the Administration on Aging reaffirmed and strengthened its long standing commitment to serve disabled older persons. State planning guidance issued in June required action plans for the implementation of Section 504 throughout the Aging Network.

B. ADMINISTRATION FOR PUBLIC SERVICES

The Administration for Public Services has responsibility for administering the Social Services programs authorized under Titles I, IV-A, X, XIV, XVI, and XX of the Social Security Act, as amended. Except for Guam, Puerto Rico, and the Virgin Islands, Title XX superseded all of the authorizing titles cited above as of October 1, 1975.

Under Title XX, grants are made to States for services to eligible individuals based on income or income maintenance status. Certain services can be provided without regard to income, or on a group basis, at State option. States may choose the services they will provide, as long as each service is directed to at least one of the five Title XX goals, and at least three services are directed toward Supplemental Security Income (SSI) recipients.

A variety of services directed to assisting needy aged persons to attain or maintain a maximum level of self-care and independence are provided through the social services program. Included are such services as adult day care, adult foster care, protective services, health-related services, homemaker, chore, transportation, and other services that assist elderly persons to remain in their own homes or in community living situations. Services are also offered which facilitate entry into institutional care when necessary.

Although data in APS is not collected by age group, it is estimated that approximately $315,000,000 will be expended on services for the aged in FY 1979. This estimate is derived based on 50% of the SSI service population which is representative of the aged persons served.

C. REHABILITATION SERVICES ADMINISTRATION

The major goal of the Rehabilitation Services Administration's program for the Aging is to rehabilitate as many older handicapped individuals as possible into gainful employment through activities of the State-Federal rehabilitation program administered by the agency.

The State Rehabilitation agencies endeavor to assist each individual to reach his most adequate functioning level and highest vocational potential. This is accomplished through a diagnosis of his condition followed by various services designed to overcome his specific handicap. Throughout the process, the emphasis is on helping the individual to help himself. These services include: evaluation and medical diagnosis to determine the nature and extent of the disability to ascertain capacity for work; counseling to help in developing a good vocational plan; medical care to reduce or remove the disability; vocational training and placement into employment; and follow-up to ensure satisfactory placement.

The Rehabilitation Services Administration cooperates with the Administration on Aging in various activities and projects and will continue to do so. A Cooperative Agreement, now in the process of being revised, has been established between the Administration on Aging and the Rehabilitation Services Administration. It is designed to bring about improved coordination between the resources of the State-Federal program of vocational rehabilitation and the resources available under provisions of the Older Americans Act of 1965, as amended.

Several Innovation and Expansion Grants are focused on rehabilitation of the disabled aged. These include a project in Wisconsin which provides services by mobile van to counties in the northern part of the State that are not easily accessible; two projects in New Jersey -- each focused on an increase in staff to expand services for the elderly, and a work opportunity project for the elderly blind in the District of Columbia.

In FY 78, special projects designed to expand and improve rehabilitation services for blind people who are at least 55 years of age were active in Hawaii, Nevada, New York and Texas, with three new projects slated for initiation in that year.

The Rehabilitation Services Administration coordinates with the Social Security Administration in utilizing the Social Security disability insurance and Supplemented Security Income disabled and blind applicant load as an important referral source of older disabled persons for State vocational rehabilitation services.

It is estimated that there are over 4 million people 45 years of age and over eligible for, and in need of, rehabilitation services, of whom nearly one million are aged 65 and beyond. In an effort to alleviate this situation, State rehabilitation agencies have been intensifying their efforts to serve aging handicapped.

Number of People Rehabilitated:

Fiscal Year	All Rehabilitants	45 Years of age and over	65 Years of age and over
1975	324,039	69,836	5,546
1976	303,328	67,213	5,886
1977	291,202 1/	62,244 1/	5,533 1/
1978	283,000 1/	60,500 1/	5,600 1/
1979	277,000 1/	59,200 1/	5,800 1/

1/ Estimated

II. SOCIAL SECURITY ADMINISTRATION

Programs Administered by the Social Security Administration

The Social Security Administration (SSA) administers programs which provide protection against loss of earned income due to retirement, disability, or death for over 90 percent of the workers and their families in the United States. Beginning January 1, 1974, SSA assumed responsibility for payments to aged, blind, and disabled persons under the Supplemental Security Income program, which replaced the State and locally administered programs of old age assistance and aid to the blind and disabled. Under different matching formulas, the Federal government paid part of the cost of these programs through grants formerly administered by the Social and Rehabilitation Service. In March 1977, as a result of the HEW reorganization, administration of the Federal share (provided through grants and contracts) of the Assistance Payments programs and the Refugee Assistance programs was transferred to SSA. At the same time, the Medicare administrative activities covering:

(1) the claim payment functions performed by contractors,

(2) services performed by State agencies in certifying and consulting with providers of services, and

(3) general direction of the Medicare program,

have been transferred to HCFA. SSA retains certain functions of the Medicare program such as enrolling persons into the program, premium billing and collection, and maintenance of the data base on entitlement and premium information.

Benefits to Older Persons

Under the retirement, survivors and disability insurance programs (title II of the Social Security Act) monthly cash benefits are paid to aged or aging persons, their dependents and their survivors. The following categories of older persons can receive monthly cash benefits:

--Insured workers age 62 to 72 who have retired.

--Insured workers age 72 and over, even if not retired.

--Insured disabled workers up to 65 years of age.

--Certain individuals age 72 and over who are not insured under the regular social security program.

--Wives or dependent husbands age 62 or over of retired or disabled insured workers.

--Widows or widowers of insured workers age 60 and over.

--Certain disabled individuals age 50 and over who qualify as widows, widowers, or surviving divorced wives of insured workers.

--Dependent parents, age 62 or older.

Of the 33,706,000 beneficiaries receiving monthly retirement, survivors or disability insurance benefits at the end of September 1977, about 25,114,000 were age 62 or over. Approximately 93 percent of all persons age 65 or over either receive retirement, survivors or disability insurance benefits or are eligible for benefits on retirement. This proportion will grow until practically all aged persons are protected. The minimum monthly benefit for a retired worker who meets the regular insurance requirements is $114.30 under present law. For retired couples the present minimum is $171.50. Benefit amounts are subject to actuarial reduction if the benefit is taken prior to age 65. Special payments for certain uninsured persons age 72 and older (Prouty benefits) are $78.50 a month for a single person and $117.80 a month for a couple. Illustrative average monthly benefits being paid at the end of December 1977 follow:

retired worker	-- $237.00
retired worker and spouse	-- $404.00
aged widow	-- $224.00
disabled worker	-- $255.00

Title XVI of the Social Security Act provides for a Federally administered and financed Supplemental Security Income (SSI) program for needy aged, blind or disabled persons. This program assures income of at least $177.80 per month for an individual and $266.70 per month for a couple. Under present law, in July 1978 the support levels are estimated to increase to $188.90 and $283.30 respectively. Certain income disregards included in the law allow some limited additional income, and encourage beneficiaries to work when they are able to do so. Lien laws are not applicable and, generally, beneficiaries may retain their home and automobiles. Eligibility requirements and support levels are the same in all States. Recipients who were on the rolls as of December 31, 1973, for the State administered programs for the aged, blind, and disabled are protected against reduction in income resulting from the changeover to a Federal program. To be eligible for Medicaid, States must agree to maintain the December 1973 income of each aged, blind or disabled recipient who received an assistance payment for December 1973 and was converted to the Federal program. In addition to this mandatory supplementation of SSI payments, States also may optionally supplement the Federal SSI benefit regardless of whether a recipient was converted or

newly eligible. States may administer their own supplementation payments or choose Federal administration. For States which choose Federal administration, the Federal government pays the costs of administering the supplementation payments. A State choosing Federal administration is protected from paying more in State supplementation, because of overall growth in the recipient population than it paid in calendar year 1972 for assistance payments to the aged, blind and disabled. Estimated Federal benefit payments to the aged, blind and disabled under this program in fiscal year 1979 will amount to $5.2 billion, of which $1.5 billion will be to persons age 65 and over.

Benefit payments are made under the Federal Mine Safety and Health Act of 1977 from general revenues to coal miners who are totally disabled due to pneumoconiosis ("Black Lung disease") and to widows of coal miners who died due to pneumoconiosis. These benefits are increased if the beneficiary has eligible dependents. Benefits also are payable to orphans, and in certain circumstances to totally dependent surviving parents, brothers and sisters. Many of the beneficiaries are aged because the Act permits former coal miners and widows to qualify without limitations on either age or how long ago the disability occurred. In fiscal year 1977, benefits paid to persons age 65 and over under this program were $662 million. Payments to such persons are expected to be $699 million in FY 1978 and $736 million in FY 1979.

Under title I of the Social Security Act (grants for Old Age Assistance), the Assistance Payments program provides financial assistance to the needy aged, blind and disabled in Guam, Puerto Rico, and the Virgin Islands, as these territories are not covered by the Supplemental Security Income program. While the Federal government covers 50 percent of covered costs under this Adult Assistance program, these costs are limited by overall caps on grants to the territories for Aid to Families with Dependent Children (AFDC) and Adult Assistance. Federal grants for the aged under the assistance payments program were $2 million in 1977. The same level of expenditure is estimated for 1978 and 1979.

Two distinct refugee groups are served through the Refugee Assistance program. Authorization to provide special assistance to refugees from Vietnam, Cambodia, and Laos is provided in the Indochina Migration and Refugee Assistance Act of 1975, as amended. The Migration and Refugee Assistance Act of 1962, was enacted June 28, 1962, following the President's establishment of a temporary program in February 1961, to meet emergency needs of Cuban refugees entering the United States. The Southeast Asian Refugee Assistance program will terminate in 1981 and the Cuban Refugee Assistance program will terminate in 1983. Benefits paid to persons age 65 and over under these programs were $32 million in FY 1977. Payments are expected to decrease to $30 million in FY 1978 and $22 million in FY 1979.

Services to Aged Individuals and to Community Groups

The social security programs are administered through a network of district and branch offices. Local communities are served by 632 district offices, 690 branch offices, 47 resident stations, over 3,000 contact stations, and 30 teleservice centers. Every attempt is made to tailor services to individual needs and desires.

Thus, all offices provide face-to-face interviewing in the office or in the individuals' home, telephone service, and mail service.

Social security district offices provide information to the public and answer inquiries about the benefits administered under titles II, XVI, and XVIII of the Social Security Act. They also receive, develop, and initially adjudicate claims for such benefits. Applicants are assisted in securing the factual information needed to determine eligibility for benefits and are advised of their rights. For adult beneficiaries who are not capable of managing their funds, a person other than the beneficiary is selected by SSA to receive the checks and is held accountable for using the benefits in the best interest of the beneficiary.

Social security offices traditionally have provided a referral service to community members, groups, and agencies. In many communities the social security office is the only point at which information and referral services are available.

In the areas of community and Government-wide planning, SSA plays a vital role. Data about the number and characteristics of beneficiaries is invaluable in planning services to meet existing needs, as well as in long-range planning endeavors. At the national level, SSA's planning is coordinated with the planning of other departments, agencies, and organizations, both public and private, such as the Department of Agriculture, Public Health Service, Administration on Aging, Health Care Financing Administration, Department of Housing and Urban Development, ACTION, American Public Welfare Association, National Council on the Aging, and the American Red Cross.

Similarly, regional offices engage in planning and coordination of SSA activities at the regional level as these relate to other public and private agencies and programs that serve the aged. The regional offices provide the liaison with the State and local agencies administering the Assistance Payments and Refugee Assistance programs and monitor State administration of these programs. To facilitate effective administration of the Supplemental Security Income program, regional teams are providing important liaison between SSA and State departments of social service to assure that applicants and recipients of assistance payments are referred to both agencies as appropriate.

At the local level, SSA participates in interagency community planning for development of resources with many health and welfare agencies. These include representatives of health and welfare councils, local government

officials, local representatives of national public and voluntary agencies such as ACTION, U.S. Department of Labor, National Council on Aging, County Commissions on Aging and senior citizens groups, American Red Cross, etc. Projects resulting from this participation often involve substantial numbers of older people recruited to perform a variety of activities throughout the community as well as in SSA offices. Examples of these activities include outreach programs such as FIND and SSI Alert, in which older volunteers contact vast numbers of potential aged individuals to assure that all who are eligible take advantage of income, health, and welfare programs available to them. Social security offices cooperate with all such projects and provide training to volunteers on eligibility requirements, procedures, etc. While some aged workers are volunteers, others are paid nominal amounts by ACTION under the Retired Senior Volunteer and Foster Grandparents programs or by the Department of Labor under contract with local groups serving the aged. Most older people working in social security offices are paid, and work part-time, performing clerical, and sometimes higher level functions. Projects and activities such as those described, sponsored by the government and by private agencies, have clearly demonstrated the effectiveness of older worker performance as well as advantages to the retiree and to the employing agency.

Research on Economic Security for the Aged

The Social Security Administration research and statistical program provides information derived from the operations of the Social Security Administration system, from population surveys and from studies of related public and private income maintenance programs that is useful for continuous evaluation of the effectiveness of the social security programs in providing economic security for the aged. Data are developed and published regularly in the Social Security Bulletin and its Annual Statistical Supplement, in special published reports and in various other ways to meet user requests.

Indicative of the types of information made available and of interest to officials and groups planning programs for the aged are: continuously reported data on claims and benefit payments to retired workers and their dependents; the findings of surveys of the aged population, which provide information about the level of economic security that social security benefits support (information obtained on income includes source of income of individuals and families, level and types of assets owned, special demands on income such as medical expenditures, etc.); special studies that show the changing share of the total national output going to the aged, what measures of income adequacy are most appropriate and meaningful, the relationship between individual and family income over the life cycle; continuing statistical series that are concerned with the totality of public and private income maintenance protections and the relative weight of the social security program in that totality. Social Security Administration research draws heavily upon basic data in the social security system, data from the population survey program and upon data from the Bureau of the Census, Bureau of Labor Statistics, and other statistical sources.

III. PUBLIC HEALTH SERVICE

A. NATIONAL INSTITUTE ON AGING

This decade is one in which aging has become a topic of great interest. Media giants such as Time and Newsweek have paid public tribute to the impact of this "gray revolution" with cover stories on the revolt of the old and the graying of America, respectively. Aging is in vogue--depleted oil wells are now described as "senile" and the slumping stock market is referred to as a "little old lady"--both acknowledging the force of gray America and revealing the deep-seated, and perhaps unconscious, prejudice against the old that pervades our culture, our economic and social systems, and the provision of medical care. Improvements in health care, especially the abolition of many childhood diseases, have given Americans a greater opportunity to live longer. This longevity is now being matched by increasing attention to the quality of life.

GERIATRIC MEDICINE

Each of us in America ought to be able to expect good health care for the whole of a lifetime--however many years that may be. But the nation has few physicians trained in the special skills of caring for the elderly, and our reasonable expectations may not be met as we grow older.

At the National Institute on Aging, we are confronted daily by the need for expanded education in geriatrics. We serve a constituency of overmedicated and undertreated older people who must seek help from physicians who are not yet fully equipped to care for them. Despite the growing number of elderly, many physicians have had to chart their

own learning programs for care of the old because training is not regularly available. Their efforts, combined with scientific advances in our understanding of the aging process, have led to the development of a special body of knowledge about the aged and aging. We believe that the time is right for this information to be incorporated into the medical school curriculum. Abetted by an Institute-sponsored conference on geriatric medicine and the private endowment of our country's first chair in geriatrics at the Cornell New York Medical Center, there has been a marked increase in interest in geriatric medicine throughout the country. However, a great deal remains to be done before geriatric medicine extends beyond a relative handful of people working in isolation and becomes a fundamental part of primary and speciality care training.

DEMOGRAPHY

Predictions of the growth of the older population are not guesswork. Those people who will be old in 2030, when the segment of our population over 65 will be more than double what it is today, are now alive. They are the children of the World War II "baby boom," the youth who "greened" America and will go on to "gray" America.

The vast increase in the absolute number and relative proportion of older people is the most startling demographic characteristic of the twentieth century. Individuals over 65 comprised 4% of the population in 1900, nearly 10% by 1972, and will comprise a projected 17% to 23% of the population in 2030. In only 45 years, it is possible that one out of every five Americans will be over 65.

HEALTH CARE COSTS

The older population is increasing rapidly, but the cost of health care is rising at an even faster rate. Fifty-six cents out of every federal health dollar--a total of $20 billion in 1976--was spent through Medicare and Medicaid on health care for the elderly. A substantial portion of this was connected with nursing homes. In 1976, the nursing home industry cost $10 billion of private, state, and federal money. One million older Americans are in our 23,000 nursing homes--more than in our short-term hospitals. Because Medicaid is a state/federal matching plan, there is variation in costs from state to state, but overall the expenses are extremely high. Last year, for example, a nursing home bed in New York State cost $15,000 per year; in Nebraska, the cost was about $11,000.

The judicious application of new knowledge acquired through research can do much to improve existing services and health care. Without new knowledge, we will continue to do the same things in the same ways while our health care costs continue to soar. Research is the ultimate service and the ultimate cost-container. Imaginative thinking about new ways to prevent disease and disability, support the family, and develop better systems of self-help and self-care may help us contain the spiraling costs of health care.

In addition to considering cost-containment, attention can also be directed towards a more humanistic attitude toward care, particularly the care of the dying. Consideration should be given to the hospice concept and to reexamining the way we administer narcotic drugs for relief of pain. Within the health care community, we must continually

coordinate our efforts to translate new laboratory findings into appropriate medical applications in a timely but cautious fashion.

SENILE DEMENTIA

A key example of the potential contributions of research is in the area of senile dementia and other chronic brain diseases. People fear few things more than losing their minds and being "put away" in a nursing home. We now know that some of the conditions that have been mislabeled as "senility" simply because the patient is old are reversible if diagnosed and treated in time. It is extraordinarily important to recognize these dementias as diseases or symptoms of other diseases, for since they are not an inevitable outcome of aging they can be studied, treated, and ultimately prevented. This year, the NINCDS, NIA, and NIMH co-sponsored an international workshop/conference on Senile Dementia/Alzheimer's Disease and Related Disorders to summarize the state of knowledge in this area and stimulate further research.

That meeting was followed by another, smaller workshop at which groups of experts began the process of forming a consensus as to how to approach the problem of the reversible organic brain syndromes through research, treatment, and prevention.

PROGRAM DEVELOPMENT

Epidemiology: In recognition of the importance of epidemiology, the study of diseases and conditions in various populations, the NIA appointed its first Associate Director for Epidemiology, Biometry, and Demography. Beginning with this appointment, the Institute hopes to initiate a broad program that might consider a range of areas, including the following:

race, gender, and ethnic factors influencing disease; and collaborative studies of hypertension and nutrition and their relation to disease in the elderly. Toward this end, the Institute has designated nutrition/prevention as a special initiative for the coming year. Our new Associate Director has already established channels of communication with the National Center for Health Statistics, the U.S. Department of Agriculture, the Center for Disease Control, and other NIH Institutes which are involved in data collection in the area of nutrition.

This fall NIA convened a special group of physicians, research scientists, ethicists and lawyers to discuss special considerations in protecting elderly research subjects. This area and that of the translation of new technologies into prosthetic devices for the elderly are among the duties of the NIA's newly appointed Special Projects Officer.

During a unique planning exercise this fall, the NIA identified special priority areas. This was done by applying the following criteria:

- the burden of illness and disability--whether or not a significant portion of the population is affected
- the potential for reducing family and personal anguish
- the potential for containing health care costs
- ripeness for research and likelihood of research advances
- availability of scientific manpower
- the degree to which major clinical problems are addressed
- the degree to which research in each area utilizes available resources such as cell lines or animal models

Brief descriptions of some of these priority areas are listed below:

Nutrition and Aging: It is clear that because nutrition influences all of life's processes, it is a subject of primary importance in any

program on prevention. NIA research on nutrition will be broadly aimed at establishing the interrelationship between dietary intake, disease prevention, and optimal health maintenance in the aged. Although the present research base on nutrition in aging is modest, primarily limited to a few studies on nutrition and health status and on the influence of dietary intake on physiologic and pathophysiologic response, the NIA is planning the development and programming the expansion of its research base on nutrition and aging. This program is already under way. A request outlining the important areas of research on nutrition and aging has been developed and circulated to the scientific community to catalyze research investigations.

Pharmacology and Aging: It is quite clear that the process of aging is characterized by changes and deterioration of many of the body's functions. Physiologic impairment of the heart, blood vessels, kidneys, digestive tract, and nervous system can alter the body's ability to metabolize and respond to drugs. This presents serious medical and social problems. At the present time, medical treatment of the diseases and disabilities of old age is based primarily on experience gained in the use of drugs in people with similar diseases but who by and large are young and middle-aged adults. The goal of the NIA's pharmacology program is to illuminate the differences between the geriatric patient and the rest of the population in response to drugs, thereby improving the effectiveness with which drugs are administered to the old. Clinical observation of older patients has revealed many adverse or paradoxical reactions to drugs that have no unusual effects on younger people. For example, some mild tranquilizers can cause

confusion and behavioral disturbances in the elderly that are often mistaken for chronic brain disease. Phenothiazines, drugs given for sedation and to treat nausea and anxiety, can increase vulnerability to accidental hypothermia, a progressive loss of deep body temperature leading to death if not diagnosed in time and treated properly.

Last spring, the NIA expanded its efforts in this area and formally notified the scientific community of its interest in receiving more grant applications in pharmacology. An innovative cooperative inter-Institute arrangement with the National Institute of General Medical Sciences provided the "personpower" for the interactions with investigators who responded, as well as for the planning and organization of a Pharmacology/Aging research workshop held in the fall. In an effort to maximize the use of available resources, NIA contracted with the Boston Collaborative Drug Surveillance Program (BCDSP) to study the age-related effects of drugs. The BCDSP has been engaged since 1966 in the collection and analysis of adverse drug reactions, drug efficacy data, and the acute and long-term effects of drugs on patients of all age groups. As a result of the contract, the BCDSP will now survey their massive files for information and observations relating to special drug problems of the elderly.

Immunology and Aging: Immune function over the life span of the individual increases rapidly in the early years of life, reaches a peak in adolescence, and then declines progressively. Since immunologically incompetent individuals are highly susceptible to infections, a weakened immune system is probably one of the major sources of the health problems of the elderly. There is good evidence

that decline in immune function is involved in the development of a variety of age-related diseases, such as cardiovascular disease, kidney disease, and rheumatoid arthritis.

Most research on aging immune function has been in the mouse; research in man has been limited to a few investigations on antibody levels and health status. An effort is now underway to study the importance of the relationship between aging and genetics with regard to immune function. Preliminary results indicate that a decrease in immune function in women beyond the age of 70 is associated with a failure in one specific gene.

Retirement: With the fall 1977 passage by both Houses of Congress of legislation changing mandatory retirement laws, the Institute has initiated a special "think tank" within the NIH to examine the social, behavioral, and medical ramifications of revised retirement policies. This task force is comprised of representatives from NIA; the National Heart, Lung, and Blood Institute; the National Institute of Neurological and Communicative Disorders and Stroke; the National Institute of Arthritis, Metabolism, and Digestive Diseases; and the National Institute of Mental Health. Until now, chronological age has been the sole criterion in assessment of ability to continue working or in determining time of retirement. Attention is now turning to the possibility of using functional ability as a basis for determining competency.

Behavioral and Social Sciences and Aging: The NIA's Congressional mandate clearly includes support of behavioral and social research on aging. A major portion of the research supported in the behavioral area is concerned with the identification and description of the

intellectual and cognitive changes that occur with aging. When we have obtained accurate information about these changes and the related physiological and biological changes which may underlie them, we may be able to modify or at least develop means of coping with tnem. Recent research findings have cast doubt on the earlier reported findings that there is a general decline in intellectual abilities with age. At least, results based on longitudinal rather than cross-sectional studies indicate tnat such decline may not appear until the latter years of old age.

While in the early part of the century the notion of a three-generation family was not very prevalent, today it is a reality. Many families face enormous emotional and financial struggles to maintain older relatives at home as long as possible. If through research we can determine which types of personal relationships and living arrangements are most beneficial for our old people and their families, we can consider changes in our social policies to enhance these optimal situations.

Hormones and Aging: The effects of aging on tne endocrine system are varied, being marked in some glands and slight or undetectable in others. Of the glands of the endocrine system, the most dramatic changes that occur with increasing age are those related to the sex glands leading to the menopause in women and a decrease in the secretion of testosterone in men. It is apparent in other glands such as the thyroid and adrenal that there is a gradual decrease in function with age. The influence these decreases have may be related to some of the deteriorative changes in mental function and in strengtn tnat occur with age.

The National Institute on Aging has begun to establish an integrated program of human and animal model studies on endocrine and neuroendocrine

changes that occur with age. This program is aimed at characterizing and quantifying many of the changes in endocrine function that occur with age. These studies may provide the basis for understanding the causes and consequences of age related decline in endocrine function. Thus, such studies may provide the means to modify or moderate some of the degeneration or disease changes of endocrine decline or dysfunction that occur with age.

Of more immediate concern is whether substitution therapy with replacement hormones or non-hormonal agents moderate the effects of age changes in endocrine function, or increase the risk of adverse side effects in other tissues or organ systems. The previous controversy over safety of use of oral hypoglycemic drugs to treat diabetics and more recently estrogen replacement therapy in the menopause illustrate the complex and poorly understood interrelationships between functional endocrine decline and the effects of substitution or replacement therapy on target tissues or organs as well as other body systems.

Intermediary Metabolism: From investigations in the Intermediary Metabolism Program of the NIA, the Institute hopes to find the key to understanding some fundamental mechanisms responsible for overall decline in the capability of an organ, tissue or cell to function properly and to devise means for successful intervention to modify or reverse these changes. One area of interest is the impaired communication between tissues when sugar molecules are absorbed into the blood stream. The presence of sugar is recognized by the pancreas which responds by presenting insulin, which in turn signals other tissues, such muscle, fat, and liver. Recent experimental results indicate that in old rats, there may be a lesion or defect in the process which determines the effectiveness of individual molecules of insulin.

Further work is underway to determine if the defect is in insulin production or function. Information is also being obtained on age-related changes in collagen, the major structural protein of connective tissue.

BALTIMORE LONGITUDINAL STUDY OF AGING

Longitudinal studies, which follow groups of individuals as they age, can help reveal those aspects of aging that are truly a result of the body's maturing process. The study of the same people over a period of years enables scientists to identify characteristics of individuals and environmental factors which may be used to predict the success with which a person ages. Over 650 male volunteers, ranging in age from 20 to 96 years, have participated for nearly twenty years in the Baltimore Study conducted at the Gerontology Research Center, NIA's intramural research facility. The study has provided valuable scientific information.

For example, even in elderly people, functional lung damage, caused by heavy cigarette smoking, can be almost completely reversed when they stop smoking.

Moreover, it has been demonstrated that the more complex functions of a system in the body decline more rapidly with age than do simpler functions. For example, the muscle strength of the arms and shoulders shows less decline with a simple task, such as pulling or pushing a stationary object, than does the overall ability to use muscle in coordinated movement, such as turning a crank.

Another discovery is that diabetes may not be as prevalent in the elderly as was previously thought. The glucose (sugar) tolerance test which is used to diagnose diabetes was administered to the Longitudinal Study volunteers, and revealed that with age the body's

ability to handle glucose decreases. Fifty percent of the Longitudinal Study subjects over 60 showed "abnormal" glucose tolerance and would therefore be considered diabetic. Nevertheless, many of them never had any diabetic symptoms--excessive loss of weight, general weakness, coma--or complications such as increased coronary disease and athero-- sclerosis (hardening of the arteries). Since, in the past, the standard for normality was arrived at by recording the responses of younger people, such as medical students or hospital employees, a great deal of diagnostic error may occur in determining if an older person is diabetic. A more realistic standard for glucose tolerance would have to be age-adjusted.

The addition of women to the Baltimore Longitudinal Study is an appropriate way to mark its twentieth anniversary, and will enable us to examine sex-linked differences in life expectancy and risk of disease.

CONFERENCES AND WORKSHOPS

Conferences and workshops offer an emerging Institute the opportunity to identify areas of special interest or need, while at the same time stimulating new and established investigators to view their areas of expertise from the perspective of aging. These meetings also provide an excellent means to disseminate information across disciplines. Alone and in collaboration with the other Institutes, the NIA has conducted or partially supported workshops/conferences in a variety of areas, including:

- animal (vertebrate) models relevant to processes of aging
- economics of aging
- immunology and aging
- geriatric medicine

- o cell tissue and organ cultures in neurobiology (international workshop)
- o epidemiology of aging
- o physical fitness and aging
- o research on health problems of the Black aged; minority aging
- o Alzheimer's disease/senile dementia
- o protection of elderly human research subjects
- o aged mammal organ, tissue, and fluids bank; new approaches to aging research via cell culture
- o pharmacology of aging
- o autopsies and the pathology of aging

In addition, the NIA, the Fogarty International Center and the World Health Organization had the privilege of co-hosting a meeting on the "Graying of Nations" with the Directors of other nations' programs in aging research.

RESEARCH ADVANCES

Studying Aging in the Laboratory: Normal human cells are known to age in a laboratory culture medium. Institute grantees have noticed that cell cultures from individuals suffering from certain life-shortening conditions "age" very rapidly in a test tube by losing various abilities, including the capacity to proliferate. In 1974, the NIA established a cell bank for aging research at the Institute for Medical Research in Camden, New Jersey. Thus far, more than 161 distinct lines of cultured cells have been acquired from normal donors of both sexes and all ages. Some of these cell cultures are derived from patients with accelerated aging or growth disorders, probably of genetic origin, or from patients with tumors both before and after radiation and

chemotherapy. To meet worldwide research needs for standard cell lines, the Institute has established two special lines of cells: IMR 90, derived from female lung tissue; and IMR 91, from the lungs of a male. These cells lines have been banked in large quantities to assure that they remain available for many decades to researchers studying the biochemical and molecular mechanisms of aging. In addition, over 200 individual human cell lines have been established by NIA laboratories using skin samples taken from Baltimore Longitudinal Study volunteers.

At GRC, scientists have effectively demonstrated that the ability of cells to reproduce is impaired with aging. This decline in cell proliferation also appears to contribute to the reduced rate of wound healing sometimes observed in older people. Another example of the decline in cell proliferation with aging is in the immune system.

Certain--Though Not All--Functions Do Decline with Age: Research indicates that certain brain diseases and a general intellectual decline are not inevitable with aging. However, other studies suggest that certain functions do decline late in life. For example, one grantee reports that the elderly are about 50 percent slower that the young in their ability to shift attention among many objects in a field of vision. This finding may have important implications for the elderly in such areas as driving or reading. For example, driving ability could be impaired by the older person's slowness in shifting attention from one item to another: from stoplight to pedestrian, to an approaching car, or perhaps to the policeman in the rear view mirror.

Another study by the same grantee shows that the old are as capable as the young of deriving and retaining ideas from meaningful information.

But when the amount of information increases and older subjects try to recall it on their own, tney are noticeably less able to recall meaningful information than young adults.

Otner research by scientists at the Gerontology Research Center indicates that learning, memory, and problem-solving ability declines very late in life, even among educated, relatively healthy people. However, for some individuals--even the oldest--there was no decline in learning, memory, and problem-solving performance, raising the still unanswered question of why some individuals decline with age and others do not.

Mnemonic Devices for Older Learners: One way to improve the quality of old age is to provide the elderly with new ways to minimize difficulties in learning and remembering. Researchers at the Gerontology Research Center have devised an effective aid for learning items on a list. The older person can learn a list of words, for example, by mentally picturing his or her residence and visualizing an item from the list at each predetermined, natural sequence of stopping places. These stopping places are effective cues for remembering the words on the list. Older people can readily learn this simple memory scheme because it is based upon well-established habits. It also prevents an overload of information that many older learners might not be able to handle. Future research will hopefully produce a mnemonic device for recalling names that go with familiar faces, a common memory difficulty of the aged.

Estrogens and the Postmenopausal Woman: The known dangers of estrogen use in young women--including increased risk of stroke and myocardial

infarction--suggested that the effects of estrogens on older women be studied as well. NIA contractors have shown that 1) postmenopausal women use oral estrogens with surprising frequency; 2) they continue to do so intermittently until well beyond age 80; and 3) in one sampling, 15 percent of 15,500 postmenopausal women were found to use oral estrogens. This figure exceeds earlier estimates of oral estrogen use among 45- to 64-year old women by about two percent.

Investigators studying some of these adverse affects on a retirement community population of postmenopausal women aged 57 to 98 found no association between estrogen use and myocardial infarction. However, the low dosages involved and the short duration of estrogen use, plus an already high coronary risk in this age group, may account for this result.

There is some evidence that estrogen may prevent or lessen the development of osteoporosis, a softening of bone that leads to hip fractures and other debilitating injuries in many elderly women. Institute grantees are now comparing the risk of hip fracture in older women who do and do not use estrogen to learn whether such a protective effect exists.

Other research is exploring the relationship between breast cancer and estrogen use in older women. Studies of this relationship in younger women taking oral contraceptives have revealed no increased risk of breast cancer.

The same contractors have shown that while estrogen use did not increase the risk of stroke in 15,500 postmenopausal women, there was a statistical association with hypertension at all dose levels in women aged 58 to 98. This is one of the first reports that estrogens predispose older women to hypertension. The finding uncovers a major public health problem

since estrogen use among postmenopausal women is so widespread. In the same study, estrogen use was found to be associated with stroke in a subgroup of women aged 70 to 79. But this association does not seem to exist in the absence of hypertension.

Another serious consequence of estrogen therapy was suggested by studies of women from the same retirement community who contracted cancer of the uterine lining. They had taken high dosages of a common form of estrogens made from the urine of pregnant mares. The risk decreased when subjects took smaller dosages of estrogens or stopped taking the drugs for intervals of four days or longer.

This finding is significant because of the rising number of new prescriptions for this estrogen preparation (from 1.6 million in 1958 to five million in 1974), because of estrogen's known ability to cause endometrial cancer, and because of the increase between 1969 and 1973 in endometrial cancer among American women. Given this newly reported relationship between estrogen use and endometrial cancer, increasing numbers of American women may be expected to contract endometrial cancer in the near future.

Reduced Hormone Response in Aging Man: Certain cells in animals, including man, have specialized parts called hormone receptors. These receptors control the cells' ability to respond to specific hormones and other body chemicals. The receptors may be located on the cell's surface or in its interior. At the GRC, members of the Longitudinal Study have contributed to furthering our information about the body's ability to respond to hormones with age. It was shown for the first time in man that concentrations of a specific cell membrane receptor for a common

type of hormones (B-adrenergic agents) decline progressively with age. Eighty-year old subjects have only half as many of these receptors as do twenty-year old subjects. Earlier studies showed similar receptor losses in aging animal tissues. Other results suggest that many animal tissues also lose their ability to respond to various hormones during aging. Thus it appears that loss of hormone receptors is a common part of aging and these losses may be responsible for decreased ability of the body to respond to hormones during aging.

Obesity and Long Life: A vast medical literature associates obesity in middle and late life with atherosclerosis, hypertension, diabetes, gout, osteoarthritis and gallbladder disease, to name but a few life-threatening conditions. Yet other major studies, including the Baltimore Longitudinal Study, have been unable to show that mild and moderate obesity, both in middle-aged and older age groups, shortens life span. Further research is needed to elaborate on this surprising result, and determine whether obesity enhances survival in some way that counteracts the recognized hazards of being overweight.

Studies of the same subjects reveal that while their cholesterol levels rose markedly between 1963 and 1971, during the past six years the trend has reversed sharply and cholesterol levels dropped. These men also lowered their intake of fat and especially of saturated fatty acids, and increased their intake of polyunsaturated fat, a shift that may explain the altered cholesterol levels.

Biofeedback Applied to Some Problems of Aging: The technique of biofeedback--an operant conditioning procedure in which subjects learn

to control such physiological processes as heart rate or bowel function--is being investigated in Institute laboratories and applied to some special problems of the elderly.

Researchers are using biofeedback to teach patients with angina pectoris to slow their heart rate upon signal. The patient watches a panel of lights while reclining on a hospital bed. A red light means he should lower heart rate, and a yellow light signals when he has done so.

Once he begins to show ability to lower heart rate, he is taught to respond without the light panel feedback. While learning heart rate control he is evaluated to see whether he can transfer this skill to mild activity. Finally, after laboratory training is completed, he is tested to see whether he can modulate his heart rate during exercise testing on a treadmill.

Urinary incontinence is another special problem correlated with age. Patients with chronic urniary incontinence often have catheters implanted in their bladders, and this increases the risk of infection of the urinary tract. In addition, urinary incontinence is socially disruptive and places many otherwise functional people in extended care facilities because their families cannot provide for their care. A project is now underway to investigate whether patients can learn to control some forms of urinary incontinence using biofeedback techniques.

A third project is aimed at improving the rehabilitation of patients who suffered myocardial infarctions. The impatience and overactivity of many of these individuals interfered with their recovery and placed them at some risk for aggravating their cardiac condition.

In this study the patients were told about the nature of their illness, asked to develop concrete goals for their own rehabilitation, and encouraged to gradually increase habitual activities. They were also taught to take their pulse to monitor their heart rate as an index of their heart's ability to deal with physical stress. All patients were seen regularly to review their data, and to discuss their clinical progress. Eight patients participated in the study and all were rehabilitated within the limits imposed by their cardiac condition.

Exercise in the Elderly: Among the greatest costs of aging is declining ability to perform daily activities which contribute not only to personal well-being but to society at large.

A variety of studies show how aging undermines physical strength and psychomotor performance. Other studies show exercise can counteract some of the harmful effects of aging.

In one project investigators at the Gerontology Research Center measured the blood pressure, heart rate, oxygen uptake and carbon dioxide elimination of 200 healthy men before, during and after exercise. One finding revealed that the main reason for reduced work capacity in the subjects was loss of muscle tissue.

Another finding, according to preliminary data, showed that during heavy exercise such as brisk walking on an inclined treadmill, the secretion of growth hormone is stimulated more in young people than in people over 50 years of age. Growth hormone has been shown to stimulate protein replication (which equates to muscle growth) in the diaphragm of the rat. Researchers hope that this process might someday be demonstrated in humans.

Other measurements of light to moderate exercise showed that men in their 60's were as efficient as men in their 20's, although the older men used a higher percentage of their total capacities to perform work or exercise. Hopefully, identification of the factors that affect physical strength and performance may eventually reveal ways to stop these total capacities from declining with age.

Exercise may, on the other hand, be the most effective anti-aging "pill" ever discovered. A three-day conference on the role of exercise in preventing physical decline, jointly sponsored by the Institute and the President's Council on Physical Fitness and Sports, re-emphasized that:

--exercise benefits pulmonary and circulatory function, helps preserve bones, maintains body weight, relieves depression and anxiety, and enhances self-esteem.

--people of all ages, including the sedentary and the physically handicapped, can benefit from exercise.

--one unique study showed marathon runners, who can cover 42 kilometers or 26.2 miles on foot, appear immune to atherosclerosis. The study speculated on factors in the marathon man's life-style that contribute to this result: he does not smoke or eat refined food; he eats foods rich in Vitamin C, pectin and bran; and he is fond of beer, raw onions, and yogurt. These dietary cravings probably relate to the fuel requirements of the marathon.

Strenuous Exercise Fends Off Heart Attacks: One study of 16,936 men, aged 35 to 74, reveals that those who participated in strenuous sports had fewer heart attacks than those who were more sedentary.

One study followed male alumni of Harvard University for six to ten years. Through questionnaires, the subjects described sports participation. Follow-up questionnaires and death certificates revealed 257 fatal and 315 nonfatal heart attacks.

Sports requiring greater total energy output and bursts of output--running, swimming, basketball, handball and squash--were the most beneficial. More casual sports like golf, bowling, baseball, softball and volleyball offered the least protection against heart attack. Tennis depended upon how the game was played: a vigorous, competitive game had a high exercise value, while a slow, lazy game ranked low.

The researchers then measured the total energy each subject expended in sports plus other activities like stair climbing and walking, and calculated the total calories burned each week.

Men who burned fewer than 2,000 kilocalories weekly showed a higher heart attack rate (57.9 per 10,000 person-years of observation) than men who burned 2,000 or more calories weekly (35.3 heart attacks per 10,000 person-years of observation). Thus, the heart attack rate was 64 percent higher for the less active group.

These rates applied regardless of other risk factors such as smoking, high blood pressure, obesity, family history of heart attack, and previous participation in athletics. However, no one should undertake a program of strenuous exercise without supervision.

Another study compared the energy output/heart attack risk experience of the Harvard alumni with 3,686 San Francisco longshoremen who were followed for a period of 22 years. Although energy levels

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were higher for longshoremen, the same trends applied. Longshoremen who spent fewer than 8,500 kilocalories per week had an 80 percent higher risk of fatal heart attack than the men of the same age who expended more energy.

Sexual Activity in Later Years: Sexual functioning in older males is known to be influenced by degree of sexual vigor throughout the life span. For example, sexually active subjects in a study of men participating in the Baltimore Longitudinal Study of Aging reported a higher frequency of coitus during early marriage and throughout the intervening years than did the least sexually active group.

The study of 188 males aged 60 to 79 has identified some previously unrecognized factors which appear to influence sexual functioning. Much sexual inactivity of the older male, for example, stems from apathy or indifference to stimuli which previously caused erotic reactions, and not from negative attitudes about sex. Sexually inactive subjects stated that they felt no pressure to perform, and the vast majority had never sought help for their condition. This lack of anxiety made their impotence far less disturbing than this condition is commonly assumed to be.

Subjects were divided into three groups of least active, moderately active and most active sexually, according to the number of sexual events reported during the preceding year. The least active group averaged 3.8, the moderately active group 20.0, and the most active group 62.3 sexual events for the year.

The most active group tended to be strongly committed to religious values, had lived on a farm before age 20, had received post-graduate

sional and technical jobs, attributes whose
unctioning remains obscure.

ge at marriage, number of years married before
us, and number of coital partners before age
sexual functioning. Most subjects considered
mportant for good health, and most rated their
as highly successful. However, tnese factors
ly related to current levels of sexual activity.

B. NATIONAL INSTITUTE OF MENTAL HEALTH

AGING

Since 1900, the percentage of the U.S. population aged 65 and over has more than doubled. In actual numbers, the increase has been from 3 million in 1900 to 23 million in 1976. 5 percent of the aged live in institutions. Of these, about 12 percent are in mental hospitals, with the remainder in nursing and other types of homes for the aged and chronically ill. The elderly comprise 7 percent of additions to State and county mental hospitals, and 28 percent of the resident patients. Approximately 80 percent of patients aged 65 and older who live in nursing and personal care homes have some degree of mental impairment. The death rate for suicide among the elderly is highest in the 55 and more age group (19.9 per 100,000 as compared with 12.7 per 100,000 for all ages). 44 percent of all male additions to inpatient services of State and county mental hospitals with a primary diagnosis of alcohol disorder are aged 55 and over.

RESEARCH

NIMH research relevant to the mental health of the aging includes projects dealing with (1) the etiology, diagnosis and treatment of mental disorders; (2) the development and delivery of mental health services; and (3) the prevention of mental disease.

A current project at Cedar-Sinai Medical Center, Los Angeles, is developing, testing, and evaluating a model service delivery system to be used by community mental health centers in responding to the multiple needs of certain high-risk elderly persons. By facilitating access to mental health and other services providers, the system will serve a preventive mental health function, not provide direct services. It will link clients with individualized packages of comprehensive assessment and screening; goal setting and planning procedure; referral to service providers; followup by a case manager; and periodic reassessment and re-referral. The system will be designed to be operated by volunteers and paraprofessionals, with consultation and supervision from professionals. The project will develop methods for applying the findings of a community survey in planning the service delivery system, particularly in identifying groups which are being served, groups which need services, and gaps in availability of services.

Another study in Newark will identify factors associated with maintenance and change of mental health in the poor, urban, black elderly, using a short-term longitudinal approach. A panel of 150 black men and women, over 60 years of age, were studied 5 years ago. They will be contacted at short, regular intervals for repeated psychological, social, and physiological measurements for a period of 3 additional

ered will include physical and mental health, solation, use of available services, environ- and friendship networks, need and use of short- acilities. Analysis of data will pay particular occur with time.

t the University of California, Los Angeles, is al, social, and emotional consequences of chil- nen. A survey of 1,200 women aged 60-70 years tus (currently married, living with spouse, or ildren (childless, or having borne and raised at ing) has been undertaken. Information is being questionnaires from equal numbers of subjects married childless, married with children, wid- with children). Seven variables will be comp- logical well-being (morale, loneliness, social verall happiness); (2) desired family size, as mily size and satisfaction with social inter- d demographic variables including financial eneral hypothesis being tested is that there is p between parity and well-being; instead, the by social-psychological variables such as (1) ruence between fertility desires and outcomes, tween expectations regarding parity and the parity.

tted to the attraction of skilled minority of aging. An innovative approach to this issue n-American researchers through a contract with on, a minority-owned research organization. A ject is being funded to produce proposals and for research relevant to mental disorders and e as experienced by aging Mexican-Americans. from which research proposals will be derived nograph form by NIMH as a means of feeding fields of research and practice.

roject has been conducted in ADAMHA Region VIII he aged within Community Mental Health Centers. consultants who are experts in geriatric mental ere made available to the CMHC's. The consul- m capabilities of the Centers and developed a sing the mental health service needs of the MHC's and 14 State and local mental health and enefited from this project.

TRAINING

ort for the development, implementation, and training models which focus on the provision of

clinical services to aging persons with mental health problems.

SERVICES

Mental health services to the elderly represent a mandatory requirement for Federal grant support to a Community Mental Health Center, under the Community Mental Health Centers Act.

CENTER FOR STUDIES OF THE MENTAL HEALTH OF THE AGING

The NIMH Center for Studies of Mental Health of the Aging was established in August of 1975.

The mission of the Center is to centralize the Institute's efforts on behalf of the mental health of the aging persons. The Center coordinates NIMH programs affecting aging persons in the area of research, training and services. It collaborates with other Government agencies, in particular the Administration on Aging and the National Institute on Aging. It also relates to public and private agencies at the national, regional, State and local levels. The goals of the Center are carried out through technical assistance, and its efforts are directed toward (1) research into areas in which knowledge is needed; (2) incorporation of mental health consideration in programs for aging in which mental health components have been neglected; (3) development and evaluation of innovative programs for the delivery of mental health service to the aged; and (4) development and dissemination of information about mental health of the aged.

COOPERATIVE EFFORTS WITH OTHER AGENCIES

A considerable array of formal and informal relationships exists between the NIMH Center for Studies of the Mental Health of the Aging and the National Institute on Aging. Research applications of interest to both organizations are dually assigned. On occasion, projects with dual assignments, approved by the primary institute but for which sufficient funds are not available, have been transferred to the secondary institute for funding consideration. During fiscal year 1977, NIMH, NIA, and the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) jointly sponsored a biomedical research conference on senile dementia. In fiscal year 1978, NIMH will be the lead agency for a followup conference on social and service aspects of senile dementia/Alzheimer's Disease.

LEGISLATIVE DEVELOPMENTS

Section 603 of the Health Services, Revenue Sharing, and Nurses Training Act of 1975 (Public Law 94-63) directed the Secretary of Health, Education, and Welfare to appoint a committee on mental health and illness of the elderly. The committee was charged with the task of making recommendations respecting (1) the future needs for mental health facilities, manpower, research, and training to meet the mental health

care needs of elderly persons; (2) the appropriate care of elderly persons who are in mental institutions or who have been discharged from such institutions; and (3) proposals for implementing the recommendations of the 1971 White House Conference on Aging respecting the mental health of the elderly. The Committee includes authorities in the fields of psychiatry, psychology, gerontology, social work, nursing, education, business, and administration. Federal funding for this Committee was as follows: NIMH ($100,000), NIA ($50,000), and AOA ($50,000). This work has been completed and will be submitted to Congress in December 1977. Major recommendations fall into six specific categories: Prevention, Services, Research, Training, Minorities, and implementation strategies.

C. HEALTH RESOURCES ADMINISTRATION

1. HEALTH PLANNING AND RESOURCES DEVELOPMENT

A primary objective of the Hill-Burton program is to stimulate the modernization and construction of facilities needed to build up an efficient, well-coordinated network of services for the acute care, ambulatory care, long-term care, and rehabilitation of all persons, including the aged and aging. Since the enactment of the Hill-Burton program, assistance has been provided for the modernization and construction of 104,995 long-term care beds in chronic disease hospitals, nursing homes, and units of general hospitals.

The need for modernization and construction of long-term care facilities continues at a high level. As the aging population continues to increase, the demand for adequate nursing home care for them must be met. In addition, the enactment of the Medicare, Medicaid and other programs partially removed the economic barriers to care of the aged. State agencies report that 354,000 long-term care beds, including extended care facility beds, need to be modernized or added.

Public Law 93-641, signed on January 4, 1975, extended and extensively revised the Hill-Burton program. Long-term care facilities will no longer be aided as a separate formula grant category. However, they will be eligible under two priorities of formula grant assistance: (1) modernization of health facilities, and (2) construction of new inpatient medical facilities in areas which have experienced recent rapid population growth. The same facilities are also eligible for

loans or loan guarantees with interest subsidy. Another type of grant assistance (Section 1625) is project grants for construction and modernization projects designed to prevent or eliminate safety hazards in medical facilities and to assure compliance with State or voluntary licensure or accreditation standards. Grant and loan assistance from 1976 and 1977 appropriations/authorizations (except Section 1625 grants) are awaiting the publication of regulations for Title XVI. At that time, $39.9 million in formula grants and $250 million in loan or loan guarantee authority will be available for the priority projects in each State. Section 1625 public facility project applications have already been approved for the $11.4 million available.

In addition, the following services provided through program staff support contribute to improved health care of the aged and others throughout the Nation: (1) technical and professional consultation regarding all aspects of facility functional planning, design, maintenance, and construction, which is available to all public agencies and nonprofit organizations; and (2) guide material relating to the planning, design, equipping, and construction of health facilities, which is continually being developed and distributed.

2. BUREAU OF HEALTH MANPOWER

Training to prepare registered nurses as geriatric Nurse Practitioners and nurse assistants with basic instruction in the skills of caring for the geriatric patient is supported under the Nurse Practitioner program. Special emphasis on the problems and diseases of the aged are stressed, as well as a deeper concern and awareness for the elderly patient.

D. HEALTH SERVICES ADMINISTRATION

1. BUREAU OF MEDICAL SERVICES

The Department of Health, Education, and Welfare has a legislative mandate to provide direct health care services to specified beneficiaries under provisions of the Public Health Service Act and the Dependents' Medical Care Act. This responsibility is discharged, in part, through the Bureau of Medical Services (BMS) of the Health Services Administration and, within the Bureau, through its Division of Hospitals and Clinics and Division of Federal Employee Health. The program authorities of the Bureau's Division of Emergency Medical Services does not encompass the direct delivery of health care services.

The Division of Hospitals and Clinics provides comprehensive health care services to American Seamen, active duty members of the U.S. Coast Guard, members of the National Oceanic and Atmospheric Administration, and to active duty Commissioned Officers of the U.S. Public Health Service. Services may also be provided to retired members of the uniformed services, to dependents of active duty and retired members of the uniformed services under the authority of the Dependents' Medical Care Act and to selected community residents.

In addition, the Public Health Service Act permits the providing of limited health services to Federal employees by the Bureau's Division of Federal Employee Health.

Health care services within the Division of Hospitals and Clinics (DHC) are provided by eight general medical-surgical hospitals, one specialized treatment center (Hansen's Disease), 26 free-standing outpatient clinics, and more than 300 contract physicians and hospitals located throughout the United States. This major system constitutes a nationwide network within the Department for the delivery of comprehensive health care services, for training, and for research. In addition, the Division of Federal Employee Health operates 143 clinics in Federal installations across the country.

As compared to Fiscal Year 1976, total workload increased throughout the system, particularly with respect to ambulatory care visits which registered 3.3% increase during Fiscal Year 1977.

Funds for clinical research studies are distributed through the Central Investigations Committee of the Division of Hospitals and Clinics, a formally-constituted body, that is also responsible for monitoring and evaluating research programs. During the year, approximately $250,000 for FY 1977 funds of the Division of Hospitals and Clinics were expended for clinical research, of which $172,820 was allocated to research related

to aging or the aging process. During FY 1977, 19 clinical research projects related to aging were operational in five USPHS hospitals (in Baltimore, Boston, San Francisco, Seattle and Staten Island). Other studies in PHS hospitals received $279,000 from the National Institutes of Health and $600,000 from the National Center for Health Services Research during FY 1977.

Most of the PHS beneficiaries are adults and the proportion of beneficiaries who are 60 years old and older is increasing, as is true in the general population. While it is known that all of the USPHS hospitals and outpatient clinics treat persons aged 60 and over, precise data regarding the number and services rendered to this age group on an outpatient basis cannot be obtained at this time. During the first six months of FY 1977, of the 16,401 discharges from USPHS hospitals in 2,719 instances, the patient was 65 years of age or over. Annualized, it is estimated that approximately 87,000 patient days were utilized by this group at an estimated cost of $11,397,000 based on an average daily rate of $131. The average length of stay for this age group is somewhat longer than for younger individuals. American seamen constitute a major PHS beneficiary group and there are probably more single males in this category than in the population at large. As a consequence, finding suitable nursing homes for those in need of long-term care constitutes one of the major difficulties in discharge planning.

Early in the calendar year 1976, the Geriatric Day Treatment Center (GDTC) located on the campus of the USPHS Hospital in Baltimore became operational. This program is jointly sponsored by the Family and Children's Society of Baltimore and the USPHS Hospital in Baltimore. Through a contract, with the Maryland State Department of Health and Mental Hygiene, Office of the Chronically Ill and Aging, the GDTC receives Title XX funds. The amount of Title XX funds from the state has increased each year the GDTC has been in operation. This program provides an alternative to institutionalization and services are delivered by a multidisciplinary staff. The program is structured around an organized regime of activities of daily living (ADL) and health services during the day in a protective group setting. Additional important program components include nutrition, counselling and transportation. Program participants are persons 60 years of age and older referred from PHS beneficiary groups, the Geriatric Evaluation Service of the Baltimore City Health Department, community organizations and private physicians. Program objectives are:

1. Enhance activities of daily living by providing instruction in self care, health maintenance, consumer education and/or referral to other services required to assist the aged to remain in or return to their homes or communities.

2. Increase effectiveness of the individual through the service and consultation of experts provided by the hospital to develop health care plans to meet the needs of individual applicants or development of general program.

3. Improve health status by providing necessary diagnostic, remedial or treatment services and arrangements for obtaining physician or hospital services in case of emergency and by maintaining necessary liaison with other providers of health services to assure the provision of services necessary to carry out medical recommendations.

4. Reduce isolation by providing the means for aged persons restricted in their mobility to get out of the house; and encourage regular attendance on individually scheduled days providing transportation.

5. Promote socialization by offering companionship in a pleasant, safe and comfortable environment and stimulate interests by offering satisfying leisure time activities.

6. Conserve family interest and support by offering respite as required during part or all of the work week and by providing individual and group counselling.

When the GDTC was established it was anticipated that it would offer extensive opportunities to serve as a demonstration model and research laboratory in the development and operation of day care programs for older persons. This aspect has been realized through the consultation and technical assistance that the GDTC has been able to offer to staff at several other USPHS hospitals, associates working on various levels of local and state government and collegues who are program managers of other geriatric programs in Baltimore and in other parts of Maryland.

This past year has been a period of increased activity and accomplishment for the GDTC. In addition to more than doubling its patient load so that they now average about 30 patients per week (75% of whom are in wheelchairs), other accomplishments include:

1. Increased capacity to treat more severely impaired patients particularly those with communication disorders.

2. More extensive collaboration with local speech pathology and hearing organizations.

3. Weekly consultation from the Psychiatry Department for patient management and staff consultation.

4. Participation in the evaluation of patients from other hospitals to consider patients for admission to the GDTC at the time or later on in the treatment process.

5. The GDTC is now the site for field work experiences for nursing students from the University of Maryland and mental health students from the Community College of Baltimore.

Other hospitals in the USPHS hospital system are developing programs in aging. Early in 1977, the USPHS hospital in San Francisco started a program of geriatric screening and referral for older people living in one of the San Francisco health districts near the hospital. This program works closely with the local city health center and is an integral part of a coordinated effort to improve the health status of older persons in San Francisco.

Potentially, the multiple facilities of the Division of Hospitals and Clinics could be used to study, develop and/or apply in new ways, various methods and techniques leading to the improvement of the delivery of services to older persons. In this regard, the Division believes it could play a significant role in a vigorous intergovernmental effort.

E. OFFICE OF ASSISTANT SECRETARY FOR HEALTH
1. National Center for Health Statistics

All health statistics prepared by the National Center for Health Statistics (NCHS) can be presented in terms of specific age groups.

Measures of morbidity among the noninstitutional population include the incidence of acute conditions and injuries, number of days of disability, prevalence of chronic conditions, and the number of persons whose activities are limited due to chronic conditions. The latter category is the measure of health status which increases most rapidly among the elderly.

These data from the household Health Interview Survey are usually presented for the broad age groups 45-64 and 65 and older so that some other characteristics which are related to both age and health can also be shown: family income, educational attainment, and living arrangements. Also reported in the interview survey are number of visits to physicians, medical specialists and dentists, episodes of hospitalization, and expenditures for various types of health services.

The Health and Nutrition Examination Survey is one of the continuing NCHS programs designed to obtain the type of health information which can best or only be determined by direct physical examinations, tests, and measurements on the population. Assessments of general health and nutritional status are being made on a national probability sample of persons 6 months through 74 years and specifically for population groups at high risk of poor nutrition, including the aged. Major conditions included in the examination are anemias, diabetes, kidney disease, heart disease, liver disease, hypertension, allergies, osteoarthritis and disc degeneration in the cervical and lumbar spine. The total prevalence known and previously unknown or undiagnosed, of the major chronic health conditions will be determined as well as the extent of limitation of activity from them and medical care sought. Evaluation of nutritional status will be made from dietary intake and food frequency data inter-related with physical examination, medical history and biochemical data. These data are usually shown by age and other relevant demographic and socioeconomic characteristics such as family income, education, race or ethnic background.

The National Nursing Home Survey, inaugurated in 1973, is a continuing series of national sample surveys of nursing homes, their expenses, residents, and staff. The basic age groups presented in the publications are under 65, 65-74, 75-84, and 85 and over, although some data are presented in 5-year intervals between the ages 65-95.

Resident data include sociodemographic characteristics; health, functional and mental status; diagnosis; services received; charges; and sources of payment. Data on facility and staff characteristics, as well as on cost of providing care are also collected.

The initial National Nursing Home Survey was conducted from August 1973 - April 1974. Reports which have been completed are "Financial and Operating Characteristics of Nursing Homes"; "Characteristics, Social Contracts, and Activities of Nursing Home Residents"; "Utilization of Nursing Homes"; and "Nursing Homes in Profile"; "Profile of Chronic Illness in Nursing Homes"; and "Charges for Care and Sources of Payment for Residents in Nursing Homes." Other reports on the characteristics of nursing home staff and the medical services received by nursing home residents are nearing completion, as is an in-depth analysis of nursing home costs. Data tapes are available to the general public.

The second National Nursing Home Survey was conducted from June through December, 1977. It was broadened to collect data on discharge residents; discharge planning by the facility; communication of needs by residents; measures of social activity; amount of monthly charge paid by the primary source of payment; facility revenues; and flu shots received by residents. Provisional data will be released in the spring of 1978. Review and analysis will begin at that time and continue throughout 1979. Once survey analysis is completed, data tapes will be made available for release to the general public.

The Hospital Discharge Survey measures morbidity associated with hospitalization in short-stay hospitals. Information is obtained from the medical record of patients including detailed diagnosis and surgical procedures. Utilization measures including discharge rates and average lengths of stay are reported annually by diagnostic categories, by type of surgery, by characteristics of the patient and by characteristics of the hospital. Data are usually presented by broad age groups but data by any grouping are available on special request. "Utilization of Short-Stay Hospitals: Annual Summary for the United States, 1975" presents the latest published data from the Hospital Discharge Survey.

The National Ambulatory Medical Care Survey, another continuing program of the Center, is designed to explore the provision and utilization of ambulatory medical care in the doctor's office. Data are provided on the number and rate of office visits, by physician's specialty, type of practice, and geographic location, and by the patient's age, sex, and race. Also provided are the number of visits by patient's medical problems, and physician's diagnosis, treatment, and disposition. One forthcoming report on 1975 data will be concerned with the visit experience of persons 65 years and older and how their experience differs from that of other age groups. Other reports nearing completion deal with visits to internists, pediatricians, obstetricians and gynecologists, general surgeons, general and family practitioners, osteopaths, and a summary report on all data collected in 1975. Analysis has begun on similar data for 1976.

IV. HEALTH CARE FINANCING ADMINISTRATION

A. MEDICAID

Title XIX, known as Medicaid, provides Federal matching payments for State expenditures for health care for the poor. In FY 1977, fifty-three States and jurisdictions were participating in Medicaid (Arizona is the only state not participating).

With the federalization of the adult categories on January 1, 1974, under the Supplementary Security Income (SSI) program, States are not in *all* cases required to provide Medicaid to all adult recipients of *cash* assistance under Title XVI, as was the case in the past under *titles* I, X, XIV, or XVI. Limited Medicaid coverage of SSI cash assistance recipients will apply in States which, in determining Medicaid eligibility, opt to apply any eligibility criteria from the January 1, 1972, medical assistance standard which is more restrictive than the eligibility requirements for the Federal Title XVI program for aged, blind, and disabled individuals. States which retain any eligibility factor(s) from their January 1, 1972, standard which is (are) more restrictive than the Title XVI eligibility factor(s) must deduct a person's medical expenses from his income in determining eligibility. (They are not required to cover Title XVI cash assistance recipients who have higher income or resources, or who otherwise do not meet the January 1972, medical assistance standard.) Fifteen States and three jurisdictions have restricted Medicaid eligibiltiy of SSI recipients under this option.

Thirty-five States extend Medicaid coverage to all recipients of cash assistance under the SSI program. States also have the option of providing Medicaid coverage to persons receiving a State Supplemental payment, subject to certain limitations. In addition, States may still elect to cover certain medically needy persons who are eligible for help only with their medical bills and who do not receive maintenance payments.

States are required to provide in their Title XIX program: inpatient hospital care, outpatient care, skilled nursing home care for individuals 21 and over, early and periodic screening, diagnosis and treatment services for children under 21, family planning, physicians services, lab and x-ray services and home health services, as well as, by regulation, transportation to medical care where needed. Use of skilled nursing home services, particularly, is primarily by the aged. Additionally, Title XIX in FY 1974 contained several provisions directed solely to those over 65: payment of Medicare premium, copayment and deductible amounts (for cash assistance recipients), and coverage of inpatient hospital services in institutions for mental diseases.

The aged account for a significant portion of Medicaid expenditures. About thirty-six percent of the $17.2 billion Federal, State and local program dollars was spent on care for the aged in FY 77, and it is estimated that 3.7 million people over age 65 received Medicaid services. For most of these persons, Medicaid was providing services which supplemented and complemented those provided by Medicare.

B. MEDICARE

Health Insurance Benefits

In fiscal 1978, an average of 26,000,000 receive Medicare protection of which 23,200,000 persons are 65 and over. 2,800,000 are under 65, disabled, and will be afforded basic Medicare protection. Under Medicare, hospital insurance beneficiaries are protected against the costs of inpatient hospital services, post-hospital skilled nursing facility services and home health services. In addition, the voluntary supplementary medical insurance program covers the cost of physicians and related services. Both parts of the Medicare program provide for payment of these costs subject to certain deductible and coinsurance amounts.

Payments to hospitals, extended care facilities and home health agencies for persons aged 65 and over under the hospital insurance program are expected to total an estimated $13.4 billion in fiscal 1977 and $14.2 billion in fiscal 1978. Supplementary medical insurance payments for aged persons in fiscal 1977 and fiscal 1978 are estimated to amount to $4.9 billion and $5.9 billion respectively.

V. EDUCATION PROGRAMS

A. PUBLIC LIBRARY SERVICES

Library and information services for the aging are supported by the Office of Education (OE) through projects funded under the Library Services and Construction Act (LSCA). In FY 77, numerous public library projects made educational, informational, and recreational materials and activities widely available to senior citizens living both independently and in institutional settings.

Since the elderly reader represents one of the highest user groups of public libraries (according to a 1973 LSCA-supported national study) and "aging" is a special project area designated in LSCA program guidelines, libraries are actively and creatively serving this vital, growing, and often neglected segment of the population.

Librarians are responding to the social, economic and physiological problems of the aging in many ways. By providing information and education on aging to professionals and laymen working with senior citizens, and by fostering cooperation among agencies concerned with the elderly's needs, the libraries contribute substantially to the achievement of a positive attitude towards the aged. Library-sponsored pre-retirement counseling and information has eased the transition from full-time work to productive and satisfying leisure for many older adults.

Involvement of the elderly in the planning process, employment of senior citizens in programs specifically designed to serve this age group, volunteer work, and participation on library boards and advisory councils are all means by which libraries utilize the time and talents of the elderly for mutual benefit.

In recognition of the growing number of older Americans in our population, library interest in service to this group is also increasing and a greater awareness of the types of services and materials desired by older persons is needed in the library field. OE has addressed itself to this need through publication of a dissemination sourcebook which contains examples of many successful library programs in operation across the country. Among the programs described in "Library Programs Worth Knowing About" are some excellent examples of special projects for the aging which hopefully will act as a stimulus to the initiation and further development of similar projects.

OE has also applied itself to furthering cooperative ties with other Federal agencies in order to strengthen the services provided for senior citizens. As a result of the Office of Education and Administration on Aging Joint Agreement, signed on December 23, 1976, some State library agencies and local public libraries have established cooperative activities among existing State and community agencies for the benefit of older persons.

Working with and through other Federal programs operating at the local level, libraries expand and enhance the total array of services being offered. At local nutrition sites, supported by Federal funds from the Administration on Aging, libraries have provided education and entertainment through books, audio-visual presentations, discussions, etc., and information through consumer pamphlets, tax forms, applications for various government benefits, and the like. Libraries have also provided the forum for National Endowment for the Humanities' programs that delve into social issues of special concern to elderly citizens.

Cooperating with national, State and local community groups has also proven effective in providing library services to older people. Through organizations such as the American Association of Retired Persons and senior citizen groups, libraries experience the benefits of working with active senior citizens and can thereby keep abreast of the special needs and desires of the elderly.

Providing the special information older people need is a library responsibility that takes many forms. Lending and reference services, along with immediate information and referral (I&R) services connect the elderly with front-line community agencies and governmental programs (for example, Social Security, MEDICARE, MEDICAID, Veterans' programs, etc.) that provide for their well-being and indeed their survival. I&R services in general, and those specifically designed for the aging population, are rapidly increasing in number. Cognizant of the elderly's special information needs, libraries are developing innovative I&R services such as the OASIS (Older American Special Information Services) program in California in which public libraries used LSCA funds to implement an I&R service delivered to rural areas from a roving van. The van is staffed with personnel knowledgeable about community agencies, specially those concerning the elderly's welfare, and equipped with communications devices which provide contact with the main library for additional resources.

The resource collections of some libraries have also been expanded to include specialized "Life Skills and Coping" collections. These materials are made readily accessible in neighborhood branch libraries and offer adults of all ages survival and crisis information and education in easily understandable formats.

Since the educational background of senior citizens is as varied as that of other cross-sections of the population, ranging from illiterate to highly skilled, libraries offer learning opportunities in a large number of ways. Adult Basic Education, including literacy instruction, taught in groups or on a one-to-one basis, reaches many older persons who need these important skills to make their retirement years more satisfying, enable them to cope with life's demands and become less dependent on others. For the increasing number of elderly citizens pursuing a lifelong learning pattern, library-centered independent learning programs offer a broad range of interests and are geared to individual study goals. For instance, retired and senior citizens are taking advantage of cultural

enrichment and continuing education offered by "Learn Your Way" centers in New York, Brooklyn, and Queens Borough Public Libraries. By making appointments to confer with "Learning Advisors," specially trained librarians who help patrons find information or special materials, these people can be put in touch with a wide range of resources and be given continuing assistance on whatever their current interests may be.

Learning and recreational interests can also be pursued by the older person by participating as an active member of the community in regular library programs. These programs include discussions, films, arts and craft demonstrations, programs on health concerns, exhibits of senior citizens' hobbies, forums on consumer issues, etc. One LSCA program in Louisiana brings classical music - opera, symphony, and chamber music - performances to senior citizens in isolated rural areas. Many library programs are brought directly to retirement and senior citizen centers and, in some cases, the elderly are provided transportation to the library for special programs. Librarians and volunteers, often older adults themselves, make person-to-person visits to the homebound, residents of nursing homes, and the aged in State-supported institutions.

The approximately 5% of senior citizens who reside in institutions are also served by libraries. An LSCA project in the Woodville State Hospital in Pennsylvania addresses the need for effective communication skills in long-term aged residents of psychiatric hospitals. Operating under the theme "There's a World Out There," project librarians developed special library services and programs to reawaken skills in reading, writing, observation, listening, and oral communication. All types of media are utilized in this effort to convey a sense of reality to the institution's residents. Such use of audio-visual materials has been shown to be an effective way of reaching geriatric populations. Travel films, old-time radio shows, cassette recordings, etc. provided by the public library also bring pleasure to the elderly who have much leisure time.

In addition to audio-visual materials, special equipment is made available by libraries to facilitate reading opportunities for the blind and physically handicapped, a large percentage of whom are aged. LSCA and Library of Congress programs complement each other in serving the elderly handicapped with talking books, braille, and other special reading materials loaned through a network of 154 regional and subregional libraries for the blind and physically handicapped throughout the country. Those elderly persons disadvantaged both by physical handicaps and by a limited ability to speak English can also receive library service in the form of talking books, large print materials, recordings and reading aids, all in their mother tongue.

Older Americans from all ethnic backgrounds are served with special bilingual programs and services that recognize their diverse needs. Outreach programs bring information, education, survival skills, cultural pride and communication capabilities within the reach of bilingual citizens. In one program in Texas, for example, the service included a Spanish-English large print card with the phone numbers of important community service organizations (police, fire, social security office, ambulance, etc.) distributed for free by the library that produced it. Another bilingual project, the "Asian Community Library," located in California, serves all members of its multi-ethnic population, but the bilingual books, magazines, films, etc. have special significance for the aged clients who strongly desire to maintain ties with their homelands and cultures.

Preserving the cultural heritage of ethnic groups and the history of geographical locales is another library activity in which the aging play a prominent role. The talents, memories, and insight of older persons are tapped by many library-sponsored oral history projects, some of which are also bilingual. An important feature in the gathering of oral history tapes and memorabilia collections is the unifying effect such an activity has on persons separated by many generations. Sharing past and present experiences can be meaningful to both young and old as demonstrated by an oral history project in Vermont which used an intergenerational approach. Called "Young People Save Yesterday," the project employed high school students, trained by the library in techniques of interviewing and preservation, to conduct extensive interviews with the oldest members of the community. By promoting interaction among different generations, the project had positive impact: the elderly felt pride in the contribution only they could make to this effort and the students gained in self-awareness and ability to relate to older people.

Serving persons of all generations often necessitates tailoring activities to better serve a particular age group. For example, public and State library outreach programs which send bookmobiles out to isolated rural areas and to poverty pockets in the city have been, in some cases, specially adapted for use by the aged population. An LSCA grant in Ohio provided for a custom-designed bookmobile which facilitated service to elderly readers in Cleveland's senior day-care centers, nutrition centers, and other locations. A hydraulic lift that raises patrons into the bookmobile makes the "Senior Bookshelf" accessible even to readers confined to wheelchairs.

Another library delivery system, Books-By-Mail, also has notable impact on elderly persons whose mailbox can connect them with free, prepaid mailings of selected readings, framed art prints, recordings, etc. Some libraries have made this popular service even more suitable for the elderly's needs by not only providing large print books, but also large print material selection catalogs.

These examples illustrate the basic goal and concept of public library service to older Americans: making library materials, services, and programs available in all usable formats and providing them in the most convenient ways for the client.

The 1973 amendments to the Older Americans Act included opportunities for strengthening library services to older adults through a new LSCA Title IV, "Older Readers Services." With no funds for the new Title, special services for the aging continue to be provided from funding available from Title I, "Library Services" of the Library Services and Construction Act.

B. ADULT EDUCATION

The Adult Education Program, authorized under the Adult Education Act of 1966, as amended, provides undereducated adults (persons 16 years of age and older) an opportunity to continue their education to at least the level of completion of secondary school and makes available the means to secure training that will enable them to become more employable, productive, and responsible citizens.

The program is a State grant operation administered by State education agencies according to State plans submitted to the U.S. Office of Education and approved by the U.S. Commissioner of Education. States are allotted grants to pay the Federal share of the cost of establishing or expanding adult education programs in local educational agencies and private non-profit agencies. The matching requirement for the State grant program is 90 percent Federal funds and 10 percent State and/or local funds.

It is anticipated that the number of participants in the Adult Education Program who are 45 and over will show a sharp increase in fiscal years 1976 through 1978. On December 23, 1976 the Commissioner of Education signed a comprehensive Joint Agreement of cooperation between the Office of Education and the Administration on Aging. Implementation at the State and local levels will result in additional efforts to provide opportunities for education for older persons. Also in FY 1977 the Bureau of Occupational and Adult Education circulated to the Regions and States a priority statement concerning special projects to encourage the involvement of older citizens in Adult Education and including suggestions for implementation under current authorities.

	%	FY 1977	FY1978	FY 1979
Estimated Total Participation		1,767,073	1,992,073	1,992,073
By Age				
16-24	33	724,500	816,750	816,750
25-34	22	477,109	537,859	537,859
35-44	15	282,732	318,732	318,732
45-54	16	159,037	179,287	179,287
55-64	10	70,683	79,683	79,683
65 & Over	4	53,012	59,762	59,762

C. UNIVERSITY COMMUNITY SERVICE AND CONTINUING EDUCATION

The Community Service and Continuing Education (CSCE) program authorized under Title IA of the Higher Education Act of 1965, as amended, provides funds to States and to institutions of higher education for three purposes: to strengthen community service porgrams of colleges and universities; and to support the expansion of continuing education in colleges and universities: and to support resource materials sharing programs. The CSCE program, made up of four distinct parts, has been especially designed to meet the educational needs and interests of adults who have been inadequately served by traditional educational offerings in their communities. The State-grant program: Special Projects program; Special Programs for the Elderly; and Technical Assistance authorities can be briefly described as follows:

1) The State Grant program is the major component of the CSCE program. Under this program funds are allotted to the States on a population formula basis, except that no State gets less than the amount received in FY 1975. The CSCE program is administered by a designated State Agency in each State which develops a State plan, establishes priorities among problem areas, and is responsible for reviewing and approving institutional proposals for support, and funds in support of projects are disbursed by the States to colleges and universities. One-third of total program costs must be met from non-Federal funds.

   Through the years the State Grants program has provided financial assistance for a number of projects designed to assist older Americans, for example:

Year	# of Projects (Including multi-problem areas)	# of States	Cost (Federal funds)
1975	77	35	1,326
1976	69	36	1,121
1977	75	37	1,325

   Activities supported by these funds have included:

   a) Mass media approaches to the problems of aging:
   b) Special educational programs for older adults, including such projects as Elderhostel, Institutes of Lifetime Learning, and Outreach programs;
   c) Pre-retirement and retirement counseling;
   d) Financial, legal and housing assistance:

e) Employment and occupational training for older citizens who wish to change or re-enter the field of work;
f) Consumer education;
g) Projects to involve older adults in local government and to serve as community resource persons, and as aides to handicapped;
h) Art, music and recreation therapy to deal with problems of aging;
i) Health and nutrition awareness and exercise skills for older adults:
j) Professional and paraprofessional gerontological human relations training for those providing care and services for older adults.

2) The Special Projects program, added to Title I in 1972 under Section 106, permits a set aside of up to ten percent of the funds appropriated for the CSCE program (not required to keep State allotments at FY 1975 levels) to make direct grants to institutions of higher education to assist them in carrying out special programs and projects. These programs and projects must be designed to seek solutions to national and regional problems relating to technological and social changes and environmental pollution. Special projects are limited to demonstration or experimental efforts and must be based on a design for an implementation of organized continuing education activity for older adults.

In 1977 two projects related to the needs of older adults received continued support at a total cost of $58,851:

a) A renewal grant of $45,487 was made to Maricopa County Community College District in Arizona for the project, Six Dimensions for People over Sixty, in which six community colleges will target services to senior adults. Each college will develop and operate a separate program focusing on a different part of the senior adult population and its continuing education needs. The individual projects will use the mass media and direct instructional approaches.

b) In addition $13,364 in renewal funds were directed to the University of Tennessee (Nashville) for Development of an Institutional Model for Community Services and Continuing Education for the Elderly in which ways to increase higher education access for the older adult will be developed and tested. A consortium of four institutions in Tennessee (Dyersburg State Community College, East Tennessee State University, Tennessee Technical University, and

University of Tennessee) will conduct the project.

3) The Special Programs for the Elderly provision was authorized under Section 110 by the Older Americans Comprehensive Services Amendments of 1973 for the support of planning, developing, and carrying out programs for the elderly with special emphasis on meeting transportation and housing needs of rural and isolated elderly individuals. To date, there have been no funds appropriated for this portion of the Title IA statute.

4) The Technical Assistance Authority, added by the Education Amendments of 1976, authorized the Commissioner to reserve up to 10 percent of funds appropriated in excess of $14,500,000 to carry out such activities as providing a national diffusion network and assisting the States and institutions in the improvment of planning and evaluation. The program is administered by the CSCE Branch. Fiscal year 1978, should the FY 1978 appropriations bill with $18 million for Title IA be signed, will be the first year for which funding for the new provisions for technical assistance will be available.

D. FUND FOR THE IMPROVEMENT OF POSTSECONDARY EDUCATION

The Office of the Assistant Secretary for Education makes grants from the Fund for the Improvement of Postsecondary Education for projects which demonstrate practical steps taken by educators and communities to strengthen educational policies beyond the high school level. This program was authorized in 1972 by Section 404 of the General Education Provisions Act. Five such projects funded during FY 1977 emphasized involvement of the elderly in programs of postsecondary education, as described below.

Bucknell University
The Cross-Generational Program
Lewisburg, Pennsylvania

The Cross-Generational Program (CGP) evolving at Bucknell is a student-run program conceived by undergraduates who were concerned with improving their educational experiences and the life-style of the rural elderly. The CGP addresses the problem of age isolation; as groups, both elderly and students often find themselves in settings where peers are the only social contacts. As a result of this separation, the learning that could occur across generations is seldom realized. The CGP works at improving the learning process through effective interaction among faculty, students and older adults. In the past year, over 200 elderly, students and faculty have been actively engaged in program activities.

Activities aim at establishing a sound foundation of personal relationships and are directed at a particular intergenerational problem (such as improving communication) or a difficulty presented by the rural area (such as contacting and transporting a rural target population). Activities include attending social/cultural events and groups that meet weekly to discuss topics of interest. The CGP also has an "Outreach" component through which students contact isolated individuals; through a "Live-in" component, elderly live as guests in the program's university residence.

In order to better utilize elderly as educational resource persons, an "Older Teachers" component is being developed. A list of elderly (along with former occupation, hobbies, and areas of specific interest or knowledge) has been prepared as a sourcebook for distribution to faculty, thus offering faculty the opportunity to invite older adults to class when topics match elderly interests. After this cautious introduction to the classroom in the student role, interested elderly will attend seminars designed to build confidence and teach skills necessary for giving short talks or presentations to a class. No time scale has been set for this process since it must proceed cautiously with constant feedback from older adults, faculty and students.

The proposed strategy should provide meaningful interactions across the generations while developing new roles for older adults. It is expected that this approach will encourage more faculty to take an active role in the program and help to institutionalize it. We expect students to benefit from an alternative education system that introduces personal perspective and experience to their study. A twofold evaluation (quantitative and phenomenological) is being conducted and the results published in a form that will describe the development of the program to serve as a manual for other universities interested in intergenerational work.

The Chicago Community Trust
Chicago, Illinois

Although they may be retired from a career, many older persons still want to remain active - to feel they are useful, contributing members of the community. Yet societal expectations define leisure and recreation as the proper pastime for all older adults. Negative and mythical stereotypes, combined with discriminatory practices and policies, inhibit many older persons from exploring other roles and pursuing new challenges.

Because it can be a gateway to personal growth and development or to a second career, education is of the greatest relevance to older people. However, aside from general societal constraints, barriers exist within the field of education which prevent many older persons from engaging in educational exper-

iences, such as high tuition costs, physical inaccessibility, inadequate counselling services, and educational settings which are geared to younger students. Although there has been an increase in educational programs for adults within recent years, this trend has focussed on the young or middle aged adult and has, for the most part, by-passed the older adult.

The Chicago Community Trust, a community foundation which seeks to be responsive to changes in the charitable needs of the community, believes that the quality of life in the community will be enhanced if older persons utilize their skills and continue to grow and develop as individuals. To increase the opportunities for older persons to participate in education, the Trust initiated and now works closely with a committee of over twenty-five colleges, universities, and social service agencies. The goal of their combined efforts is to promote a full range of educational opportunities for older adults from diverse socio-economic backgrounds through the establishment and operation of a regional coordinating agency, the Metropolitan Chicago Older Adult Life Options Education Network.

The Network itself will not provide educational opportunities, but will work through existing organizations, linking institutions of higher education, human services agencies, local government, and business and industry. These organizations will be encouraged and assisted to increase educational opportunities for older adults, both for credit and not for credit, in traditional classrooms as well as through alternative modes and settings. Some of the projects to be implemented by the Network in the first year include: compilation of information and materials regarding existing educational opportunities; brokering services to link older persons with the most appropriate educational experience; outreach to encourage older persons to consider participation in education; faculty development seminars which focus on techniques for teaching the elderly; and increasing the public understanding of the relevance of education to the elderly.

Through its activities and projects, the Network will have four important consequences. First, the Network will alter the ways in which educational services and programs are planned, organized, and delivered to older adults. Second, the Network will increase the participation of older adults in every aspect of education - not only as students, but also as educators and other staff. Third, by associating with employment and volunteer programs for the elderly, the Network will assist older persons to participate in these activities. Lastly, the Network can serve as a model of process and structure which can be adapted by other communities.

Franconia College
Franconia, New Hampshire

Twenty-four million people in the United States are 65 years old and older. They are faced with retirement, inadequate pensions, increased immobility, and loss of family and friends. Governmental agencies and responsible families alike tend to view the elderly as a social problem to be managed efficiently and mechanically. This can cause a personality destruction so intense and complete that even the best adjusted are likely to accept society's image of the useless elderly. One factor in this process of disengagement is the helpless resentment older people feel towards the many public activities which, on the one hand, tax them beyond their means, and on the other hand, discourage them from participation. When, in addition, the elderly view public education as either frivolous or contrary to their fundamental values, a strong foundation has been laid for a negative, retrogressive political movement of great potential effort.

Franconia College, with three summers of experience in educating the old and young together, has developed a component which expands the accessibility of higher education to the elderly. The cornerstone of the PIONEERS Project is the restructuring of a series of courses into a modularized format. During the Fall 1977 and Spring 1978 terms, the College is offering six eight-week courses. Each course is composed of four distinct two-week modules. Each module is a complete unit, requiring participation in neither a previous nor a subsequent module, yet linked to the other modules such that the four two-week segments compose the equivalent of one full semester course. PIONEERS may thus participate for as few as two or as many as eight weeks. The courses are offered for full academic credit. Younger residential students and Continuing Education students as well as PIONEERS are encouraged to enroll.

In addition to participation in the courses, PIONEERS are invited to live on campus in standard dormitory facilities. They are asked to participate in the governance, work program, and social life of the College on the same basis as younger students. The program operates with the cooperation of local agencies serving the elderly to identify course needs, seek out potential participants, and evaluate project accomplishments. An average of 20-25 PIONEERS per module are to participate, approximately one half of whom live in the local area.

The project will generate a restructuring of the Franconia College curriculum. The modularized course format offers new, more flexible scheduling for younger students. It will enable older Americans who would not otherwise seriously consider higher education to take advantage of the College's resources. In meeting the following three objectives, the project will serve as a model for the creation of an entirely new network of educational services for the elderly: (1) to begin to break through the problem of age-segregation of the elderly, (2) to enrich the period of retirement through education, and (3) to evaluate the impact of age-integrated programs on learning and the organization of higher education.

Macalester College
St. Paul , Minnesota

The problem this project attempts to alleviate deals with extending effective educational opportunities to older persons (defined as age 55 and over), particularly in intergenerational settings, thus also enriching the traditional programs for the young. This older group, the fastest growing minority in the U.S.A., is not now adequately served by our several national education systems. Although we have some beginnings modestly funded, by (1) Title I of the Higher Education Act of 1965, (2) Title III of the Older Americans Act, and (3) FIPSE, much more needs to be done to coordinate, sustain, enrich, and increase these and other promising efforts.

During the first year of funding, the project trained a staff of representatives from each of the Minnesota educational systems: The University of Minnesota; The Private College Council; The State Community College Board; the Area Vocational-Technical Institutes; and The Minneapolis Public School System. The method of training was a seminar presented by expert gerontologists. This staff then took their expertise throughout Minnesota to share it with interested institutions. In the second year of the project the staff will continue to travel to such institutions in an effort to reach as many as possible. Such visits include verbal presentations, sharing important printed material, and a newly developed video tape. In addition to these visits, which are the primary thrust of this phase of the project, a pilot faculty/staff training seminar in intergenerational education will be offered in March, 1978. Finally, as we move toward Minnesota as a national center for intergenerational education, a newsletter will be published and alternative blueprints for action will be developed for use by individuals, institutions, systems or states interested in this new area of educational programming.

This project has the cooperation of all of the educational systems heads in the state. Such a cooperative climate is due in large part to the earlier efforts of the Minnesota Intergenerational Education Consortium comprised of the University of Minnesota, Mankato State University, the Colleges of St. Benedict, St. Thomas and St. Catherine, St. Paul Area Vocational-Technical Institute, North Hennepin Community College and the Minneapolis Public Schools. This ad hoc consortium has been operating for the past three years under a "model projects" grant from the Administration on Aging (HEW).

The goals of this inter-agency project are: (1) to train a staff of resource persons who will then translate their expertise into training sessions for remaining institutions throughout Minnesota; (2) to use these training sessions to raise the consciousness level of these institutions and their systems in the direction of integrating retired persons as a new clientele; (3) to develop Minnesota as a national center in intergenerational education.

Holy Names College
Oakland, California

Older adults residing in large urban communities often find themselves physically and psychologically isolated from the broad range of resources and options available to the city's younger residents. This situation often results in feelings of alienation, loneliness, and powerlessness which undermine the physical and mental health of these older citizens.

Holy Names College has initiated a program in two San Francisco East Bay communities designed to improve the quality of life for the older adults. Educational programs based upon the philosophy of the Brazilian philosopher-educator Paulo Freire, are being designed for delivery in short courses at two walk-in health clinics. Active Learning and Interest Centers for Elders (ALICE) are operated cooperatively by the staff of Holy Names College and the Clinica de la Raza (a family-oriented clinic for Spanish-speaking people in Oakland) and the Over 60 Health Clinic (operated by the Grey Panthers for a predominately Black older adult population in Berkeley). The program seeks to inform and motivate the older adults to take action which will affect their own lives as well as their peers in the community. In addition to taking courses of varying length at their respective clinics, roughly 25% of the adults are receiving further training to become peer teachers which enables them to assist others in the community who may or may not be members of the clinics. Among topics initially addressed in the curriculum are self-care, self-advocacy, nutrition, civic responses to the needs of elders, financial survival skills, and psychological aspects of aging.

Extensive on-site, in-service training is also provided for the clinic staff, clinic advisory boards, and participating faculty to familiarize them with the learning needs of older adults and the teachings of Paulo Friere.

Unlike other postsecondary educational programs which bring older adults onto the campus, ALICE seeks to integrate educational services into existing community health programs. Hopefully this program can serve as a model for future cooperative efforts between educational institutions and communities to address the unique needs of urban older adults.

VI. OFFICE OF THE INSPECTOR GENERAL, HEW

The functions of the Office of the Inspector General have an effect upon the quality, scope, and cost of services to the aging in numerous ways. Described below are major activities of the Office in 1977 which had an impact directly or indirectly on services for the aging, along with some discussion of planned activities in 1978.

GENERAL

The mission of the Inspector General is to prevent and detect fraud and abuses in HEW programs and to promote economy and efficiency in the Department's operations. He also is charged with reporting to the Secretary and to the Congress on deficiencies and problems related to HEW programs and on the necessity for and progress of corrective actions.

The Inspector General's Office is the first statutory position of its kind ever established in the Federal civil government. It is the result of Public Law 94-505 enacted on October 15, 1976. The law itself is the result of Congressional initiative, inspired at least in part by disclosures of fraud, abuse, or waste in Federal/State medical and welfare programs. The legislation balances the functions prescribed for the Inspector General between preventing or ferreting out wrongdoing and recommendations for program improvements anywhere in HEW.

Thomas D. Morris is the first Inspector General, taking office on April 1, 1977. He is a former Assistant Comptroller General of the U.S.

ORGANIZATION

The Inspector General's Office has three main elements prescribed by statute:

The Assistant Inspector General for Auditing heads the HEW Audit Agency, a long-standing professional staff of auditors that comprise a sizable and highly proficient resource for the department. This staff prepares or reviews more than 7,000 audits of HEW and its contractors and grantees annually. Its responsibilities include auditing of some 50,000 universities, schools, and nonprofit activities. It also serves as the auditor for other Federal agencies for their grants or contracts awarded to universities and colleges.

One of the agency's most valuable resources is its computer analysis expertise that is being adapted to new initiatives of the Office of Inspector General.

The Assistant Inspector General for Investigations heads a staff that investigates HEW-related activity of a potentially criminal nature. Until two years ago, HEW had no investigations staff of its own and relied on the FBI and State investigators, as appropriate. At the time the Inspector General's Office was formed, the Office of Investigations had developed a staff of about fifty. It is now authorized a staff of 114, and is rapidly approaching that strength.

Its backlog of cases has grown rapidly since it became a part of the Inspector General's Office. In addition, it has a high-priority role of overseeing the investigation of more than 2,400 cases by Federal or State teams under Project Integrity. The Office of Investigations also has a new role of assisting in the certification and monitoring of the State Medicaid Fraud Control Units authorized under H.R. 3 legislation.

The Assistant Inspector General for Health Care and Systems Review heads a new small staff of senior experts with specialized experience across the range of HEW activities. Now numbering about 20 people, it is expected to grow to about double this strength. This office heads the program delivery assessment staff, and the review of the fraud, waste, and abuse activities of the major units of HEW. It also plans new initiatives to combat fraud, abuse, and waste, some of which are discussed further on in this report.

ASSISTANCE FROM OTHER ORGANIZATIONS

A basic philosophy of the Office of Inspector General is to seek use of existing departmental resources in a cooperative way to accomplish its mission. Close working relationships have been built with the Health Care Financing Administration, the Social Security Administration, and other major elements of the Department in order to maximize resources devoted to common problems. The Inspector General also maintains close liaison with the Justice Department, the Treasury Department, and the Postal Service, and has obtained significant help from them, especially in investigations.

MAJOR PROJECTS IN 1977

Program Delivery Assessments

One of the most broad-scale tasks that the Secretary has asked the Inspector General to undertake is evaluating how well HEW programs work at the recipient level. He has asked the Inspector General to design, test, and monitor the implementation of a nationwide series of "Program Delivery Assessments" which seek to determine the cost and effectiveness of services being delivered to beneficiaries. The measurement of the effect of the Department's services on its clients is an area in which data generally is too weak or nonexistent. In this effort, the Inspector General is being assisted by other elements of HEW, including a small assessment staff in the newly reorganized regional offices. These staffs need to work closely with State and local agencies, and the Inspector General has received many assurances of State support in this effort.

One of the first evaluations in this service delivery assessment is the effectiveness of home health care agencies - a matter of special concern to older Americans.

The initial studies are being done in Florida, in cooperation with the State, which was already planning such a review.

We have also begun an evaluation of Head Start and will be measuring effectiveness of other social programs to determine their worth versus alternatives in the coming year.

Departmental Program Reviews

Another major long-term task given the Inspector General by the Secretary in 1977 is the systematic review of how effectively each HEW program is organized and staffed to combat fraud, abuse, and waste. In reviewing management of programs, particular attention will be given to Management Information Systems, Quality Control Systems, Program Integrity, and Technical Assistance to States. The Secretary asked the Inspector General to give first priority to such a review of the Aid to Families with Dependent Children program. This effort is underway, with a small but highly qualified team working with the Social Security Administration.

Project Integrity

One of the first initiatives begun by the Office of the Inspector General immediately upon formation of the Office is aimed directly at fraud and abuse in medical services supported by the Department. Project Integrity seeks to use computer technology to find the initial indications of wrongdoing, thereby eliminating laborious manual screening of records.

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In its first phase, Project Integrity is concentrating on physicians and pharmacists in the Medicaid program.

For analysis purposes, reasonable limits were established by experts for 22 services or procedures by physicians, and for 26 procedures by pharmacists. Services in excess of those limits were turned up by the computer as aberrant or abnormal. For example, more than 25 prescriptions for Valium for the same patient in a year were considered abnormal. Examination of some 250 million billings across the country rendered in 1976 produced some 47,000 cases of physicians and pharmacists that appeared to exceed reasonable limits in some way. The Inspector General then selected approximately 2,500 of those that appeared most flagrant, choosing about 25 physicians and 25 pharmacists from each State for field investigation.

The States are cooperating in this effort and have committed more than 350 personnel to the effort. Some 170 Federal officers are participating.

Most of the cases turned up by the computer, including cases selected for early investigation, will not be fraudulent. But those in which fraud is indicated will be referred to U.S. Attorneys for prosecutorial decision.

The technique will be extended to examining records of other health care professionals and institutions in the future, and it is also applicable to Medicare. For nursing homes, special studies are being conducted in three States in an effort to learn the best techniques for computer analysis of nursing home records in order to apply these on a nationwide basis. For hospitals, a special study is being conducted in New York State that may lead to development of computer analysis of hospital records to disclose abnormal costs or procedures.

Project Match

Under this project, begun by the Inspector General in mid-1977, computer comparison is made between Federal pay records and welfare rolls (Aid to Families with Dependent Children) to screen for Federal employees improperly receiving welfare benefits. This project was undertaken after reviewing results of efforts by U.S. Attorneys in Detroit and Chicago, who worked with State welfare authorities to indict a surprising number of Federal employees for welfare fraud.

The Inspector General is conducting this effort in cooperation with the Family Assistance Administration, the Department of Justice, and the States. In the initial effort, comparisons were made of welfare rolls and Federal payrolls in 21 major jurisdictions or States. Raw matches amounted to about 26,000 persons, about half of whom are currently employed by the U.S. Government, the others having been employed in the recent past on either a full-time, part-time, or temporary basis.

By the end of 1977, some 13,358 cases had been turned over to the appropriate Federal agencies for verification of employment and salary. This information will then be furnished to the State welfare agencies for redetermination of eligibility. Undoubtedly, a sizable portion of the Federal employees on the rolls will be found to be drawing benefits properly, due to low income or large family, or both. But others will be found totally ineligible or overpaid or underpaid in benefits. Cases which appear seriously fraudulent will be turned over to U.S. Attorneys for possible prosecution, and other cases involving improper benefits will be dealt with administratively.

The Civil Service Commission, Justice Department, and HEW have agreed on procedures to insure protection of privacy for the 2.8 million Federal employees whose records are being screened. No data on individuals will be disclosed publicly unless this becomes necessary during prosecution of that person.

ACTIVITIES IN 1978

Program Delivery Assessments

We plan to expand considerably our evaluation of HEW social and health programs at the recipient level during 1978 and a number of these studies are expected to relate directly or indirectly to services for the aging. At this writing, most of these assessment efforts have not been selected. However, the Inspector General and regional assessment staffs will complete their evaluation of Home Health Care, and have already decided on four new assessments in 1978. These include:

a. Disability Insurance Benefit Determination, in which the client's experiences in the Social Security Administration's disability determination process will be evaluated.

b. Education for the Handicapped, to ascertain the extent to which handicapped children benefit from educational services.

c. Foster Care Services.

d. Family Planning for Teenagers.

Departmental Program Reviews

As part of his major assignment to review the efficiency of the Department's programs in combating fraud, abuse, and waste, the Inspector General expects to review the Medicaid program in 1978. This is one of the Department's most rapidly growing programs in terms of costs, and it is one that many aged people depend on for their medical care.

ALCOHOLISM

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
Alcohol, Drug Abuse, and Mental Health Administration:					
National Institute on Alcohol Abuse and Alcoholism:					
Budget Authority	$146,048,000	$148,433,000	$160,306,000 1/	$168,636,000	$174,307,000
Obligations	(167,633,000) 2/	(189,945,000) 3/			
National Institutes of Health:					
National Institute of Arthritis, Metabolism, & Digestive Diseases	4/	4/	4/	4/	4/
TOTAL, PHS:					
Budget Authority	146,048,000	148,433,000	160,306,000	168,636,000	174,307,000
Obligations	(167,633,000)	(189,945,000)			
Office of Human Development:					
Rehabilitation Services Administration:					
Basic State Grants	32,640,000	33,134,000	34,795,000	34,982,000	36,131,000
Facilty Improvement	35,033	27,600	39,413	39,120	39,120
TOTAL, RSA	32,675,033	33,161,600	34,834,413	35,021,120	36,170,120
TOTAL	$178,723,033	$181,594,600	$195,140,413	$203,657,120	$210,477,120

1/ Excludes $115,000 in reimbursements from the Department of Transportation and the Health Resources Administration.
2/ Includes $21,585,000 in FY 1973 court released funds.
3/ Contains $41,512,000 obligated in transition quarter.
4/ Obligations cannot be identified.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute on Alcohol Abuse and Alcoholism

ALCOHOLISM

BACKGROUND FACTS

Alcoholism and alcohol abuse are recognized as one of the Nation's most serious health problems. There is no method of accounting that fully measures the tragic loss of human resources stemming from the misuse of alcohol. The economic cost to our society alone is estimated at $43 billion annually, with $19.6 billion attributable to lost productivity, $12.7 billion to alcohol-related health care costs, $5.1 billion to motor vehicle accidents, $0.43 billion to fire losses, $2.8 billion to violent crime, and $1.9 billion to social response programs to alcohol abuse.

Regarding the prevalence of alcoholism, there are 10 million alcoholics and problem drinkers in the U.S.A. Current findings indicate that: alcohol shortens life expectancy 10 to 15 years; men are nearly twice as likely to be heavy drinkers as women; and 74 percent of in-school teens are drinkers (youth drinkers are defined as having had more than two or three drinks ever) and 19 percent are problem drinkers. Problem drinking was defined as either drunkenness at least six times in the past year or when two or more negative consequences resulted from drinking such as getting in trouble with the police, teachers, friends, etc. The proportion of teenage problem drinkers increases steadily with each successive grade in school. While 5 percent of seventh grade boys and 4.5 percent of seventh grade girls are problem drinkers, nearly 40 percent of twelfth grade boys and 20 percent of twelfth grade girls are problem drinkers.

Alcohol has a profound effect on the quality of life. Thirty to 50 percent of annual motor vehicle fatalities are associated with alcohol. Data are now available that 185,095 alcoholics died prematurely in 1975. From 6,700 to 10,000 of all suicides are alcohol-related. From 10,000 to 15,000 (40-70 percent) of all homicides are alcohol-related. Recent studies revealed that heavy use of alcohol by women during pregnancy may result in a pattern of abnormalities in the offspring termed the Fetal Alcohol Syndrome (FAS). The latest data on arrests show that 38 percent were alcohol-related.

Alcohol research is providing much needed information regarding the consequences of excessive alcohol use, the nature and extent of the problem, and the efficacy of various treatment modalities. However, many questions remain unanswered. For example, although many major health problems associated with alcoholism have been described, few effective preventative or therapeutic measures are available to the medical community. In addition, more reliable and efficient

strategies for the prevention and treatment of the problem drinking behaviors themselves also need to be developed. This can best be achieved through continued research into the causes of alcoholism and investigations of new therapies, with emphasis on those groups of individuals who are especially vulnerable to developing alcohol-related problems, or who may have special psychological needs.

Prevention and treatment reports have confirmed the fact that alcoholism is treatable with appropriate resources. Two-thirds of those alcoholics who receive psychologically-oriented therapy improve or abstain. A study of alcoholism treatment centers indicated that there is nearly a $3.00 net benefit to the national economy for each $1.00 spent. There are now over 2,000 occupational alcohol programs in corporations and work organizations.

FEDERAL LEGISLATION RELATING TO ALCOHOL ABUSE

In an effort to reduce the misuse of alcohol within our society and promote nonharmful drinking behaviors, Federal legislation was passed in 1970 creating the National Institute on Alcohol Abuse and Alcoholism within the National Institute of Mental Health and authorizing formula and project grants to support prevention, treatment and rehabilitation services in local communities. This "Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act" (P.L. 91-616) has consistently been lauded as landmark legislation, promoting the wide-spread recognition of alcoholism as a treatable illness, rather than the sociopathic disorder it was generally considered in the past.

In 1971, the National Conference of Commissioners for Uniform State Laws developed the "Uniform Alcoholism and Intoxication Treatment Act," which stipulates that alcoholic individuals should not be subjected to criminal prosecution because of their consumption of alcoholic beverages but rather that they should be provided with appropriate treatment within their communities. This model legislation has since been widely adopted by State governments.

In 1974, the "Amendments" (P.L. 93-282) to the 1970 Act established the NIAAA as a separate agency within the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), furthered the emphasis and direction of the original legislation, and authorized special grants to States which adopted the basic provisions of the model "Uniform Alcoholism and Intoxication Treatment Act." In the execution of its legislative mandate, the annual budget of the NIAAA grew from $34 million in FY 1971 to $168.6 million in FY 1978.

In 1976, Congress further amended the 1970 Act, providing $600 million in authorizations for alcohol programs over the next three years. The bill continues funding for formula grants and community assistance programs, places special emphasis on treatment

for underserved populations, women and youth, and mandates a new emphasis on alcohol research.

PUBLIC HEALTH SERVICE
Alcohol, Drug Abuse, and Mental Health Administration
National Institute on Alcohol Abuse and Alcoholism

Among the many interesting developments in the field of alcoholism during the past seven years, perhaps the most significant event has been the wide-ranging commitment of the Federal government to the problems of alcohol abuse and alcoholism.

The National Institute on Alcohol Abuse and Alcoholism, created by an Act of the United States Congress (Public Law 91-616), was formally established in May 1971. The Institute develops and supports programs to (1) improve treatment services for alcoholic persons in States and communities, (2) treat and rehabilitate employees with drinking problems in Government and private industry, (3) modify public attitudes toward alcoholism and alcohol-related problems by developing a program of education and public information, (4) train professional and nonprofessional personnel, and (5) determine through research the causes and prevention of alcoholism and alcohol abuse. The Institute is rapidly developing a coordinated national alcoholism program. As a step toward the accomplishment of this goal, the National Institute on Alcohol Abuse and Alcoholism is providing funds for the development of adequate treatment services for alcoholic persons, based, whenever possible, on existing services.

Fiscal year 1972 was the Institute's first full year of operations, a year of dynamic growth and challenge. Throughout the country, along with the expansion of programs initiated in FY 1971, new programs for alcoholic people were developed such as those for public inebriates and the alcoholism poverty program.

During FY 1973 the Institute moved substantially closer to its primary goal of making effective treatment available at the local level to every alcoholic person in the United States. The development of alternative fiscal resources was also stimulated in order to expand services and make projects more financially independent. Further, recognizing that no illness has ever been eradicated by just treating the casualties, the Institute made a sound beginning towards the long-range goal of prevention. Sophisticated educational and informational techniques were initiated to foster the concept of appropriate use of alcohol among those who choose to drink.

During FY 1974, the Institute continued to foster the development of community-based resources for alcoholism treatment. The alcoholism field in general continued its significant growth at State and local

levels in response to the awareness and momentum generated by the Federal leadership. The NIAAA leadership role was enhanced by its placement as a separate Institute within the new Alcohol, Drug Abuse, and Mental Health Administration. In FY 1974, the Institute also began more intensive enlistment of the Nation's private enterprise system to the national alcoholism effort. NIAAA initiated programs to foster the development of guidelines for counselor certification and alcoholism program accreditation as an important step towards generating greater third-party payments for treatment services. An increasing number of private companies initiated occupational alcoholism programs for their employees. In the prevention area, the NIAAA's National Center for Alcohol Education began operations, and the need to respond to increasing public awareness sparked a significant expansion in the activities of the National Clearinghouse for Alcohol Information. Near the end of the fiscal year, the program authorities of the NIAAA were renewed and expanded by the passage of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act Amendments of 1974 (P.L. 93-282).

During FY 1975, the Institute began to make inroads with accreditation of alcoholism programs under newly adopted national standards to provide more effective treatment through patient fees, health insurance, and other third-party sources. Federal alcoholism efforts began to include the basic provisions, where necessary, for financial support, clothing, shelter, health care, legal assistance, and vocational training.

Occupational alcoholism programs were greatly expanded in 1975. Largely resulting from Federal initiatives, more than 275 new occupational programs were established independent of NIAAA funding throughout the Nation to currently serve a work force of nearly 2,750,000 people. These programs were established in the private and public sector for the benefit of the employees suffering from alcohol abuse and alcoholism. Significant partnerships also have been developed with the Civil Service Commission and the Department of Defense to foster Congressionally mandated occupational programs for Federal employees and servicemen with alcohol-related problems.

One of the major activities conducted by the Institute in 1975 was a National Alcohol-Health Promotion Conference which brought together scores of medical professionals, corporation executives, college educators, labor and management leaders and key individuals from the country's voluntary organizations.

The number of research grant applications reviewed during FY 1975 was 263, and this represents a 289 percent increase in applications received over FY 1971. This growth in research grant applications reflects an increasing awareness on the part of researchers of the importance of alcoholism as a public health problem.

During FY 1976, as a result of new leadership in the Institute, the commitment of the Institute was and will be for the next few years directed to "Operation Mainstream." NIAAA has attempted to bring alcoholism into the mainstream of our Nation's health care delivery system, into our total social and health care organization and the payment system that supports it. NIAAA is utilizing the concept of the total systems approach to health care delivery. It involves all phases of the Institute's mission including research, prevention, training, and treatment.

One of the first accomplishments during FY 1976 was the strengthening of the integration of the Institute's programs. Elements of prevention, research, training, and treatment activities interact in significant ways and it was essential to maintain a continuous cross-fertilization between research findings and therapeutic practice. Realizing that primary health care personnel do not know enough about alcoholism, and do not diagnose it early enough, the Institute supported career teacher training programs, funding teachers in medical schools, and many practicing physicians are being instructed by these teachers. At the present time, it is estimated that approximately 40,000 of the country's medical students and practicing physicians have participated in educational courses or programs developed or led by these 39 career medical school teachers. As the "Mainstream" concept has strong implications for the research field and as top biomedical and behavioral researchers have not been involved to the degree needed in alcohol research, the Institute has expanded the intramural and extramural research programs to keep pace with investigations now going on across the country. The Institute, through its studies and through grant and contract support, has made some important discoveries in research. During FY 1976 our studies provided us with a better idea of how alcohol affects the liver and the functioning of the brain, the effects of alcohol on the heart, gastrointestinal system, and nutrition. We have found how prolonged heavy use of alcohol by men affects the production of testosterone and can cause sex changes. More research is being conducted on the effects of alcohol abuse on the fetus of the mother (Fetal Alcohol Syndrome). We learned that a very high proportion of pregnant women who abuse alcohol give birth to children who may have some defect and we have widely publicized this data. NIAAA is interested in demonstrations of the aggresion factor and how this is seemingly triggered by alcohol. About half of the cases of child abuse and wife beating, and of car accidents and fatalities, involve persons with alcohol in their bloodstreams.

During FY 1976 the Division of Prevention engaged in extensive campaigns directed toward our target audiences--youth, women, and minorities. The proportion of American youth who drink has been on a continuous increase, particularly in the age group of 18-20.

The Federal resources administered by the NIAAA reached States, communities, and individuals through the activities of five operating Divisions: Special Treatment and Rehabilitation, Resource Development, Prevention, Intramural and Extramural Research. During FY 1976 NIAAA

supported 856 projects, grants and contracts, which included 56 State Formula grants, and 288 projects during the transition quarter, July 1 through September 30, 1976.

During FY 1977 the development of a National Plan was initiated for implementation during the next five years. In the area of intramural research, the Institute's goal is to build a strong program in basic and clinical alcohol research. The Division has started to relocate its research activities from Saint Elizabeths Hospital in Washington, D.C. to Rockville, Maryland. The Division of Intramural Research, which was established late in FY 1976, has reorganized into three new branches, the Laboratory of Preclinical Studies, the Laboratory of Metabolism, and the Laboratory of Clinical Investigations. These branches operate an in-house program of research on the multiple determinants of alcoholism and the critical factors in the prevention, treatment and rehabilitation of alcoholism.

In FY 1977 in the extramural research area, a new program of research support was initiated. Five Alcohol Research Centers were established. They are designed to complement the regular grant program and to take advantage of outstanding research capabilities across the country by providing long-term support for interdisciplinary research programs with a distinct focus on a particular research theme relating to alcoholism and other alcohol-related problems. These focus on areas such as the control of the nervous system, the gastrointestinal tract, behavior genetics, treatment, and social epidemiology. In FY 1978 the five centers will be continued. In FY 1979 these five centers should be out of the development stages and be in full operation, and it is anticipated that two additional centers will be funded during FY 1979. The five present Alcohol Research Centers are at: the Salk Institute, San Diego, Cal.; Mt. Sinai School of Medicine, New York; University of Colorado; University of California at Berkeley, Cal.; and Washington University, St. Louis, Mo.

To facilitate coordination between the various components of the Institute, the Office of Program Coordination has established and is implementing an Institute-wide management information and control system (MICS) to provide a total programmatic and functional picture of the applications on hand, grants and contracts awarded, and the workload of the Institute. This office has continued to expand coordination of interagency activities with other Federal departments and agencies, with special emphasis on those emanating from interagency agreements on alcohol abuse and alcoholism.

During FY 1977 the Interagency Committee on Federal Activities for Alcohol Abuse and Alcoholism, which is chaired by the Director, NIAAA, convened four times. The purpose of this committee is to evaluate the adequacy and technical soundness of all Federal programs and activities which relate to alcohol abuse and alcoholism and provide for communication and exchange of information. In FY 1977 NIAAA started to collect and analyze current Federal data and extablish an information base. During FY 1978 this basic task will be completed

to establish an all-Federal project inventory and develop procedures for its continued maintenance. An annual report will be made as part of the Institute's Annual Report to Congress.

A major portion of the Third Special Report to Congress on Alcohol and Health was prepared during FY 1977 for delivery in FY 1978.

During FY 1977 the effectiveness of the Institute funded treatment programs was evaluated through the NIAAA National Alcoholism Program Information System (NAPIS). This system collected data on the client treatment effectiveness and assessment of changes in client condition. Another evaluation system, the State Alcoholism Profile Information System (SAPIS), provided NIAAA with annual data regarding all State or Federal alcoholism programs. The particular emphasis is to determine the relative impact of the NIAAA funded Formula Grant Program in terms of programs supported, staff available, and training, treatment, research, and prevention activities.

In the prevention area, two major efforts were noteworthy during FY 1977 and will be continued. One was to develop strategies to create a social environment more conducive to a healthy attitude toward drinking and nondrinking of alcoholic beverages, and to strengthen community and individual resources toward such goals. The overall emphasis was on, and will be in the future, primary prevention. The second major effort was to develop, implement, and evaluate alcohol prevention strategies for youth. These activities involved: the development of audio-visual and print material for junior and senior high school-aged youth; an outreach effort to involve colleges and universities in the development of alcohol abuse prevention programs; and technical assistance to voluntary organizations to develop prevention programs utilizing their own resources. In addition, 22 demonstration programs have been funded to test a variety of prevention strategies. Three of the most promising model programs have been selected for replication to determine if the models will produce similar results in different settings and with different staff. In the future, the results of the replication projects will be analyzed and programs which result in reducing negative consequences of drinking recommended for implementation on a wide scale.

The National Clearinghouse for Alcohol Information (NCALI), a contract effort, is being monitored by the Division of Prevention. It is an information service of NIAAA established to search out worldwide information on alcoholism prevention, treatment, and research, and to share this information with the professional community and the general public. During FY 1977 the NCALI began an Alcohol Epidemiologic Data System to provide data support for the Epidemiological and Special Studies Branch of the Division of Extramural Research.

During FY 1977 the Division of Resource Development administered and implemented programs from the training of alcoholism counselors to assisting the States in implementing the provisions of the Uniform Alcoholism and Intoxication Treatment Act. Programs were under

development in three areas: 1) "Operation Mainstream," a developing grants program for incorporating alcohol-related course material and practicum experience into professional schools of graduate education; 2) "Network Development," a planning process to insure the development through identified communication channels, information exchange, instruction of trainers, managing training resources, and technical assistance to States, education institutions and community programs of a systematic approach to the delivery of quality training services; and 3) "Volunteer Resource Development Program," a new demonstration grant program for State-level organizations to encourage the growth and development of volunteer activities in the alcoholism field to document the impact of such activities and demonstrate improved techniques for volunteers. Another effort included the monitorship of a contractual operation of the National Center for Alcohol Education (NCAE) and a grants program for four Area Alcohol Education and Training Programs. The central function of the NCAE is to research, design, and develop quality training programs and educational materials.

The Division of Special Treatment and Rehabilitation administered and monitored the treatment, referral and rehabilitation programs of the Institute. Three major functions are performed in the three branches: The Special Projects Branch is involved in the direct delivery of services for the alcoholic persons in the community through the grant mechanism; the Occupational Alcoholism Branch sensitizes employers in various industries to the importance of implementing programs for alcoholic persons in the work force, and assists employers in the public and private sectors to develop and implement occupational programs for employees whose job performance has become impaired because of alcohol abuse and alcoholism; and the Services Analysis Branch designs and conducts studies which analyze a broad range of issues involving the identification, treatment, and rehabilitation of alcohol abusers and alcoholic people for the purpose of improving service delivery at the community level.

Fiscal Summary

During FY 1977, NIAAA funded 894 projects (769 grants, 69 contracts and 56 formula grants) amounting to $160,301,000, of which 158 were associated with Indians for $16,360,000.

DIVISION OF SPECIAL TREATMENT AND REHABILITATION

This Division reflects the Institute's original goal to assure that high quality treatment services are available to all who require them. These services are administered by its three branches: Special Projects Branch, Occupational Alcoholism Branch, and the Services Analysis Branch. To achieve this aim, the Division provides leadership in filling the unmet needs of special, high-risk population groups such as American Indians/Alaskan Natives, Women, Youth and Minorities. It stimulates the development of third-party resources to support State and local services programs. The Division supports

demonstration projects that advance the state-of-the-art of the alcoholism services field, including the development of new treatment approaches. The programs of the Division, particularly in the occupational area, encourage early identification and referral for treatment of persons experiencing problems with alcohol.

Special Projects Branch

The Special Projects Branch provides leadership and assistance to communities in the development of high quality services to meet their needs. In contrast to a referral network, programs of this Branch involve the direct delivery of services for the alcoholic person in the community. They are geared to help the community take advantage of State and local funding bases to ensure the continued delivery of quality services and assistance in obtaining third-party payments for the person in treatment.

In addition to comprehensive centers established to treat all residents of the area, direct project grants support program activities that cover a wide range of treatment and rehabilitation strategies. A large number of alcoholic persons are served by these grants, including American Indians and Alaskan natives, Blacks, Spanish-Americans, migrant workers, women, youth, drinking drivers, public inebriates, the poor, persons referred by the criminal justice system, the aged, and persons living in rural areas. The primary goal of all programs is to ensure that adequate and appropriate services are available to all.

Occupational Alcoholism Branch

A primary mission of the Occupational Alcoholism Branch is to sensitize management (governmental and private) and labor leadership to the benefits derived by both the worker and the employer from the implementation of occupational alcoholism programs for employed people.

These systems for reaching the employed alcohol abuser early in his deviant behavior means earlier - and, hence, more effective - treatment. The alternative to accepting effective treatment is the specter of dismissal for continued inadequate job performance. That is, the threat of job loss is frequently effective in inducing acceptance of appropriate treatment, and is therefore an aid to early identification and treatment.

A network of trained "occupational program consultants" employed by State and local alcoholism agencies has been created to work with labor and management at the State and community levels. A voluntary professional organization of over five-hundred such consultants has been organized. Staff of the Occupational Alcoholism Branch, on request, provides assistance, in the form of materials and information designed to facilitate and improve the number and quality of these programs.

The Branch also has the responsibility for assisting the Public Health Service to implement the Federal Employee Assistance Program as mandated by Public Law 91-616.

In addition, the Occupational Alcoholism Branch administers a grant program designed to demonstrate more effective methods and initiatives to improve and make more effective these programs designed to identify employees whose job performance has become impaired because of alcohol abuse or alcoholism.

Focus of this grant program is largely on programs dealing with specially employed populations, such as professionals (attorneys, physicians and surgeons, university teaching staff, and high level executives in management).

Particular emphasis at the present time is directed toward employed women, a group in which increasing numbers are manifesting problems with alcohol.

Services Analysis Branch

The newest Branch of the Division designed and conducted studies which analyzed a broad range of issues involving the identification, treatment, and rehabilitation of alcohol abusers and alcoholic people for the purpose of improving service delivery at the community level. In coordination with other Institute offices, the Services Analysis Branch analyzed the results of service efforts in both the Occupational and Special Project Branches as well as the results of services in general. The aim is to increase knowledge about what kind of service works best for which individual and what are the health risks and benefits of providing these services. The Branch's efforts should aid not only the Division but also the entire field in upgrading knowledge and improving and insuring quality client care at reasonable cost with minimal dependence on Federal financial support. Current activities include: 1) a contract with SRI to conduct internal analyses of the National Alcohol Program Information System (NAPIS); 2) a joint project with the Program Analysis and Evaluation Branch to assess the reliability of NAPIS, recommend modifications and design an on-going quality control system; 3) a feasibility study of Blue Cross coverage for alcoholism treatment; 4) the development of treatment program typologies; 5) preparation of states-of-the-art papers regarding social and medical detoxification, use of Antabuse and deinstitutionalization; 6) Contracts to explore innovative ways to reach and treat the underserved women and youth populations; and 7) demonstration projects for detoxification, Antabuse and deinstitutionalization.

DIVISION OF RESOURCE DEVELOPMENT

The activities of the Division of Resource Development encompass a wide range of programs from the training of alcoholism counselors to assisting the States in implementing the provisions of the Uniform Alcoholism and Intoxication Treatment Act. With its two branches--Training and State Assistance--Resource Development is responsible for planning, developing, and administering programs in two key areas: manpower development and State alcohol programs. These areas are vital to the goal of integrating alcoholism services into the health

care delivery system since they help assure that qualified personnel and adequate funding are available for the care of alcoholic persons. In addition, activities relating to Institute resources which overlap treatment, prevention, and research are Division responsibilities, such as collaborative work with voluntary agencies, State and county groups and national organizations.

During FY 1977 the Office of the Director, Division of Resource Development, initiated program development in three areas: 1) "Operation Mainstream," 2) "Network Development," and 3) "Volunteer Resource Development Program." In addition, this office monitored the contract for the operation of the National Center for Alcohol Education (NCAE) and a grants program for four Area Alcohol Education and Training Programs (AAETP's), of which three will be concluded in FY 1978.

Training Branch

As a necessary step toward the NIAAA goal of providing quality treatment and rehabilitation for the alcoholic, the Training Branch seeks to ensure that an adequate number of qualified personnel will be trained to provide such services. The need for trained personnel becomes more crucial as the NIAAA comes closer to achieving the integration of alcoholism services into the mainstream of the health care delivery system.

Among the Branch's priorities, the definition of manpower resources is of prime importance. In this connection, activities have been initiated which will begin to identify manpower needs utilization and distribution.

In the attempt to improve quality services to alcoholic people, to increase the probability of third-party payments for such services, and to provide to alcoholism counselors the status they deserve, the Institute, in conjunction with ADAMHA, supported a Planning Panel on Credentialing of Alcoholism Counselors. The Training Branch was the focal point with this activity. The purpose of this Panel was to examine the issues involved in the credentialing of alcoholism counselors and to make recommendations concerning a national organization to facilitate the credentialing of alcoholism counselors. The Panel made recommendations to the field and the Institute to develop the organization which would participate in the credentialing of alcoholism counselors. The Training Branch will work closely with the Planning Panel in implementing this report in order that every attempt be made to improve services to alcoholic people.

The Branch is working toward the continued development of leadership capabilities among professionals especially in the areas of administration and evaluation. These areas were seen as important by State alcoholism authorities as well as by Institute staff.

In an effort to increase the number and quality of researchers prepared to conduct research focusing on the multiple determinants of alcoholism, the Training Branch has funded individual and institutional research training grants. The highest priority in research training is in social, behavioral and clinical research.

Branch strategies embrace the training of both degreed and non-degreed personnel in order to meet the varied needs of the alcoholism field. The Branch is also promoting the use of continuing education programs to reach professionals in all health related fields whose experience, prior education and training should enable them to provide services to alcoholic people. With the National Institute on Drug Abuse, joint funding has been provided in an effort to increase the amount of alcohol/drug education taught in the medical and public health schools in the Nation. Since 1972, 39 Career Teachers projects have been funded by both Institutes.

In all of the clinical training grant activities, an effort is made to include minorities both as faculty members and as students. In addition, there are programs supported specifically for minority populations. In FY 1977, 13 percent of the grants supported were directed specifically to the Indian population, 5 percent to Spanish-speaking, and 5 percent to Blacks.

State Assistance Branch

The role of the State Assistance Branch is to promote and facilitate State programs in both the prevention and treatment of alcoholism. The Branch administers three grant programs: formula grants, special grants for implementation of the Uniform Alcoholism and Intoxication Treatment Act, and volunteer resource development grants.

Formula Grants

Formula grants are available to the designated State alcoholism agencies to assist them in planning, establishing, maintaining, coordinating, and evaluating projects for the development of more effective prevention, treatment, and rehabilitation programs to deal with alcohol abuse and alcoholism. Formula grant funds are allotted to the States on the basis of the relative population, financial need, and the need for more effective prevention, treatment, and rehabilitation programs. To qualify for funds, the State agency must have an approved State plan, which is reviewed and updated annually. The plan is a public document and it is expected that the people of the State will have input into the planning. Among other things, the plan must include a survey of need for programs and facilities for the prevention and treatment of alcohol abuse and alcoholism; and the identification of the need for prevention and treatment of alcohol abuse and alcoholism by women and by individuals under 18 years of age. The State is also required to have an advisory council--made up of citizens representing a broad range of interests and including care providers, consumers, and consumer advocates--to consult with the State agency in carrying out the plan.

Special Grants--Uniform Alcoholism and Intoxication Treatment Act

Special grants for implementation of the Uniform Alcoholism and Intoxication Treatment Act are made available to States as an incentive to enact legislation which , among other things, decriminalizes public intoxication and mandates services rather than incarceration for alcoholic and intoxicated persons. To qualify for a grant, the State must demonstrate that its law is in accordance with the basic provisions of the Uniform Act, and the law must be in effect on the date of the award. A State may receive up to $150,000 plus 20 percent of the State formula grant if it meets the criteria. These grants may be awarded once a year, up to a total of six years. During FY 1977, 25 States received Uniform Act Grants at the maximum allowable amount. By the close of FY 1979, approximately 13 additional States are anticipated to qualify for grants.

Volunteer Resource Development Program

A volunteer resource development program has been initiated to provide limited support to State-level organizations to encourage the Statewide growth and development of volunteer activities relating to prevention and treatment of alcoholism; to document and assess the impact of such volunteer activities; and to demonstrate improved techniques and principles that will enhance the contribution of volunteers in the delivery of alcohol-related services. Any domestic State-level public or private nonprofit organization is eligible to apply for a grant. Each grant will be limited to a maximum of $50,000 a year for up to three years, and only one grant per State may be awarded. So far 21 grants have been awarded in FY 1978.

National Center for Alcohol Education (NCAE)

Under its legislative mandate for manpower development, the Institute established the National Center for Alcohol Education (NCAE) in May 1973. The Center's primary goal is to improve the effectiveness of alcohol-related services through the development of model training programs which can be widely used by practitioners in the field and the development of educational materials for the general public. These programs and products aim through education to reinforce resources and strategies for primary prevention, and through training to develop and increase skills and resources for the delivery of a wide range of services to alcoholic people.

The target groups for NCAE training programs are: 1) people in the alcoholism service delivery system, principally, the major caregiver, the non-degreed professional, and 2) caregivers in the larger health service delivery system beginning with the Community Health Nurse.

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Training programs currently available for caregivers in the alcoholism service delivery system include You, Youth and Prevention, Using Volunteers in Your Agency, Management Skills, Training Alcoholism Trainers, and Programming Community Resources.

According to national utilization data initiated in July 1977, and currently available through November 1, 1977, 553 trainers are training a minimum of 2,326 youth workers with You, Youth & Prevention 432 trainers are training a minimum of 1,882 administrators in volunteer utilization; 503 trainers are training 1,449 staffers in management; 500 trainers are training 1,465 additional trainers in training delivery; and 502 trainers are training 1,534 staffers in Programming Community Resources.

Early in the next fiscal year, two Counselor Skills Training Programs will be available, namely Counseling Alcoholism Clients and Planning Alcoholism Programs. The Community Health Nurse Training Program designed for delivery in continuing education settings, will be available in mid-fiscal year 1978.

Educational materials have been developed by the NCAE for the NIAAA targeted client populations, namely, Blacks, Parents of Young Children, and Women--as reflected in the production of the Decisions and Drinking Series entitled "An Ounce of Prevention" (Blacks), "Parents of Young Children" (Youth), and "Reflections in a Glass" (Women). This series will be available early in FY 1978.

The NCAE distributes its training programs and educational materials through the National Clearinghouse for Alcohol Information (NCALI). The Center also plays a role in the growth and development of an education and training network through its assistance to Regional and State training programs and to Summer Schools of Alcohol Studies.

Area Alcohol Education and Training Programs (AAETP's)

While the Institute and NCAE provide a national sense of direction on alcohol training, the main thrust of the Area Alcohol Education and Training Programs (AAETP's) is to enrich and expand area-wide, State and local manpower planning and educational efforts in response to local needs.

The AAETP training was tailored as closely as possible to local and area needs and includes upgrading qualifications of personnel, promoting alcoholism training among other service providers, meeting the specialized education needs of target populations, and educating the public in order to facilitate early identification of alcoholism problems. There are four AAETP's headquartered in Atlanta (Southern Region), Chicago (Midwestern), Hartford (Eastern), and Reno (Western), which were funded in FY 1977 for $1,382,000.

FY 1977 was the third year of a three-year funding period for the four AAETPs initially funded in FY 1974. These grants were initially funded to provide a variety of services primarily through a sub-grant program designed to expand State, area, and local manpower and training efforts. When the three-year funding period expired in FY 1977, NIAAA announced that the AAETPs could no longer continue the sub-grant activity due to the cost associated with these training activities. Therefore, each AAETP was encouraged to submit a renewal application designed to meet a series of new activities relating to the original goal of providing expanding State, area, and local manpower and training efforts.

Operation Mainstream - An Interdisciplinary Training Program

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) has developed, among other activities, a major strategy of integrating alcoholism services into the total health care delivery system. A significant component of this strategy is being initiated in the Division of Resource Development through an Interdisciplinary Training Award Program. The long-range goal of the program is to enable an increasing range and number of caregivers in the health and human service delivery systems to respond to a person and/or a family with an alcohol-related problem in a timely, appropriate, and effective manner. A corollary of this goal is that earlier identification and intervention concerning alcohol problems can be anticipated.

Proposals will be considered for graduate and continuing education programs which incorporate two or more disciplines, for example, Clergy, Law, Nursing, Psychology, Social Work and Vocational Rehabilitation.

It is expected that each training program will have a significant lasting impact on the educational programs involved and provide varied models for other institutions to adopt. To assist in the achievement of the desired outcomes, each program will be required to participate in an NIAAA-sponsored program evaluation designed to provide the information necessary to judge performance against goals with regard to curriculum development and the professional student's practice insights and skills. The Division plans to fund a minimum of six programs in FY 1978.

DIVISION OF PREVENTION

A basic, but long-range goal of the Institute is to work toward the prevention of alcoholism and problem drinking. To achieve this goal, NIAAA created the Division of Prevention. The primary function of the Division has been the development, testing and evaluating of practical methods of preventing the abuse and misuse of alcoholic beverages.

Through its Youth Education and Community Prevention Branches and the National Clearinghouse for Alcohol Information, the Division seeks to develop strategies and programs designed to give people the facts they need to make informed decisions about whether to drink and, if they choose to drink, to do so in a setting that enhances their well-being and quality of life.

Within the framework of "Operation Mainstream," prevention efforts are aimed at integrating new prevention strategies and health education programs into the mainstream of everyday life in order to reduce, and ultimately eliminate, the incidence of new cases of alcohol abuse and alcoholism.

The Division has the responsibility for Youth Education, Community Prevention and Training, and for supervising the activities of the National Clearinghouse for Alcohol Information. The Division has the monitorship of a contract for the operation of the Clearinghouse.

Youth Education Branch

NIAAA has initiated major efforts toward the goal to develop, implement, and evaluate alcohol abuse prevention strategies for youth. These activities include: 1) The development of audio-visual and print materials for junior and senior high school-aged youth; 2) An outreach effort to involve colleges and universities in the development of alcohol abuse prevention programs (Programs on campuses have been expanded to 563 previously uninvolved schools); 3) A technical assistance effort to non-profit organizations to encourage them to undertake programs utilizing their own resources; and 4) The support of 22 demonstration projects to test innovative approaches to alcohol abuse prevention, 14 of which are currently active.

The demonstration programs are testing various prevention strategies to determine the efficacy and effectiveness of projects for schools, communities, and youth-serving agencies. Though all programs strive to reduce the negative consequences of drinking, emphasis within the programs ranges from materials development and training to development of techniques to reach populations such as college students, school drop-outs, and risk groups such as American Indians or children of alcoholics. Achievements of the demonstrations both as model programs which can be replicated and as initiators of new techniques for preventing alcohol problems are contributing to the development of a knowledge base regarding alcohol abuse prevention.

During FY 1978 and 1979, NIAAA will be replicating three prevention models targeted toward youth which have produced promising results during their first three years as demonstrations. Each model will be replicated in a minimum of two additional sites in order to determine the effects of differing environments, organizational

structures, and personnel upon the successful implementation of the program models. The overall replication process will be undertaken in close cooperation with the State Alcoholism Authorities. The entire replication process will be carefully evaluated, as will be the impact of the program on the drinking patterns and attitudes of the participants at the various replication sites. As information is obtained through the replication process, monographs will be prepared and disseminated to the field describing this process and evaluating the individual strategies undergoing field testing.

Community Prevention Branch

The Community Prevention Branch seeks to develop strategies to create a social environment more conducive to a prudent attitude toward drinking and nondrinking of alcoholic beverages, and to strengthen community and individual resources working toward such goals. As a key part of this effort, the Branch aims to achieve an effective level of health education in the community regarding the use, misuse, and nonuse of alcohol. The overall emphasis is on primary prevention.

Strategies developed should be applicable to the drinking as well as the nondrinking population, and to those who drink at unhealthy levels as well as those without drinking problems. Examples of such strategies are: influencing attitudes to perceive drunkenness as unacceptable behavior; educational measures which bring about a positive understanding of use and nonuse of beverage alcohol; and social policies that diminish the availability of alcohol, influence the act of unhealthy drinking, and change the cultural meaning of alcohol. All of these approaches will influence drinking patterns and modify the social environment of both the drinker and nondrinker.

One of the major efforts of the Branch has been the development of the State Prevention Coordinator (SPC) program which established a staff position for prevention in each of the 48 participating State and territorial alcoholism authorities. This promoted the development of State-sponsored, community-oriented, primary prevention programming aimed at the reduction of drinking problems by the use of positive measures directed at how people drink, their attitudes toward drinking, and their welfare while drinking.

The SPC's are encouraged to provide the opportunity for citizens to examine their attitudes and behavior regarding drinking and nondrinking in order to determine what measures they might use to prevent alcohol problems. SPC's work in a variety of public education campaigns, initiate public discussions with local communities, assist youth and adult groups in surveys of drinking patterns, and develop prevention advocacy groups.

The other major activity within the Branch is the project grant program. It supports prevention projects that are action-oriented demonstration projects. These afford the opportunity for communities to organize, study, and implement creative prevention approaches to modifying harmful drinking practices within the community.

National Clearinghouse for Alcohol Information (NCALI)

The National Clearinghouse for Alcohol Information (NCALI) is an information service of NIAAA established to search out worldwide information on alcoholism prevention, treatment, and research, and to share this knowledge with the professional community and the general public.

The Clearinghouse shares its alcohol information through a variety of services and products designed to assist the many different users of NCALI. Through a system of acquiring, evaluating, analyzing, processing, formatting and reformatting of all kinds of information about alcohol, thousands of persons can get the kind of information they need in a form that is most helpful to them. Responses to requests range from NIAAA-prepared pamphlets and posters to a demand bibliography or computer search.

Current awareness services and materials are designed to search out new users of Clearinghouse services and to keep registered users up-to-date on new developments in the field. The Clearinghouse prepares two publications: NIAAA Information and Feature Service, a medium for news and features; and Alcohol Health and Research World, a quarterly paid-subscription magazine, contains in-depth articles, bibliographies and book reviews.

For users who want to receive more technical information on a regular basis, Current Awareness offers two other services. After indicating his/her user profile by selecting topics from a list of interest categories, a user can register to receive Individualized Interest Cards, issued monthly, and Grouped Interest Guides issued semiannually.

A unique feature of the Clearinghouse is the Information Dissemination Program (IDP), which is designed to assist the Institute's prevention program through the enlistment of previously uncommitted resources in the campaign against alcoholism. IDP is currently focusing on three target audiences--women, youth, and blacks. Working through such organizations as women's centers, national youth-serving organizations, Opportunities Industrialization Centers, and others, IDP activities are aimed at motivating and helping these groups to apply their own resources to establishing alcoholism prevention programs for their members.

During FY 1977 the Clearinghouse began an Alcohol Epidemiologic Data System to provide data support for NIAAA's Epidemiology and Special Studies Branch. The new system is being designed to acquire, index and store data derived from a variety of sources, including publications and data already contained in machine-readable form at various data centers around the country.

DIVISION OF EXTRAMURAL RESEARCH

The Division of Extramural Research reflects NIAAA's increased commitment in the research area. It will continue to support basic and applied research into the causes and treatment of alcoholism, particularly in the areas of clinical research, prevention and education, behavioral and psychological studies, and the physiological effects of alcohol. The Division is made up of two units: the Extramural Research Branch, which supports research outside of the Institute, and the Epidemiological and Special Studies Branch, which collects and analyzes data on a national and international basis on the prevalence and incidence of alcohol abuse and alcoholism. Through these two branches, the Division supports and conducts research programs for improving treatment strategies and developing new prevention programs to reduce the incidence of new cases.

Extramural Research Branch

Studying all aspects of the potential causes and consequences of alcoholism is the objective of the Extramural Research Branch. Through an extensive grant program based largely in university and research laboratories, research programs are conducted in a wide variety of biomedical and psychosocial areas in alcoholism.

Biomedical support is provided for basic and applied studies in areas such as the fetal alcohol syndrome, metabolism of alcohol, alcohol-related liver disease, effects of alcohol on the heart, gastrointestinal system, and nutrition. In the behavioral area, support is provided for studies on the drinking practices, and the attitudes and beliefs of subcultures, ethnic groups, socioeconomic groups and families toward alcohol use and alcoholism. Other studies in this area are aimed at illuminating the social and psychological characteristics of alcohol abusers.

As an example, NIAAA recently sponsored a workshop on the Fetal Alcohol Syndrome which served to establish the importance of this medical problem in the country. The result of this workshop was a health warning which alerted both physicians and women to the syndrome and, it is hoped will reduce the future incidence of the problem. In addition, support is currently being provided for studies to more clearly define the nature and extent of the syndrome, to investigate the physiological mechanisms involved, and to develop effective means of dealing with the problem.

Support is also provided for studies of alcoholism among specially targeted populations. These populations include youth, aged, women, and ethnic or racial minority groups. For example, NIAAA-supported researchers are investigating the causes and consequences of problem drinking in adolescents. One such study is focussed on Black adolescents, another will compare adolescents in the United States with those in Western Europe, while a third will attempt to define the relationship between problem drinking and delinquency.

Special problems of women are also being investigated, including a study of the halfway house experience for women alcoholics. As a final example, NIAAA is providing support for research assessing psychological and other factors involved in successful treatment of alcoholism, including a study evaluating jobbased programs for problem drinkers.

Some specific areas in which additional research is needed include studies pertaining to alcohol's effects on the central nervous system, the relationship between alcohol and hormones, the carcinogenic effects of alcohol, and the fetal alcohol syndrome. An increased research effort on all aspects of alcohol use and abuse in women and youth is also required.

In FY 1977, the NIAAA initiated a new program of research support. The five Alcohol Research Centers which were established are designed to complement the regular grant program by providing long-term support for interdisciplinary research programs with a distinct focus on a particular research theme relating to alcoholism and other alcohol problems. These focus on areas such as the central nervous system, the gastrointestinal tract, behavior genetics, treatment, and social epidemiology. Two additional centers were established in FY 1978. In FY 1979 it is planned to have seven centers from development stages into full operation, and it is anticipated that two additional centers will be funded. The five present Alcohol Research Centers are at: the Salk Institute, San Diego, Cal.; Mt. Sinai School of Medicine, New York; University of Colorado; University of California at Berkeley, Cal.; and Washington University, St. Louis, Mo.

In addition to the support of research, the Branch provides funds through the Research Scientist Development Program for the training and development of promising scientists to pursue a career in research.

Epidemiological and Special Studies Branch

This Branch develops and analyzes data on alcohol abuse and alcoholism for a better understanding of its natural history, trends and patterns of occurrence in order to help the Institute establish priorities in research, prevention, and treatment.

The Branch has three data gathering and analysis functions: surveillance, medical epidemiology, and social psychology. Surveillance is concerned with the collection of data over time to document use and abuse of alcohol. Data will be analyzed in terms of national and international trends and patterns, with attention to improving methodology toward developing indicator systems. In medical epidemiology, by delineating the role of alcohol in clinical problems, the goal is to increase physician awareness and competence by developing a heightened index of suspicion for specific syndromes in which immediate intervention could have clinical importance. Studies in the social psychology area are conducted in order to identify the sociological and psychological determinants and consequences of alcohol consumption in order to provide a sound basis for prevention and treatment policies and thereby enhance the likelihood of successful intervention.

DIVISION OF INTRAMURAL RESEARCH

The Institute's goal is to build a strong program in basic and clinical alcohol research. An important step in reaching this was the establishment of a new Division of Intramural Research. The Division is in the process of relocating its research activities from St. Elizabeths Hospital to Rockville, Maryland, and has reorganized into three new branches--the Laboratory of Preclinical Studies, the Laboratory of Metabolism, and the Laboratory of Clinical Investigations. These operate an in-house program of research on the multiple determinants of alcoholism and on the critical factors in the prevention, diagnosis, treatment and rehabilitation of alcoholism. The Division collaborates with agencies, universities, and scientific organizations in the conduct of basic and clinical research on alcohol and its effects. It also trains research investigators in advanced methods of alcohol research.

Laboratory of Preclinical Studies

The Laboratory of Preclinical Studies will (1) plan and conduct investigations into the basic physiological, pharmacological, developmental, anatomical and chemical properties of nervous tissue in experimental animals; (2) will investigate the effects of alcohol administration and alcohol withdrawal on these anatomical and chemical properties; (3) will supervise and train research investigators in the techniques of preclinical investigations carried out by the laboratory; and (4) will collaborate with organizations outside of the Institute in investigations related to preclinical alcoholism studies.

Laboratory of Metabolism

The Laboratory of Metabolism will conduct basic biochemical studies related to the metabolism of alcohol and the associated disturbances of metabolic and physiological function resulting from acute and chronic alcohol ingestion. Areas of study include theoretical and experimental aspects of cellular, membrane, lipids, protein, enzyme, and energy metabolism pertinent to alcohol consumption, dependence, and withdrawal. Studies will focus on (1) determination of changes in brain energy and neurotransmitter metabolism during ethanol intoxication, addiction and withdrawal; (2) effects of ethanol on hepatic fat metabolism and the relationship to changes in blood lipids; (3) abnormalities in liver energy metabolism induced by alcohol consumption and the relationship of these metabolic changes to hepatic and cerebral dysfunction; (4) investigation of genetic, physiological and biochemical factors which affect alcohol intake; (5) training research investigators in biochemical techniques applicable to the metabolism of alcohol; and (6) collaboration with organizations outside of the Institute in investigations related to the metabolism of alcohol.

Laboratory of Clinical Investigations

The Laboratory of Clinical Investigations will (1) plan and conduct a coordinated program of clinical research dealing with the medical and

psychological consequences of alcohol abuse and alcoholism; (2) will investigate organ system pathology caused by the use of alcohol as well as pharmacological and related diagnostic treatment, and preventive approaches; (3) will train research investigators in clinical research approaches to alcohol abuse and alcoholism; and (4) will collaborate with organizations outside of the Institute in the conduct of clinical research on alcohol abuse and alcoholism.

OFFICE OF PROGRAM DEVELOPMENT AND ANALYSIS

The Office of Program Development and Analysis (OPDA) serves as the focal point for Institute international activities, and for Institute program planning and evaluation. Within the Office are three branches: Program Development and Planning, Program Analysis and Evaluation, and Policy Studies and Special Reports.

Just as alcohol is worldwide in its usage, NIAAA must take advantage of resources around the globe in its efforts to obtain information and offer counsel on the best available programs for the alcoholic and his family. NIAAA is working with agencies such as the World Health Organization (WHO) and other international public health groups in an effort to develop policies and guidelines for the planning and development of alcoholism services on an international basis, as well as applying new and improved techniques to services in this country.

OPDA also has responsibility for planning and preparing special reports including major scientific reports with significant policy implications such as the Alcohol and Health Reports to Congress. Selection of the areas of research, evaluation and integration of the data and findings, and coordination of the writing, editing, and production of these reports are monitored from this Office.

Significant accomplishments in FY 1977 include: completion of the major portion of preparation of the Third Special Report to Congress on Alcohol and Health; further development of the National and NIAAA alcoholism planning process; expansion of the evaluation function to a broader range of NIAAA activities, establishment of the Policy Studies and Special Reports Branch; and solidification of communications links between the United States and other countries and international organizations concerned with alcoholism. Future activities will involve primarily improving upon and maximizing the utility of Office programs currently in place.

Program Development and Planning Branch

The Program Development and Planning Branch serves as the focal point at NIAAA for identifying program needs and coordinating the development and modification of program objectives as progress is achieved. It carries out special projects which have important implications for overall Institute policy or national program development. One such area of vital importance to the alcoholism field involves health insurance. The Branch is monitoring several projects

whose ultimate goal is the eventual inclusion of alcoholism benefits in all health insurance policies throughout the Nation. Significant demonstration projects of this sort are being conducted in Health Maintenance Organizations (HMO's), and in an Incentive Contract Program that gives support for profitmaking organizations willing to establish occupational programs for the prevention and treatment of alcoholism among employed persons.

Another responsibility of this Branch is the development and coordination of program planning activities and maintenance of an operational planning system in program evaluation, management analysis, and financial management. Program Development and Planning also reviews related Federal activities and maintains liaison with other agencies in areas where interagency cooperation is required.

Program Analysis and Evaluation Branch

Evaluation is an integral and essential component of programs funded by public monies and is emphasized in both the legislation establishing the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and in Institute policy. The responsibility for carrying out the evaluation function at NIAAA rests primarily with the Program Analysis and Evaluation Branch. The evaluation process is initiated early in the life of each major program and continues through program implementation and operation. Information obtained through the analysis and evaluation activities conducted by the Institute is used on an active and ongoing basis for use in developing information for program accountability, management decisionmaking, planning, and resource allocation. Past studies and available evaluation data are utilized to maximize the use of resources and fill information gaps.

Major accomplishments in FY 1977 included studies and research into areas of high priority to the Institute. Evaluations were also conducted within the functional program areas of greatest need. The primary study areas included: Treatment, Prevention, Training, Management, State Coordination, Cost/Benefits, Youth, and Women.

One of the key evaluation information collection projects has been the National Alcoholism Program Information System (NAPIS), through which management and evaluation data are collected from all Institute funded alcoholism treatment projects, and analyzed to determine the effectiveness of treatment in NIAAA funded grants. By means of monthly and quarterly output reports, individual treatment projects are afforded continuous feedback of evaluative data concerning their specific project. These data concerning project performance and effectiveness may be used by the individual projects for self-assessment and comparison with other treatment programs. Client treatment effectiveness is determined by a set of outcome measures produced by follow-up interview and interviewer assessment of changes in client condition.

A State Alcoholism Profile Information System (SAPIS) provides annual reports from each State regarding all State or Federal alcoholism programs. The purpose of this project is to determine the relative impact of the Formula Grant Program in terms of programs supported, staff available and training, treatment, research, and prevention activities funded. A complete profile of services provided through State and Federal efforts, program funding sources and funding levels, and other pertinent alcoholism program information is compiled through SAPIS.

Other current projects include a study of the costs/benefits of alcoholism treatment in selected communities, an assessment of the clinical training grant program, the development of an integrated State alcohol management/evaluation information system, the evaluation of State and community prevention programs and a study of the data reliability from the National Alcoholism Program Information System. As a means of assessing longer-term effects of treatment, two follow-up studies have been initiated, namely, a four year follow-up of former clients from selected Alcoholism Treatment Centers and a follow-up of Texas State Hospital alcoholism clients.

Other recently completed evaluation studies concerned the National Clearinghouse for Alcohol Information, the National Center for Alcohol Education, the assessment of the NIAAA/NIDA Career Teacher Program, the State Prevention Coordinator Program and the development of a pilot State alcohol/drug monitoring system.

During the coming year, the operation of both NAPIS and SAPIS will continue as well as the evaluation of a prevention model replication study. Planned studies will examine the impact of the Uniform Act grants and the Formula grants to the States, determine the reliability of SAPIS information; a new publication will be compiled which will contain a complete statistical report on the NIAAA treatment projects. The newly formed Research Centers also will be the subject of an evaluation study beginning during their first years of operation.

Findings of NIAAA evaluation studies are used not only by management and program personnel at the Institute and managers at the NIAAA funded projects for self-evaluation, but are also widely disseminated through prepared reports, professional periodicals, and presentations to appropriate government agencies and professional health oriented groups.

Evaluation Findings

As a result of recent and ongoing studies, information has emerged leading to appropriate Institute action/reaction:

. Early intervention means faster recovery at a reduced cost. Therefore, outreach efforts are being emphasized.

- Staffing patterns have been modified utilizing paraprofessional staff to a greater degree in NIAAA's treatment program.

- Training emphasis has been given to inservice training of paraprofessionals already in the alcoholism field.

- Outpatient care has been shown to be as effective for certain problems as treatment in an inpatient setting and, therefore, can be utilized to provide care at a lesser cost per patient.

- Evaluative information led to revisions in funding of treatment grants from the eight-year staffing mode to more community-oriented three-year projects.

- Third-party payment and client fees have represented a relatively small amount of revenues to treatment programs. Therefore, model insurance packages and Incentive Projects were developed to attract more third-party funds.

- Cost/benefit information has been widely promulgated to foster stronger local and State support of alcoholism programs.

- Training and prevention efforts were shown to be receiving little support in the States. Therefore, more emphasis was placed on these areas with State authorities.

- Women and Youth have been shown to need more alcoholism services. NIAAA has placed high emphasis on these priority areas. Women and Youth Demonstration Treatment Programs are to be established to stimulate the development and validation of high quality, well-integrated treatment and rehabilitation services. These programs will be evaluated for impact and replication.

Policy Studies and Special Reports Branch

The Policy Studies and Special Reports Branch serves as a focal point for conducting policy studies and developing NIAAA policy. The Branch plans, initiates, and conducts policy studies concerning alcohol-related problems and in support of programs aimed at alleviating these problems. It makes recommendations to the Director concerning alcohol-related policy matters.

The Branch also has responsibility for planning and preparing special reports including major scientific reports with significant policy implications, such as the Alcohol and Health Report to Congress. For the development and preparation of these special reports, data

from research programs, program analysis, program evaluation, treatment services, surveys, and other sources are obtained and integrated. In addition, state-of-the-art reviews and critical analyses and evaluations of special alcohol-related topic areas and issues are initiated and implemented by the Branch.

The Branch will complete the Third Special Report to the Congress on Alcohol and Health for delivery in FY 1978. A system for conducting periodic literature searches and summaries on approximately 60 policy-related topics has been initiated. Studies pertaining to youth at risk; national patterns of alcohol use and abuse and attitudes about alcohol; and development of a model for a community response to alcohol problems have been initiated. Current studies pertaining to the relationship between alcohol consumption and cancer and development of models for estimating the prevalence of alcoholism are continuing.

PROGRAM COORDINATION

The Office of Program Coordination serves as the focal point for coordination and evaluation of all NIAAA programs as a total, integrated system, and for liaison between elements of the system. To facilitate this effort, a management information system has been developed that will provide a total programmatic and functional picture of Institute program activities for use in decisionmaking and control by the Director and his staff. The effort to develop and implement an efficient centralized Institute-wide Management Information and Control System will help to integrate and advance the innovative approach of "Operation Mainstream" which will assist the Institute in accessing timely information for policy decisions in pursuit of its programmatic objectives.

Program Coordination is also responsible for coordinating interagency activities involving the Institute and other Federal agencies, especially those growing out of interagency agreements dealing with alcohol abuse and alcoholism. Among such collaborative efforts that led to interagency agreements between NIAAA and other Federal agencies during FY 1977 were:

NIAAA and National Center for Health Statistics (NCHS)
Title: Development of a Funds Allocation Formula for the Alcoholism Program.
Purpose: NCHS developed for NIAAA a methodology for allocating alcoholism formula grant funds to States based on the relative incidence and prevalence of alcohol abuse and alcoholism among States. The determination of the incidence and prevalence of alcohol abuse among States was synthetically derived and is the third component of the Formula to determine the State allotment of funds; the other two components are the population within a State, and the financial need in accordance with the per capita income.

NIAAA and Navy Department, the Assistant Chief of Naval Personnel for Human Resources (ACNP) Management
Title: NIAAA/BUPERS ACNP for Human Goals Interagency Agreement.
Purpose: NIAAA did provide assistance in the form of services, needs assessment and evaluation in support of the Alcohol Abuse Control Program for delivery to or utilization in support of, designated Naval activities, personnel, and specified program efforts.

NIAAA and National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD)
Title: Workshop on Collagen Metabolism in the Liver.
Purpose: NIAAA co-sponsored a workshop on collagen metabolism in the liver. This workshop addressed the general area of hepatic fibrosis and collagen with specific discussions and a session devoted exclusively to the role of alcohol in the induction of diseases of the liver.

NIAAA and the National Highway Traffic Safety Administration (NHTSA) of the Department of Transportation (DOT)
Title: Alcohol Safety Action Programs (ASAP).
Purpose: To reduce traffic accidents, death and injuries caused by drinking drivers through (1) an information and education program on the misuse of alcohol and referral to treatment programs and (2) to review the effectiveness of short-term treatment (90 days) in 10 ASAP sites where there are NIAAA supported projects. The interagency effort reduced the number of drinking drivers on the road through the treatment process.

NIAAA and the Law Enforcement Assistance Administration (LEAA) of the Department of Justice
Title: Linking Treatment of Alcoholic Criminal Offenders with the Criminal Justice Referral Program for Drug Abuse Offenders.
Purpose: To arrange for treatment of criminal alcoholics through the National Treatment Alternatives to Street Crime Program (TASC) utilizing LEAA's referral mechanism, and provide treatment by NIAAA grantees.

NIAAA and the National Highway Traffic Safety Administration (NHTSA) of the Department of Transportation (DOT)
Title: Collaboration on Programs and Projects Involving Alcohol and Highway Safety.
Purpose: To coordinate and collaborate on programs and/or projects involving alcohol and highway safety. These efforts pertain to research, treatment, prevention, training, public education, and information exchange.

NIAAA and Office of Education (OE) (Phase 1) (Office of Education and the National Audiovisual Center), NIAAA and the National Audiovisual Center (Phase 2)
Title: Development and Production of Educational Films for Jr. High and Sr. High School Alcohol Education.
Purpose: To develop and produce films (Phase 1) and to provide for free loans of educational films relating to alcohol abuse and alcoholism to the school systems throughout the country (Phase 2).

NIAAA and National Center for Health Statistics (NCHS)
Title: Identification of Data Sources for Information Pertaining to Alcohol Consumption and Related Analyses.
Purpose: Phase I involved examining and identifying all data collection systems within NCHS in order to identify any information relating to the use, abuse, and consequences of alcohol. Phase II for FY 1978 will involve an analysis of specific hypotheses or of specific descriptive research questions such as causes of death, mortality analysis, to determine the alcohol contributing factors of death, if the diseases involving alcohol-related death are not cited.

NIAAA and National Institute on Drug Abuse (NIDA)
Title: Development of an Inventory of Research Projects.
Purpose: This inventory was performed to provide NIAAA with a base line to conduct a research program. NIDA had contracted for the establishment of a qualitative and quantitative inventory of Federal Substance Abuse Research Inventory and Analysis thereof. NIAAA has by means of a reimbursable agreement asked that this inventory for FY 1975 also include the research performed on alcohol abuse and alcoholism. This covered 14 agencies.

NIAAA and the National Highway Traffic Safety Administration (NHTSA)

This agreement has been executed between the NIAAA and NHTSA to develop a joint evaluation for State traffic data implicating alcohol in highway fatalities. Purpose: To assess the accuracy, completeness, and comparability of data currently being collected for generation of rates of alcohol abuse and to determine how the present system might be improved in the reporting of highway fatalities with implicated alcohol.

NIAAA and Bureau of Health Planning and Resources Development (BHPRD), Health Resources Administration (HRA)
Title: Development of Criteria Guidelines for Use by the Health Systems Agencies (HSA's).
Purpose: For review and approval or disapproval of applications for alcoholism programs within its health service areas. The BHPRD is reimbursing NIAAA for this effort that is being performed by contract.

NIAAA, National Institute on Drug Abuse (NIDA), and the Bureau of Community Health Services (BCHS), Health Services Administration (HSA)
Title: Needs Survey to Determine the Size and Dimension of Drug, Alcohol, and Mental Health Problems in Migrant Health Centers.
Purpose: To conduct a study of nine migrant health centers for the following purposes: (1) To develop a methodology to determine the dimensions and size of drug, alcohol, and health problems among migrant workers; (2) To collect and analyze existing record data regarding drug, alcohol, and health problems of migrants, and types of services delivered in order to provide a preliminary data base regarding these problems; and (3) To determine the need for an integrated service delivery system.

Renewal of an Agreement Between the National Clearinghouse for Alcohol Information, Division of Prevention, NIAAA, and the National Technical Information Service (NTIS) of the Department of Commerce
Title: Registration, Abstracting, and Marketing of Grant and Contract Reports to the Public.
Purpose: This agreement is for the registration, abstracting, publication, and marketing of grant and contract reports to the public through the NTIS. This service includes publications in selected research magazines, in government reports, professional journals, etc., and provides bibliographies. This permits industry and business utilization of government supported technology.

Privacy Act (P.L. 93-579) Implementation

To comply with the Privacy Act, the Privacy Act Officer, being the Associate Director for Program Coordination, reviews all proposals for contracts to ascertain that: (1) personal information about individuals which is collected and retrieved by individual name or identifier by Federal agencies be limited to that which is legally authorized and necessary; (2) such information be maintained in a manner which precludes unwarranted intrusions upon individual privacy; and (3) a subject individual be given notice and access to records about him/her in existence, the opportunity to review such records, to challenge the contents and to request amendments. In addition, all record systems pertaining to grants have been reviewed and published in the Federal Register.

Guidance is provided on a continuing basis to the project officers and system managers to ascertain that no individually identifiable information is collected unless a system notice has been prepared and its purpose has been published in the Federal Register. Prior to publication, the required clearances have to be obtained. The Privacy Act Officer keeps NIAAA informed of all necessary mandatory provisions and exceptions that must be adhered to by contractors pertaining to contracts, and by Federal employees and consultants pertaining to applications and grants.

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The Institute system managers and the Privacy Act Officer have prepared monthly reports detailing the inquiries and the access requests received, the amendments made, the employee training activities undertaken, and the problems and issues arising from the implementation of the Act. This accounting is made for the preparation of the President's annual report to the Speaker of the House, and to the President of the Senate as required by the statute.

Confidentiality of Patient Records

The provisions of the Rules and Regulations of the Confidentiality of Alcohol and Drug Abuse Patient Records has been administered and monitored by the Associate Director for Program Coordination and has been implemented by NIAAA in strict adherence of Title 42, Part 2--Confidentiality of Alcohol and Drug Abuse Patient Records. This involved all patient data collected by contractors for the monitoring system or for other purposes of research and evaluation. To assure that strict confidentiality of patient data was achieved, no individually identifiable information was transmitted to NIAAA by any contractor or treatment center. All system forms were coded and information was transmitted to NIAAA with client code only. Each contract has been reviewed to assure that even for purposes of research, audit, and evaluation, only "qualified personnel" did analyze and evaluate individually identifiable patient records.

Rural Health Initiative (RHI) and Health Underserved Rural Areas (HURA) Programs

I. Objectives

The purpose of the Rural Health Initiative (RHI) and Health Underserved Rural Areas (HURA) programs is to improve accessibility, availability, and quality of primary health care services in rural areas that have been identified as having critical health manpower shortages or as being medically underserved.

The Office of Program Coordination, NIAAA, has been designated to coordinate this effort between NIAAA, ADAMHA, the PHS Rural Health Coordinating Committee, the Regional Offices and other agencies, and is participating in this effort with the ADAMHA working committees and the PHS Rural Health Coordinating Committee.

The RHI program is a Public Health Service (PHS) effort. In FY 1976 the financial resources were provided to the greatest extent from the Health Services Administration (HSA). The HURA program is authorized under Section 1110 of the Social Security Act and funded with Title XIX Medicaid funds.

II. Accomplishments

During FY 1976, 191 RHI/HURA grants were made in the amount of $27.2 million (of which 139 were RHI grants in the amount of $17.2 million and 52 were HURA grants in the amount of $10 million). An applicant was funded on a three-year basis ($200,000 per year or $600,000 for three years, with a reduced amount after the third year).

Results for NIAAA: Of the 139 RHI grants, 36 (25.7%) were NIAAA grantees that received $5,417,615. Of the 52 HURA grants, 19 (36.5%) were NIAAA grantees who have received $3,708,888; 23 other HURA recipients have linked with providers of alcoholism services. Thus, a total of 42 (80.7%) of the 52 HURA grantees have linked with alcoholism providers. Therefore, in FY 1976, 55 NIAAA grantees did receive RHI/HURA grants amounting to $9,126,403 and an additional 23 HURA recipients linked with alcoholism providers. In summary, a total of 78 linkages were documented for FY 1976 with alcoholism providers. The $9,126,403 are 33.5% of the 1976 RHI/HURA funds of $27.2 million. (None of the $9,126,403 was from NIAAA funds). The original goal for FY 1976 was to develop 10 linkages and for FY 1977, 15 linkages. It was many-fold exceeded by the accomplishment of 78 linkages.

Benefits for Alcoholism Services

This Rural Health Initiative Program provided the alcoholic patients with a comprehensive health care delivery program. It provided total health care delivery in lieu of only treatment for alcoholism. The linking of alcoholism with all other health care delivery services enabled the patients to receive continuity of care, and also enabled the providers of alcoholism services and that of other health care services to integrate and/or utilize each other's professional capabilities without engaging in contract services. As far as NIAAA is concerned, the $9,126,403 in FY 1976 and at least this amount of funds in FY 1977 and FY 1978 is additional funding that was made available to NIAAA grantees from HSA for comprehensive rural health care services.

Extensive assistance has been given to NIAAA grantees by the Office of Program Coordination and supported by Division staff during the application cycle for RHI/HURA grantees. In FY 1977 the grants of FY 1976 were renewed and an extensive effort is being made to develop linkages between primary health care providers and NIAAA grantees or applicants in FY 1978 and FY 1979.

PUBLIC AFFAIRS

The Institute's Public Affairs program continued to encompass a wide range of efforts designed to increase public awareness of the facts about alcohol use and abuse and to develop and disseminate public information materials to enable the general public to make responsible decisions about the use or nonuse of alcoholic beverages.

Functions performed were in the following areas:

-- Collection, dissemination, and coordination of public information
-- Public awareness information campaign
-- Media contacts
-- Preparation and clearance of publications
-- Support services

Public Service Education Campaign

The radio series "All About Alcohol" answered the most asked questions sent in by the general public. The series was used by approximately 3,500 radio stations. This included the American Forces Radio Service.

Media Contacts

A major responsibility of Public Affairs was to coordinate speaking engagements, newspaper and magazine interviews, and appearances on radio and television. A program of media contact was continued as part of the Institute's overall effort to raise the public awareness level of alcoholism problems. Because of the excellent quality of materials made available to both radio and television, NIAAA received a large share of the highly competitive public service time made available by the electronic media to non-profit organizations.

Through the coordinated efforts by Public Affairs, the Institute's role in the Nation's alcohol problem was given high visibility in such major publications as Time, U.S. News and World Report, New York Times, Los Angeles Times, and Chicago Sun-Times, and on TV programs "Maude," "Days of Our Lives," "Dinah Shore," "Good Times," etc. The Office of Public Affairs responds to approximately 100 requests a week from reports from all media. They were interested in NIAAA thrusts, policies, and general statistics.

Of particular importance was the development and release to the Nation of information about the Fetal Alcohol Syndrome in which alcohol was identified as the unquestionable causative element. Much of the research and many related findings resulted from grantees funded by the NIAAA.

Support Services

An essential responsibility of Public Affairs was to provide professional communications and information services for the staff of NIAAA.

Public Affairs gave programmatic and technical advice to the Division of Prevention and the Office of Education in the production of the series of films for junior and senior high school alcohol curricula.

Technical Assistance

Public Affairs provided technical assistance to the National Center for Alcohol Education and on NIAAA division-level activities.

OFFICE OF PROGRAM SUPPORT

The administrative functions of the NIAAA are performed in four branches that comprise the Office of Program Support.

Contracts Management Branch develops and implements standards and procedures for the management of the Institute's contracts program, and negotiates, executes, and administers the Institute's contracts and reimbursable agreements.

Grants Management Branch develops, implements and coordinates the application of Institute standards, methods and procedures for the management of grants, performs all necessary tasks to insure compliance with grant management policies and procedures, and provides guidance to NIAAA staff, applicants, and grantees on the management of grants programs.

Financial Management Branch coordinates the formulation, presentation, and execution of the NIAAA budget, including review and approval by various levels of the Executive Branch and Congress, as well as managing the current year appropriations in each program area.

Management Services Branch coordinates activities concerned with the provision of general services to the Institute, including the use of manpower resources and the development of policies and procedures to increase the effectiveness and efficiency of management.

INTERNATIONAL ACTIVITIES

Since its inception, NIAAA has supported gathering and exchange of information within the field of alcohol abuse and alcoholism on a worldwide basis. The objectives have been twofold: (1) to take advantage of research skills wherever they may be found; and (2) to capitalize on distinctive demographic and cultural factors which exist only in countries other than the United States. As a means toward this end, the Institute has funded research grants to outstanding European scientists and to the Pan American Health Organization, and has funded contracts with the World Health Organization. Examples range from cross-cultural studies of the relationship between alcohol and cancer and cardiovascular disease to investigation of the alcoholism program development process in communities at varying stages of development. Analyses of data obtained from these research, demographic, cultural, programmatic, and epidemiological studies permit selective application of knowledge to NIAAA's own prevention/education, treatment, and rehabilitation programs. These projects also serve as the basis for development of a well-trained, multidisciplinary, international cadre of advisors to provide training and technical assistance to all nations in all phases of development.

NATIONAL INSTITUTES OF HEALTH

National Institute of Arthritis, Metabolism, and Digestive Diseases

ALCOHOLISM

Alcoholism has been defined by many criteria, but a universally accepted or practical definition is not available. A biochemical marker of long-term heavy drinking, therefore, would enable objective evaluation of different treatment modalities for alcoholism and would also aid in an early assessment of patients and facilitate early detection and treatment.

NIAMDD grantee Dr. Charles S. Lieber of the Mount Sinai School of Medicine has shown that the ratio of plasma alpha-amino-n-butyric acid to leucine (A/L), substances usually found in the blood, is abnormally elevated in alcoholic individuals, and that this amino acid abnormality can be utilized as an objective empirical marker of alcoholism. The A/L ratio was found to correlate well with the degree of alcoholism in an active alcoholic population, and it can identify the majority of alcoholics within that population.

Analysis of blood samples obtained from 42 hospitalized alcoholics and 39 non-alcoholic control subjects revealed that the mean A/L ratio in alcoholics is more than twice that of control subjects. It was shown, furthermore, that these abnormal A/L ratios are not dependent on the presence of alcohol in the blood, and that valid measurements can be made for a week or more after cessation of drinking.

In separate investigations, Dr. Lieber has also offered an explanation for the diarrhea and abdominal colic experienced by alcoholic subjects who are commonly treated by liberal milk supplementation. He has obtained evidence to indicate that chronic alcohol ingestion may unmask, or exaggerate, lactose intolerance in adult alcoholics with a genetically determined deficiency of the enzyme lactase which can cause such symptoms.

His studies have revealed a striking association of alcoholism with decreased intestinal enzyme activities of lactase and sucrase, a defect which improves during alcohol abstinence. Because of the likelihood of significant milk intolerance in alcoholics, the common practice of liberal milk supplementation in these patients should be reconsidered, particularly in ethnic groups such as blacks, American Indians, Eskimos, and persons of Oriental ancestry with preexisting low lactase activities.

In known alcoholics, oral administration of the milk sugar lactose resulted in markedly lower blood glucose levels than normal, indicative of poor lactose absorption, and in a higher incidence of colic, diarrhea, and a dumping-like syndrome of gastric distress. This has been observed largely among black alcoholics. These findings suggest that chronic alcohol ingestion decreases intestinal activity of disaccharidase enzymes and is associated with increased gastrointestinal symptoms after lactose administration. Thus unexplained gastrointestinal morbidity could follow ingestion of seemingly innocuous amounts of lactose, such as are found in many foodstuffs.

OFFICE OF HUMAN DEVELOPMENT SERVICES

Rehabilitation Services Administration

ALCOHOLISM

Over the past several years, people with the primary disability of alcohol abuse have constituted between 4% and 5% of the total number of individuals rehabilitated by State rehabilitation agencies. The Rehabilitation Act of 1973 requires that priority in services be afforded severely handicapped individuals, and neither the Act nor the Federal regulations includes alcoholism within the definition of severe handicap. Therefore, it appears probable that there will be little increase in the number of alcoholic individuals served by State rehabilitation agencies in the future.

The Rehabilitation Services Administration works closely with the National Institute on Alcohol Abuse and Alcoholism. The basic strategy for serving alcoholics is the stimulation and support of close ties between NIAAA-funded treatment programs and vocational rehabilitation programs on the State and local level.

Numerous special projects in alcoholism have been conducted by State rehabilitation agencies. In New Jersey, for example, the State agency has worked in close cooperation with private industry and organized labor in identifying and providing necessary services for employees whose jobs are endangered by alcohol abuse. Other projects designed to serve alcoholic people have been active in Alabama, Alaska, Connecticut, Florida, Washington, Wisconsin, and Texas.

Rehabilitation Research

Research and Demonstration projects concerned with alcoholism have (1) developed methods of counseling, placement and follow-up of members of skid row populations; (2) conducted long-term follow-up studies of rehabilitated alcholics; (3) studied career patterns of alcholics to identify factors in successful vocational adjustment; (4) established a half-way house for homeless alcoholic men; (5) studied problems of alcoholic offenders; and (6) developed two series of films on rehabilitation of alcoholics based on research results, one intended for public showing over television and the other series for professional training.

Also administered by the Office of Research and Evalutation is the Special Foreign Currency Program. Evaluation and reports on progressive action programs in Poland and Yugoslavia are of value to the United States and other countries where there is concern about the increasing number of alcoholics and problem drinkers.

There is a greater recognition by programmers in this field that these men and women need social and psychological rehabilitation services. New projects emphasize an interdisciplinary approach to ascertain the most efficient methods of bringing about vocational rehabilitation in a community setting for alcoholic and problem drinkers. This program will be closely integrated with the domestic rehabilitation research program.

Number of People Rehabilitated:

Fiscal Year	All Rehabilitants	Persons Rehabilitated With Alcoholism
1975	324,039	14,873
1976	303,328	13,719
1977	291,202 1/	13,002 1/
1978	283,000 1/	12,400 1/
1979	277,000 1/	12,100 1/

1/ Estimated

ARTHRITIS

More than 29 million people in the United States are afflicted with arthritis and other rheumatic and connective tissue diseases, at a cost to the nation of over $13 billion annually. There are about 100 different rheumatic disorders. The most severely crippling form of these diseases is rheumatoid arthritis. Systemic lupus erythematosus seems to be an increasing problem among the serious connective tissue diseases. Nearly half of all people over age 55 are affected by the most prevalent form of arthritis, which is degenerative joint disease or osteoarthritis. Over one million Americans have gout. Several important forms of arthritis affect children and young adults. In view of these figures, biomedical investigators are continuing basic and clinical research aimed at understanding and control of the rheumatic diseases and related disorders through the strong support by the National Institute of Arthritis, Metabolism, and Digestive Diseases.

/ Obligations

	1975	1976	1977	1978 estimate	1979 estimate
National Institutes of Health: National Institute of Arthritis, Metabolism, & Digestive Diseases	$16,860,000	$18,602,000	$24,204,000	$30,201,000	$30,965,000

NATIONAL INSTITUTES OF HEALTH

National Institute of Arthritis, Metabolism, and Digestive Diseases

The national arthritis program conducted and supported by NIAMDD is continuing investigations of abnormal connective tissue activation in rheumatic diseases; the eroding effects of collagenase and lysosomal enzyme release and of immune complexes in rheumatoid arthritis, immunologic derangements in systemic lupus erythematosus; the mechanics of normal and arthritic joints and of those fitted with prostheses (artificial joints), and many other related subjects. Scientists are seeking to expand our basic understanding of connective tissue and associated musculoskeletal disorders through research in immunology, including autoimmunity and disturbances of immune systems, the "ground substances" of connective tissue such as the mucopolysaccharides and mucoproteins; and the relationship of structure and function to collagen, elastin and other proteins of connective tissues.

Establishment of Multipurpose Arthritis Centers

Significant efforts are being made to reach the goals called for in the National Arthritis Act of 1974 (as amended in 1976) and the subsequent National Arthritis Plan which was presented to the U.S. Congress in 1976. The Arthritis Plan was the result of a thirteen-month study and survey by the National Commission on Arthritis and Related Musculoskeletal Diseases. The NIAMDD is performing a central role in the implementation of the several mandates of the Act, and is working to fulfill the requirements of the National Arthritis Plan within the framework of existing fiscal and manpower resources.

In the Arthritis Plan presented to the Congress, the Arthritis Commission called for intensified action to apply currently known treatments for arthritis, to teach necessary professional skills, to demonstrate and stimulate prompt and effective application of available knowledge for treatment of patients, and to develop new knowledge through Multipurpose Arthritis Centers. As recommended, such Centers have been established in various parts of the country within the past year having been selected competitively to provide for both excellence and equitable geographical representation.

The Institutions awarded the initial Arthritis Center grants in 1977 are the University of Alabama School of Medicine in Birmingham, $213,060; the University of Arizona College of Medicine in Tucson, $141,600; the Boston University School of Medicine in Boston, Massachusetts $182,247; the University of California School of Medicine in San Francisco, $257,826; the Dartmouth Medical School in Hanover, New Hampshire, $148,509; the Harvard Medical School in Boston, Massachusetts, $131,268; the Indiana University Foundation in Indianapolis, $141,056; the Johns Hopkins University School of Medicine in Baltimore, Maryland, $153,672; the Louisiana State University in New Orleans, $122,074; the University of Michigan School of Medicine in Ann Arbor, $333,537; the Medical University of South Carolina in Charleston, $162,135; the Louisiana State University School of Medicine in Shreveport, $81,600; the Stanford University School of Medicine in Palo Alto, California, $165,107; the University of Texas Health Science Center in Dallas, $75,866; and the Washington University School of Medicine in St. Louis, Missouri, $135,675.

Rheumatoid Arthritis

The cause of rheumatoid arthritis continues to be elusive, but many investigators believe that the mechanism at work in causing this widespread chronic inflammation involving the joints as well as various systems of the body is an abnormal reaction of the body's immune system, a reaction stimulated perhaps by infection or other triggering factor resulting in a misdirected attack by the body's defense systems on its own tissue (an autoimmune reaction). Researchers are pursuing many lines of evidence that seem to support this theory in hopes of discovering the causative link. Although various infectious agents have been sought, and in some instances, identified, from tissues of patients with rheumatoid arthritis, investigative work to date has been unable to establish definitely any of them as a cause of the disease.

The role of prostaglandins, hormone-like substances produced by the body that act locally in many body tissues when they are inflamed, continues to be a subject of intensive investigation. It has been established that large doses of prostaglandin E_1 can suppress inflammation and tissue damage in rats with experimentally induced arthritis. Scientists think that the prostaglandins may act to switch off inflammation by inhibiting the release of potent tissue-dissolving enzymes (lysozymes) from white blood cells that usually gather at inflammation sites.

Not all prostaglandins act alike; some indeed exhibit a variety of opposing reactions in different body tissues. In recent studies, Dr. Armen H. Tashjian, Jr. and his associates at Harvard University, supported by an NIAMDD grant, demonstrated that bone resorption activity may result in part from activity of prostaglandin E_2 in the synovial tissue of the patients' joints. Such bone resorption is an important component of the joint destruction and deformity in patients with rheumatoid arthritis. Although the mechanisms involved in this process are not yet completely understood, the researchers think that indomethacin and related nonsteroid anti-inflammatory compounds, sometimes useful in the treatment of rheumatoid arthritis, may act to prevent or retard bone destruction by inhibiting the biosynthesis of prostaglandin.

NIAMDD grantee Dr. Morris Ziff and his associates at the University of Texas have shown via electron microscopy that rheumatoid articular cartilage previously thought to be normal because of its appearance does sustain erosion through degradation in vivo by enzymes present in synovial fluid, or released by polymorphonuclear cells in close contact with the cartilage surface. The results of the study indicate that the surface of rheumatoid arthritic cartilage undergoes erosion in areas that are free of pannus (abnormal cellular growths and inflammatory material in joints of patients with the disease), and that this erosion may be so minimal that it is demonstrable only with the electron microscope at the ultrastructural level. The changes appear to be caused by lysosomal enzymes either present in synovial fluid, such as neutral protease and collagenase, or by enzymes released by polymorphonuclear cells attracted to the cartilage by certain immune complexes in the surface layer of such cartilage.

Synovectomy, the surgical removal of the affected lining from a diseased joint, is often temporarily beneficial in advanced cases of rheumatoid arthritis. A five-year multi-center evaluation of synovectomy supported by the Institute, however, has now shown that while the procedure may be of value in selected joints of certain patients, it has little place in the general management of the disease since it has little effect on the long-term nature and progress of the disease. The results of this study do not lessen the temporary value of synovectomy in severely painful joints with large synovial proliferations nor the value of tenosynovectomy in wrists with threatened rupture of extensor tendons. The procedure is not recommended, however, in general treatment of rheumatoid arthritis nor as a measure to prevent recurrent articular damage.

Rheumatoid arthritis can be controlled in many cases with a program including rest, physical therapy, and administration of salicylate drugs such as aspirin. Other cases seem to respond better to corticosteroid drugs, which may be administered alone or in combination with aspirin or gold salts. Severe cases which cannot be controlled by the more conventional approaches are being treated experimentally with such immunosuppressive drugs as azathioprine and cyclophosphamide. Such drugs must be used with great care because of their toxic nature, as must other drugs currently under investigation, such as D-penicillamine, levamisole, methotrexate and chlorambucil.

Clinical research is continuing on the efficacy and hazards of all of these agents. An important part of NIAMDD's arthritis program has been and continues to be clinical trials of drugs and other forms of intervention for the treatment of arthritis and related disorders. A multi-centered apparatus involving 10 excellent arthritis clinics has been recently established for these purposes.

Systemic Lupus Erythematosus

NIAMDD grantee Dr. Ronald P. Messner and his associates at the University of New Mexico are investigating the question of whether susceptibility to systemic lupus erythematosus (SLE), a connective tissue disease occurring predominantly in young women, is genetically determined and if it can be traced within a family as an abnormal immune response. The investigators are studying lymphocytes from SLE patients and their families to examine what role antilymphocyte antibodies, found in these individuals, play in altering the function of T and B lymphocytes. This research could provide important knowledge of the pathophysiology of the immune system in SLE and lead to development of a method for detecting genetic predisposition to the disease and hence earlier and more clear-cut diagnosis.

Another grantee of the Institute, Dr. Charles R. Steinman of the Mt. Sinai School of Medicine, and his associates have correlated histologic findings in kidney tissue with serum binding of antidouble-stranded DNA antibodies in patients with lupus nephritis, a serious kidney complication of SLE, and suggests that the procedure may be of value in assessing disease activity.

Antibodies to double-stranded DNA, which characterize SLE and reflect the disease process, are measured by testing serum against "native" DNA. Because such preparations are contaminated by nondouble-stranded DNA and assay results are ambiguous, the investigators recently have employed a synthetic DNA copolymer (dAT) to measure binding to antibodies. Binding of dAT was found to correlate closely with clinically-judged active lupus nephritis, and the investigators sought histologic confirmation of this observation by examining kidney tissue. Their findings suggest that dAT binding may provide a useful, noninvasive means of clinically assessing both nephritis activity and the intensity of deposits in the kidneys, important information for the clinical management of patients with this complication.

The outlook for young patients with SLE is more favorable than previously thought, according to results of a long-term study by NIAMDD grantee Robert L. Vernier and his associates at the University of Minnesota.

Children with SLE have multisystem involvement, just as adults do, which may pursue a progressively deteriorating course. Investigators in this study treated children with SLE with corticosteroid drugs in an effort to normalize results of urinalysis and renal function tests, eliminate proteinuria (the abnormal presence of protein in the urine), and maintain normal serologic tests.

According to the researchers, the ten year survival of 86 percent of this group constituted the lowest reported mortality rate for SLE patients. The major cause of death in the group was infection and there was no mortality that could be linked to renal failure. Similar more favorable prognoses in SLE have been reported in other series, including those with mostly adult patients.

The scientists suggest that intensive observation and monitoring of young SLE patients, along with aggressive steroid and immunosuppressive drug therapy, brought about these results and a more favorable prognosis for children with SLE. They also found that the outcome in SLE patients is related less to kidney dysfunction, as has been previously thought, than to nonrenal aspects of SLE and complications of infection.

Although the investigators express optimism regarding long-term survival of children with SLE, they emphasize that this condition must be considered a controllable, but life-long, systemic disease. They conclude that close and consistent monitoring of patients, along with coordinated care, are essential if the outlook for individuals with SLE is to continue to improve.

Spondylitis

Researchers are establishing an important link between immune mechanisms of the body and rheumatic diseases, and have documented a remarkable association between the histocompatibility antigen HLA-B27, an inherited characteristic of various body cells, and ankylosing spondylitis. Research reports indicate that this rheumatic disorder of the spine which generally affects young men has the same strong association with the antigen in women as well. These studies also suggest that the prevalence of spondylitis in apparently healthy women and men who carry the antigen may be far greater than had been thought. There may be more than two million Americans with this disorder.

Investigators in the Southwestern Field Studies Section of NIAMDD's Epidemiology and Field Studies Branch have recently studied histocompatibility antigens in relation to ankylosing spondylitis and vertebral hyperostosis. They report that in fact the Pima Indians show a less strong association between the presence of HLA-B27 and ankylosing spondylitis than has been found among Caucasian populations. The

investigators hypothesize that an alternative HLA type or other immune response gene marker may be implicated in the development of this disorder, and they are pursuing this possibility in further studies in an attempt to identify a spondylitis-associated antigen which is more specific for both Indians and Caucasians than HLA-B27.

Lyme Arthritis

Dr. Stephen E. Malawista and his associates at Yale University and the Medical College of Virginia have added new evidence to that previously reported suggesting a role for an arthropod (insect) vector in Lyme arthritis. They also identify erythema chronicum migrans, a characteristic skin lesion, as a unique marker for the disease. In 1976, the researchers reported results of an initial retrospective study of 51 patients from three contiguous communities, Lyme, Old Lyme, and East Haddam, Connecticut, after emergence in that vicinity of what appeared to be a new, infectious form of mild arthritis marked by recurrent attacks of joint pain, and preceded in many cases by an unusual skin rash.

The investigators now report findings of a prospective study conducted during the summer of 1976 suggesting that the presence of serum cryoprecipitates, or immune proteins that react characteristically in the cold, may be helpful in diagnosing Lyme arthritis. This seems to support the hypothesis of a common origin for the skin and joint lesions and to imply that serum immune complexes may have a role in the occurrence of the disorder.

Bone Diseases and Orthopedic Research

The Institute supports a broad program of research in orthopedics and bone diseases, including basic and clinical studies of skeletal tissues under normal and disease conditions. There are projects on calcium metabolism and bone formation, fracture healing and fixations, bone transplantation and preservation of skeletal tissue, prostheses (such as artificial joints) and relevant biomaterials, biomechanics and bioelectricity, musculoskeletal dynamics and physiology of normal and abnormal gait. Many are very important for the rheumatic diseases.

Replacement of diseased joints by prostheses has been the major outstanding development in the field of orthopedics during the past decade. Many orthopedic surgeons now regularly implant artificial hips and knees, improving dramatically the quality of life of patients. A new prosthetic knuckle has been developed which enables patients with deformed and crippled hands to grasp and pinch again. There have also been important advances in development of prosthetic ankles, shoulders and elbows. The artificial knee, the second most frequently replaced joint, although promising, is not yet as successful as total hip replacement, and the Institute is currently increasing support of investigations into the kinetics, biomechanics, and various prostheses for knee and certain other joints. Other work continues to develop the best possible materials for fabrication of joints that will display minimal antigenicity and toxicity, maximum acceptance by the body and will exhibit reduced wear or corrosion over extended periods.

A major advance has taken place this year in understanding biochemically how bone is formed, matures and is remodeled -- knowledge of particular importance in the field of bone diseases. The work involves the discovery of a new calcium-binding protein called osteocalcin, particularly abundant in bone, and determination that its rate of synthesis is vitamin-K dependent. Animals who are vitamin-K deficient have reduced rates of the protein in their bones. Understanding calcium binding is of importance in investigating a variety of biological processes such as blood clotting and the formation of certain kinds of kidney stones, the calcifications that occur in soft tissues in such diseases as dermatomyositis and scleroderma and in the plaque of atherosclerotic lesions, and is of particular importance to the area of bone metabolism and structure. This new advance by NIAMDD grantee Dr. Melvin Glimcher and his associates at Children's Hospital in Boston should permit more rational therapy to be devised in a wide range of bone diseases.

Several Institute grantees have developed noninvasive methods via resonance, electromagnetics and ultrasonics for measuring the in vivo properties of bone to determine the rate of healing. The use of electrical stimulation to promote healing of fractures and non-unions continues to be investigated by a number of researchers, and this technique is also being tested in efforts to induce bone in-growth into porous ceramics. This exciting field is experiencing considerable success and appears to hold great potential.

Dr. Henry Mankin and his associates at Harvard University, working under NIAMDD support, have reported studies in which a cartilage-degrading enzyme, collagenase, and an inhibitor of collagenase were found in osteoarthritic cartilage. The findings suggest that degradation of the osteoarthritic joint surface to the base bone occurs with end-stage osteoarthritis as a result of locally synthesized collagenase. This and other work of these investigators in studying the normal and abnormal histology and chemical response of cartilage in relation to bone tissue in osteoarthritis is serving to elucidate the pathophysiology of this disorder.

Such studies as these are adding to our store of knowledge and improving treatment of numerous diseases. In the area of metabolic bone diseases, however, advances have been few and, unfortunately, the number of individuals with these diseases appears to increase in our aging population. Calcitonin therapy has shown encouraging results for patients with Paget's disease in which there is abnormal bone thickening, dissolution, and deformity. While previous studies showed that a combination of calcium, vitamin D and fluoride therapy was promising in treating osteoporosis, longer-term studies have not borne out the initial encouragement. Research in the area of osteoporosis poses difficult problems for scientists, and a workshop is planned to encourage the development of new departures in the study of this disease.

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Outlook

These examples of research in arthritis, rheumatic diseases, and related disorders of connective tissue and bone are just a few of more than 150 ongoing, Institute-supported or intramural studies in these fields. The findings reported here reflect the Institute's continuing commitment and its intensified efforts as its staff and resources are concentrated on the new and ambitious objectives and directions outlined in the National Arthritis Plan. This attack will enhance the progress being made against these disorders, improving treatment and control of many arthritic and rheumatic diseases, while building a foundation of basic knowledge that is essential to their eventual prevention or cure.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

ARTHRITIS

Osteoarthritis and disc degeneration of the spine are major causes of disability in terms of limitation of activity and mobility among many people. The total extent of this problem in this country has not been determined previously. The Health and Nutrition Examination Survey in the present program is obtaining x-rays of the cervical and lumbar spine among adults 25-74 years of age (the lumbar x-rays for women are limited to those 50-74 years) which are being interpreted by experts in arthritis. From these x-ray interpretations, the physical examination findings and medical history the total prevalence and severity of osteoarthritis and disc degeneration of the cervical and lumbar spine in the adult population will be determined for the first time.

BURN CENTERS

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
National Institutes of Health:					
National Institute of General Medical Sciences 1/	$ 2,500,000	$ 3,769,000	$ 3,340,000	$ 5,030,000	$ 6,456,000
Health Services Administration: 2/					
Grants	-0-	-0-	3,140,314	3,000,000	3,000,000
Direct Operations	-0-	-0-	-0-	-0-	-0-
Total, HSA	-0-	-0-	3,140,314	3,000,000	3,000,000
Health Resources Administration:					
Bureau of Health Manpower 3/	118,492	100,000	354,470	347,762	358,625
Health Planning and Resources Development	4/	4/	4/	4/	4/
Total, HRA	118,492	100,000	354,470	347,762	358,625
TOTAL, PHS	$ 2,618,492	$ 3,869,000	$ 6,834,784	$ 8,377,762	$ 9,814,625

1/ For burn research.
2/ For burn care demonstration projects.
3/ For nursing burn research.
4/ Obligations cannot be identified for Burn Center activity.

BURN RESEARCH PROGRAMS

Severe burns are a very destructive and disfiguring form of injury. They evoke a myriad of systemic responses (respiratory and cardiovascular collapse, metabolic dysfunction, kidney failure, stomach ulceration, etc.) and require the most intensive care that hospitals can provide. Among surviving patients, hypertrophic scarring, skin contracture, and the loss of joint motion can result in extreme disfigurement and physical disabilities, accompanied by severe psychological stress and many years of rehabilitative effort.

Of the nearly two million Americans who suffer medically significant burns each year, 130,000 are hospitalized and 70,000 require intensive care at a cost of more than $300 million. One third of the 10,000 who die are children under 15, with the great majority being preschoolers. Another large fraction involves people 65 years and older. Although the number of burn deaths is small compared to the great killers--heart disease, cancer, and stroke--extensive burn injury is unquestionably catastrophic to the patient and the psychological after-effects and the prolonged reconstructive period cause severe suffering and expense to the involved families.

Burn research and burn patient care, including rehabilitation, are important concerns of the Public Health Service. The National Institutes of Health, primarily the National Institute of General Medical Sciences (NIGMS), supports research and research training on the biomedical aspects of burn injury.

Collaborative Activities

The NIGMS has established communication among several groups within DHEW. These include: 1) staff participation in review of burn care demonstration center proposals submitted to the Emergency Medical Services (EMS) Program, Health Services Administration (HSA); 2) consultation with the Division of Nursing, Health Resources Administration (HRA) re: nursing burn research; and 3) referral of potential R & D proposals received by NIGMS to the Division of Health Systems Design and Development, HRA. Activities outside DHEW include communication with the Department of Commerce re: Fire Prevention and Control Act and regular interaction with the Surgical Research Unit, Brooke Army Medical Center, Fort Sam Houston, San Antonio, Texas.

NATIONAL INSTITUTES OF HEALTH

National Institute of General Medical Sciences

BURN CENTERS

The importance of burn research cannot be overly emphasized. In several burn centers, the death rate for severe injuries involving 30 percent or more of the total body surface has been reduced from 100 percent to about 50 percent over the past 10 years. However, the overall mortality remains high. The time of death following burn injury has shifted, from one to two days post-injury to two or more weeks. This is due largely to development of more effective means of resuscitation and other early supportive measures. The massive long-range impact of burn injury upon vital organs and systems of the body has only recently been recognized as the number of survivors increased. These efforts pose a difficult challenge for the very best efforts in biomedical science.

NIGMS Research Program

The NIGMS supports burn research centers and projects within the Trauma-Burn Program. The research centers are multidisciplinary efforts where basic laboratory findings are rapidly translated to improved patient care. Eight trauma burn research centers are supported presently. Two of these are devoted entirely to problems of burn injuries, while the others have significant burn-related research components. The broad goals are to understand the basic cellular and tissue changes induced by injuries and thereby to prevent death, mitigate pain, and lessen both the recovery time and degree of disability of severely burned patients.

The Institute recently announced a special grants program to provide initial support for independent research by talented physicians who wish to address the challenging research problems presented by trauma and burns. This mechanism should help to bridge the gap between research training and independent research. To qualify for this program, the research project must be designed to answer a specific question related to trauma and burn research in basic science areas such as physiology,

biochemistry, and microbiology.

Recent Accomplishments

Burn wounds, which remain open for many weeks, are prone to colonization by various microorganisms. Infection, especially by aerobic gram negative bacteria, has been responsible for the high morbidity and mortality that accompany extensive burn injury.

Silver compounds have long been in general use for burn wound antisepsis. They have proven useful because of minimal systemic absorption and little tendency toward the induction of silver resistant bacterial strains. However, silver nitrate or sulfadiazine does not consistently eliminate or suppress bacterial growth when wound size exceeds 50 to 60 percent of total body surface area (BSA). Either gram positive (e.g. Staphylococcus) or gram negative (e.g., Pseudomonas) organisms can be isolated.

Recently, zinc sulfadiazine was reported by a grantee to exhibit equivalent antibacterial activity with a possible additional bonus of providing zinc for wound healing. Other workers have demonstrated the effectiveness of cerium compounds. When cerium nitrate was used clinically, gram positive bacteria predominated. By contrast, wounds exposed to silver salts alone harbored predominantly gram negative flora. In studies published recently (May 1977), it was noted that the combination of cerium nitrate and silver sulfadiazine exhibits a broad spectrum activity inhibitory to both gram types of bacteria.

A 2.2% cerous nitrate - 1% silver sulfadiazine cream has been used for topical antisepsis on the wounds of 117 consecutive hospitalized burned patients: 41 had burns greater than 20% BSA, 23 of these had burns of 40% BSA or more. The six patients with deep burns of 70% BSA or more who were alive after 72 hours ultimately survived. There were no deaths from sepsis. Seven of the 10 deaths occurred during the first 72 hours; they were related to cardiopulmonary problems, as were the three late deaths.

Of 2238 quantitative wound surface cultures, 1,570 (70%) yielded no growth. Gram negative bacteria were found in 8% of cultures. Gram-positive bacteria, especially Enterococcus and Staphylococcus aureus were recovered from 312 cultures (14%), but generally in moderate or low density. In only 15 of the 2238 cultures was the bacterial density greater than the dangerous level of $10^5/cm^2$.

Cerium salts are relatively non-toxic and are poorly absorbed from local tissue sites. Hepatic, renal, cerebral, hematological or other toxic manifestations were not observed in the study referred to above. To date, it appears that this synergistic-like activity has not been associated with increased toxicity.

Investigators at the University of Texas Southwestern Medical School, Dallas, are using modified techniques for semi-microanalysis of intracellular muscle electrolytes. They have developed equipment for measuring membrane potentials which permit the use of small tissue samples. Serial biopsies can now be made in the same subject without major influence from the procedure itself. Most importantly, these studies can be extended from experimental animals to patients, both burned and non-burned.

Serial in vivo measurements of the transmembrane potential of baboon skeletal muscle cells coupled with determination of total fluid content of biopsied muscle have recently shown that large quantities of both sodium and water shift into the cells within 60 seconds following burn injury, occurring in muscle both near and distant to the site of injury. These findings are consistent with earlier clinical observations showing loss of fluid from the extracellular fluid compartments prior to the formation of significant wound edema.

The implication of abnormal cellular function associated with changes in transmembrane potential suggests the need for further in-depth investigation. It also provides valuable new information for use in the development of rational approaches to fluid therapy. These NIGMS supported studies demonstrate the need for more rapid fluid replacement with saline solution in order to restore sodium deficits while meeting needs for effective plasma volume restoration. New guidelines for clinical fluid resuscitation derived from these studies have been adopted by the American College of Surgeons Committee on Trauma.

Investigators at the burn research center in Seattle have designed a computer controlled system with the goal of achieving continuous response-based control of parenteral fluid therapy of the burn shock victim in the initial 24 hour period.

A 24 hour evaluation was conducted in a 70% total body surface area canine burn model. At four hours postburn, after the shock state was reached, the animal was connected to the resuscitation system. Minute-by-minute closed loop control of clinical variables was utilized to maintain adequate organ perfusion while minimizing sodium loading. Since the system determines fluid infusion rate entirely on the basis of patient responses, the need to estimate fluid requirements for the entire first 24 hour postburn period was eliminated.

The system is based on the use of standard hospital monitoring equipment and intravenous infusion pumps. The computer elements consist of small, reliable, and inexpensive microprocessor components including central processing unit, memory units and analog-to-digital and digital-to-analog convertors. With these, a highly sophisticated digital computer system is implemented on a circuit board 6" x 12" size, at a fraction of the cost of a large minicomputer system. A burn treatment algorithm has been designed and programmed which governs computer treatment decisions based on measured patient variables.

Measurements were made of arterial blood pressure, central venous pressure, and hourly urine output. The intravenous infusion rate was adjusted every minute so as to maintain blood pressure and urine output within safe limits.

Should further animal studies prove this to be a fail-safe method, it will be tried in humans. So far, results indicate that response-based intravenous fluid therapy can be implemented easily in a reliable and cost effective manner through the use of automated intravenous therapy utilizing microprocessor technology.

At the April 1977 meeting of the American Burn Association a plenary session was devoted to diagnosis and management of inhalation injury. Three of the four panelists were NIGMS grantees or applicants. All were in agreement that inhalation injury from fire is the number one killer of severly burned victims, that very little is known about the mechanism of the injury, and that treatment is less than optimal. In addition to the high mortality rate, inhalation injury produces significant morbidity leading to the chronic changes of obstructive pulmonary disease. Thirty percent of the severly burned individuals show signs of inhalation injury. This is in contrast to 5% in the early 1900's before the advent of plastics and other flammable products. Currently the only available diagnostic tests are xenon lung scan and fiberoptic bronchoscopy. Of these, the latter is most useful, but it too has shortcomings because it cannot diagnose distal alveolar injuries.

At the burn research center in the Massachusetts General Hospital, Boston, both laboratory and clinical studies of the pulmonary response to burn and smoke injury are being carried out. The laboratory studies are concentrated on the importance of carbon particles as the carrier of both heat and chemical toxins down the respiratory tract. The changes observed are correlated with the dose of thermal energy with particular concern to alveolar capillary permeability and surfactant activity. Similar studies in humans involve quantitative measurement of capillary permeability using indocyanine green fluorescence. Previous experience with 30 patients has shown the test to be safe. If further studies prove it to be an accurate diagnostic measurement it could provide a better means of assessing effectiveness of therapy.

Investigators at Cornell Medical Center have been studying the effects of burns on the clotting mechanisms, particularly fibrin split products. They have observed that pulmonary dysfunction and thrombocytopenia often occur following severe burns. They found that fibrinogen degradation products are usually elevated for several weeks after burn injury. Previous studies have demonstrated the development of pulmonary dysfunction and acute thrombocytopenia in unanesthetized, unburned rabbits following infusion of purified human fragment D. The current work identifies possible mechanisms of this effect and proposes a therapeutic agent to prevent the development of a pulmonary lesion.

This work already has demonstrated that pulmonary dysfunction induced by the infusion of fragment D is not attributable to any contamination by fragment E and that the striking thrombocytopenia, pulmonary dysfunction, and pathologic pulmonary tissue changes attributable to fragment D can be prevented by pretreatment with diphenhydramine HCL (Benadryl). Human studies with use of Benadryl are in progress.

Research Manpower

The NIGMS has long recognized the necessity of a rigorous training activity to assure continuing momentum and success in research on the pressing problems of burn injury. Under the old surgery training program, support for training in burn research was provided to several institutions. In June 1975, the Institute activated an institutional fellowship program in burn and trauma research under the new National Research Act. Nine awards have been made to train physicians and scientists interested in research in these areas. The program uses a multidisciplinary approach, in order to prepare the trainees to advance our knowledge of the body's total response to injury and burns. There are 22 trainees who receive instruction from a supervisory staff including trauma surgeons and/or burn specialists as well as basic scientists who provide research training in related fields such as physiology, biochemistry, and microbiology. In addition, support has been provided for one individual fellowship, two career development awardees, and one career awardee in the area of trauma and burns.

Numerous Institute Workshops and meetings with investigators in related fields have permitted staff a critical look at the problem inherent in the research activities in trauma.

Applicants have expressed concern to the Institute over the small number of funded applications in these areas. In analyzing the NIH data, all mechanisms and types of support were included - research, research training, fellowships and research career development awards for new, renewal and continuation applications. The data show that there is a dearth of trauma related applications. The Workshop discussions revealed the problem as one of manpower shortage both in clinical service and research. This shortage was also apparent to the Interagency task force on burn centers in which NIGMS staff participated. The report of the task force was submitted in October, 1976, in response to a Senate inquiry on the status of burn centers in the U.S.A. It states: "Annually only one or two physicians complete the two formal programs in the United States for training physicians in burn care...there are a number of existing specialized treatment facilities without an adequate number of trained staff to provide the level of care required....at least eleven of the nation's sixty large burn care facilities are unable to recruit medical directors...The mission of the National Institutes of Health is to advance scientific knowledge of the effects of burns on the body and the development of techniques to reduce fatalities and permanent damage resulting from burns. Specific goals include continuation of current research and

research training programs."

Outlook

One of the major concerns of the Institute has been the failure to develop more activity in the area of trauma and burns. Trauma remains the number one killer of the 1-44 year age group. There are several new avenues of research which the Institute plans to encourage in this scientific area. Studies into the progressive organ failures following severe multiple injury should provide a better understanding of the total body metabolism. Specific questions include the reasons for inadequate protein production or utilization known to occur in liver failure and for the alteration of the intermediate metabolism of carbohydrates and fats following severe multiple injuries. New approaches and methodologies to elucidate far more completely the pulmonary response to injury will also be fostered.

Wound healing ranks equally high on the list of priorities. There are approximately 14 million cases of postoperative and post-wound infections each year. The body's total metabolic response to wounds must be determined, including disclosure of those factors that may inhibit or induce biological repair. NIGMS will seek to fund high-quality research in this area, ranging from studies of the induction of collagen synthesis in cells in the injured area through investigations of the body's organ and system responses to burns. Studies on the causes of antibiotic therapy failure and of the role of immunological responses in skin grafting, the most important method for repair of burned skin, will be encouraged.

Outlook

These examples of research in arthritis, rheumatic diseases, and related disorders of connective tissue and bone are just a few of more than 150 ongoing, Institute-supported or intramural studies in these fields. The findings reported here reflect the Institute's continuing commitment and its intensified efforts as its staff and resources are concentrated on the new and ambitious objectives and directions outlined in the National Arthritis Plan. This attack will enhance the progress being made against these disorders, improving treatment and control of many arthritic and rheumatic diseases, while building a foundation of basic knowledge that is essential to their eventual prevention or cure.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

ARTHRITIS

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HEALTH SERVICES ADMINISTRATION

BURN CENTERS

During 1977, the Health Services Administration, HMS, Division of Emergency Medical Services awarded a series of contracts, as authorized by P.L. 94-573, The Burn Injury Program. By a competitive proposal process, contracts were awarded for (1) the six New England States, (2) the State of Virginia, (3) the State of Alabama, (4) the Syracuse/ Rochester region of New York, (5) the San Diego region of California, and (6) the Dallas/Fort Worth region of northern Texas. These six sites have a population of 28 million people. The sites are planned for a three year period to collect uniform data for (1) a census of all burn patients admitted to the hospital; (2) a sample of outpatients reporting a burn injury, and (3) the cost, charges, and reimbursements. Data will be collected for both the acute and rehabilitation phases of the injury, but no longer than 18 months for a single patient. The six sites are also undertaking a series of research tasks to examine certain problems of national interest, including the development of a burn injury severity index; how fabrics contribute to the degree of burn injury, and the development of a burn nurse education curriculum.

A contract has also been awarded to Arthur Young and Company to assess all of the information and data, collected by the six sites, and perform the analyses which will describe the nation's burn delivery practices.

The information on patient care and finances will be used to provide a comprehensive description of the nation's current burn care capability. This information will be used to develop and present to the Congress a National Burn Care Strategy. This was requested by the Senate Committee on Appropriations in 1975.

The funds for 1978 and 1979 will be used to provide second and third year funding for the current burn contracts. This program is working closely with the National Institute of Medical Sciences, the National Institute for Health Statistics, the National Center for Health Services Research, the Consumer Product Safety Commission, and the National Fire Prevention and Control Administration.

HEALTH RESOURCES ADMINISTRATION

Bureau of Health Manpower

BURN CENTERS

The Bureau of Health Manpower does not have an on-going program that relates to the categorical target of Burn Centers. However, the Division of Nursing has awarded a few grants which emphasize educational training, instruction, and research of burn phenomena to prepare nurses at the master's level of education to become experts in the care of patients suffering thermal injury and trauma in emergency and clinical settings.

Health Planning and Resources Development

The Hill-Burton program has always encouraged the development of new services which would render better health care and at the same time concentrate scarce health resources and skills. This is especially true of Burn Centers which have been given both planning assistance by Hill-Burton State agency and DHEW regional office staff and assistance by Hill-Burton funds on several occasions.

Public Law 93-641, signed on January 4, 1975, extended and extensively revised the Hill-Burton program. Burn Centers will be eligible under two priorities of formula grant assistance: (1) modernization of health facilities, and (2) construction of new inpatient medical facilities in areas which have experienced recent rapid population growth. Another priority would include the outpatient areas of Burn Centers. The same facilities are also eligible for loans and loan guarantees with interest subsidy. A third type of grant assistance (Section 1625) is project grants for construction and modernization projects designed to prevent or eliminate safety hazards in publicly owned medical facilities and to assure compliance with State or voluntary licensure or accreditation standards. Grant and loan assistance from 1976 and 1977 appropriations/authorizations (except Section 1625 grants) are awaiting the publication of regulations for Title XVI. At that time, $39.9 million in formula grants and $250 million in loan or loan guarantee authority will be available for the priority projects in each State. Section 1625 public facility project applications have already been approved for the $11.4 million available.

CEREBRAL PALSY

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
National Institutes of Health:					
National Institute of Neurological and Communicative Disorders and Stroke	$16,540,000	$17,079,000	$17,404,000	$18,490,000	$18,014,000
Office of Human Development Services:					
Development Disabilities: 1/					
State Grants	---	---	33,058,000	33,058,000	49,880,000
Special Projects	---	---	19,617,000	19,567,000	5,557,000
University Affiliated Facilities	---	---	5,250,000	6,500,000	6,500,000
Total, DD	---	---	57,925,000	59,125,000	61,937,000
Rehabilitation Services Administration:					
Basic State Grants	4,760,000	4,322,000	4,442,000	4,563,000	4,713,000
Special Projects	---	---	---	150,000	404,000
Innovation and Expansion	---	---	---	102,000	113,000
Total, RSA	4,760,000	4,322,000	4,442,000	4,815,000	5,230,000
TOTAL, OHD	4,760,000	4,322,000	62,367,000	63,940,000	67,167,000
TOTAL	$21,300,000	$21,401,000	$79,771,000	$82,430,000	$85,181,000

1/ Funds indicated are the amounts appropriated for all developmental disabilities included in the Developmantal Disabilities Services and Facilities Construction Act, as amended.

NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological and Communicative Disorders and Stroke

CEREBRAL PALSY

Cerebral palsy is a chronic disability characterized by loss or impairment of control of voluntary muscles, appearing early in life and not the result of recognized progressive disease. Cerebral palsy is not a single disease, but a group of conditions which differ with regard to the parts of the body affected, and with regard to specific manifestations, associated handicaps, and causation. Cerebral palsy can result from damage to the developing nervous system before, during, or after birth, and its manifestations may be associated with varying degrees of mental retardation, speech defects, or convulsions.

Although cerebral palsy is always the result of maldevelopment or damage of the brain's motor control centers, the damage can be of varied and frequently obscure origin. There is no single effective preventive measure, and no cure. However, good medical care throughout pregnancy, during labor and delivery, and in the newborn period can prevent some cerebral palsy, and the development and use of the rubella vaccine and of the Rh immunoglobulin serum have also resulted in the prevention of some cases of cerebral palsy. Spasticity, the dominant motor handicap in most cases of cerebral palsy, can be treated symptomatically by physical and occupational therapy, and with orthopedic and neurological techniques such as tendon lengthening procedures or blockade of nerves, and sometimes with medication. Early therapeutic and educational intervention may minimize the effects of cerebral palsy and encourage compensation for developmental delays.

The United Cerebral Palsy Associations, Inc., a national voluntary health agency, estimates that there are 750,000 persons in the U.S. with cerebral palsy. Each year, 15,000 babies are born with brain damage that causes cerebral palsy.

The Department of Health, Education, and Welfare's research activities in cerebral palsy are centered in the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) of the National Institutes of Health.

Types of Cerebral Palsy and Associated Disabilities

Although symptoms vary, two common types of cerebral palsy (CP) are the spastic, characterized by tense, contracted muscles, and the athetoid type, characterized by involuntary movements of arms and legs. Cerebral palsy is also categorized as monoplegia, diplegia, paraplegia, or hemiplegia, according to which limbs or regions of the body are affected.

Some children show signs of more than one type of cerebral palsy. Associated defects such as seizures and mental retardation may be more disabling than the motor problem. Half to two-thirds of the children with CP score within the mentally retarded range on psychological testing, about half of these below the level generally accepted as educable. About a third of children with CP have some type of seizure disorder. Abnormalities of the visual system affect about half of the children with CP, and deafness or problems with sensation affect others. Speech and learning disabilities are a major additional handicap in children with CP. Social and emotional maladjustment is frequent, and depression in adolescents is extremely common.

Frequency, Mortality, and Acquired Forms of CP

In the Collaborative Perinatal Project of the National Institute of Neurological and Communicative Disorders and Stroke, which will be discussed below, cerebral palsy including mild CP was identified in 5.2/1000 of children examined at the age of seven years. Twelve per cent had apparently acquired their neurological abnormality through known damage after the first month of life. The most common causes of acquired brain injury resulting in CP were meningitis and physical injury; child abuse was a substantial contributor in the injuries sustained.

CP was more common in boys than in girls, and more common in white than in black children. The prevalance of clearly handicapping CP (total CP minus mildly affected cases) was 3.1/1000 for white and 2.3/1000 for black children at the age of seven years.

Among children with cerebral palsy at age one year, 11% had died before the seventh birthday. Spastic quadriplegia, a type of CP affecting all four limbs, was associated with a mortality of 28% between the first and seventh years. An average life span of 30 years has been estimated for persons with CP in other studies.

Causes of Cerebral Palsy

Any condition which damages the centers in the brain which control movement, and acts early in life, can result in cerebral palsy. The proportion of CP related to each possible cause is not known with certainty, but it is thought that deprivation of oxygen late in pregnancy, during the process of delivery, and in the first days of life is a common factor. Hemorrhage, which may be related to oxygen lack or to physical injury in the birth process, can severely damage the newborn's brain, and convulsions may occur. Certain infections of the mother during pregnancy, or of the young infant, such as German measles (rubella), syphilis, toxoplasmosis (a parasitic infection), cytomegalovirus, and herpes simplex are among the important examples of infections which may cause CP and other evidence of brain damage.

Brain damage may occur in the newborn period to infants seemingly predisposed to it by such factors as low birth weight or difficulty in adapting to life immediately after birth. Disordered brain function in the premature or low birthweight infant may also be of genetic origin.

Illnesses and injuries in later infancy and early childhood, such infectious diseases as meningitis and encephalitis, account for 10-15% of cerebral palsy cases, as indicated above. Battering (nonaccidental injury) contributes a significant proportion of cases, and in some series is a more frequent cause of injury than accidents.

Management and Treatment of Cerebral Palsy

In the therapy of CP attention is directed at assisting the child to achieve his maximum intellectual and physical potential, using specialized techniques for specific defects. Physical therapy, bracing, and at times orthopedic surgery are indicated if the potential for functioning warrants it. Drugs such as diazepam may sometimes be effective in reducing tension and in limiting other problems connected with nerve damage. Physical, speech, and hearing therapy by skilled professionals are important features of any program in preparing the cerebral palsied child for success in school and in life.

Physical therapy and educational management vary with the child's age, the type and severity of involvement, the presence or absence of seizures, and the level of intellectual capacity.

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The recent focus on the whole child and his family, including social and educational factors, has helped family adjustment and the child's education and future occupation.

Collaborative Perinatal Project

By far the largest portion of the Institute's research on cerebral palsy is centered in the Collaborative Perinatal Project. The Project began in 1959 as a prospective, multidisciplinary, long-term investigation of 55,000 pregnancies from birth through early childhood. Scientists in 12 participating hospitals observed these children, and recorded data about them to determine if it is possible to discover clues to the causes of neurological disorders of early life, including cerebral palsy, and then to develop strategies for prevention and intervention.

The data collection phase of the Project was completed in 1974, and the information collected is now undergoing analysis and interpretation. To provide a framework for this effort, a Comprehensive Plan for Analysis and Interpretation of Collaborative Perinatal Project Data was established and is being implemented. Work now underway in the Collaborative Perinatal Project of the National Institute of Neurological and Communicative Disorders and Stroke (NCPP) is directed toward an understanding of the maternal, obstetric, social and neonatal conditions antecedent to cerebral palsy, in an effort to understand the interwoven factors involved in the causation of this handicapping childhood disability. The aim is to identify areas in which preventive efforts could most effectively be concentrated.

Analyses in the NCPP have also concerned the prevalence of cerebral palsy, as already mentioned, and its natural history, the nature and frequency of associated handicaps, and the identification of risk factors in the pregnant mother and newborn child which are predictors of cerebral palsy.

The double disability of cerebral palsy and severe mental retardation was investigated, and four groups of neonatal factors were found to be especially important as antecedents: (1) small size at birth, (2) difficulty in initiating and maintaining independent breathing, (3) anemia in the infant, and (4) neonatal seizures. While preterm low birthweight babies are over represented in the group of children with cerebral palsy and mental retardation, an important fact is that 70% of these severely handicapped children were of full term weight and gestational age.

Neurological findings at one year have been evaluated in comparison with subsequent cerebral palsy diagnosis at age seven, suggesting that children with early mild cerebral palsy often lose their motor deficits by school age, but remain at heightened risk for intellectual subnormality.

Analyses in four areas dealing with major abnormalities of pregnancy with special relevance to cerebral palsy are in progress or completed. These are toxemia, maternal infection during pregnancy, neonatal hyperbilirubinemia, and anesthesia analgesia given the mother during labor and delivery. So far, these analyses have produced positive correlations between adverse pregnancy outcome and large maternal weight losses (more than one pound per week) but not excessive weight gain, and valuable information on the epidemiology of virus infections in relation to abnormal pregnancy outcome through the use of immunologic techniques.

Viral Research

Damage to the developing nervous system which can result in cerebral palsy is being studied by NINCDS scientists at its laboratories in Bethesda, Maryland, and Institute grantees at medical centers throughout the country.

NINCDS investigators are using experimental animals, tissue culture techniques, and histopathological studies to complement the strict serological approach being used on mother's sera obtained during pregnancy as part of the Collaborative Perinatal Project.

Other researchers have recently found that several viruses of human origin or viral vaccines produced for humans cause anomalies in rhesus monkey fetuses. Investigators at The Johns Hopkins University are studying many model infections and describing the evolving disease process.

Cytomegalovirus (CMV) infection may be only a mild disorder for the mother but a serious threat to the fetus and infant. This agent has also been called "salivary gland virus" because it is often detected in the salivary glands. Principal findings of congenital infection with CMV are spasticity, cerebral calcification, seizures, and retardation.

In a study supported by the United Cerebral Palsy Research and Educational Foundation, Inc. (UCP), a researcher at Harvard University is seeking more information about CMV to see if a safe and effective vaccine might be developed against it. This scientist, a Nobel Laureate, has played a leading role in basic research which led to the development of the polio vaccine and the rubella vaccine. At The Johns Hopkins University, another grantee of the UCP, is also conducting tests with specific vaccines against known or suspected causes of cerebral palsy. Epidemiological studies of perinatal infection, including one conducted by an NINCDS scientist, have shown that about one per cent of all infants are born infected with CMV. The NINCDS Collaborative Perinatal Project, with its large number of patients, is especially useful in providing the necessary data for this type of investigation.

Anoxia Research

The major responsibility for research on anoxia, considered by many researchers to be the single most important cause of brain damage culminating in cerebral palsy, resides in the NINCDS Laboratory of Perinatal Physiology. Many years ago this laboratory established the rhesus monkey model which has been widely utilized to show what can happen when oxygen transport from mother to fetus is totally cut off or interrupted at different intervals.

Partial deprivation of oxygen from any cause may be the primary event which sets in motion a vicious cycle of brain edema (swelling) which cuts off blood circulation and causes brain tissue to die. These events can occur in the absence of fetal circulatory collapse or of fetal head compression, two factors previously felt to be necessary for brain injury. The role of brain swelling and of circulatory and metabolic factors have been investigated.

These findings are clinically important because they offer the possibility of intervention which could prevent or lessen brain damage.

One of the researchers who participated in these experimental studies has been setting up a clinical research program on cerebral palsy at Emory University, Atlanta, where he will observe in human infants the problems related to decrease of oxygen near the time of birth which he saw produced experimentally in the rhesus monkey, and is investigating the usefulness of medical interventions in the early hours of life.

Other Research

The NINCDS supports a large program project at Children's Hospital Center in Boston. Among their other studies, investigators are studying the development of evoked potentials and analytic techniques for detection of early sensory deficits and the development and application of biofeedback techniques which might be effective in reducing seizures and hyperkinesis.

The use of biofeedback is also being explored at Emory University where another grantee of the NINCDS is systematically evaluating its efficacy in overcoming spasticity and related neuromuscular effects of cerebral palsy patients. In previous research, he demonstrated the value of biofeedback in increasing control over voluntary movement in children with athetoid cerebral palsy.

The NINCDS supports investigation into the damage to nerve cells by lack of oxygen and other factors, and studies of the manner in which the form and function of nerve cells are altered by such injuries. The ability of nerve cells to redirect their growth in response to injury of their normal input, and thus possibly to minimize the functional disability following damage, is under study in two centers.

Progress in Prevention of Cerebral Palsy

There is no cure for cerebral palsy, but considerable knowledge is now in hand to assist in preventing cerebral palsy due to birth injury. Through research conducted, supported, and stimulated by this and other Institutes of the NIH, by the United Cerebral Palsy Research and Educational Foundation, Inc., and by the American Academy for Cerebral Palsy, efforts are being made to develop other preventive measures.

It has been estimated by the United Cerebral Palsy Associations, Inc., that the vaccine to immunize against German measles has prevented 25,000 to 30,000 children from being born with the rubella syndrome this year.

Improved perinatal care with better management of problems in respiration and early nutrition, and progress in eliminating neonatal jaundice and kernicterus through the use of Rh immunoglobulin for the prevention or sensitization to the Rh factor have contributed to a lessening of the toll of cerebral palsy. Other important preventive measures have been the early identification of high risk fetuses and newborns so that appropriate intervention or intensive services can be instituted promptly.

Coordination of Government Research on Cerebral Palsy

Just as no single professional can provide all that is needed for children with cerebral palsy, no one component of Government can respond to such a mandate. Consequently, responsibilities for research and service to children with cerebral palsy cross both departmental and agency lines and require cooperation and coordination at many levels.

Recent developments along these lines include the establishment of the Interagency Panel on Early Childhood Research and Development to facilitate Federal interagency coordination in planning, funding, and analyzing early childhood research and development, including those related to cerebral palsy. The NINCDS is a member of this Panel.

The Institute is also represented on the NIH Coordinating Committee on Low Birth Weight. As noted, low birth weight is one of the factors

associated with brain damage resulting in cerebral palsy. Late this year, the National Institute of Child Health and Human Development opened a Special Care Nursery in its Perinatal Center at the NIH Clinical Center. Among the problems being studied there is low birth weight. It is anticipated that clinical research findings from this research will develop new information with special relevance for cerebral palsy.

Additionally, the Director of the NINCDS is an ex officio member of the National Advisory Council of Services and Facilities for the Developmentally Disabled. The Council studies and evaluates programs authorized by the Developmentally Disabled Assistance and Bill of Rights Act (P.L. 94-103) to determine their effectiveness.

The NINCDS also has a long history of cooperation with the United Cerebral Palsy Associations, Inc., and the National Easter Seal Society for Crippled Children and Adults, two voluntary health agencies working in the area of cerebral palsy, and with the American Academy for Cerebral Palsy, the professional society in the field. Cooperative efforts with these organizations include research but also extend to informing and educating both the lay and medical publics about cerebral palsy through publications, workshops, conferences, and symposia.

OFFICE OF HUMAN DEVELOPMENT SERVICES

Developmental Disabilities

CEREBRAL PALSY

Under the Developmental Disabilities Services and Facilities Construction Act, as amended, cerebral palsy is one of the four primary disabilities covered by this Act. Because of the nature of cerebral palsy, it often is combined with one or more of the other three disabilities--mental retardation, epilepsy, or autism--in the individual with cerebral palsy. This multiple handicapped condition prevents the identification of specific monies which may be expended solely for cerebral palsy.

A multi-disciplinary approach is required to meet the lifetime condition and wide array of services needed. An individualized plan is adapted with the principals of normalization which look upon each person as having different abilities, interests, values, and needs, and that each person is capable of development, growth, and learning. The principle emphasis of the Developmental Disabilities Program is, however, on planning for services rather than providing direct services. The service delivery system associated with this program is oriented toward the provision of grant funds to a grantee who, in turn, provides direct care services to a population specified in the approved grant application. The Developmental Disabilities Program funds services through basic State formula grants, protection and advocacy grants, project grants awarded according to priorities established by the State councils within the annual State plan, and support of university affiliated facilities.

Under the State Grants Activity, a State submits an annual comprehensive plan on serving the developmentally disabled and after approval of this plan, receives grant funds based on a formula distribution. These funds may be used to support evaluation; diagnosis; personal care; education; treatment; information and referral; follow-along; recreation; counseling; sheltered employment; training; special living arrangements; day care; transportation; socio-legal; and domiciliary care. Included in the State plan is the estimated prevalence rate of cerebral palsied individuals who may be reached through direct or indirect services afforded in the plan.

Under the Special Projects Activity, discretionary grants are awarded for the purposes of providing technical assistance; training; demonstrations of established programs which hold promise of improving services; elimination of attitudinal and environmental barriers through public awareness and public education programs; coordination of available community resources; demonstrations of services to be provided to the developmentally disabled who are economically disadvantaged; improving techniques in the development of services; improvement of the quality of such services; and gathering and disseminating information.

A grant was awarded to Creative Growth which is a community-based, nonprofit program dedicated to the idea that all people, no matter how severely handicapped can gain strength, enjoyment and fulfillment through creative self-expression in the visual arts. Counseling, communication and independent living skills are integrated into the program. Currently 85 developmentally disabled persons are served weekly. One such person is Samuel, a quadriplegic with cerebral palsy and unable to communicate verbally. He has worked persistently on a large painted wooden sculpture for one year. He is able to do some sanding with a special block that can slip onto his foot with leather bands. He also saws, while in his wheelchair, by using a bolted down miter saw. The joy he receives from his work is contagious to all around him.

Another grant to United Cerebral Palsy of Delaware is for a prevocational training program designed to aid the vocational rehabilitation counselor in determining employment feasibility of their clients. A supportive program is designed to positively reinforce the clients' abilities, as well as to provide learning experiences in areas of need. Five basic areas are emphasized: educational, personal, social goals, realistic vocational goals, and work sampling. Progress is noted on a daily basis, and areas of specific need are slowly worked through until the client feels confident and shows gains in the area. The ultimate goal of the program is reaching the level of referral into employment, whether sheltered or competitive.

One grant, a project of national significance, will have a great impact for the cerebral palsied because of their affected muscular control causing involuntary and uncontrolled movements or a disturbed sense of balance and depth perception. This project is the Fire Safety Evaluation System for the Developmentally Disabled in Residential Facilities. A survey of data on residential facilities throughout the United States is being conducted which includes the general type of building, number of occupants, and general category of developmentally disabled involved. Research is being conducted in the following areas: decision analysis; behavior in fire emergencies; alarm and communication systems; smoke control systems; fire and smoke detectors; and automatic extinguishment.

The University Affiliated Facilities Activity concerns grants for core support for administering and operating demonstration facilities and interdisciplinary training programs for persons who render specialized services to persons with developmental disabilities. Client services available as a benefit from these training programs include identification and assessment; treatment; educational services; counseling; and family support services.

OFFICE OF HUMAN DEVELOPMENT SERVICES

Rehabilitation Services Administration

CEREBRAL PALSY

The Rehabilitation Act of 1973 requires that the vocational rehabilitation program give priority in the provision of services to people who have the most severe physical or mental handicaps. Rehabilitation of the individual with cerebral palsy will be a priority activity, not only because of the severity of the disability itself, but also because of the broad range of handicapping conditions it presents. In virtually every case, a multidisciplinary approach is essential to the development of an appropriate rehabilitation program for individuals with cerebral palsy. In an effort to expand and intensify rehabilitation services for this disability category, the Rehabilitation Services Administration has utilized several of its grant programs, and some examples of these grant activities are cited below.

A project was supported to operate a special rehabilitation program for severely disabled college students, including those with cerebral palsy, attending the University of California at Berkeley. The grant assisted with the costs of living in a residential unit staffed with professionals to provide the services necessary to maintain the students' health at an optimum level while they were in college. This project was so successful in meeting the needs of these severely disabled students that its activity has now been taken over by the California Department of Rehabilitation as part of its operating program.

In recent years the Rehabilitation Services Administration has supported short-term training courses in such areas as: (1) vocational rehabilitation methods for professional staff of local affiliates of the United Cerebral Palsy Association; (2) rehabilitation counseling techniques with the cerebral palsied client for the State rehabilitation agency counselors; and (3) executive development for administrators of cerebral palsy programs.

Special Projects for the Severely Handicapped are authorized by Section 304(b)(1) of the Rehabilitation Act to expand or improve rehabilitation services for groups of people with severe impairments. In FY 78, it is planned to support one or two projects devoted to cerebral palsy under this grant authority.

Rehabilitation Research

In addition to 3 Rehabilitation Research and Training Centers in Mental Retardation (University of Wisconsin RT Center, University of Oregon RT Center, and the Texas Tech RT Center), six Medical Rehabilitation Research and Training Centers are engaged in studies on cerebral palsy. These research projects deal with the measurement of life success in terms of survival, and educational, vocational and marital achievement in CP, self-care in CP, muscle spasticity in CP, and the medical and allied health services needed by the Developmentally Disabled, including the cerebral palsied. In addition, the George Washington University RT Center has involved clients with severe disability due to cerebral palsy in research projects dealing with the development of modern vocational objectives for the severely disabled homebound.

Neurological research is a priority area for RSA support. Neurological research is considered to cover central nervous system and neuromuscular disorders including cerebral palsy, multiple sclerosis and muscular dystrophy. In previous years neurological research was unfocused. Since the resolution of neurological disorder provlems through rehabilitation will greatly contribute to the understanding of many other difficulties experienced by the severely disabled, RSA's current R & D strategy is to synthesize our efforts and give this problem area further attention.

Number of People Rehabilitated:

Fiscal Year	All Rehabilitants	Person Rehabilitated With Cerebral Palsy
1975	324,039	2,033
1976	303,328	1,861
1977	291,202 1/	1,660 1/
1978	283,000 1/	1,600 1/
1979	277,000 1/	1,600 1/

1/ Estimated

CYSTIC FIBROSIS

Obligations for Programs in Cystic Fibrosis

	1975	1976	1977	1978 estimate	1979 estimate
National Institutes of Health:					
National Institute of Arthritis, Metabolism, & Digestive Diseases	$2,680,000	$2,153,000	$2,285,000	$2,300,000	$2,305,000
National Heart, Lung and Blood Institute	not available	not available	$1,738,000	$2,000,000	$2,000,000
National Institute of Allergy and Infectious Diseases	$ 932,000	$1,026,000	$1,150,000	$1,250,000	$1,375,000
National Institute of Child Health and Human Development	not available	$ 68,000	$ 70,000	$ 70,000	$ 80,000
National Institute of Dental Research	$ 100,000	$ 100,000	$ 100,000	$ 100,000	$ 100,000
National Institute of General Medical Sciences	$ 35,000	$ 35,000	$ 35,000	$ 35,000	$ 35,000
Division of Research Resources	$ 198,000	$ 197,000	$ 203,000	$ 214,000	$ 214,000
TOTAL	$3,945,000	$3,579,000	$5,581,000	$5,969,000	$6,109,000

CYSTIC FIBROSIS

Affecting one infant in every 1,600 live births, cystic fibrosis (CF) is the most common lethal genetic disease among Caucasians. At present, there are approximately 20,000-30,000 children and young adults afflicted with CF. Moreover, estimates indicate that there are now 10,000,000 asymptomatic genetic carriers of the disease, persons who carry the potential of having offspring who are affected.

Cystic fibrosis is characterized by the abnormal production of thick, sticky mucus by the exocrine (outward secreting) glands, particularly those in the respiratory and digestive systems. This unusually viscid mucus obstructs the breathing passages, creating a breeding ground for bacteria which leads to chronic, pulmonary infections -- the cause of 90% of all deaths from CF. Because thick mucus also blocks the passageways carrying vital enzymes from the pancreas to the intestine, where they are needed for the digestive process, CF patients suffer from impaired digestion and malabsorption of food. Although the clinical signs of the disorder involve the exocrine glands, current research suggests that a fundamental metabolic defect may be present in all of the body's cells.

Because CF also affects the sweat glands, the sweat salt levels of these patients is three-to-five times higher than normal. This characteristic of high levels of salt in sweat is used as a procedure for diagnosing symptomatic patients, but there is no specific method yet available to identify reliably the asymptomatic carrier of the CF trait. The development of such a test is of paramount importance in that with each pregnancy, children born to two asymptomatic carriers have a one-in-four chance of inheriting the disease, and a one-in-two chance of being a carrier themselves.

An inherited metabolic disease which claims the lives of most victims in childhood and adolescence, cystic fibrosis now costs the nation over $200 million annually in treatment alone.

NATIONAL INSTITUTES OF HEALTH

National Institute of Arthritis, Metabolism, and Digestive Diseases

Investigations conducted and supported by the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) are aimed specifically at defining the precise cause and physiologic effects of the disease, at determining the biochemical aberrations associated with CF, and at developing improved methods of prompt diagnosis, more effective treatment, recognition of carriers, and eventual prevention of the disorder. The research approach to cystic fibrosis is two-pronged: in addition to investigations carried out at its laboratories and clinics in Bethesda, Maryland, the NIAMDD supports through its extramural grant programs many CF study projects at medical centers and research institutions across the country. This combined effort has opened up promising new avenues which will hopefully lead to pre-

cise definition of the molecular defect in this metabolic disorder, thus establishing the necessary groundwork for development of improved therapeutic and preventive approaches.

Pediatric Metabolism Branch, NIAMDD

The Pediatric Metabolism Branch, the Institute's focal point for cystic fibrosis research, has been headed by Dr. Paul A. di Sant'Agnese since 1959. A research specialist in diseases of childhood, Dr. di Sant'Agnese is regarded both in the United States and abroad as one of the most eminent clinical investigators in CF. His discovery that children with cystic fibrosis excrete excessive amounts of salt in their perspiration resulted in the development of the "sweat test" which is now widely used in the diagnosis of CF. Since joining the NIAMDD, Dr. di Sant'Agnese and his collaborators have made significant contributions to the present understanding of the pathogenesis of this disorder.

In addition to the development of new knowledge, the Pediatric Metabolism Branch has evolved into a unique training environment where numerous clinical investigators and research fellows have been introduced to the exciting research challenges associated with cystic fibrosis. These individuals are among the cadre of young, innovative investigators and clinicians throughout the country who are bringing new ideas and techniques to CF research.

RESEARCH ACCOMPLISHMENTS

Animal Model for CF

The ultimate goal of any biomedical research program is to develop knowledge that will subsequently lead to the cure, or even more desirably, to the prevention of disease. To this end, NIAMDD supports a number of programs that are attempting to identify the basic cause of CF. Progress in this area of research has been hampered, however, by lack of an appropriate animal model that can be used to help unravel the complex cystic fibrosis research problems.

Recently, a significant advance in this area has been achieved at the University of Missouri in Columbia. NIAMDD grantee Dr. J.R. Martinez and associates have developed an experimental rat animal model which produces a series of exocrine gland abnormalities resembling those characteristic of CF. This model will permit more extensive investigation of the exocrine system in an effort to pinpoint the basic cause of the disorder.

Ciliary Inhibitory Factor in CF

Numerous investigators have been attempting to identify unique molecules that may be the gene product responsible for the clinical manifestation associated with CF. Research by grantee Dr. Barbara H. Bowman and associates at the University of Texas Medical Branch at Galveston isolated a factor found in the serum of CF patients that inhibits ciliary action in such biological systems as oyster gills and the rabbit trachea. Subsequent research demonstrated that cul-

tured skin cells from CF patients also produced a similar ciliary inhibitory factor. These investigators have shown that this factor is a positively charged protein. Present research activities of Dr. Bowman and her associates are now aimed at purifying this factor and preparing an antibody against it. Once quantitative immunoassay methods become available, it may be possible to use this technique as a simple, reliable diagnostic test for CF, and for detection of CF trait carriers.

Enzymatic Assay for Detection of a CF Factor

In related research, NIAMDD grantee Dr. G.M. Harrison and associates at Baylor College of Medicine in Houston have reported a rapid, quantitative and readily available assay for detection of a CF factor. In addition, they have developed a purification procedure for the factor from saliva. As a result, this procedure has provided sufficient quantities of the purified protein to allow extensive investigation of its physical and chemical characteristics.

These studies have helped to explain many of the anomalies reported in the literature about the activity and stability of the various CF factors. The information resulting from such investigations will assist scientists in maintaining conditions under which the factor is active, and in evaluating the validity of comparative studies using various assay methods. The purification procedure has also allowed its developers to begin chemical studies on the purified factor to identify it structurally.

Enzyme Deficiency in CF

Research by Institute grantee Dr. H.L. Nadler and associates has yielded the first evidence of a specific enzyme deficiency associated with cystic fibrosis. In studies at Children's Memorial Hospital in Chicago, the investigators noted that levels of protein "CF factors" are elevated in CF patients due to a deficiency of the enzyme arginine esterase which ordinarily hydrolyzes (splits chemically) and inactivates such factors in normal tissues. The findings are the first to suggest that this enzyme deficiency in the plasma and saliva of these patients is related to the elevated levels of the CF protein factors.

Abnormal Fucose Metabolism in CF

An NIAMDD grantee at Children's Hospital in Philadelphia is exploring the hypothesis that the pathology of cystic fibrosis is expressed as an alteration in the surface membrane of organs affected by the disease. Dr. M.C. Glick and associates have demonstrated an abnormal fucose metabolism (fucose is a sugar found as a chief constituent of mucus) in skin cells and serum of CF patients. Although there is no evidence as yet that the abnormal fucose metabolism is directly related to the disorder's primary genetic defect, the investigators continue to correlate it with the structural and functional changes in CF, specifically, with the alterations in the normal production of mucus.

Young Adults with Cystic Fibrosis

Approximately 15 years ago, few children with cystic fibrosis lived beyond the age of five or six. Today, as the result of improved diagnostic procedures and the increased use of antibiotics to control the chronic pulmonary infection associated with cystic fibrosis, more than 50 percent of the patients can be expected to live past 18 years of age.

Although the clinical syndrome in adults with cystic fibrosis is basically similar to that of children, there are important differences in the two age groups in the relative incidence of certain complications. NIAMDD intramural scientists, Drs. Paul di Sant'Agnese and Pamela Davis, are continuing to describe and evaluate these clinical differences between the two patient populations. Information resulting from these studies suggests that CF should be considered in the diagnosis of young adults with chronic bronchitis, infertility, chronic pulmonary disease, unexplained cirrhosis or other CF-related factors to assure prompt initiation of correct treatment.

Assisted Ventilation in CF Patients

The use of assisted ventilation in the treatment of CF has been a subject of controversy among physicians caring for the severely ill patient.

Drs. Davis and di Sant'Agnese have recently reported on the results of a study assessing the use of assisted ventilation in the treatment of cystic fibrosis patients. Results of an analysis of 51 episodes of assisted ventilation in 46 patients demonstrated satisfactory results in only three episodes of three patients. The remaining patients died either while on the respirator or within a short time after assisted ventilation treatment. The results demonstrate that assisted ventilation is of little value in the treatment of CF.

NIH Supports Cystic Fibrosis Foundation Study

The continuing commitment of the National Institutes of Health to CF research is reflected in the recent award of a contract to the Cystic Fibrosis Foundation for a one-year state-of-the-art analysis to determine critical needs in future research.

Co-supported by the NIAMDD and the National Heart, Lung and Blood Institute (NHLBI) the study is assessing current levels of basic, clinical and epidemiological knowledge and research, clinical care, and quality of life considerations to identify gaps in our knowledge and the ordering of new, logical research priorities.

The study's implications for health are broad: eventual results of the evaluation can benefit not only cystic fibrosis patients, but also victims of related pediatric pulmonary diseases such as asthma, bronchiectasis and bronchitis, gastrointestinal disorders, and a variety

of genetic syndromes. Research directions identified by the project will contribute to expediting the search for better methods of CF management, prevention and cure. Eventually the finished report will be presented by the NIH to the Congress which has indicated enhanced interest in CF.

NIH Cystic Fibrosis Coordinating Committee

Programmatic responsibility for extramural cystic fibrosis research has traditionally resided in the National Institute of Arthritis, Metabolism, and Digestive Diseases. Because of the multidisciplinary nature of the disease, however, support and management of CF-related investigative efforts have come to be shared among several of the Institutes and Divisions of the NIH. Prominent among these are the NHLBI because of the important clinical aspects of lung disease in CF, and the National Institute of Allergy and Infectious Diseases, because of the chronic infectious aspects of these pulmonary complications which are the ultimate cause of death in most CF patients.

To facilitate coordination of these research activities, the Director of the National Institutes of Health has established a CF Coordinating Committee staffed by representatives from the various NIH components involved in the support of cystic fibrosis-related research activities. The Committee will coordinate the overall course of investigations in order to avoid needless duplication of effort and to facilitate recognition of specific research requirements in this field.

CF Perspectives: Past and Present

The historical evaluation of the NIAMDD cystic fibrosis program can best be described by outlining some of the numerous contributions that have been made by Institute-supported grantees over the years toward understanding the etiology, pathology and treatment of CF. In terms of the treatment of the disease, the NIAMDD supported the program that first introduced physiotherapy in the U.S. as a standard clinical procedure for treatment of the pulmonary alterations associated with the disease. The use of localized clapping and vibrations coupled with controlled patient breathing exercises has now become an important component of cystic fibrosis therapy.

Largely through NIAMDD support, investigators also demonstrated that broad spectrum antibiotics have a useful place in the management of pulmonary infections in cystic fibrosis. Improved therapeutic regimens for the treatment of the gastrointestinal and nutritional complications of the disease have been developed as a result of NIAMDD grant support. The increased life expectancy of the CF patient has been attributed to the introduction of these methods to treat the pulmonary aspects of the disorder and to prevention of chronic malnutrition consequent to the intestinal malabsorption defect in CF. These contributions have gone far toward improving not only the span of life but also the quality of life for the CF patient.

In addition to these categorical CF programs, the NIAMDD is funding numerous other projects that, while not directly aimed at cystic fibrosis, should give insights into the understanding of this and other metabolic abnormalities. These programs include basic metabolism, cell morphology, physiology and biochemistry. Similarly, through training and research career development awards, the NIAMDD has supported specialized training of many investigators who are now actively involved in cystic fibrosis research.

NHLBI Research in Cystic Fibrosis

The National Heart, Lung, and Blood Institute supports research on cystic fibrosis as part of a broadly based program directed against pediatric pulmonary diseases.

Cystic fibrosis is characterized by excessive production of abnormal mucus, a factor also associated with a number of other lung disorders. Thus areas of NHLBI research interest include 1) the secretion of mucus, 2) the clearance of mucus and entrapped foreign particles and toxic substances by the action of ciliated cells lining the lung airways, and 3) the chemistry of respiratory tract mucus in health and various disease states, including cystic fibrosis.

Recently, improved techniques for collecting tracheal mucus for physiochemical analysis, measuring the rate of mucus clearance, and measuring ion and water movement in airway tissues have been developed in laboratory animals to the point where some of these may be clinically applicable in man. They may help provide new insights into the role of airway secretions in CF and other lung diseases and on the effects of environmental factors and lung disease processes on mucus secretion and transport.

The search also continues for a biochemical or genetic marker that might identify individuals who are heterozygous carriers of the gene for CF. Such a marker might also make possible the prenatal diagnosis of CF by amniocentesis when the risk is great that the unborn infant may be afflicted.

A factor that inhibits the ciliary action of airway cells (and so impedes mucus clearance) has been found in CF patients. It has also been obtained in cultures of cells from parents of CF patients. The parents were heterozygous for the genetic determinants of CF. Some progress is being made toward isolating and characterizing this substance, called ciliary inhibitory factor. This work may permit classification of its role (if any) in CF and assessment of its potential in the identification of carriers or in early diagnosis of the disorder.

NIAID Research in Cystic Fibrosis

Patients with cystic fibrosis are particularly susceptible to life-threatening respiratory infections. Through an extensive research program in infectious diseases, the National Institute of Allergy and Infectious Diseases (NIAID) supports studies aimed at preventing and controlling some of the major respiratory infections that affect the lives of CF patients.

In recent years, the antibiotic bacterium, Pseudomonas aeruginosa, has emerged as the predominant cause of serious respiratory infections in CF patients. A majority of these people develop chronic pseudomonas infection that is virtually impossible to eliminate with available antibiotics. As with other microbes, the development and spread of drug resistance seems to be partly due to so-called R factors, which can be passed from strain to strain and species to species.

How these factors are spread is the subject of investigation by an NIAID grantee at the University of California at Berkeley. Dr. Alvin Clark and his co-workers are interested in the molecular and biochemical basis for the spread of multiple antibiotic resistance among bacteria. They are working on the hypothesis that the genes for R factors -- carried on extrachromosomal genetic packets, known as plasmids -- are transferred by a type of genetic swapping called conjugation. After conjugation, these transferred plasmids are then inherited by other bacteria through another genetic swapping known as recombination. Understanding the basis for these processes may lead to the eventual control of the spread of antibiotic resistance among strains and species of bacteria.

The search for effective drugs against the Pseudomonas is another area of research supported by the NIAID. Dr. Graham C. Windridge at the Virginia Commonwealth University is developing synthetic analogs of polymyxins -- a class of antibiotics produced by certain soil bacteria -- for use in systemic pseudomonas infections and in infections caused by other gram-negative bacteria. In previous studies, immunosuppressed patients with gram-negative infections appeared to respond well to polymyxins. These drugs may eventually benefit CF patients with pseudomonas and other gram-negative infections.

The NIAID is supporting several projects focusing on the prevention of pseudomonas infections through passive and active immunization. Dr. Pinghui Liu, an NIAID grantee at the University of Louisville, is analyzing the role of toxic substances produced by the pseudomonas in the organism's ability to cause disease. Dr. Liu has produced and purified large quantities of one particularly lethal substance -- exotoxin A -- and is attempting to produce a toxoid that will provide active immunity to it. The production of antitoxins is also being pursued by Dr. Liu as another method of providing passive immunity to the toxic effects of the bacteria.

Developing and testing a vaccine for several gram-negative bacteria, including Pseudomonas aeruginosa, is the work of Dr. William McCabe at the Boston City Hospital. Most vaccines are effective against only one microorganism or strain, but Dr. McCabe is looking at the possibility of immunizing against a number of gram-negative bacteria by using vaccines containing antigens shared by these bacteria. A preparation containing one such shared antigen (Re) has been produced by the Boston scientist and has been found to be safe and effective in rabbits. Human testing is expected to begin upon completion of the animal studies.

An NIAID intramural scientist -- Dr. Robert Aduan, Laboratory of Clinical Investigation -- has developed an experimental animal model for studying pseudomonas respiratory infections. Dogs treated with cytoxan -- an immunosuppressive drug -- have been found to mimic immunosuppressed patients, who are the ones most likely to develop pseudomonas infections. Studies are under way to evaluate the effect of various antibody preparations on the survival of these animals after exposure to lethal doses of the pseudomonas organism.

Several years ago, another intramural scientist, Dr. Charles Zierdt, collaborating with other scientists, reported that CF patients are infected with only one mucoid strain of P. aeruginosa, which is unique to them. These scientists have been attempting to convert other, non-mucoid strains of the bacteria to the mucoid variety using body fluids (sputum, urine) from CF patients. To date, these attempts have proven unsuccessful, but the investigators are hopeful, that with success, they will have a better understanding of how the mucoid strain is produced.

In addition to the pseudomonas studies, the NIAID supports research on the development and testing of vaccines for other respiratory infections that affect CF patients. For instance, NIAID-supported scientists played a key role in the development of the first effective vaccine against pneumococcal pneumonia. The vaccine was recently licensed by the FDA, and is effective in at least 80% of the people who receive it. Vaccines against the influenza virus, respiratory syncytial virus and parainfluenza viruses are in various stages of development and evaluation.

NICHD Research in Cystic Fibrosis

The National Institute of Child Health and Human Development (NICHD) conducts and supports research into both normal and abnormal development of the individual from the moment of fertilization through maturation. Much of the research supported by the Institute that is relevant to cystic fibrosis is in the program area of human developmental genetics. This program includes basic biological as well as therapeutic, clinical, and family studies for the identification of specific deficiencies responsible for genetic diseases and disability.

Current NICHD-funded research is centered on the development of diagnostic testing for detection of cystic fibrosis. One group of investigators has developed a method for differentiating the diseased person, the trait carrier, and normal individuals through detection of protein markers, using isoelectric focusing. Further study is needed to assure reproducibility of these methods and the uniqueness of these factors to individuals with CF before applicability of this test for screening purposes is determined. Evidence also exists for an abnormality in a serum protein known as alpha$_2$-macroglobulin in this disease. Some investigators believe this may be the basic defect in CF since alpha$_2$-macroglobulins bind proteases, and free proteases could account for the various organs damaged in cystic fibrosis patients.

Two other factors have been found in sera of patients with CF using two different bioassays: a) a ciliary inhibitor and b) a ciliary dyskinesis factor. It is not yet known, however, whether these factors are the same. The latter factor is also found in asthmatics, and NICHD-funded investigators have recently determined, using column chromatographic techniques, that the ciliary dyskinesis factor of asthma is different from that in patients with cystic fibrosis. These factors are produced by leukocytes, and tests are now under way as a first step toward application as an antenatal screening method to see whether the factors are synthesized by cells from CF patients.

NIDR Research in Cystic Fibrosis

Changes in the composition of saliva and the resultant drop in flow rate also can be used to diagnose cystic fibrosis when results of sweat tests are equivocal. Dr. Irwin D. Mandel, a grantee of the National Institute of Dental Research, and associates at Columbia University in New York City recently reported that in CF, saliva from the minor salivary glands inside the lip has elevated levels of calcium and protein. The thick viscous material in the patients' saliva apparently restricts the salivary flow and actually can close the tiny glands. In three minutes time, investigators can measure flow rate employing one of several techniques -- the most recent one uses a standard strip of filter paper and a meter originally developed by dental scientists to measure the fluid from the gingival cuff around the crowns of teeth. This simple test can clarify the diagnosis of CF.

The Columbia University team previously reported that in CF, saliva from the submaxillary gland, which has its opening at the floor of the mouth, has increased levels of calcium phosphate and protein. In contrast, only minor changes are found in saliva from the parotid glands, the glands on the sides of the jaw that are affected by mumps.

A test developed for the study of saliva is helping to diagnose pancreatic insufficiency in patients with cystic fibrosis of the pancreas. Developed by Dr. Robert O. Wolf of the National Institute of Dental Research, the test is made on blood instead of duodenal fluid. It is easier to obtain blood samples than duodenal fluid, which is retrieved by inserting a tube through the nose or mouth until it reaches the intestine.

By separating out the pancreatic and the salivary amylase in blood, Dr. Wolf can identify CF patients with pancreatic insufficiency. Such patients have lower levels of pancreatic enzyme. The previously-tried measure of total amylase did not contribute to the diagnosis of pancreatic involvement because the level of salivary amylase in serum does not differ significantly, Dr. Wolf reported.

Exceptions to the new findings occurred in three of seventeen patients with CF and normal pancreatic enzyme function; two years ago they had higher than normal amylase values. The investigators believed then that the three patients were in an early stage of progressive pancreatic involvement during which tissues were being disrupted and increased amylase was being released. Subsequent tests now under way appear to support their hypothesis.

NIGMS Research in Cystic Fibrosis

The National Institute of General Medical Sciences (NIGMS) supports research and research training in the basic medical sciences. Since the basic defect in cystic fibrosis is not understood, numerous programs supported by the NIGMS are developing information that will in all likelihood have some bearing on our understanding of the disease.

In addition to the support of basic research, NIGMS funds projects that are directly related to cystic fibrosis. Of particular significance is the contribution of one group of investigators supported by the Institute's Pharmacology-Toxicology Program. Dr. Milo Gibaldi and associates at the New York State University, Buffalo, have conducted a series of studies attempting to increase the understanding of antibiotic disposition in adolescent patients with CF.

In related research, a human mutant cell repository has been established by the NIGMS Genetics Program at the Institute for Medical Research in Camden, New Jersey, to maintain, in culture, a bank of human cells representing a variety of genetic diseases. The Human Cell Line Repository accepts, stores, and distributes, for basic and clinical studies, human fibroblast and lymphoid cell cultures representing biochemical disorders and chromosome abnormalities. Currently, there are 19 cell lines obtained from CF patients and members of their families in this resource facility.

DRR Research in Cystic Fibrosis

The Division of Research Resources, through the General Clinical Research Centers Program, provides institutional clinical research resources for investigators in widely scattered geographic locations. The primary goal of the program is to establish a research resource for use in the clinical investigation of human health problems in order to increase the total body of knowledge of the etiology, progression, prevention, control and cure of human disease.

With respect to cystic fibrosis, the General Clinical Research Centers provide the clinical resources for independently funded patient-oriented investigations. Nine projects now active at seven different GCRCs deal with the control of infection in the lungs of CF patients, methods of improving their nutrition, and drug therapy for malabsorption.

Outlook

Although the outlook for CF patients has improved over the years, the basic defect of this inherited disease is still not known. The problem is further complicated by the fact that although a reliable test is available for the diagnosis of symptomatic patients, no specific method has yet been devised which will pinpoint the asymptomatic carrier of the trait.

Faced with these research challenges, investigators are exploring the basic biochemistry of exocrine glandular secretions, the secretory process, and the roles of polyamines in the abnormal mucus secretions in CF. Research into the sweat electrolyte defect, antibiotic therapy for chronic pulmonary disease, as well as diagnostic tests for CF and for detection of carriers is also under way at universities and medical centers across the country through NIAMDD support.

While the findings of previous years have contributed significantly to the expanding knowledge base of cystic fibrosis, it is hoped that these extending avenues of research will lead to the final solution to the CF puzzle.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

REPORT ON DAY CARE

A REPORT TO THE

HOUSE COMMITTEE ON APPROPRIATIONS

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Federal Funds Expended for Day Care
(Dollars in thousands)

	1977 Actual	1978 Estimate	1979 Estimate
OFFICE OF HUMAN DEVELOPMENT SERVICES:			
Administration for Public Services:			
Social Services	$528,980	$564,568	$580,350
Research and Evaluation	93	100	150
Subtotal, APS	529,073	564,668	580,500
Work Incentives Program	44,500	45,600	45,600
Subtotal, WIN	44,500	45,600	45,600
Administration for Children, Youth and Families:			
Child Welfare Services	2,961	2,961	2,961
Head Start	475,000	625,000	680,000
Research and Demonstration	2,165	2,500	3,700
Subtotal, ACYF	480,126	630,461	686,661
Subtotal, OHD	1,053,699	1,240,729	1,312,761
OFFICE OF EDUCATION:			
Vocational Home Economics	1/	1/	1/
Education for the Handicapped	555	555	300
Subtotal, Education	555	555	300
TOTAL	1,054,254	1,241,284	1,303,061

1/ Estimates are not available on the portion of this program's budget supporting day care.

Report on Day Care

(Fiscal Year 1979)

The Department of Health, Education, and Welfare funds several programs which provide day care services to children of working mothers. These include day care services under the Work Incentive Program (WIN), Social Services Programs, and the Child Welfare programs, all administered by Human Development Services. In addition Head Start, administered by the Administration for Children, Youth and Families in the Office of Human Development Services, provides care during the day for many children from low-income families. Day care benefits of the Head Start program are ancillary to the major purpose of Head Start, which is the provision of comprehensive developmental services (educational, nutrition, health, social and psychological) to children and their families. The Vocational Home Economics program in the Office of Education also provides day care to many pre-school as an outgrowth of its main purpose.

The Department of Health, Education, and Welfare also supports research and demonstration efforts to develop knowledge and strategies to assure that DHEW and other day care resources will be most effectively utilized to provide quality day care services meeting the needs of children, families and communities.

HUMAN DEVELOPMENT SERVICES

Federal Funds Expended for Day Care
(Dollars in thousands)

	1977	1978 Estimate	1979 Estimate
		(in thousands)	
Work Incentives Program	$ 44,500	45,600	45,600
Administration for Public Services:			
Social Services	528,980	564,568	580,350
Research and Evaluation	93	100	150
Subtotal, APS	529,073	564,668	580,500
Administration for Children, Youth and Families:			
Child Welfare Services	2,961	2,961	2,961
Head Start	475,000	625,000	680,000
Research and Demonstration	2,165	2,500	3,700
Subtotal, ACYF	480,126	630,461	686,661
Total, Human Development Services	1,053,699	1,240,729	1,312,761

HUMAN DEVELOPMENT SERVICES

WIN Child Care

The Work Incentive Program, authorized under Title IV of the Social Security Act, is a State-administered program designed to encourage and assist recipients of Aid to Families with Dependent Children (AFDC) to achieve self support through a program of training, work experience, employment, child care, and other supportive services. The 1971 Amendments to the Social Security Act authorized child care and other supportive services to be provided to all WIN registrants who need such care and services to enable them to accept work or training. State expenditures are matched by Federal payments at the rate of 90%.

Child care services include full-time and part-time care for children of WIN participants. Child care may be provided in their own home, in family day care homes, or in day care centers. Of the child care provided, about two-thirds is full-time and one-third part-time. Child care for children in their own homes accounts for about 48% of the total, while 33% receive care in family day care homes and 19% are cared for in day care centers.

	1977 Actual	1978 Estimate	1979 Estimate
Federal funds.....	44,500,000	45,600,000	45,600,000
Average number of children receiving child care.....	84,650	86,000	86,000
Average monthly number of children.....	114,600	116,000	116,000
Number of new registrants.....	1,100,000	1,100,000	1,100,000

Administration for Public Services

Day Care Services

The Administration for Public Services has responsibility for administering the social services program authorized under Titles I, IV-A, X, XIV, XVI, and XX of the Social Security Act as amended. Except for Guam, Puerto Rico, and the Virgin Islands, Title XX superseded the services under all of the above cited authorizing Titles.

Under Title XX, grants are made to States for Services to eligible individuals based on income or public assistance status. States may choose the services they will provide, as long as each service is directed to at least one of the five goals stated in the Act.

Within the broad spectrum of services provided under the above Titles are day care services to children and adults. Services may be provided in the individual's own home or outside the home, including care in family day care homes, group day care homes, and day care centers.

Child care services furnished must be suited to the age, special handicaps or other conditions of individuals children and selected with the participation of the mother (or other responsible relative) insofar as possible.

State licensing laws and standards must be enforced to assure that child care facilities used by the agency are licensed or approved as meeting the standards of the licensing authority. All out-of-home care must comply with the Federal Interagency Day Care Requirements.* Prior to April 1, 1978, the Department is scheduled to submit a report to Congress on the appropriateness of these requirements.

In F.Y. 1979, it is estimated that States will use $580,350,000 in Federal funds through the Social Services program for day care.

* P.L. 95-171 suspended some staffing ratios required for children aged 6 months to 6 years in group day care homes and care centers through September 20, 1978. Family day care homes need not count school age children of the provider.

(Dollars in thousands)

	1977 Actual	1978 Estimate	1979 Estimate
Social Services	$528,980	$564,568	$580,350

Administration for Public Services

Research and Evaluation

Day Care

The 1978/1979 Research and Evaluation program includes a project to (a) develop models for delivery of after school day care for children 6-15 years of age; (b) develop standards for State regulations that are appropriate for ages to be served; and (c) assess size and nature of problems surrounding school-age day care. This will include determining the state-of-the-art of school age day care as well as the current and projected needs for the service

1977 Actual	1978 Estimate	1979 Estimate
$93	$100	$150

OFFICE OF HUMAN DEVELOPMENT SERVICES

Administration for Children, Youth and Families

Day Care

The Administration for Children, Youth and Families (ACYF), located within the Office of Human Development Services serves as an advisor to the Secretary, the Assistant Secretary for Human Development Services, and other Federal agencies on matters pertaining to the care and development of children.

Child development program efforts aim at improving child care delivery systems and designing programs to improve the quality of life for children and their families throughout the Nation. Major activities are focused on meeting the developmental needs of pre-school-age children from low-income families and on improving services to particular populations of vulnerable children such as the abused and neglected, children in foster care, children in need of adoptive homes, and children in institutions. A variety of research and demonstration activities are also conducted. They are designed to improve the quality of children's programs, such as day care and emergency services, and to measure their impact on the children and families served. The three major child development programs are Head Start, Child Welfare, Research and Demonstration, and the Child Abuse and Neglect Prevention and Treatment Program.

Administration for Children, Youth and Families

Day Care Services

Title IV of the Social Security Act (Child Welfare Services State Grant Program) provides funds to match State money for a variety of social services to children and their families including day care services. There is no income test for eligibility for these services except as set by States.

Based on data supplied by the States, it is estimated that $2,961,000 of Federal funds will be used for day care services in FY 1979.

(Dollars in thousands)

	FY 1977	FY 1978	FY 1979
Child Welfare Services day care.....	2,961	2,961	2,961

Head Start
(Dollars in thousands)

	FY 1977	FY 1978	FY 1979
Head Start Total	$475,000	$625,000	$680,000

Head Start is a comprehensive preschool program which serves children and their families, primarily those who are poor. It encompasses a wide range of development activities including education, medical, dental, nutritional, social and other services with particular emphasis on parent involvement. Head Start funds full-year and summer programs. The full-year programs provide service either on a full-day or part-day basis. A variety of training and technical assistance activities are provided to local program staff to enhance the quality and effectiveness of the services offered. Head Start also conducts experimental programs such as the Child and Family Resource Program which provides family-oriented child development services according to the assessed needs of individual children, and Developmental Continuity, a program to facilitate continuity of educational and social gains made in preschool programs into elementary school.

In FY 1977 Head Start assured that 10 percent of the enrollment opportunity in each State are available to handicapped children. This is in accordance with the legislative mandate contained in P.L. 93-644. Prior to FY 1976 Head Start had implemented a policy of making 10 percent of the enrollment opportunities nationwide available to handicapped children. Head Start now services handicapped preschool children in an integrated setting with the non-handicapped and has established service delivery linkages with State and local agencies concerned with handicapped children.

The Head Start Policy Manual states that the appropriate duration of an educational or enrichment program for pre-school children is no more than six hours per day. Beyond this period, it is desirable for a child to "return to his own family unless there is no suitable caregiver in the home due to employment, illness or other reasons." Only in such cases may the basic Head Start program be supplemented to provide full day care for the child.

Low-income children and families, like other segments of the community, differ greatly in their need for child care and developmental services. Ideally, Head Start programs should be tailored to the special and diverse needs of each individual community and child, with particular emphasis placed on serving those with the greatest need. Thus, size permitting, each Head Start program should provide a balanced program of remedial and developmental services that reflects the full array of needs in the community.

Research and Demonstration
(Dollars in thousands)

	FY 77	1978 Estimate	1979 Estimate
Research and Demonstration (Day Care)	$2,165	$2,500	$3,700

The aims of ACYF's day care activities are to develop knowledge and strategies to assist in the effective utilization of Federal, state, local and private resources and in contributing input for major legislation designed to improve the quality and availability of national day care.

The overall goal for ACYF in Day Care is to improve the quality and availability of day care services nationwide. The ACYF approach to achievement of day care-related goals and objectives emphasizes a multi-faceted, multi-year effort, involving (1) basic and applied research in areas of relevance for day care policy; (2) development and validation of program models and service delivery systems which incorporate research findings; (3) evaluation of demonstration model operations and impacts; (4) translation of research and development findings into training and technical assistance programs for intermediate target groups at State and local levels; and (5) dissemination of knowledge throughout the day care community.

All of the current efforts contribute toward the overall goal of achieving a better understanding of the needs fo the children who are in Day Care as a basis for providing quality Day Care, taking into account a variety of factors including costs. The results of several of the projects initiated during FY 1975 and 1976, including the day care center and home cost-effective studies, will provide data essential for activities having a direct impact on this goal.

The National Day Care Center Study is being conducted in 64 day care centers in Atlanta, Seattle and Detroit. Approximately 2,400 pre-school children and their parents are being examined. This project is a three-year, three-phased effort designed to examine in depth, three major cost-related policy issues in day care--caregiver/child ratio, group size and the level of caregiver professionalism-- and to systematically examine variations of different levels of these variables to determine what relationship exists when measured against classroom process, child outcome variables and costs. Sound research and corresponding cost information generated on these major provisions contained in the Federal Interagency Day Care Requirements (FIDCR) should have significant impact on the fiscal level of Federal involvement in day care and should be helpful in setting levels of program input quality for Federal Interagency Day Care Standards. Thus enhancing HEW's responsiveness to Congressional report requirements under Title XX. The Study also should provide a firm basis for resolving the important national, state and local issues relating to "professionalizing" the pre-school caregiver occupation.

This research effort is also examining the significance of other center-based program variables and therefore should assist policy planners and practitioners at the local, state and national levels in the design and formulation of operational guidelines for day care. The Study has already been cited in several Congressional hearings on the appropriateness of FIDCR as being a major contributor to the overall FIDCR assessment.

The National Day Care Home Study is a two-year, two-phase effort to characterize family and group day care homes in urban settings. Phase I, has provided profiles of family day care in major family day care markets throughout the United States. Phase II constitutes an intensive investigation of family and group day care program processes, costs and outcomes with particular regard for variables of demonstrated Federal policy significance. This phase was funded in FY 1977 upon completion of Phase I.

Although much general information is available in the field of day care, a need exists for more specific usable information designed to aid the providers of day care at the Federal, State and local level in their efforts to deliver quality day care at reasonable cost levels.

In this regard, there is a need for more specific information about the benefits that children and parents derive from various day care programs and services as related to the cost of providing such programs and services. Information of this type is particularly important because policy makers at all levels of government as well as practitioners need this type of information to develop the best possible day care programs for the children at the lower possible cost to the consumer. Little careful research has been performed on the relationship between major cost variables in day care, such as the ratio of center staff to children and the level of professionalism of a center staff, to benefits derived by children in a day care center.

Another need exists in the area of parent perceptions of what they consider to be important to their children in day care. Little reliable information exists to describe current usage patterns and different consumer preference patterns among various groups using day care, the actual and perceived barriers to the use of different kinds of day care, and the trade-offs parents would make between various levels of service and costs and between different types of arrangements and localities.

In addition, ACYF has funded the first phase of a Day Care Supply study which will develop a supply model based on nationwide center level programs, staff and cost characteristics which can be used to simulate on a state-by-state basis, the impact of changes in FIDCR-type regulations on the availability and fee structure of public subsidies. It will also assess the impact of changes in local economic conditions on the supply of day care. Data will also be used to generalize the findings of the National Day Care Center Cost-Effects Study from the three target sites to the major day care market in the United States.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Federal Funds Expended for Day Care
(Dollars in thousands)

	1976	1977	1978	1979
OFFICE OF EDUCATION:				
Vocational Education	1/	1/	1/	1/
Education for the Handicapped	705	555	555	300
Total, Office of Education	705	555	555	300

1/ Estimates are not available on the portion of this program's budget supporting day care.

Office of Education

Vocational Education

The Vocational Education Act of 1963, Part F, Consumer and Homemaking Education, provides grants to States for educational programs which prepare youths and adults for homemaking and wage earner roles. An ancillary function of the Act and a general objective of vocational home economics education is the training of personnel to operate child care/day care development centers. This training represents one component of comprehensive child care development programs. The day care courses are furnished in home economics in-school laboratories and centers which perform the dual role of training potential child care/day care workers and providing a conductive atmosphere for the growth and development of preschool children. Programs are developed on the local and State level with national technical support. Coursework may include training in child care and development occupations, infant, toddler and school age care, child nutrition, program planning, working with parents, foster family care, administration and supervision.

Since day care personnel training is part of comprehensive child care training programs which vary in scope according to locality, a breakdown of obligations specifically for day care courses is not feasible.

Enrollment in child care programs has increased from 8,453 students in fiscal year 1967 to over 200,000 in fiscal year 1975. These figures represent enrollment in all child care development programs of which day care training is one component. Each fiscal year since 1972, approximately 374,000 preschoolers have received either direct of incidental day care services through vocational home economics child care programs. In addition, many children between 6 and 14 years of age have also received some type of service offered by these programs.

In addition, under the Vocational Education Amendments of 1976, States are allowed to provide day care services for children of students in secondary and postsecondary vocational education programs under the State grant program. Fiscal year 1978 will be the first year that such services are supported.

Education for the Handicapped

The Handicapped Children's Early Education Program, Part C, supports demonstration preschool projects which are designed to stimulate the development of comprehensive educational services for handicapped children from birth through age 8 and their families. Programs funded to organizations such as universities, school districts, and mental health centers cooperate with day care centers and programs but the day care services provided are often incidental to the specialized education provided. Other projects involve funding day care centers directly.

The projects which are funded to other agencies work with day care centers in a vareity of ways, including focusing on mainstreaming or integration of handicapped youngsters with their normal peers, providing inservice training, and encouraging inter-agency coordination both on an individual child basis and at the programmatic level. In many cases, the day care centers represent the least restrictive environment for many handicapped pre-schoolers and is thus the most beneficial placement for them.

Each of the day care centers funded directly have developed into exemplary programs that are being continued by their parent agencies and used as models by others. Their activities include identification, referral , and diagnostics services; direct services to handicapped preschoolers and their parents; curriculum design; coordination with other agencies; program evaluation; and supplementary services. Current federal funding is being used entirely for outreach efforts for most of the projects.

The following projects are examples of the day care center projects now focusing on outreach:

The Saginaw, Michigan Child Development Center was funded to develop a demonstration day care program to serve emotionally and mentally handicapped children so they could be assimilated into the public school system. In fiscal year 1976, $115,000 was utilized to expand the pilot program. In fiscal year 1977, the funding estimate was $115,000. In fiscal year 1978, the funding will be $48,000.

Alpha Plus Corporation DBA Circle Preschool, Piedmont, California was funded to demonstrate the preparation of speech impaired emotionally disturbed children (aged 3-5) for successful enrollment in regular and primary-grade classrooms by teaching them necessary survival skills in language and socialization. From fiscal year 1973 through fiscal year 1975, 51 children participated, 278 were screened and 140 teachers were trained. Since then direct day care activities have been assumed by the local agency and federal funding has concentrated on outreach.

Mile High Child Care Association - Denver, Colorado was funded to develop a demonstration model for training day care personnel to identify developmentally delayed and emotionally disturbed preschool children and to program for them within the regular day care setting.

DIABETES

Obligations

	1975	1976	1977	1978 estimate	1979 estimate
National Institutes of Health:					
National Institute of Arthritis, Metabolism, & Digestive Diseases	$19,108,000	$19,273,000	$41,546,000	$ 59,306,000	$ 60,890,000
National Cancer Institute	$ 219,000	$ 250,000	$ 270,000	$ 270,000	$ 270,000
National Eye Institute	$ 4,763,000	$ 5,246,000	$ 9,449,000	$ 11,517,000	$ 11,800,000
National Heart, Lung and Blood Institute	$ 5,588,000	$ 7,070,000	$11,160,000	$ 12,700,000	$ 12,750,000
National Institute of Neurological and Communicative Disorders and Stroke	$ 782,000	$ 331,000	$ 1,849,000	$ 2,667,000	$ 2,680,000
National Institute of Dental Research	$ 451,000	$ 400,000	$ 728,000	$ 728,000	$ 728,000
National Institute of General Medical Sciences	$ 730,000	$ 775,000	$ 1,000,000	$ 1,300,000	$ 1,300,000
National Institute of Child Health and Human Development	$ 1,476,000	$ 2,230,000	$ 5,354,000	$ 5,962,000	$ 5,978,000
National Institute on Aging	$ 177,000	$ 490,000	$ 563,000	$ 612,000	$ 627,000
National Institute of Allergy and Infectious Diseases	$ 0	$ 463,000	$ 2,035,000	$ 2,335,000	$ 2,390,000
Division of Research Resources	$ 5,733,000	$ 6,075,000	$ 8,002,000	$ 8,587,000	$ 8,587,000
TOTAL, NIH	$39,027,000	$42,603,000	$81,956,000	$105,984,000	$108,000,000
Center for Disease Control:	$ ---	$ ---	$ 1,500,000	$ 1,500,000	$ 1,500,000
TOTAL, PHS	$39,027,000	$42,603,000	$83,456,000	$107,484,000	$109,500,000

NATIONAL INSTITUTES OF HEALTH

DIABETES

Diabetes -- also known as diabetes mellitus or sugar diabetes -- is a very common disease state the principal metabolic derangement of which is the inability properly to convert nutrients into the energy necessary for normal activity. Normally, the sugars and starches (carbohydrates) in the food we eat are processed by digestive juices into a simple sugar called glucose which circulates in the blood. This glucose or blood sugar is the major fuel which provides energy sources for normal body functions. Insulin, a hormone produced by the pancreas, is the major regulator of the utilization of glucose. When the right amount of insulin is present at the right time and place, the right amount of glucose is either metabolized or stored for future use in the form of glycogen and fat (triglyceride).

In the diabetic individual, there is an impairment of insulin activity. Either the body doesn't produce enough insulin, or the available insulin is somehow prevented from influencing its target tissues and cells, and thus insulin is prevented from performing its primary function. Because of this impairment, glucose is not properly utilized by the body and excessive glucose accumulates in the blood and tissues and overflows into the urine. Too much glucose in the blood and glucose in the urine are signs of diabetes. The inability of insulin to perform its normal function also results in an impaired ability of the body to utilize fats and proteins normally; abnormalities of fat and protein metabolism are characteristic of diabetes.

Diabetes is also characterized by the development of degenerative lesions -- the so-called long-term complications -- which involve virtually every tissue of the body, and in particular the blood vessels, the nervous system, kidneys and eyes. How these chronic complications are related to the abnormalities of glucose, protein and fat metabolism and insulin remains to be determined with certainty.

The National Commission on Diabetes in its report to Congress in 1976 estimated that 10 million Americans are or will be affected by diabetes and that the incidence of this disease in the population is increasing. Diabetes is the fifth leading cause of death by disease in the nation even without considering mortality due to its various complications; about 35,000 Americans die each year with diabetes and in several times that number of victims diabetes is a contributing factor to heart attacks, stroke, kidney failure, vascular (blood vessel) disease, and blindness. In patients with juvenile diabetes, it is now the leading cause of blindness and abbreviated life expectancy.

The direct and indirect impact of diabetes on the nation's economy is currently estimated at more than $5 billion per year -- even without considering the costs of serious and impairing complications.

The National Diabetes Mellitus Research and Education Act of 1974 established the National Diabetes Commission, which submitted its long-range plan to combat diabetes to the Congress the following year. In October 1976, the Congress enacted comprehensive legislation for the purpose of implementing this Diabetes Plan. The legislation included provisions for substantially increased funding for diabetes research in FY 1977, more than doubling the FY 1976 effort, and it authorized creation of a series of new and highly specialized multi-purpose centers for research, training, and education in diabetes. Moreover, the Congress established a National Diabetes Advisory Board for the purpose of reviewing and evaluating implementation of the Diabetes Plan. The National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD), together with other NIH Institutes and Federal agencies have begun to implement this Plan.

Current diabetes research is a very extensive, broad-spectrum effort which includes, among others, emphasis on the: 1) etiology, pathogenesis and epidemiology of diabetes; 2) synthesis, secretion and action of hormones with special emphasis on insulin, glucagon, somatostatin and the gastrointestinal hormones; 3) use of recombinant DNA techniques to produce insulin; 4) complications of diabetes; 5) improved diagnosis and monitoring of the diabetic state through such potential tools as genetic markers, capillary basement membrane thickening, altered platelet function, fibrinolysis and glycosylated hemoglobin levels; and 6) development and refinement of new methods of treatment of diabetes and its complications through pharmacology, pancreatic transplantation, the development of an artificial device to sense the concentration of glucose in, and deliver insulin into, the blood, and photocoagulation of damaged retinal blood vessels.

NATIONAL INSTITUTES OF HEALTH

National Institute of Arthritis, Metabolism, and Digestive Diseases

Diabetes Research and Training Centers

In October 1976 the NIAMDD announced its intention to establish a number of Diabetes Research and Training Centers (DRTCs) in order "to increase the scope and tempo of Federally-supported research and training activities" in diabetes mellitus. This is one of several new programs initiated by the Institute in its effort to implement the long-range plan to combat diabetes, as recommended by the National Commission on Diabetes.

One year later, in October 1977, the Institute announced the award of nearly $5 1/2 million in grants to establish five such Centers. The new awards were made in accordance with the National Diabetes Mellitus Research and Education Act and the recommendations of the National Diabetes Commission.

The institutions awarded initial grants are the University of Chicago School of Medicine, the University of Indiana Medical Center in Indianapolis, the Washington University School of Medicine in St. Louis, Mo., the University of Michigan School of Medicine in Ann Arbor, and the Albert Einstein College of Medicine, Bronx, New York.

Each Center will conduct research in the diagnosis and treatment of diabetes mellitus and related endocrine and metabolic disorders, and will also conduct training and information programs for physicians and allied health personnel who provide primary care for patients.

It is anticipated that establishment of a number of additional DRTCs will be announced by the Institute periodically, as applications from eligible institutions are received, evaluated and approved.

Diabetes Information, Education and Data

Enactment of the National Diabetes Mellitus Research and Education Act also has resulted in the creation of the National Diabetes Information and Education Clearinghouse, and the National Diabetes Data Group. The former is designed to be an effective and efficient national center for housing and disseminating the most current diabetes information and educational materials. These materials are oriented toward the health professionals engaged in basic diabetes research, the general public, and, particularly, the diabetic patient and his or her family.

The National Diabetes Data Group has been established to foster the collection, analysis, and dissemination of data on diabetes that will impact on both the scientific and public health policy issues of this disease. Drawing on the expertise of the research, medical, and lay communities, the Data Group will identify and define the key problems that diabetes imposes on the United States and will develop sources of information that can address these issues. Since much of the data will be collected by other Federal diabetes programs, a close collaboration has been established between the Data Group and the pertinent Institutes of the NIH, the Center for Disease Control, and the National Center for Health Statistics. This collaboration will result in development of a common plan among these agencies and integration of Federal resources for collecting data. Of great importance, to complement ongoing basic and clinical research, will be development of epidemiologic studies on diabetes, and the Diabetes Data Group has contacted the epidemiologic and biostatistical community to interest them in diabetes research. In addition, a compilation of some of the most recent data on diabetes is being prepared, and this document will be distributed to pertinent lay, scientific, and governmental audiences.

National Diabetes Advisory Board

The National Diabetes Advisory Board was established by the October 1976 Amendments to the Arthritis, Diabetes, and Digestive Diseases Act (Public Law 94-562). In March 1977 the Secretary of Health, Education, and Welfare announced the appointment of the members of the newly created Advisory Board.

In addition to 12 public members, the Board includes the Assistant Secretary for Health, DHEW; the Director of the NIH; the directors of various NIH Institutes and other Federal agencies involved in diabetes research; and the Associate Director for Diabetes, Endocrinology, and Metabolism, of the NIAMDD, the NIH Institute with primary responsibility for diabetes research programs.

The Board makes recommendations to the Secretary, DHEW, and to other Federal officials on Federal programs in diabetes with particular reference to the Long-Range Plan to Combat Diabetes. It also evaluates programs in diabetes treatment, education, and training, and will submit an annual report on its findings.

Etiology of Diabetes

Evidence is rapidly accumulating that a variety of factors, both hereditary and environmental, may be involved in the etiology and pathogenesis of diabetes. Genetic, immunological, infectious and nutritional factors have been implicated.

Recent basic, clinical and epidemiological studies by NIAMDD-supported and other researchers strongly suggest that non-genetic environmental factors contribute to the development of juvenile diabetes in genetically susceptible individuals. For example, there is evidence that juvenile diabetes may be triggered by a common childhood viral infection. It has been proposed that during the course of naturally occurring infections, common human pathogenic viruses attack and, in genetically susceptible individuals, destroy the pancreatic beta cells (the cells which produce insulin). Damage to the beta cells may be sufficiently severe to produce metabolic abnormalities concomitant with, or immediately after, the infection, or expression of beta cell damage may be delayed. There is also evidence that sensitization of the host consequent to beta cell injury may also occur and that immunologically-mediated cytotoxicity might contribute to beta cell damage. It is possible that other environmental agents may play a role in the etiology and pathogenesis of diabetes.

The heritable host factors which determine and predict individual susceptibility to diabetes and to non-genetic environmental etiologic factors are the subject of intensive study. Significant advances in this area and in an understanding of the genetics of juvenile diabetes have resulted from studies of histocompatibility antigens in diabetes. The data available from the most recent research seem to indicate the presence of at least two diabetes-predisposing genes in the HLA region (HLA B-8 and BW-15), and there is evidence suggestive of the existence of a gene protective against the development of juvenile diabetes.

HLA B-8 and BW-15 are believed to predispose children with an inherited susceptibility to juvenile diabetes to an abnormally altered immune response. Thus, when they are subject to viral infections, their cell-mediated immunity systems go awry and attack and destroy their own insulin-producing pancreatic beta cells. Such an altered immune response, or autoimmune reaction, is also associated with other diseases such as multiple sclerosis, rheumatoid arthritis, and lupus erythematosus.

Children with HLA B-8 or BW-15 have a three to four times greater chance of developing juvenile diabetes than those without such genetic markers. Current studies are geared toward pinpointing the precise relationship between such markers and the virus that may trigger the altered immune response and, ultimately, juvenile diabetes.

Glucagon and Somatostatin

As noted in last year's special report on diabetes, many maturity-onset, non-insulin dependent diabetics demonstrated excessively high plasma levels of glucagon, the hormone produced by the alpha-cells of the pancreas, which is antagonistic to the action of insulin. It has been postulated that hyperglucagonemia, rather than (or in addition to) a deficiency of insulin action, is a primary contributor to the development of hyperglycemia in maturity-onset diabetes.

NIAMDD grantee Dr. Philip Felig of Yale University, New Haven, has now demonstrated that glucagon is not essential for the development and maintenance of hyperglycemia inasmuch as glucagon suppression does not reduce elevated blood glucose levels to normal.

Last year's special report on diabetes also indicated that administration of the newly discovered hypothalamic hormone, somatostatin, had been found to lower elevated plasma glucose levels in diabetic subjects by lowering abnormally elevated glucagon levels. Thus, it was suggested that somatostatin might prove to be a useful adjunct to insulin in the treatment of diabetes. Dr. Felig has, however, shown that prolonged infusion of somatostatin actually worsens the diabetic state in patients with maturity-onset diabetes. Somatostatin, under conditions of prolonged infusion in maturity-onset diabetics with residual insulin secretion accentuated hyperglycemia, hyperketonemia and hyperaminoacidemia. These observations suggest that somatostatin "therapy" is contraindicated in maturity-onset diabetic patients with residual insulin secretion. Dr. Felig suggests that because many patients with juvenile-onset diabetes also have some residual insulin secretion, the use of somatostatin might also be deleterious in these patients. Further studies will be required, however, to determine whether this is the case.

Complications of Diabetes

Most patients with diabetes are subject to a gradual onset of progressive changes in various organ systems, leading to the long-term complications of diabetes: gradual deterioration of the blood vessels of the kidneys, nervous system and eyes. Patients with juvenile diabetes are particularly susceptible to these chronic complications. While treatment of these complications has improved in recent years, finding the cause and methods for the prevention of complications are goals constantly being pursued.

For example, atherosclerosis, or "hardening of the arteries," resulting from arterial degeneration with local deposition of cholesterol, is a common and serious complication of diabetes, but little is known about cholesterol metabolism in diabetes. Thus, the NIAMDD's Drs. Lynn Bennion and Scott Grundy have studied several aspects of cholesterol metabolism in a homogeneous group of diabetic subjects, the Pima Indians, (notable for their unusually high incidence of diabetes) before and during treatment with insulin.

Before insulin treatment and during uncontrolled hyperglycemia, both plasma cholesterol and triglycerides ("neutral fats" in the blood) are significantly elevated, a setting which might contribute to acceleration of atherosclerosis. Insulin therapy appeared to reverse the increased fat levels. Such treatment, however, also appeared to enhance the risk of formation of cholesterol gallstones by reducing the concentration of bile acids and secondarily saturating gallbladder bile with cholesterol.

Cholesterol metabolism was investigated in six Pima Indians with poorly controlled maturity-onset diabetes under strict metabolic ward conditions. Both cholesterol balance and fasting plasma cholesterol were higher during uncontrolled hyperglycemia than during periods when blood sugar levels had been reduced to normal values by insulin administration. The same was true of plasma triglycerides, fecal bile acid excretion, and bile acid pool size. Insulin treatment reduced cholesterol levels 17% and triglycerides 40%.

Gallbladder bile was significantly more saturated with cholesterol (181% vs 114%) during insulin treatment than during uncontrolled hyperglycemia. Although improved blood sugar control reduces plasma lipid concentrations, and hence possible atherosclerotic damage to the arteries, it apparently enhances the risk of cholesterol gallstones.

Diabetic Ketoacidosis - In its severe "brittle" form, untreated "juvenile" diabetes readily progresses to a grave metabolic disorder, ketoacidosis, which may result in coma and death unless controlled by insulin administration and specific supportive therapy. For many years it was thought that high-dose insulin therapy was necessary to manage this complication of diabetes. Recent research has shown, however, that low-dose continuous insulin therapy may actually be more beneficial and less risky, but the efficacy and safety of this approach has also been questioned and the need for a prospective clinical trial has been emphasized.

NIAMDD grantee Dr. David Heber of Harbor General Hospital, Torrance, Calif., has prospectively compared patients with ketoacidosis treated either with insulin infusion at the rate of six units per hour, or with high-dose, intermittent subcutaneously administered insulin, by studying their hormonal responses. Supportive therapy was similar in both groups.

Low-dose insulin therapy appears to be as effective as conventional insulin therapy for diabetic ketoacidosis, while offering several advantages over conventional therapy. These include relative ease of insulin administration; a predictable, relatively linear rate of fall of glucose levels (not seen with conventional therapy), and the fact that low-dose therapy can be withdrawn abruptly in the event that hypoglycemia (undesirably low blood sugar levels) occurs.

Monitoring Blood Glucose Levels

Last year's special report on diabetes made brief mention of a new method of assessing long-term blood glucose regulation in the diabetic patient. The new test, as pioneered by Dr. Kenneth H. Gabbay, a NIAMDD grantee at Children's Hospital Medical Center, Boston, involves periodic measurement of several glucose-containing minor hemoglobin components in the red blood cells.

Several recent findings have indicated that good blood glucose control might prevent, delay, or ameliorate the long-term complications of diabetes, especially vascular disease. Unfortunately, currently used methods of assessing blood glucose levels measure such levels only at the moment the blood sample is drawn and are of limited use in determining general glucose levels over a period of time; thus, it has been extremely difficult to establish the nature of the relationship between the degree of blood glucose control and diabetic complications.

Dr. Gabbay's research has revealed that the glucose containing hemoglobin component levels are two-to-three times higher than normal in diabetic patients and that they correlate reasonably well with prior abnormally elevated blood glucose levels, and thus with diabetic control. Frequent testing for levels of these glycosylated hemoglobins may thus provide a better means of assessing the state of diabetic control than heretofore available, of determining the relationship between control of blood glucose and diabetic complications, and of evaluating the effectiveness of various therapeutic measures.

Dr. Gabbay's test is based on the fact that hemoglobin, when it is manufactured in the bone marrow, contains no glucose. As the red cells containing hemoglobin circulate during their normal 120-day life span, however, glucose molecules present in the blood attach themselves to certain hemoglobin molecules in a process called glycosylation. This process is irreversible and, in many cases, reflects the average glucose level over a period of time.

It was shown that about 7% of the hemoglobin is glycosylated in the normal, healthy person, with a range of 5% to 9%; in many diabetic patients, however, 14% of the hemoglobin is glycosylated, with a range of 10% to 20%. All three forms of glycosylated hemoglobin molecules (Al_a, Al_b, and Al_c) are elevated in the diabetic patient, but Al_c appears to be the most abundant and most reliable index of blood glucose concentration. When blood sugar levels of diabetic patients were carefully and optimally regulated, levels of glycosylated hemoglobin gradually reverted toward normal in 5 to 8 weeks time.

NIAMDD-supported investigators in several laboratories are continuing to refine this new methodology and to determine the extent of its usefulness in assessing long-term "diabetic control." Dr. Gabbay's group, employing its new test, has begun a 5-year study of 100 diabetic patients to determine the relationship of blood glucose control to development of diabetic small blood vessel disease. These scientists will also investigate the relationship of glucose control to such coronary disease risk factors as high cholesterol and high triglyceride levels, as well as high blood pressure.

Treatment Innovations

Transplantation of Insulin-Producing Cells

NIAMDD grantees Drs. Walter Ballinger and Paul Lacy of Washington University, St. Louis, demonstrated in 1972 that experimental diabetes in rats can be ameliorated by transplantation of pancreatic islets (clusters of specialized cells, among which are also the insulin-producing beta cells). Subsequently, they attained prolonged reversal of the diabetic state in these animals by injecting such islets into the portal vein (the major vein leading to the liver). They now have defined the histology and chronology of events, hitherto unknown, surrounding the establishment of pancreatic islet grafts within the liver.

Their study reaffirms previous reports that the portal vein site within the liver is an excellent locus for implantation of free pancreatic islets. The islet grafts develop a rich blood vessel supply or vascularization derived from both venous and arterial sources, and the islet cells maintain their structural and functional integrity after implantation. Evidence of an active ingrowth of nerves into the islet grafts has also been noted.

Implanted pancreatic islets were found widely dispersed throughout the liver and their hormone-producing cells were structurally normal. Insulin-producing beta cells in the islets responded initially to severe hyperglycemia by marked degranulation, or loss of intracellular granules, but regranulation occurred by the 14th day. Active vascularization of the grafts was apparent within 48-72 hours, and, by the 11th day, a dual vascular supply derived from both arterial and venous sources had developed. These findings tend to reinforce use of the portal vein site, which has become the principal site for investigating pancreatic islet implantation. The usefulness of other more readily accessible sites is, however, being investigated.

Transplantation of Whole Pancreas

Almost simultaneously, NIAMDD grantee Dr. Josiah Brown of UCLA has shown that a single fetal pancreas cultured in a normal adult rat can completely reverse the hyperglycemia and glucosuria (presence of sugar in the urine) of experimentally-induced diabetes when transplanted into a diabetic adult rat, suggesting that good blood sugar control in the first host may enhance the function of the grafted organ.

In previous studies Dr. Brown had shown that experimentally-induced diabetes in the adult rat can be completely reversed by transplantation into the animal of four or more fetal pancreases. Host animals received insulin injections for eight days to provide partial control of their diabetes during establishment of the fetal grafts. Transplantation of less than four fetal organs failed to reverse completely the diabetic state.

He now has shown that a single fetal pancreas graft can completely reverse the hyperglycemia and glucosuria of experimentally-induced diabetes in the adult rat if the fetal organ is cultured or grown in a normal adult rat of the same strain prior to transplanting it into the host animal. Results indicate that such a normal environment enhances the growth or function of the fetal pancreas' beta cells, and also suggest that good blood sugar control in the diabetic recipient following transplantation may be an important element in enhancing the growth and function of the transplanted fetal beta cells.

Hyperglycemia, glucosuria and weight loss were completely reversed by transplantation of either one or two fetal pancreases which had been cultured in a normal rat for 3 weeks. The culture period apparently is critical, inasmuch as organs cultured for 1 or 2 weeks had no significant effect, while those cultured for 4 or 5 weeks only partially reversed the diabetes. Organs which reversed diabetes contained 108 milliunits of insulin, while those which failed contained only 9 milliunits.

The findings may have relevance to human diabetes in that a single donor is desirable in allografts, which would minimize the major problem of histocompatibility (non-matching of tissue types when several different individuals are the sources of the grafted material) and thus the problems of immunologic tissue rejection. Other means of minimizing rejection are vigorously being investigated.

Diabetes-Related Research by the National Eye Institute

Diabetes is one of the main causes of visual loss and blindness in the United States today. It can damage sight in a number of ways, but usually it affects the retina of the eye, producing a variety of pathological changes collectively referred to as diabetic retinopathy. Less frequent but no less serious are a variety of other ocular complications of diabetes, including cataract, a form of glaucoma which is extremely difficult to treat, and optic nerve disease.

Although an estimated half of all diabetics undergo some changes in the retina which are visible upon ophthalmoscopic examination, most of these, fortunately, will not suffer major visual loss. However, at least 3 percent, or approximately 300,000 people, are threatened with blindness. The chances of an individual with diabetes suffering severe, handicapping loss of vision rise with age from 3 percent in those under age 30 at the time diabetes is diagnosed, to 32 percent in those over age 60. There are approximately 150,000 people in the United States who suffer significant visual impairment due to diabetic retinopathy of whom 22,000 are legally blind.

Although the underlying ways in which diabetes damages ocular tissues is unknown, and there are no means of preventing these changes from occurring, two important treatments for diabetic retinopathy have been developed within recent years which have made major contributions to the clinical management of this disorder. The first, photocoagulation, the use of finely focused beams of light to seal off and destroy hemorrhaging retinal vessels and diseased retinal tissue, was shown in a nationwide collaborative clinical trial supported by the National Eye Institute (NEI) to be of substantial benefit in reducing the risk of severe visual impairment from diabetic retinopathy. However, this treatment does not prevent diabetic changes from taking place, nor is it uniformly effective. The second technique, vitrectomy, in which vitreous humor which has become scarred and opaque as a result of massive hemorrhage within the eye is surgically removed, offers hope to people already blind from diabetic retinopathy. A second cooperative clinical trial is now underway to determine the optimal timing of this procedure and whether the overall visual result can be improved.

Both treatment and knowledge of this disease have been greatly enhanced by the development of fluorescein angiography, a safe and effective technique to photograph the flow of blood through the retina vessels, and by a now widely-used system for classifying different types and stages of retinopathy based on a standard set of retinal photographs.

Laboratory research is contributing to knowledge of how diabetes damages ocular tissues. Study of experimental sugar cataract in laboratory animals by Drs. J.H. Kinoshita of the NEI and S.D. Varma of the University of Maryland has led to the identification of a specific enzyme, aldose

reductase, which triggers the conversion of excess blood sugar into sugar alcohol in lens fibers. The accumulating alcohol, which cannot pass through cell membranes, creates an osmotic pressure which brings water into the lens, leading to swelling and, eventually, cataract formation. This important discovery has led to the development and testing of a series of compounds which inhibit aldose reductase and thereby actually slow down the development of sugar cataracts in laboratory animals. Several potent chemical inhibitors of the enzyme are now available which effectively delay the formation of experimental sugar cataracts.

The discovery of aldose reductase in other tissues, notably blood vessel walls and neural cells, has led to speculation that this enzyme may play a role in the more common complications of human diabetes, retinopathy and neuropathy. Drs. S.M. Buzney, R.N. Frank, and W.G. Robison of the National Eye Institute have developed the first tissue culture technique capable of sustaining retinal capillary cells. Using this technique, the NEI investigators, in association with Dr. Varma and Dr. T. Tanishima of the NEI and Dr. K.H. Gabbay of Children's Hospital Medical Center in Boston, found evidence of the presence of aldose reductase in certain cells of the retinal capillaries. Whether the enzyme is involved in the development of retinopathy will have to await further experimental documentation.

NEI grantee A. Patz and associates at Johns Hopkins Hospital studying the effect of tumor angiogenesis factor on retinal blood vessels have shown that this substance is capable of inducing new blood vessels to form on the optic nervehead. This finding is highly suggestive that an analogous substance may play a major role in inducing similar pathologic changes in diabetic retinopathy.

NEI-supported studies just getting under way include a new clinical trial to determine the optimum stage in the development of diabetic retinopathy in which to initiate photocoagulation (a question which was not addressed in the original trial); the effectiveness of this treatment on diabetic-related disease of the macula, the part of the retina responsible for sharp central vision; and whether regular use of aspirin systemically can prevent or retard the progression of diabetic retinopathy. Fundamental studies will be pursued which are focused on discovering the cause of diabetic retinopathy and the basic mechanisms underlying this disorder. Other studies will attempt to identify ocular and systemic risk factors associated with the progression of this disease.

The National Eye Institute will also continue to place emphasis on the translation of findings from fundamental studies to clinical research applications and the transfer of scientifically assessed knowledge from clinical trials to the hands of practitioners for the benefit of their patients.

Diabetes-Related Research by the National Institute of Child Health and Human Development

Diabetes Major Research Program Grants

In addition to its continuing support of research and training projects related to diabetes, several new Major Research Program (MRP) grants have been initiated by the National Institute of Child Health and Human Development (NICHD) in its efforts to implement a long-range plan to prevent complications in pregnancy due to diabetes and problems of infants born to diabetic mothers. These endeavors are in accord with recommendations of the National Commission on Diabetes.

In June 1976, the NICHD announced that it would establish a number of Major Research Program grants with emphasis on "Disordered Fetal Metabolism: Antenatal Intervention." Potential applicants were asked to submit letters of intent in order to determine if the proposal met the MRP definition, followed by personal interviews to assess the overall program interests of the applicants. Authors of attractive proposals were encouraged to submit full applications for evaluation of scientific merit by the Maternal and Child Health Research Committee and for determination of program relevance by the National Advisory Child Health and Human Development Council.

During the FY 1977, two MRPs were awarded. One of the MRPs is directed at investigating the problem of diabetes in pregnancy and its effect on the immediate and long-term outcome of the offspring and the mother. The scope of the program includes clinical studies of the mother during pregnancy, the events prior to, during and after delivery as they affect the infant, and then the long-term consequences for the infant and the mother. Metabolic, endocrine, psychological, genetic, and developmental aspects of the problem will be explored. The program involves collaborative efforts by the disciplines of internal medicine, obstetrics, genetics, pediatrics, anesthesiology, psychology, statistics, community health and preventive medicine, psychiatry, neurology, nursing, social work, ophthalmology, biochemistry, surgery, pharmacology and chemistry.

The second MRP is designed to develop tools which will permit the antenatal detection of abnormal fetal metabolism, identification of the mechanisms involved, and ultimately the prevention of aberrant development and brain damage by appropriate antenatal intervention. The proposal focuses on two high risk situations -- the infant born to a woman with diabetes mellitus and intrauterine growth retardation (IUGR). In each, the materno-fetal delivery of substrates is altered, the intrauterine environment is disturbed, fetal development and neonatal adaptation are disrupted, and the fetus or newborn infant is placed at risk. The investigators believe that antenatal intervention to improve fetal energy supply can restore a "normal" intrauterine environment and reduce risk. The investigators propose to develop methods for detecting aberrant maternal and fetal metabolism, to develop appropriate antenatal interventions for infants of diabetic mothers, and to develop a multifactorial statistical algorithm which will enable them to identify IUGR antenatally so that appropriate intervention measures can be taken as early as possible.

Research Grants in Diabetes

In December 1976, the NICHD issued a request for applications for new research grants (RFA) concerning "Diabetes in Pregnancy: Effects on Mothers and Offspring." Between December 20, 1976 and March 1, 1977, the staff of the Division of Research Grants assigned 23 grant applications in the area of diabetes to NICHD. Of these, 12 were in response to the RFA.

Diabetes and Fetal Development

Diabetes contributes to disorders of fetal metabolism that can contribute to death, malformation, morbidity or central nervous system damage. Continuing research in this area focuses on the development of tools permitting antenatal detection of abnormal fetal metabolism, the delineation of the mechanisms involved and the prevention of aberrant development and brain damage by appropriate antenatal intervention. Studies on newborn adaptation are being carried out to explore the factors influencing oxygen transport, gastrointestinal function and related mechanisms, and with particular reference to maternal diabetes.

Efforts in this area also include the investigation of fetal hormonal action as affected by diabetes. Studies on pulmonary surfactant regulation in the fetus and newborn, and studies on nutrition and hormone interaction in lung development will improve our understanding of the respiratory distress syndrome. Other studies include the examination of fetal carbohydrate metabolism and its relationship to organ blood flow. These investigations can provide a better understanding of how diabetes contributes to neonatal morbidity and mortality.

Diabetes in Pregnancy

Pregnancy in the already diabetic patient and gestational diabetes are two different problems. Diabetes in pregnancy must be considered either known prior to pregnancy or developing during pregnancy with remission after completion of pregnancy. Spontaneous abortion, toxemia, excessive amniotic fluid and lethal defects are more frequent during the second and third trimester in diabetic pregnancies than in non-diabetic pregnancies. The effects of diabetes on the fetus are increased risks in excessive fat accumulation, congenital defects and stillbirth, and on the delivered infant of prematurity, serious hypoglycemia, hyperbilirubinemia and respiratory distress syndrome. The increased frequency of diabetes during pregnancy and the associated perinatal mortality and neonatal morbidity indicate the importance of this area of investigation.

Investigations sponsored by NICHD continue to examine multiple interrelationships of numerous metabolic and clinical parameters, and correlate these parameters with subsequent events in both mother and fetus. Studies of the long-term events in the diabetic pregnant woman include research on development of retinopathy, changes in capillary basement membrane thickness and development of permanent glucose intolerance. Epidemiologic studies will be encouraged that

aim to collect and interpret longitudinal data on the health of diabetic women and their offspring in order to provide a better understanding of the pattern of normal and abnormal maternal metabolic patterns which are essential to improved clinical management of the chronically diabetic and gestationally diabetic woman.

Workshop on Early Detection of Potential Diabetes

In June 1977, NICHD sponsored a workshop to explore risk factors concerning insulin-dependent diabetes, to identify existing data resources on risk factors, to develop the best ways to identify infants or children at high risk for insulin-dependent or insulin-independent diabetes, and to develop possible modes of therapeutic intervention in those children identified as being at risk.

Diabetes-Related Research by the National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases (NIAID) has a special concern about the problems confronting diabetics. This interest stems from the fact that infections occur more frequently and in more serious forms in diabetics, as a group, than in the general population. In addition, many diabetics develop an allergic response to life-supporting doses of insulin.

Current NIAID projects dealing with diabetes include studies of these complications of the disease. The Institute is also sponsoring studies of the mechanism of hormone action as it relates to diabetes, and the assessment of the role of viruses in causing the disease. The immunologic aspects of the development of diabetes and complications in treatment due to autoimmune processes or allergic reactions are also of special interest to NIAID-supported scientists.

In addition, research at NIAID is directed at the role of genetic factors in diabetes mellitus. This includes identification of specific genetic markers which identify individuals who have predisposing genes for diabetes and the mechanism by which genes associated with these markers express themselves.

The Institute supports a large amount of applied and developmental research on organ transplantation, tissue matching, and reagent production and evaluation. It also supports basic research on the mechanisms of immune recognition and graft rejection. Obviously such research has potential of making significant contributions to pancreas or pancreatic islet transplantation. The funding data do not include support for this work which is currently less directly related to diabetes or a diabetes-associated problem.

An example of a major intramural project at NIAID concerning diabetes is a study in the Laboratory of Clinical Investigation (LCI) of the molecular and genetic basis for the immune response to insulin in man and experimental animals.

Looking at the T cell response of guinea pigs to insulin, NIAID scientists demonstrated that the Ir genes -- which appear to control the ability of animals to mount an immune response to a specific antigen -- operate, at least in part, at the level of the macrophage. Their research suggests that the macrophage plays a fundamental role in selecting the appropriate portion of a complex antigen (with more than one determinant) to be recognized by immune T cells -- thymus-derived lymphocytes. This information adds to the basic understanding of insulin allergy and has implications for treatment of diabetes.

Allergy to insulin is a major but poorly recognized complication of the management of insulin-requiring diabetes. During the past year, over 100 diabetics have been admitted to NIAID's clinical service at the National Institutes of Health for a detailed study of the character of their immune response to insulin. Results of this study have not yet been reported but the investigators are hopeful that their findings will make management of diabetes more effective.

Diabetes-Related Research by the National Institute of General Medical Sciences

Since the goal of the National Institute of General Medical Sciences (NIGMS) is to increase knowledge of fundamental mechanisms related to health and disease in general, without regard to specific disorders or syndromes, the NIGMS does not focus on diabetes research per se, as a directed effort. Rather, the Institute supports diabetes-related investigations that logically fall within, and often are a part of, larger studies in areas of particular concern to the Institute. Twenty-seven such studies were funded in Fiscal Year 1977, involving a total obligation of $1,024,000.

Genetics, one of the major biomedical program areas supported by NIGMS, holds a burgeoning promise for understanding diabetes -- not only in order to discern more clearly the hereditary components of the disease but also to fathom the basic mechanisms which control the cellular synthesis and secretion of insulin and other critical hormones. Scientists at the NIGMS-supported Albert Einstein College of Medicine Genetics Research Center, for example, have had some success in propagating, in culture, three cell lines from a tumor of the pancreas of a hamster, an insulinoma. The three lines differ in that one appears to secrete high levels of insulin, one, moderate levels, and one is incapable of insulin synthesis. An exciting new tool may thus be at hand to determine how insulin secretion is controlled. The investigators also are testing the effect of a variety of drugs on the cells, a project that has major direct implications for improving the treatment of diabetes.

The Einstein grantees also are studying genetic factors that influence the activity of several enzymes that have been reported to be abnormal in patients with diabetes. The investigators theorize that these enzymes may play a causative role in the damage to small blood vessels (microangiopathy) which frequently characterizes diabetes.

In another of the Institute's programs, Physiology and Biomedical Engineering, a grantee at the University of Wisconsin has developed an instrument to monitor continuously blood glucose levels of the hospitalized patient whose condition is in poor control. The instrument employs immobilized enzyme electrode technology and has an accuracy of 98 percent. In use, a small-gauge needle is inserted into a vein of the patient for serial analysis of the blood, at two-minute intervals. The determinations are recorded directly on a strip chart, providing to the attending physician a continuing guide for the administration and evaluation of therapy. A manufacturing firm is now making a number of prototypes of this instrument for clinical evaluation over the next year, after which commercial production and distribution of the instrument is anticipated.

Diabetes-Related Research by the National Institute of Dental Research

Scientists are gaining a better understanding of the accelerated breakdown of tooth-supporting periodontal structures common in diabetic patients. With support from the National Institute of Dental Research (NIDR), investigators have found that in diabetes changes take place both in the synthesis of collagen (the main structural protein of bone and connective tissue) and in the activity of collagenase (the enzyme responsible for collagen breakdown).

Dr. Lorne M. Golub of the State University of New York at Stony Brook has shown that collagen metabolism and activity of gingival collagenase are altered in rats with alloxan-induced diabetes. In the laboratory animals, one type of collagen, the alpha-1 chain, has a higher molecular weight than it does in normal rats. In addition, they found that in culture gingival specimens from diabetic rats produce an increased amount of collagenase. After three weeks of insulin therapy less enzyme is produced, but the amount made is still significantly more than that synthesized by gingiva from normal rats. Dr. Golub is now studying diabetic humans undergoing surgical treatment for periodontal disease to see whether his findings in rats hold true for human diabetics.

Scientists at the National Institute of Dental Research have shown for the first time that a virus can infect human pancreatic beta cells. Beta cells produce insulin which is required to control blood sugar levels. The techniques developed by the NIDR scientists open new avenues for investigating the possible role of viruses as a cause of diabetes in children. Should their research prove viruses to be one of the causes of juvenile diabetes, then attempts could be undertaken to produce a vaccine to protect children from developing the disease.

To date, the NIDR virologists have found that insulin-producing beta cells of the pancreas can be infected in culture with mumps virus. That virus was selected for testing because clinical reports have associated the onset of certain cases of juvenile diabetes with mumps infection. If experiments underway show that only certain viruses

have the capacity to infect beta cells, then the investigators will test the ability of those viruses to produce diabetes in non-human primates. On the other hand, if many viruses replicate equally well in all beta cell cultures, then the investigators will have to devise other methods to determine which viruses are potentially diabetogenic.

The investigators' earlier studies with EMC (encephalomyocarditis) virus and its ability to cause diabetes in certain strains of mice and the scientists' experience gained in genetic studies of these animals both have yielded techniques for the current investigations. The NIDR team included Drs. Abner L. Notkins, Gregory Prince, Alfred B. Jenson, Takashi Onodera, and Ji-Won Yoon.

Diabetes-Related Research by the National Institute on Aging

Within the framework of the mission of the National Institute on Aging (NIA) the study of the processes of aging are of primary importance. The study is complicated by the increasing prevalence of a number of diseases, which may influence not only the biological variables being studied but also morbidity and mortality rates. Diabetes is a prime example of this complexity of the interaction of aging processes and disease states.

A decline in glucose metabolism with age has been repeatedly documented and is now well accepted. What is not clear is whether this decline, as demonstrated by the widely applied glucose tolerance tests, is to be considered a normal "physiological" effect of aging or whether in fact it represents the emergence with age of a variant of the disease. The question is, does this biochemical change with age represent a true disease which should be treated as such? The question is not a trivial one; were the standards derived from the performance on these tests of young adults applied without any adjustment for age, then approximately 50% of those over the age of 60 would be classified as diabetic. This finding creates uncertainty as to the effects of the poorer glucose tolerance of older asymptomatic individuals.

The NIA, through the Baltimore Longitudinal Study of Aging, is conducting a prospective, multidisciplinary study of normal aging in over 1,000 male volunteers aged 20 to 90 years. Since 1963 several of the clinically used diagnostic tests for diabetes have been administered repetitively to these volunteers. Nomograms, which permit percentile ranking of an individual's performance, as compared to his age peers, have been developed from these tests. The prospective nature of the study should provide data as to whether age-adjusted standards are more appropriate than an absolute level of hyperglycemia for evaluating performance on these tests.

The multidisciplinary nature of this longitudinal study allows examination of variables which may be of great importance both in aging and in diabetes, for example, body composition (obesity), nutritional factors, activity levels, medications, serum lipids, and habits. In addition, the effects of changes in glucose metabolism can be correlated with biological, medical, psychological and social variables which may change with age and which may be affected by changes in glucose metabolism.

In addition to these large scale epidemiological studies, efforts to elucidate the mechanism of the decline in glucose tolerance with age have been conducted at the NIA. This research on the physiology of glucose-insulin interrelationship includes studies on (1) beta cell responses to hyperglycemia and to the gut hormone, gastrointestinal inhibitory polypeptide, (2) sensitivity of tissues to insulin, and (3) computer modeling of both insulin kinetics and insulin action. In all these studies the interrelationships of aging, diabetes, and obesity are stressed.

The necessity of understanding normal physiology in interpreting the pathophysiology of disease states is well recognized. Equally important is the understanding of the normal physiology of age changes. Interpretation of, for example, differences in hormonal responses between diabetics and normals, requires knowledge of how aging influences these responses before a judgment of pathology can be implied.

Outlook

Enactment in 1974 of the National Diabetes Mellitus Research and Education Act has resulted in an unprecedented attack on diabetes by the NIAMDD, together with other NIH components and Federal agencies. This concerted effort already is paying dividends, as detailed in this report, and prospects are greatly increased that the rate of emergence of symptomatic maturity-onset diabetes in predisposed individuals will diminish, and that the severity of juvenile diabetes and its grave complications may be blunted in the future.

CENTER FOR DISEASE CONTROL

DIABETES

Background

The National Commission on Diabetes in its report to Congress on December 10, 1975 recommended establishment of a series of State or more locally based diabetes control programs under the sponsorship of the Center for Disease Control (CDC). In making the recommendation, the Commission recognized that the effectiveness of health services provided by divergent care sources to patients with diabetes is often diminished because of inadequate planning, coordination and evaluation of effort.

The Commission envisioned that the CDC-sponsored control programs would improve coordination among health agencies and organizations at the local level; compile data about needs, services and resources for use locally and nationally; and conduct or participate in studies of etiology and program evaluation. Technical consultation and support for the community-based diabetes control programs would be provided by CDC.

CDC's appropriation for fiscal year 1977 included $1.5 million and 10 positions for the diabetes control program.

The Center has been engaged in 3 major activities since the program's inception, specifically: (1) support of the 10 diabetes control demonstration projects; (2) CDC-based epidemiologic studies and special evaluations; and (3) coordination and collaboration with other Federal, State and local agencies and groups. Each is discussed below.

Diabetes Control Demonstration Projects

A request for Proposal (RFP) for the Community Diabetes Control Demonstration Projects was released on May 24, 1977 with a response deadline of July 12, 1977 in order to complete the procurement process by September 30, 1977. A total of 29 States responded to the solicitation, which was limited to 50 State Health Departments, the District of Columbia, and the Commonwealth of Puerto Rico.

On September 28, 1977 contracts were awarded to the State Health Departments of Colorado, Georgia, Illinois, Maine, Michigan, Mississippi, Nebraska, New York, Rhode Island and South Carolina.

In FY 1978, during the first phase of the 2-phase contracts, the demonstration States will assess needs and resources, begin to coordinate interested groups and organizations, and develop a problem-oriented program plan for submission to CDC for approval. Completion schedules for Phase I vary from State to State and take up to 12 months to complete.

Implementation and evaluation of the intervention plan will be conducted in Phase II of the contracts. Continued technical and financial support will be required in FY 1979.

In keeping with the Commission's recommendations, knowledge and experience gained from the demonstration projects will be used to develop guidelines for State and local control programs.

Epidemiologic Studies and Special Evaluations

In Fiscal years 1978 and 1979, CDC will compile data from the demonstration projects and define baseline measurements. From these and other data, various measures of morbidity and mortality will be studied and the results used to develop additional indicators for evaluation of the impact of the demonstration projects on morbidity and mortality. Epidemiologic investigations of unusual patterns of cases and of excess mortality among juvenile diabetes patients and infants of mothers with diabetes will also be conducted.

Currently, diabetes is estimated to affect 2-5 percent of the population and account for more than 100,000 deaths per year (fifth leading cause of death) and cost over $6 billion per year. As the true magnitude and scope of the problem posed by diabetes becomes better defined, planning estimates and evaluation of effort will also improve. Meanwhile, the following 5-year goals have been set in the pilot project States:

(1) Reduce excess days of hospitalization among persons with diabetes by 50% (5.5 hospital days per year for diabetics versus 1.5 hospital days per year for non-diabetics).

(2) Eliminate the 10-fold excess in perinatal mortality associated with pregnancies of diabetic women.

(3) Reduce by 50% deaths associated with diabetic coma in juvenile diabetics.

Attainment of goals 2 and 3 also serve as "indicators" of improved quality of care which is expected to have a favorable effect upon overall mortality from diabetes.

In addition to evaluation of effort in the pilot project States, CDC has awarded a contract to evaluate the effectiveness of health education on the attitudes and behavior of patients with diabetes.

Coordination and Collaboration with Others

CDC has pursued an active role at the national level on the National Diabetes Advisory Board, Diabetes Mellitus Coordinating Committee and

Diabetes Data Group. In addition to maintaining a close working relationship with the National Institutes of Health and the National Center for Health Statistics, the health departments of the 3 project States (Illinois, Michigan, and New York) also receiving Research and Training grants are coordinating their activities with the RTC's in their States.

CDC has also developed and maintained a close working relationship with the American Diabetes Association and Juvenile Diabetes Foundation at both the the national and project level.

While technical support for the demonstration projects shall continue to receive first priority during Fiscal years 1978 and 1979, a concerted effort is also being made to provide technical consultative services and maintain the interest and collaboration of States not awarded contracts.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

DIABETES

The basis for determining for the first time the total prevalence of diabetes mellitus in the U. S. adult population 20-74 years of age is being obtained in the present program of the Health and Nutrition Examination Survey as an aid to the increased authority of the National Institutes of Health and Center for Disease Control (Public Law 93-354) for diabetes prevention, control, research and training. The diagnoses for the prevalence estimates will be obtained from the physical examination, medical and dietary history, blood and urine tests following the fasting diagnostic glucose tolerance test given a probability sample of those adult examinees not presently taking insulin.

The Health Interview Survey has collected prevalence and incidence data by numerous demographic population characteristics for the year 1976. In addition to determining the prevalence and incidence of diabetes in the population, the 1976 Health Interview Survey determined the level of knowledge about this condition of individuals reported to be diabetic. It is planned to collect incidence and prevalence data about diabetes again in 1979.

DRUG ABUSE

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
Alcohol, Drug Abuse, and Mental Health Administration:					
National Institute on Drug Abuse.....	$219,813,000	$232,130,000	$259,747,000	$262,099,000	$275,271,000
Office of Education:					
Drug Abuse Education...	4,000,000	2,000,000	2,000,000	2,000,000	2,000,000
Elementary & Secondary Education, Support and Innovation Grants.....	1,200,000	718,000	1/	1/	1/
Higher Education.....	55,000	68,500	50,000	50,000	---
Total, OE.....	5,255,000	2,786,500	2,050,000	2,050,000	2,000,000
Office of Human Development Services:					
Rehabilitation Services Administration:					
Basic State Grants....	9,520,000	10,805,000	10,364,000	10,647,000	10,996,000
Special Foreign Currency Program.....	50,000	50,000	---	---	75,000
Total, OHD.....	9,570,000	10,855,000	10,364,000	10,647,000	11,071,000
TOTAL.....	$234,638,000	$245,771,500	$272,161,000	$274,796,000	$288,342,000

1/ In FY 1976, these funds were consolidated under Support and Innovation grants consolidation program. Dollar amounts are not available.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute on Drug Abuse

DRUG ABUSE

Overview

Drug Abuse is defined as the use of any substance in such a manner as to adversely affect some aspect of the user's life. Such abuse includes excessive use, inappropriate self-prescribed use, over-the-counter drug misuse, and dependent and habitual use (physical and/or psychological) of a wide variety of psychoactive drugs and substances. Drug abuse can lead the user into socially deviant or even criminal behavior; it often results in impaired health and renders the user incapable of discharging family and/or social responsibilities. The consequences of drug abuse vary greatly, depending upon the drugs used, the extent of use, and the route of administration.

Drug abuse in the United States, represents an economic and social cost to the nation in excess of $10 billion a year, of which $6.4 billion is for heroin alone. Lost productivity for all drug abuse resulting from absenteeism, unemployment, and death represents $4.1 billion, with lost productivity resulting from incarceration and time lost in criminal activities adding an additional $2.6 billion. The direct costs of law enforcement, the judicial system, and corrections is estimated to be $1.9 billion. Drug Traffic Control and other drug abuse prevention efforts account for another $1.1 billion of expenditures. Within this latter amount is $515 million spent directly to provide drug abuse treatment services. All other social costs total $600 million and consist mainly of the cost of medical treatment by physicians and hospitals for the abuser. The social cost estimate of $10.3 billion does not include the value of goods stolen, estimated to be $4.4 billion a year, since this cost is not considered by economists to be a cost to society, but rather an involuntary transfer of funds within society as a whole.

The National Institute on Drug Abuse uses several survey sources for determining the extent of illegal and legal drug use, and the impact of prevention and treatment efforts among specific segments of the population. The major current sources of drug indicators are:

1. The National Survey on Drug Abuse - a biennial survey which gathers medical and non-medical drug data for past month, past year and life-time usage of 11 drugs (heroin, other opiates, cocaine, marihuana/hashish, hallucinogens, inhalants, sedative/hypnotics, stimulants, tranquilizers, alcohol and cigarettes) on a sample of 12-17 year olds, 18-25 year olds and over 26 year old men and women.

2. The High School Survey - gathers the same types of data as mentioned above on high school students.

3. Client Oriented Data Acquisition Process (CODAP) - a monthly treatment utilization data system.

4. Drug Abuse Warning Network (DAWN) - collects emergency room and medical data from 24 selected Standard Metropolitan Statistical Areas (SMSAs) on drug-related emergencies and deaths.

5. Center for Disease Control (CDC) - reports data on drug-related hepatitis.

The National Institute on Drug Abuse does not rely on any one single indicator alone. However, when a number of indicators move in the same direction, this fact tends to strengthen the conclusion that the indicators are showing actual drug abuse patterns. The indicators suggest that in mid-1976 heroin use began to level off at a relatively high rate after a constant increase between 1973 and 1976. Preliminary data for 1977 suggest that heroin use may be declining, while other forms of drug use continue to increase.

Three specific drugs of abuse -- heroin, marihuana and cocaine -- highlight several critical drug abuse issues:

Heroin remains the nation's number one drug abuse concern. The drug abuse indicators strongly suggest that there was a steady increase in the number of heroin-related deaths and heroin-related emergency room episodes from 1973 through the first half of 1976. A decline in heroin-related episodes which began during the latter half of 1976 has continued into first half of 1977. Drug-related hepatitis cases show a relatively level pattern since 1973. Admissions and readmissions for the treatment of primary heroin use were level through the first three quarters of 1976 and showed a drop in the period ending in June 1977, commensurate with the drop in admissions to drug treatment programs.

Marihuana has joined alcohol and tobacco as one of the three most commonly used drugs in America. Over sixteen million use it currently and over five and one-half million describe themselves as "regular" users. Among young people (12-17) marihuana use increased 130 percent between 1969 and 1977. Recent studies indicate that among college students, decriminalization of marihuana has little effect on the frequency or intensity of the use of this drug.

Cocaine usage has experienced a resurgence since 1972. Use by youth has increased every year but has not taken the jump characterized by adults. About four percent of the youth (ages 12-17) in the latest 1977 National Survey ever used cocaine, with less than one percent using it in the past month. About six percent of adults ages 18 and over (about nine million) have ever used cocaine, with about one percent, one and one-half million, using it in the past month.

Other drugs also are of concern, such as barbiturates and amphetamines. Barbiturate use among male high school seniors almost tripled between 1969 and 1977. More women than men, 21 percent compared to 17 percent, report ever using sedatives including barbiturates for medical purposes. Amphetamine use among male high school seniors more than doubled between 1969 and 1977. Twice as many women as men report ever using amphetamines for medical purposes.

In response to this serious national drug abuse problem, NIDA continues to strengthen its activities in the planning and implementation of a wide range of drug abuse activities. Due to continuing concern over heroin addiction, the Institute has maintained its treatment capacity of 102,000 treatment slots. A capacity maintenance strategy has been adopted, enabling NIDA to support treatment projects at the prevailing declining match basis until the funding level for any given project is equal to 60 percent NIDA and 40 percent local share. NIDA will continue to support drug abuse treatment services in this manner, sharing the burden with state and local agencies at a constant level until national health insurance, medicaid, or another viable third party source which includes drug abuse treatment, can assume some portion of this expense. This long-term funding strategy recognizes that the local sector is not in a position to accept further declination in the Federal contribution to the national treatment effort. The plan also assumes that the state role will be strengthened through greater reliance upon statewide contracts awarded through Single State Agencies as the primary treatment support mechanism. The states will continue to be assisted in their efforts to develop procedures to capture third party payments for their programs, and the Federal Government will be better able to phase down its treatment activities when, and if, these alternative funding sources come into being.

Other assistance activities supported by NIDA are assuming increased importance. The national data retrieval and dissemination systems have been established and will be maintained to provide management, at both state and Federal levels, with essential programmatic, scientific, and technical information on the nature and extent of drug abuse in the United States. Resources available for drug abuse prevention efforts can be most effectively utilized when such questions as treatment service utilization, Federal and non-Federal funding activities, and changes in drug abuse patterns can be answered. This capability has greatly aided the states in assuming primary responsibility for planning and coordinating their drug abuse activities.

Since large scale drug abuse treatment is a relatively new field, NIDA must provide assurance that treatment projects are operating in accordance with acceptable standards of performance. At the same time, a coordinated program is needed for career development of treatment workers. Toward this end, ongoing NIDA funded treatment

service projects are monitored and audited by Institute staff to maintain treatment effectiveness. Specialized training and education courses are developed by the Institute-supported National Drug Abuse Training Center and state-produced training packages are modified for national distribution to maintain a sufficient number of trained treatment workers to staff the national treatment network. NIDA is working with Single State Agencies in establishing a competence based credentialing model for all drug abuse workers. This model can be applied to career ladders, employee assessment, and evaluation of training and education programs, and state-initiated certification or licensing processes.

Long-term treatment effectiveness studies have demonstrated that the traditional treatment models -- methadone detoxification and maintenance, therapeutic communities and drug free outpatient treatment -- are beneficial to clients. A four year followup study indicates that the longer a client remains in treatment the better their community adjustment is, the more likely that they will be employed, and the less likely that they will abuse drugs after treatment. Clients return to treatment when they feel it is necessary; nearly 60 percent of clients returned to treatment during a four year followup period. It is also apparent that the more severe the drug problem, the more restrictive the therapeutic intervention must be at the initial stages of treatment.

The Treatment Outcome Prospective Study (TOPS), a long-term longitudinal study to follow drug abusers from the time they enter treatment, is now being initiated. This study will provide a natural history analysis of clients entering treatment, examining their in-treatment progress, and their post-treatment successes and failures. It will provide an opportunity to appreciate the various treatment modalities, and their effectiveness in treating clients with clearly described demographic variables and drug use patterns.

The final solution to drug abuse continues to depend upon development of new knowledge on the causes, treatment, and control of such behavior. The fundamental significance of the endorphins, a newly discovered endogenous opiate-like substance, is being investigated. New treatment techniques, such as the use of the therapeutic drug naltrexone are being developed to block the effects of heroin. Investigations on behavior and psychodynamics provide knowledge which has been directly translated into improved treatment procedures, and NIDA is also studying the mechanisms common to various types of substance abuse including drinking, smoking, and drug abuse. Extensive epidemiological data of drug abuse have begun to clarify usage patterns and trends in different age groups and in a variety of special populations, and may provide useful information for prevention programs. Additional marihuana studies are being undertaken in light of recent findings which raise questions concerning the possible

effects of marihuana on the body's immune response system, cell metabolism, and male sex hormone levels. Progress is being made in determining those personality variables which may contribute to preventing drug use in groups known to have above average risk of serious drug abuse involvement. NIDA's Addiction Research Center continues to be concerned primarily with investigating the nature of the addictive process and assessing the abuse potentiality of narcotics, depressants, stimulants, and hallucinogens in an attempt to identify addicting drugs early and through appropriate control, limit their abuse.

Summary Objectives for FY 1979

The Institute's drug abuse prevention efforts in FY 1979 will focus increasingly on developing the Federal role of providing assistance to the states in the management of treatment programs, and in their planning and implementing of adequate licensing and credentialing programs for facilities and workers in the field. Additionally, the Institute will be involved in projects designed to evaluate treatment effectiveness and in the development of new methods of treatment for special populations. These activities, together with continuing research directed at, among other things, the development of new chemotherapeutic and behavioral treatment approaches, evaluation for abuse potential of substances apearing on both the licit and illicit drug markets, and continuing evaluation of the effects of marihuana, reflect the major thrusts of the Institute's plan for FY 1979.

Research

Research programs of the National Institute on Drug Abuse are authorized by Section 301 of the Public Health Service Act to maintain support for a wide-range of biomedical, psychosocial, clinical-behavioral, and service-related research which focuses on priority areas that offer promise of significant breakthroughs in our understanding of the mechanisms underlying drug abuse and of the behavioral symptoms which occur as a consequence of drug use. Major program objectives are:

1. To build on previous accomplishments and improve the drug abuse treatment system through (a) the continued development of longer-acting narcotic substitutes and antagonists; e.g., LAAM and naltrexone, and (b) the creation of a central capability which will encourage and coordinate collaborative research on different treatment modalities.

2. To identify and support basic research in areas with a high likelihood of successful clinical application, such as studies of the role of endorphins and enkephalins in addiction.

3. To coordinate research activities related to the common mechanisms underlying various types of substance abuse behavior, such as smoking, drinking, and drug self-administration. Since these behavior patterns are associated with various physical illnesses, another aspect of this objective is disease prevention through the creation of programs which discourage the development of these maladaptive lifestyle factors.

Programmatic achievements during FY 1978 include the following:

-- The continued development of LAAM and naltrexone as therapeutic drugs for the treatment of heroin addiction.

-- Continued studies on the endogenous opiate-like substances and opiate receptors, including the identification of three different types of receptors. These receptors are responsible for the euphorigenic, sedative, and hallucinogenic effects of this general class of drugs. This finding opens up possible new clinical approaches to the treatment of narcotic addiction.

-- Publication of a major study of cocaine abuse in the United States.

-- Initiation of studies on the impact of policy changes on drug abuse in the United States, and of epidemiological studies of drug abuse in women, elderly persons, and addicted infants.

-- Development of knowledge concerning the effects of drug use on performance, economic behavior, criminal activity, and suicide.

The research effort can be divided into ten major program areas which encompass different facets of the overall goal.

a. Epidemiology is the estimation of the nature and extent of the drug abuse problem by providing continuously updated data on prevalence, incidence, and trends of drug abuse. Major efforts in this area include studies of female drug use and addiction, a nationwide follow-up of addicted mothers and their children, and a more accurate estimate of the true extent of heroin use in identified populations.

b. Etiology is the determination of the biological, behavioral, psychological and societal factors which cause increased risk to drug abuse. During the past year, NIDA researchers have uncovered evidence that low activity levels of a certain enzyme may be predictive of future drug use. In addition, it seems possible that deficiences in endorphins (naturally-occurring morphine-like substances) may cause some individuals to be more prone to addiction. Discoveries such as these now make it possible to mount a serious research effort concerning the biomedical causes of drug abuse which may have significant impact on treatment and prevention methodologies. In 1979, NIDA will initiate etiological studies of the basic mechanisms of nicotine addiction and withdrawal and on the biomedical, psychological and social factors which predispose many, but not all, individuals to experiment with cigarette smoking.

c. Hazards is the research component which represents investigations into the adverse effects of abused drugs on the physical and mental health of the individual and the consequences of drug abuse on society. High priorities in FY 1979 will be a new study of the special hazards of marihuana use for children ages eleven to fifteen; new programs to increase our understanding of the psychological and physiological effects of PCP, as well as its pattern of use; and, a targeted grants program aimed at stimulating increased research into the relationship between drugs and criminal behavior. Another high priority is the assumption of Department of Defense studies. The DOD has discontinued

its program of research related to drug abuse even though many of the projects it had sponsored were both unique and of general applicability in the research field. NIDA, in cooperation with DOD, will renew on a competing basis studies of such subjects as drugs and driving performance, the effects of drugs on visual signal detection, possible enhanced performance due to drugs, and the mechanisms by which heroin epidemics occur in the military service.

d. Prevention research attempts to develop methods of interfering with and controlling the variables which lead to drug abuse. In FY 1979, NIDA plans to launch the first comprehensive, controlled assessment of the impact of specific media messages on drug-using behavior. The ultimate goal of this initiative will be to determine whether messages directed toward selected abuse prone populations can have positive results.

e. Treatment research seeks to determine the most effective therapeutic procedures for reducing drug abuse. In FY 1979, LAAM will continue to be developed as a standard therapeutic drug, studies on LAAM in women will be initiated pending approval by the Food and Drug Administration, and large-scale studies of the narcotic antagonist naltrexone will be begun. In addition, a new drug which may have significant potential as a treatment agent will be developed. This drug, buprenorphine, seems to be capable of blocking the effects of narcotics, to be significantly less toxic than other treatment drugs, and to produce little if any physical dependence.

f. Basic Research advances knowledge of the biomedical and behavioral characteristics of abused drugs, especially in regard to sites and mechanisms of action in man and the physical processes of drug dependence, tolerance, and addiction. As an example of this activity, intense work is under way in several laboratories to clarify the properties of naturally-occurring morphine-like substances in the brain, called endorphins, and to explore their role in the various aspects of opiate addiction. In FY 1979, a new toxicology program will be established in order to give NIDA in-house capability of meeting FDA requirements for toxicity data on new therapeutic drugs, and of assessing the abuse potential of "non-drugs" or common chemicals being abused because of their psychoactive properties.

g. General Research Support grants and contracts provide for the development of methods and other resources required to further drug abuse research. Activities in FY 1979 will be funded at the FY 1978 level and will include development and refinement of current assay methods, quality control techniques for analyzing large number of assays, supply of controlled drugs and substances to researchers, preparation of monographs and reports, and implementation of a research analysis program to ensure macimum utilization of presently available research findings with minimal time loss between findings and their applications.

h. Research Centers consolidate human and technical resources within collaborative organizational settings to maximize the development and the outcome of drug abuse research. Efforts of these programs focus on clinical and behavioral studies of the addiction process, basic central nervous systems mechanisms, social, psychological, and etiological factors involved in drug abuse, and the ability of various theories to predict or explain drug use behavior. Two new research centers will be established to explore the role of endorphins (naturally-occuring morphine like substances in the body) in the addiction process. Past research has indicated that an endorphin deficiency may cause an individuals to be more prone to addiction. These centers will not only advance knowledge in this important area but they will also ensure a rapid transfer of research findings into clinical use.

i. Research Scientist Development Awards enable the recipients to prepare for independent drug abuse research in a productive scientific environment. There is currently a consensus that a deficiency exists in the numbers and sophistication of clinical researchers in the field of drug abuse treatment. In FY 1979 an important new program will be initiated to develop a cadre of clinical researchers with knowledge of the basic skills required for the design of studies, the administration of research clinics, and the collection and processing of data.

Intramural Research is performed primarily at the Addiction Research Center in Lexington, Kentucky. Both basic and applied research are carried out at this institution which, since 1935, has represented a federal commitment to the investigation of the mechanisms and treatment of drug abuse. Current projects include studies on such issues as the relationship between low activity levels of biogenic amines and undesirable alterations in mood and feeling states; the role of conditioning and other learning processes in relapse to narcotics; the relationship of nicotine to the addictive process of tobacco smoking; the abuse-liability of new analgesics and ampheta-

mines and the validation of urine testing methods. The relocation of the A.R.C. to a more suitable location is being considered. Since the Bureau of Prisons prohibited research using prisoner subjects, the A.R.C. has not been able to carry out necessary clinical studies on the abuse liability of new compounds and has been hampered in its development of new therapeutic agents. Relocation will enhance the A.R.C.'s research capabilities by improving the possibility of recruiting volunteer patients and by proximity to other Federal intramural research facilities.

Primary Objectives for FY 1979

NIDA will continue and expand existing research activities in such areas as the genetic effects of abused drugs on the sensory systems, phase III testing of naltrexone, drug use by young women, and the long-term hazards of inhalant abuse. The FY 1979 budget request includes the increases recommended by the preliminary report of the President's commission on Mental Health. Specific new efforts for FY 1979 include the establishment of two new research centers to conduct follow-up studies of the relationship of naturally occurring morphine-like substances to addiction, tolerance, analgesia and other basic biobehavioral phenomena; the evaluation of the ability of media messages to change abuse patterns; the expansion of clinical research; and, the relocation of A.R.C. should such a decision be made.

Training

The NIDA Training program is authorized by Sections 301, 303, and 472 of the Public Health Service Act. Its purpose is to ensure an adequate supply of skilled manpower to meet the needs of the service system, and the production of skilled researchers in priority research areas. Clinical training activities include the National Drug Abuse Training Center (NDATC), which assesses training needs, validates existing training materials and programs, develops new materials, and identifies training resources nationwide; the five Regional Resource Support Centers, which work in conjunction with the NDATC to provide more specific technical assistance to the states in needs assessment, training design and evaluation, and career development; the State Training Support Program, which provides direct financial support to the states in developing their own training capabilities; and, the Developmental Training Grant Program, which supports the training of students who are preparing for clinical service careers in the drug abuse field. Research Training encompasses both individual and institutional awards for training in areas of biomedical and behavioral research.

The FY 1979 budget request will enable NIDA to maintain its major contract program of support and technical assistance through the National Drug Abuse Training Center, the Regional Resource Support Centers, and the State Training Support Program. Through these contracts, NIDA provides the course designs and materials for use in state drug abuse training programs, maintains information and resource exchange among the states and other components of the national training system, trains state drug abuse personnel in effective implementation of state training plans and, in conjunction with the states, provides training to approximately 23,000 drug abuse workers per year. In FY 1979, 57 renewal contracts will be supported, no new contracts are planned, and the total funding level will be $6,230,000.

Through the Developmental Training Grant program, NIDA will continue its ongoing projects and support a limited number of new model in-service training programs for treatment/rehabilitation professional and paraprofessional staff. In addition, NIDA will expand the Career Teacher Grant Program which seeks to improve medical students' training in the drug abuse field by the establishment of drug abuse curricula in the medical schools. Twenty-one continuing and ten new grants will be supported at a funding level of $3,149,000.

NIDA will also continue its program of developing trained researchers through individual and institutional research training awards. Primary emphasis will remain on postdoctoral fellowships, but new and renewal predoctoral fellowships will be awarded as well. Seventeen continuing and twenty-four new fellowships will be supported at a funding level of $784,000.

Primary Objectives for FY 1979

A total of 13,639 persons will receive direct NIDA training support. Grants, contracts, and fellowships will be funded at a maintenance of effort level. The National Drug Abuse Training Center will continue to be the center of the national training system, with its primary goal being to support and strengthen state training programs.

Community Assistance Programs

Community Assistance Program activities center on the ongoing provision of primary prevention, demonstration, and service programs for drug abusers. In FY 1979, priority attention will again be directed toward funding Single State Agencies for Drug Abuse to administer a comprehensive and coordinated treatment approach within each state. The major long-range goals of the Institute will continue to be: (1) maintenance of a fully utilized Federally-funded treatment capacity until the demand for treatment abates and/or the states can achieve alternative sources of funding; (2) continued provision of consultation and technical assistance to the Single State Agencies to help them maximize their effectiveness as primary partners in the provision of drug treatment services; (3) upgrade and support of national treatment standards to control the quality of treatment until states are able to establish their own standards which meet or exceed the Federal standards; (4) emphasis on the state plans as the working managerial document of Single State Agencies for program planning; (5) provision of special research treatment services which support clinical research activities requiring patient clientele; (6) development and dissemination of findings from treatment and rehabilitation demonstrations; and (7) promotion of the development of primary prevention/education methods.

The National Institute on Drug Abuse (NIDA), as the lead Federal agency concerned with drug abuse treatment, has requested sufficient funds in FY 1979 to be able to continue a "maintenance" treatment funding strategy in which a fully utilized 102,000 treatment slot ceiling will be supported. This maintenance strategy enables NIDA to support treatment projects at the prevailing declining match basis until the funding level for any given project is equal to 60 percent NIDA and 40 percent local share. Again some shifting of funded treatment capacity among communities is planned so that resources which are not being adquately utilized in one area can be shifted to another area in which there is an unmet need. In order to ensure attainment of the above goals, the Institute will continue to provide monitoring and technical assistance support.

Community Assistance programs fall into five major categories. The first assists communities to establish treatment programs for narcotic addicts and drug abusers and to fund treatment costs associated with research programs through the awarding of grants. Programs in the second category utilize the contract mechanism to establish individual service contracts and statewide service contracts with Single State Agencies and other public or private non-profit contractors under which individual projects are subcontracted. It also includes contract projects which provide specific treatment support services. The third category represents the demonstration initiatives in the field of drug abuse treatment and rehabilitation. The fourth category represents the Institute's effort in drug abuse prevention and

education. Finally, the formula grant program comprises the fifth category in which grants are awarded to states and territories on the basis of population, financial and program need. These categories are described in detail below.

The Community Assistance Grant Program

Drug Abuse Service Projects Grants (Sec. 410, DAOT Act as amended by Sec. 10, P.L. 94-237)

Drug Abuse service project grants are awarded on a matching fund basis for the total operational costs of projects for the treatment of narcotic addicts and other drug abusers. To obtain an award, a program must offer one or more of the following services: detoxification, institutional care, or community-based aftercare. In FY 1978, 74 projects were awarded at a Federal funding level of $31,624,000, providing a treatment capacity for 24,508 patients. Seventy-three of these programs, originally funded under Section 256 of the Community Mental Health Centers Act, were eligible for a maximum of eight years support. The remaining one program was funded since April 1973 under the Drug Abuse Office and Treatment Act for three years of Federal support, with possible renewal for three additional years. Continued emphasis will be placed on incorporating significant numbers of these individual grant projects into statewide services contracts. In FY 1979, this program will again emphasize quality treatment service for a fully utilized level of 19,698 treatment slots.

Research Treatment Projects (Sec. 410, DAOT Act as amended by Sec. 10, P.L. 94-237)

This program supports the treatment component of clinical research projects. Although the primary purpose of these projects is the performance of research, the provision of treatment to patients and control subjects is an essential element of that research. Volunteer patients are recruited from local area treatment programs for specific experimental objectives. Upon completion of the research study, the patients return to the treatment programs. Research treatment funds cover the costs of the staff, facilities, and equipment related to the treatment of patients during the research projects. In FY 1979, it is estimated that six projects will be funded at a cost of $1,200,000.

The Community Assistance Contract Program

Statewide Service Contracts (Sec. 410, DAOT Act as amended by Sec. 10, P.L. 94-237)

This program is a cost-reimbursement, cost-sharing, contractual mechanism through which the Institute can fund a number of drug treatment projects under the auspices of the single state drug authority. This program began in FY 1973 with contracts awarded to the States of

New Jersey, New York, and Texas. Currently this mechanism is operational in forty-nine states and territories with increased effort anticipated as individual grant projects are incorporated. Subcontracts are awarded by the states to support local treatment projects which have the same basic objectives and requirements as the drug abuse service grants. This program is the primary mechanism by which states assume greater direct administrative responsibility for their drug abuse treatment activities. The continued growth of the program is evidenced by the Institute's effort to consolidate as many treatment programs as possible under this support mechanism. Funding for these treatment service contracts will increase from $95,675,000 in FY 1978 to $101,205,000 in FY 1979 and will strive to maintain a fully utilized treatment capacity of 75,144 slots.

Services Contracts (Sec. 410, DAOT Act amended by Sec. 10, P.L. 94-237)

This funding category, formerly considered a subset of the statewide services contract category, consists of individual contract awarded to public and private non-profit agencies for the provision of treatment and rehabilitation services. As with the grant treatment program, efforts will continue to be made to incorporate these contracts into the statewide services contracts program. The FY 1979 funding requirement for this program is $11,210,000.

Treatment Support (Sec. 410, DAOT Act amended by Sec. 10, P.L. 94-237)

The treatment support category results from the increased development and maturation of the drug abuse services treatment program. These projects are funded to provide information and assistance essential to the efficient operation of the treatment program. They enable NIDA to monitor the management, fiscal and programmatic activities of Federally-funded treatment programs, ensuring compliance with the Federal funding criteria and maintenance of a fully utilized treatment capacity. They also provide specific information and evaluation services essential to the effective operation of the treatment program. In FY 1979, it is estimated that nine projects will be funded at a cost of $6,650,000.

The Narcotic Addict Rehabilitation Act (Sec. 607, NARA)

There are currently two contract agencies serving 152 persons providing evluation and examination, inpatient care, and supervised after care under these civil commitment projects. It is anticipated that all NARA agencies will either have terminated or been incorporated into the project grants or statewide service contracts by FY 1979; therefore, no funds have been requested for FY 1979 in this area.

Demonstration Grants and Contracts (Sec. 410, DAOT Act as amended by Sec. 10, P.L. 94-237)

Demonstration projects are funded to develop and evaluate promising new theories or approaches relating to substance abuse treatment and rehabilitation services. There are three aspects to this activity: the contruction of innovative models to improve the quality of services for all drug abuse clients; the development of evaluation methodologies designed to determine program effectiveness and to make possible the integration of new methods into community programs; and the gathering of data to define appropriate treatment and rehabilitation approaches for client groups with unique cultural geographical and/or psychological characteristics. Reports on all these studies are disseminated to all NIDA funded drug abuse treatment programs, to Federal and state agencies, and to private and professional organizations in the drug abuse treatment field. During the past year, reports have been issued in the following areas of completed demonstration work: management information systems for the use of state and local programs; coordinated drug/alcohol programming; drug abuse in industry; and service delivery to minorities, women, and elderly. Current demonstration efforts include: service delivery in rural settings; service delivery to criminal justice client; studies of the nature and extent of amphetamine/barbiturate use and development of treatment service methodologies; study of discriminalization as it is directed against drug abuse clients in the areas of job, housing, licensure, etc.; evaluation of the utility of family therapy/counseling for drug abusers; service delivery to youth; and study of PCP use. In FY 1979, 31 continuing projects will be funded for a total of $6,478,000. No new awards will be made.

Prevention Grants and Contracts (Sec. 410, DAOT Act as amended by Sec. 10, P.L. 94-37)

This activity supports a comprehensive program of development, evaluation, technical assistance and dissemination of model approaches to the prevention of drug abuse through information, education, alternatives, and intervention. Grants are awarded to applicants who demonstration expertise in the field of drug abuse prevention and who have the capacity to comprehensively evaluate the impact of their projects on youth attitudes toward drugs and drug-taking behavior. Contracts are awarded to public and non-profit private institutions to determine the cost effectiveness of prevention programs and to provide technical assistance to the Single State Agencies, community organizations, schools and colleges, and other interested groups. NIDA focuses primarily on the evaluation of promising prevention methodologies and on encouraging the Single State Agencies for drug abuse to assume greater responsibility for the funding of community service programs. NIDA will continue 30 selected prevention projects which hold promise for providing effective models at a funding level of $5,090,000. No new awards will be made.

The Formula Grant Program

Formula Grants (Sec. 409, DAOT Act as amended by Sec. 7, P.L. 94-237)

Financial assistance is provided to the states for planning, establishing, conducting, and coordinating projects for the development of more effective drug abuse prevention functions in the states and for evaluating the conduct of such functions. Funds are allocated to states based on a formula which measures the relative population, and the financial and program needs of each state. Federal funding through the formula grant mechanism will be maintained at $40,000,000 in FY 1979. Estimates have shown that the states are utilizing their formula grant funds in approximately the following manner: (1) treatment and rehabilitation programs - 51 percent; (2) prevention programs - 30 percent; (3) training efforts - 6 percent; (4) research and evaluation initiatives - 3 percent; and (5) administration - 10 percent. In FY 1979, formula grants will continue to serve as the mechanism through which states will assume coordinating responsibility for their drug abuse prevention programs. Also, continued emphasis will be given to strengthen the state plan as a working document so that it is used as a management tool by the Single State Agencies and by NIDA to evaluate and measure a state's performance.

Summary Objectives for FY 1979

In FY 1979, NIDA will continue its support for a fully utilized national treatment program which will be maintained at the FY 1977 increased capacity level of 102,000 treatment slots. A matching funding strategy to support community-based treatment projects at the prevailing declining match basis down to 60 percent NIDA and 40 percent local share will also be continued. NIDA will thus share the burden of providing drug treatment services with state and local agencies until alternative sources of funding can be developed to assume a greater portion of the expense. This long-term funding strategy recognizes that the local sector is not in a position to accept a further contribution to the national treatment effort. The plan also places greater reliance upon statewide contracts awarded by NIDA to single state agencies as the primary treatment support mechanism. The states will also be assisted in their efforts to develop procedures to capture third party resources and will be held increasingly responsible for the effectiveness of their programs. Finally, the National Institute on Drug Abuse will strengthen its activities in the planning and implementation of a wide range of drug abuse prevention activities.

Division of Scientific and Program Information

The Division of Scientific and Program Information (DSPI) is responsible for the design and implementation of data systems to meet the technical and programmatic information needs of the National Institute on Drug Abuse (NIDA). In discharging this responsibility, the Division has developed a management information system to meet critical management needs of Federal and state drug abuse programs. In cooperation with 56 states and territories information is collected which is vital to the management and administration of these drug abuse efforts. Successful data collection activities have been facilitated by the provision of high quality technical assistance in the use of management information for state and local policy-making. Approximately 30 states received state-level management data on computer tapes monthly. In addition, technical assistance sufficient to allow state processing and analysis of its own data is provided. The Institute's major data systems are: 1) the Client Oriented Data Acquisition Process (CODAP), 2) the National Drug Abuse Treatment Utilization Survey (NDATUS), 3) the Financial Management Information System (FMIS), and 4) the Grants/Contracts Management System (GCMS). Each component serves a specific management information need. While each is different in scope and operation, all share a common construction which allows comparisons between the systems.

NIDA has achieved a significant level of Federal agency cooperation. The DSPI data systems provide information to the Veterans Administration, Bureau of Prisons, Department of Justice, and the Food and Drug Administration, thus making NIDA the principal repository of national drug abuse information.

In order to assist all states in more fully participating in drug abuse program management, the Division of Scientific and Program Information has provided the Single State Agencies the option of sharing responsibility for data by incorporating important features of the national level management information systems into the state data systems. This effort is known as the Integrated Drug Abuse Reporting Process (IDARP).

Client Oriented Data Acquisition Process

The Client Oriented Data Acquisition Process (CODAP) is the only national recurring client data system collecting drug abuse treatment information. CODAP is concerned with the monthly collection of client data regarding the drug abuse phenomena in drug abuse treatment clinics which have Federal treatment funds. Public Law 92-255 established the provision for the collection of uniform client-related data. CODAP has been operational since May 1973. Currently, an average of 35,000 forms are processed monthly from 1,900 treatment units across the country.

CODAP employs five forms: an Admission Report, a Discharge Report, a Client Flow Summary, an Activity Report and a Client Progress Report. Data are collected at two crucial points in the treatment cycle: admission and discharge. This affords CODAP data users the capability to examine changes in drug abuse patterns affected by the treatment process. The Client Flow Summary provides data on the aggregate clinic population and some measure of activity during the month. The Activity Report is submitted only on clients supported by the Veterans Administration (VA) and the Client Progress Report on clients in programs supported by the Bureau of Prisons (BOP). The Client Progress Report is a quarterly submission; the others are submitted monthly.

CODAP is designed to supply both Federal and state managers with data on the demographic and educational characteristics of clients, their drug problems and drug abuse history, treatment modalities and environments, length of time in treatment, and other major indicators of drug abuse-manifestation. A revised CODAP was implemented in January, 1977. This allowed additional flexibility to meet Federal, state, and program needs.

Since its inception CODAP has been producing national, state and program management level reports on a quarterly basis. NIDA also produces the "Quarterly Statistical Series" consisting of special studies of topical items based on CODAP data. In addition, data tapes of cumulative Admissions, Discharges, and Client Flow Summaries are available and are presently distributed, on request, to 26 states. The information contained on the tapes is, and can be, examined in many combinations at various levels of reporting thus providing a wide range of useful data displays for management use. Special studies and reports are regularly produced to meet unique needs of managers, researchers and epidemiologists.

The following CODAP objectives for FY 1977 were met: 1) implemented the revised CODAP forms and procedures; 2) increased data analysis and utilization by placing emphasis on trend reports, analysis of drug use, age of first use and patterns of drug use at discharge; 3) enhanced validation activities through the development of a Data Management Manual and ongoing activities to develop a national strategy for measuring the accuracy of CODAP data; 4) continued accelerated effort to provide technical assistance to states to enable them to independently process and analyze CODAP data through visits, consultations and by providing manuals and materials; and 5) improved control of CODAP submissions by reorganizing and developing procedures for in-house handling of data and by the implementation of automated error report mechanisms.

In order to continue development and enhancement of NIDA's management information capability, the following objectives were established for FY 1978 and 1979: 1) maintain field support and training for OMB approved modifications to CODAP; 2) produce CODAP output reports on a more timely basis; 3) produce 1977 Annual Summaries of CODAP data; 4) produce on a recurring, timely basis special reports specific to NIDA management needs; and 5) monitor validation efforts on CODAP data and evaluate future requirements.

National Drug Abuse Treatment Utilization Survey

The National Drug Abuse Treatment Utilization Survey (NDATUS) is an annual survey of all known drug abuse treatment and administrative units in the United States, Puerto Rico, District of Columbia, and the Virgin Islands regardless of funding sources. NDATUS is authorized by Public Law 92-255 as amended by Public Law 94-237.

NDATUS evolved from a survey implemented in 1973 by the Special Action Office for Drug Abuse Prevention. The survey was a national effort to determine the scope of drug abuse treatment and the need for continuing fiscal support of such treatment throughout the United States. This effort was assumed by NIDA in 1974 and is now known as NDATUS.

NDATUS is designed to identify and measure the utilization of available treatment facilities at the state and national level; trends in treatment utilization; funding patterns; staffing patterns; FDA methadone distribution and availability; stabilization of methadone clients; and third party payments.

The potential NDATUS respondent universe includes 3,100 drug abuse treatment service and 900 administrative units in the nation. Included among treatment service units are the approximately 700 methadone dispensing units previously required to report separate methadone data to the Food and Drug Administration (FDA). In FY 1978 NDATUS will become the only mechanism for legislated methadone reports requirements.

In prior years, FDA required all methadone treatment facilities to submit an Annual Report for Treatment Programs Using Methadone in order to maintain close control over the distribution and availability of methadone, and to determine whether or not it is a safe and effective drug for long term maintenance. In FY 1978 NDATUS will assume responsibility for collecting the data needed by FDA to meet this reporting requirement. This will be accomplished by including on the NDATUS Survey Form, selected items from FDA's Annual Report for Treatment Programs Using Methadone. FDA reporting is authorized by 21 CFR 291.505, Conditions for Use of Methadone (formally 21 CFR 310-505). The combined survey represents a significant step in the direction of reducing the respondent burden through cooperation and coordination between NIDA and FDA.

The data supplied to the FDA through NDATUS will contain information on individual programs as well as aggregate figures to permit that Agency to maintain close control over the distribution and availability of methadone for the treatment of narcotic addiction. FDA will use this data to either maintain or modify FDA regulations for the use of methadone by treatment units.

The following NDATUS summary objectives will continue to be emphasized for FY 1978: 1) to assist NIDA and state management to access and predict treatment resource requirements for existing and future drug abuse treatment services; 2) to assist FDA to meet their mandated reporting requirements concerning methadone treatment; 3) to analyze general treatment utilization trends and conduct various analyses of NDATUS data for the Nation, regions, and states; 4) to provide FDA, SSA's and the Veterans Administration with computer produced reports and provide states with inventories of all reported drug abuse treatment units which can be developed into a state directory; 5) to provide data to assist states in preparing their State Action Plans required to receive NIDA 409 funds; and 6) to provide states, and treatment units with technical assistance to ensure capability to report, analyze, and use NDATUS data to generate program level management reports.

Financial Management Information System

Unlike both CODAP and NDATUS, the Financial Management Information System (FMIS) is not a Federal reporting system. FMIS is a model financial information system for state use. It is designed to provide states with the information on state grant and/or contract funds, program income sources, expenditures and unit cost data.

The FMIS model is flexible and can be adapted to the individual needs of each state with the added capability of becoming a more comprehensive system at the state's option. This is accomplished by the use of a modular design whereby individual modules may be implemented according to state preference. FMIS is composed of four modules: 1) Grant/Contract Identification Module; 2) Expenditure Reports Module; 3) Program Income Module; and 4) Functional Cost Module.

The system has been designed and tested. It is currently available for state use. Over 36 states have requested either the manual or automated version of FMIS.

The FY 1978 objective is to continue to make the FMIS package available to states and provide technical assistance to states desiring to implement the package.

Grants/Contracts Management System

The Grants/Contracts Management System (GCMS), is not a reporting system, but the internal funds management system for all NIDA treatment grants and contracts. Designed to provide NIDA management with regular reports on the status of all current treatment grants and contracts, it also provides other agencies such as ADAMHA and PHS with fiscal data on grants and contracts. GCMS is similar in nature to the Grants/Contracts Identification module of FMIS.

As the sole central control point for Institute grants and contracts the FY 1978 objective is to maintain the system and its reports for NIDA management and modify its output to assist in the monitoring of treatment slot utilization.

Integrated Drug Abuse Reporting Process

The Integrated Drug Abuse Reporting Process (IDARP) was developed to provide Single State Agencies with funds and technical assistance to facilitate the development of state and Federal capabilities to insure maximum use of CODAP and NDATUS data while minimizing overlapping, and duplicative reporting requirements. Current activities are centered upon the provision of technical assistance and guidance to maximize data analysis, and use for state level decision making.

The IDARP effort complements the development of CODAP and NDATUS by helping obtain active cooperation from states by assuring compliance from local units and editing forms and verifying data input. IDARP differs significantly from earlier efforts in Federal/state cooperation in that its primary focus is upon creating information generating capabilities at the state in addition to Federal level, thus insuring compatability of information, while minimizing developmental and operational costs. Funds for the maintenance of IDARP, which was a three-year experimental effort, will be expended by the end of FY 1978. IDARP has proved itself as a highly successful Federal/state effort, and every attempt will be made to continue the impetus through alternative means.

IDARP results in a continuous responsibility for the state to implement and monitor CODAP through data control measures and error correction procedures, and as importantly to be aware of data utilization as a management and planning resource. Ongoing effort in FY 1977 indicated significant progress by the states in the following areas, which also constitute the FY 1978 objectives for IDARP: 1) to provide technical assistance to improve data analysis; 2) to improve reports to local units; 3) to provide states with the production capabilities of generating reports for state and local use; 4) to facilitate state plan updates and preparation; and 5) to provide states with the capability to process CODAP and/or NDATUS data.

In summary, the DSPI collects, edits, processes and reports drug abuse information of a technical and scientific nature for the purpose of governmental and public dissemination in the form of reports, fact sheets, analysis and other publications to Congress, the Office of Management and Budget, Federal agencies, state and local units of government, the public, and special interest groups. Information is disseminated through the participating Single State Agencies and NIDA.

OFFICE OF EDUCATION

DRUG ABUSE

The Drug Abuse Education Act of 1970 (P.L. 91-527), enacted December 7, 1970, authorized drug abuse education demonstration projects in schools and communities and dissemination of information on drug abuse. The program was designed to alleviate the drug abuse crisis among youth by promoting awareness and understanding of the nature of the problem and developing and disseminating prevention and early intervention strategies aimed at attacking the causes of drug abuse rather than merely treating its symptoms.

P. L. 91-527 expired on June 30, 1973. The program operated at reduced level in fiscal year 1974 under a one-year extension of the Act. In September 1974, the Act was amended and extended through June 30, 1977 under P.L. 93-422. Initially, the program funded projects in 55 State and territorial education agencies to develop curricula and conduct in-service training programs for local education agencies and supported 57 local school, community, and college-based demonstration projects.

As experience with these and other projects accumulated, it became evident that virtually all communities have or could have some sort of drug problems, which vary widely in nature and scope from community to community. It became clear that a key factor in successful projects was coordination of the efforts of all segments of a community - family, school, church, social, health and civic agencies and local government.

Experience suggested that a realistic Federal role would be to provide training for school and community leaders to help assess and define their problems, state their goals in attainable and measurable terms, assess recommended strategies, methods and materials as tools appropriate to the realization of their particular goals and involve their communities in cooperative efforts. In fiscal year 1972, therefore, the "Help Communities Help Themselves" program was launched. Under it 803 interdisciplinary community teams of five to seven persons were given two weeks of intensive training and follow-up technical assistance through seven Regional Training Centers to develop alcohol and drug abuse prevention programs geared to their local needs and resources.

In fiscal year 1973, in addition to continuing support for State education agency and demonstration projects, and the National Action Committee, the technical assistance arm of the program, the program through its seven Regional Training Centers provided training and technical assistance to an additional 900 teams bringing the total to approximately 1700 communities served. In fiscal year 1974, an additional 240 community teams were trained and a nationwide program for training and evelopmental assistance to 336 local school district teams in prevention and early intervention was initiated. Two models for the college level pre-service training of educational personnel were instituted. In one model a total of 180 teams (900 administrators, faculty and students) from colleges of education were given three days of training and were provided follow-up assistance on request. In the other model, six projects for development and validation of pre-service training models were initiated. The National Action Committee was continued.

In fiscal year 1975 under the school-based primary prevention and early intervention program 200 additional local school district teams were trained at five Regional Training Centers. (With reduced funding the program was supporting five instead of seven Centers.) The six pre-service demonstration projects were continued for a second year. The National Action Committee continued to provide technical assistance to USOE funded projects as well as State education agencies and Single State Agencies.

In fiscal year 1976, the five Regional Training Centers did not train any new school or community teams. Rather they concentrated on providing technical assistance to the universe of some 3,000 teams trained since 1972. The pre-service demonstration projects were continued for their third and final year. The National Data Base, an information support system providing varieties of data on local activities generated by school and community teams, was continued. The National Action Committee continued to function as the technical assistance arm to the entire program. Finally, the Self-Knowledge project, a research project at the University of Massachusetts to develop validated measures of human development, was supported for its third and final year.

In fiscal year 1977, as resources available to the program decreased, the program set as its major priority the challenging problem of alcohol and drug abuse in large cities. In addition, under an interagency agreement with the Law Enforcement Assistance Administration the program adapted its national training system to the problems of school crime and violence. Eighty-one school teams were trained and provided with follow-up technical support to develop local programs to deal with crime and violence in the schools.

In fiscal year 1978 the program continued its focus on large city school systems. Forty clusters of four schools each (normally a high school and its feeder schools or schools organizationally related) in urban areas were supported for training and technical assistance through the five Training Centers. The purpose of this new "cluster" effort was to concentrate more resources in urban school districts to enable them to establish networks for building their own prevention/education programs. The cluster concept was also applied to the LEAA/USOE interagency pilot venture in school crime and violence and 55 clusters from large urban school districts were to be trained over a two-year period. A contract was let to develop a plan to provide technical assistance to State education agencies and to conduct a follow-up of graduates of the six pre-service demonstration projects funded in Schools of Education between 1974-1977.

In fiscal year 1979 emphasis will be on using existing trained urban clusters to develop a local training capability to expand to other new clusters in their school districts and to develop appropriate approaches for elementary schools. The Training Centers will continue to disseminate the most promising practices for adaptation by school districts to their local circumstances. Emphasis will be placed on parent education and parent involvement as well as unique responses such as programs in bilingual/bicultural settings. The technical assistance contract to State education agencies will be continued as will the follow-up of the graduates of the pre-service demonstration projects.

Support and Innovation Grants

State departments of education and local educational agencies receive funds under Title IV of the Elementary and Secondary Education Act for support and innovation activities. Drug abuse education is an allowable use of these funds although under current reporting requirements, information is not available on the extent to which States are using the funds for that purpose. Support and Innovation Grants is a consolidated program. Under one of its prior components, funds were used for drug abuse education, and it is possible that such programs are continuing.

Higher Education Title I, University Community Services

Title I of the Higher Education Act of 1965 (University Community Services) pioneered the use of Federal funds to direct higher education resources toward the solution of the drug abuse problem before the enactment of the Drug Abuse Education Act of 1970. Since that time, Title I activity in this area has declined.

In fiscal year 1976 only two projects dealing with drug abuse were funded, reaching about 2,000 participants. It is anticipated that the fiscal year, 1977 activity in this area is at the same level.

There has been no budget request for the Title I program for FY 1979. Currently in fiscal year 1978, Federal funds are being made available under a Continuing Resolution.

OFFICE OF HUMAN DEVELOPMENT SERVICES

Rehabilitation Services Administration

DRUG ABUSE

Unless drug abusers are provided those services which will allow them to prepare for, enter, and remain in gainful employment, the long-term success of drug abuse treatment programs will be questionable. State rehabilitation agencies are important resources for providing services such as vocational evaluation, work adjustment, vocational training, counseling, and placement assistant to eligible drug abusers. The experience gained in serving alcoholics and the mentally ill has been carried over to working with these clients.

The Rehabilitation Services Administration has worked closely with the National Institute on Drug Abuse to develop strategies for the more efficient utilization of services and has been a continuing participant in the various analytic and evaluation efforts undertaken by the Office of Drug Abuse Policy.

State vocational rehabilitation agencies usually serve drug abusers in close cooperation with specialized drug abuse treatment programs. The rapid growth of these programs has resulted in increased demands for vocationally-oriented services for treated drug abusers.

The Rehabilitation Act of 1973, as amended, requires State agencies to give service priority to the more severely handicapped. Competing claims for service by persons disabled by other conditions make it unlikely that the number of rehabilitated drug abusers will increase. Projections indicate that the present level of rehabilitations will remain substantially unchanged.

Rehabilitation Research

Research and Demonstration projects concerned with drug abuse have shown the effectiveness of a drug rehabilitation program conducted under the auspices of a State Department of Mental Health. The project has been incorporated into the ongoing programs of the State under total State funding. Another project, conducted within the organization and policies of a psychiatric hospital, has shown great success in rehabilitating psychiatric drug abusers. This project, no longer receiving Federal support, is continuing under hospital auspices as an ongoing unit of the hospital.

The Special Foreign Currency Program administered by the Office of Research and Evaluation is supporting one project in Egypt which involves the delivery of rehabilitation services in an outpatient type facility where the clients are called "members" and the families of the clients are intimately involved in service delivery. The "family unit" is kept intact, which tends to enchance rehabilitation.

Number of People Rehabilitated:

Fiscal Year	All Rehabilitants	Persons Rehabilitated With Drug Abuse
1975	324,039	4,394
1976	303,328	4,383
1977	291,202 1/	3,873 1/
1978	283,000 1/	3,800 1/
1979	277,000 1/	3,700 1/

1/ Estimated

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EPILEPSY

Obligations for Programs in the Epilepsies

	1975	1976	1977	1978 estimate	1979 estimate
National Institutes of Health: National Institute of Neurological and Communicative Disorders and Stroke	$10,421,000	$12,960,000	$14,345,000	$16,120,000	$16,350,000

NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological and Communicative Disorders and Stroke

Our brain is constantly receiving information from inside and outside our bodies by way of sense organs. The brain sorts that information, evaluates it, stores some of it for future reference, and acts on the rest through a network of nerves and muscles.

To keep this intricate mechanism working, brain cells (neurons) generate energy impulses which sweep rhythmically along the neuronal networks. When there is a job to be done, neurons which control the part of the body to be activated send impulses until the work is finished, and then "turn off". Sometimes, some neurons do not shut off when a job is done. Sometimes adjacent neurons are excited and send additional unnecessary impulses involving the whole body and producing erratic movements. These excessive physical and mental activities are called "epileptic seizures". When they happen repeatedly to an individual, the person is said to have epilepsy.

The usual epileptic seizure is of short duration characterized by a fall, a jerky and violent contraction of the body musculature and a loss of awareness of surroundings. A seizure usually runs its course quickly. The brain energy necessary to maintain the seizure has then presumably been exhausted. Because this energy is not rapidly replaced, a stupor or brief sleep may follow.

The Problem

Epilepsy is the recurrence of seizures in an individual. There are wide variations in the types and severity of seizures, seizure frequency, causes, age of patient at onset, and response to medical treatment. In 1969, a Commission on Terminology of the International League Against Epilepsy established a new, highly detailed classification of convulsive seizures. The most common of these are: generalized tonic-clonic (grand mal), generalized absences (petit mal), complex partial (psychomotor, temporal lobe) and simple partial (Jacksonian). Determining precisely which types of seizures an individual has is vital because response to medication can vary according to seizure type. There are many other descriptive terms to describe seizures. A common term is "febrile convulsions" when high temperature of an illness is present.

Epilepsy afflicts between one and two percent of the American population. Estimates vary because the definition of epilepsy is not uniform and diagnosis is complicated and not always precise. Many people with epilepsy are either unaware of it or unwilling to reveal it.

Federal, state and local expenditures for epilepsy tops the $3 billion annual mark. Of this total, drug costs, vocational rehabilitation and special education costs account for approximately $187 million. Care for institutionalized persons with epilepsy, by itself, requires an annual investment of almost $1 billion. Approximately $38 million goes for research and prevention aspects.

Seizures often begin in early childhood. Studies indicate that more than half of persons who have epilepsy are under age 20. Epilepsy does not usually shorten one's life span. Fortunately, most cases can now be partially or completely controlled with a drug or combination of drugs. This is in sharp contrast to previous thousands of years when the only treatment was magical non-scientific therapies. Although the causes of epilepsy are not fully understood, much more is now known about the problem. Many people with epilepsy continue to function very effectively even when having frequent seizures. However, some persons' seizures do not respond to present therapy. Research must continue to find other therapy to control their seizures in order that they, too, may have productive lives. Others have side-effects from their drugs, which are not life threatening, but are serious enough that they would benefit from new drugs.

It is known that seizures may occur in association with birth trauma or birth defects, brain infections, drug or alcohol abuse, head injury, tumor, or strokes. In most people a definite association is never found. But the specific underlying cause is not known — why seizures occur in one person and not in another with a similar disease or injury. The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) scientists believe that an interdisciplinary scientific approach will ultimately clarify the cause or causes of epilepsy. Such an effort incorporating improved methods of analysis of fine anatomical structure, electrophysiology, neurochemistry, and neuropharmacology, will lead to more detailed knowledge of brain structure and function. Research of this type, both basic and clinical, is currently being conducted and supported by the Institute.

Epilepsy Research

Interest in the field of epilepsy has increased greatly during the last decade. Practically every aspect of the disorder is receiving intensive study. In addition to laboratory research, studies are being conducted on rehabilitation, education, occupational and general life adjustment. Some of the advances and indications of future research directions are presented in publications sponsored by the Institute. These include the following: Basic Mechanisms of the Epilepsies, (1969); Antiepileptic Drugs, (1972); Experimental Models of Epilepsy, (1972); Neurosurgical Management of the Epilepsies, (1975); Complex Partial Seizures and their Treatment, (1975); Infantile Spasms (1976); and Antiepileptic Drugs: Quantitative Analysis and Interpretation (1978). Abstracts of numerous scientific epilepsy papers from journals appear in Epilepsy Abstracts, which is partially funded by NINCDS.

Diagnosis

Diagnosis of epilepsy is made by obtaining a detailed history on the patient, and a general physical and neurological examination. Often specialized diagnostic techniques are used. These include an electroencephalogram (EEG), or recording of brain waves; x-rays of the skull; psychological tests; lumbar puncture to sample spinal fluid; brain scan; pneumoencephalogram; arteriography; neuro-ophthalmological evaluation; and blood and urine tests. The most recent advances in diagnosis is a non-invasive and painless technique called Computerized Axial Tomography (CAT) which provides a multi-dimensional view of the brain by scanning the head with x-rays and computer evaluation of the resulting data.

A physician must determine whether there is a recognized treatable cause of the seizures such as tumor or cerebrovascular disease. In most cases, a cause cannot be determined. Also, identification of the seizure type is a necessary aspect of treatment. Until recently, seizures other

than the tonic-clonic type have been poorly described and often inaccurately diagnosed, particularly among children where complex partial and absence seizures are frequently confused. Recent advances in recording equipment have led to the development and increasing use of a combined long-term EEG and television monitoring of patients. Split-screen techniques showing the patient and the EEG (brain wave) picture simultaneously are helpful in diagnosis. Telemetry has made it possible to monitor a patient's seizures in various settings, free from laboratory or hospital restrictions. EEG cassette recording systems are being developed which allow monitoring of patients in their homes without restrictions.

Therapy

Drug control of seizures began in 1857 when bromide was introduced. Modern medication started with use of phenobarbital in 1912. Phenytoin (diphenylhydantoin; Dilantin) was not introduced until 1938. Although the barbiturates or the hydantoins, alone or in combination, control seizures in a significant proportion of the epileptic population, patients with absence seizures and complex partial seizures are little improved. Also, when doses of these medications are increased, undesirable side-effects become more apparent. The first drug specifically for control of absence seizures, trimethadione, was not developed until 1946. In 1954, primidone (Mysoline) was introduced for use in complex partial seizures. The most recent additions -- carbamazepine (Tegretol) and clonazepam (Clonopin) became available in the United States in 1974 and 1975, respectively, as a result of the support and coordination provided by the NINCDS.

For the past six years the Institute has evaluated and compared the efficacies of standard and new anticonvulsant drugs. The Epilepsy Branch of the NINCDS's Neurological Disorders Program coordinates most of the nation's research in these areas. This research is guided by an NIH Epilepsy Advisory Committee composed of physicians, pharmacologists, and other specialists from academic institutions and the drug industry. One promising new drug being investigated by the Institute and Abbott Laboratories is valproic acid (Depakine) which has been used extensively in Europe and Japan for at least 10 years. Efficacy and safety studies are being conducted at the University of Virginia School of Medicine, Charlottesville; the New Castle State Hospital, New Castle, Indiana, and the NIH Clinical Center. Foreign use of the drug has shown it effective against a variety of seizures without serious side-effects.

The NINCDS Anticonvulsant Screening Project (ASP) of the Antiepileptic Drug Development (ADD) Program began in January 1975 to provide evaluations of the anticonvulsant activity of new chemical compounds. In the first 3 years of the Project, 1780 compounds were submitted for testing. Eight

hundred were from 43 medicinal chemists at universities and the remaining 980 were supplied by 32 commerical firms. Results of Stage 1 screening are complete on all of these compounds; of these 29 percent had anti-convulsant activity at doses of 100 mg/kg or less without signs of neurological deficit and have either completed or are scheduled for Stage 2 screening (Anticonvulsant Quantification). The remaining 71 percent exhibited activity at doses greater than 100 mg/kg or showed no anticonvulsant activity at doses tested and will undergo no further study. Currently, there are nine compounds undergoing further testing (Stage 3 screening) and additional compounds are being added as possible candidates for Stage 3 as more Stage 2 evaluations are finalized.

Within the past 10 years, a wealth of information has been accumulated on the most frequently used antiepileptic drugs. Also the newer analytical methods of gas-liquid chromatography, immunoassay, and high pressure liquid chromatography, make it possible to determine accurately the amount of an antiepileptic drug in a patient's blood. Such measurements assure that the correct amount of drug is present in a patient and helps the physician to prevent many toxic side- effects and to improve the results of therapy. Physicians who rely on measurements of drug levels in the blood have become increasingly concerned over the variability of results reported by the laboratories who make the measurements. The Epilepsy Foundation of America, a voluntary health agency, established an Antiepileptic Drug Level Quality Control Program in 1974, after a survey of clinical laborstories revealed unacceptable variabilities. The program helps each laboratory evaluate its own performance. Participation in the program does not assure quality of performance or imply reliability but it provides a reference for the laboratory and assistance as needed. The first year's funding was made by the Epilepsy Foundation of America; the second by the Developmental Disabilities program of HEW; and now, the program is supported by the laboratories which use its services. A directory of laboratories participating in the program is available to physicians from NINCDS. Information about the program may be obtained from the Department of Neurology, Columbia College of Physicians and Surgeons.

Surgery is sometimes used for patients who do not respond to drugs, and it is being done in a number of centers in the United States. However, stimulation of the cerebellum is an experimental technique which does not appear to warrant widespread use at the present time.

There is much interest in the possibility of reducing seizures by so-called feedback modification of EEG (brain wave) activity. Much controlled research and data analyses are needed to know whether this technique is beneficial in controlling seizures. This is considered an exciting possibility as it might provide seizure control without antiepileptic drugs or surgical intervention. However, because of research design difficulties, it will probably be some years before the role of feedback in seizure treatment is known.

Experimental Animal Studies

Much research has been devoted to studies which probe how antiepileptic drugs work to suppress seizures. Not only does this provide insight into how the nervous system acts, but it will help develop more effective forms of therapy. Several new and promising lines of investigation have focused upon how phenytoin interacts with excitable membranes and exerts its membrane stabilization. Several investigators have determined what goes into this excitable state of nerve tissue and the ways phenytoin modifies this state. Other researchers are concerned with the mechanisms of action of other antiepileptic drugs.

Prognosis

The NINCDS Collaborative Perinatal Project collected data on mothers in over 50,000 pregnancies and their offsprings from 1959-1974 in an effort to learn about many neurologic disorders including epilepsy. Researchers recently examined the data on children who had febrile seizures (convulsions that accompany fever of illness), and learned that prior neurologic and developmental status and family history of seizures are important predictors of epilepsy after febrile seizures. Children whose neurologic or developmental status was suspect or abnormal before any seizure, whose first febrile seizure was complex (longer than 15 minutes, multiple or focal), and those who had members of the immediate family having experienced seizures without fever, had a much higher rate of development of subsequent epilepsy. If small subgroups of children at high risk for subsequent epilepsy development can be determined, it may be possible to direct clinical treatment with anticonvulsant medications to children who are a special risk.

Infantile spasms are an unusual form of epilepsy that are limited to infants and children. The seizures are frequently accompanied by developmental retardation and a chaotic electroencephalographic pattern called "hypsarrhythmia." This triad of abnormalities is often called West's syndrome. A unique feature of infantile spasms is the age of onset. The spasms characteristically begin in the first year of life, suggesting a developmental disaster in the brain. Infantile spasms are highly resistant to conventional antiepileptic therapy. Mental retardation often persists after the spasms have ceased. To stimulate research interest in the catastrophic problem of infantile spasms, the Institute has published a systematic and thorough review of current knowledge about categorization, diagnosis, and treatment of infantile spasms, and supports a pilot study of quantification and treatment of this disorder.

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Comprehensive Epilepsy Research Programs

Five Comprehensive Epilepsy Programs are being developed at the University of Minnesota Health Sciences Center, Minneapolis; Good Samaritan Hospital and Medical Center, Portland, Oregon; University of Virginia Medical Center, Charlottesville; the University of Washington School of Medicine, Seattle; and the Medical College of Georgia, Augusta. The programs perform clinical research and ensure the rapid transfer of technology from concept to clinical application. They provide excellence in epilepsy research, education, and patient care, including the latest and best methods of prevention, diagnosis, treatment and rehabilitation. They also develop new methods of prevention, diagnosis, treatment and rehabilitation, and distribute knowledge as widely and as quickly as possible.

Commission For The Control of Epilepsy and its Consequences

Legislation signed by the President in July 1975 directed that a nine member national commission be appointed to conduct a study of epilepsy and the way the country is dealing with it. The Commission's findings, including over 400 specific recommendations (67 applicable to the NINCDS) were recently submitted to the Congress. Input to the report came through a series of regional hearings, consumer and professional workshops, expert statements, literature analysis, governmental agency and legislation review, and detailed Governor's communications. Recommendations totalling $73.7 million for the first year, were made in the areas of medical services, research, prevention, education and employment, social adjustment and mental health, public, patient and professional education, and achievement of independence and equality.

Research Centers

The University of California at Los Angeles, and the Universities of Washington, Yale, Baylor, and Stanford have epilepsy centers supported by the Institute. Each center focuses on brain mechanisms and functions and on new treatments. NINCDS also supports 44 individual research projects throughout the country.

Communication

To ensure rapid communication of epilepsy research results to scientists and physicians, the Institute sponsored a Symposium on the "Mechanisms of Action of Anticonvulsant Drugs" in St. Louis, Missouri (proceedings to be published by mid-1978), to help understand the means by which drugs work; and sponsored meetings of the Subcommittee on Anticonvulsant Drugs of the NIH Epilepsy Advisory Committee. It has also continued sales of a motion picture, "The Absence Seizure" through the National Audiovisual Center, and free loan distribution by the National Medical Audiovisual Center.

Through its Office of Scientific and Health Reports, NINCDS has responded to requests from the scientific, medical, paramedical, and lay public for 21,000 epilepsy pamphlets, monographs, magazine reprints, and specific personal information. Materials available for general public inquiries include newspaper and magazine articles, health columns, radio and TV spots. TV appearances by Institute scientists also have generated interest in the publications and work of the NINCDS.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

REPORT ON POPULATION AND FAMILY PLANNING ACTIVITIES

A REPORT TO THE
HOUSE COMMITTEE ON APPROPRIATIONS

PREPARED BY

OFFICE OF POPULATION AFFAIRS

FEBRUARY 1978

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I

INTRODUCTION

This report describes the population research and family planning activities of the Department of Health, Education, and Welfare.

Population research and family planning activities in the Department of Health, Education, and Welfare include support of services--making family planning information and services available and accessible; training--meeting the professional and lay manpower needs in health, social services, and education; research--promoting and supporting research and research training in the biomedical and broad behavioral aspects of fertility, sterility, population dynamics, and program implementation; and public education--increasing opportunities for sex education, public understanding of human sexuality, and information about family planning and population growth.

Family planning services, as an integral part of adequate medical care, have been routinely and easily available to the majority of the population. In his message to the Congress, President Nixon emphasized that "...no American woman should be denied access to family planning assistance because of her economic condition." Under the Social Security Amendments of 1967 (PL 90-248), subsidized family planning services are available through a variety of sources to some of those who want but cannot afford them. The Social Security Amendments of 1972 (PL 92-603) required that family planning services be offered and provided promptly upon request to all recipients of Aid to Families with Dependent Children (AFDC). The Social Services Amendments of 1974 (PL 93-647) added a Title XX[1/] to the Social Security Act (SSA). Under Title XX, the major provisions of PL 92-603 continue in effect. Under the Social Services Amendments of 1976 (PL 94-401), States may elect to provide family planning services to individuals regardless of their income.

The Family Planning Services and Population Research Act of 1970 (PL 91-572) established Public Health Service (PHS) Act Title X, the major direct source of Federal support for family planning services programs. PHS Act Title X was extended through fiscal year 1978 by PL 95-83.

Legislative Highlights - FY 1968 Through FY 1977

1. On January 2, 1968, the Social Security Amendments of 1967 (PL 90-248), which included the Child Health Act of 1967, were enacted. This Act established categorical project grants for family planning services and required that not less than six percent of the monies appropriated for Maternal and Child Health under SSA Title V be available for family planning services. This same legislation required that under SSA Title IV-A, the AFDC program, family planning services were to be offered in all appropriate cases. Acceptance of such services was to be voluntary.

1/ SSA Title XX applies to the 50 States and the District of Columbia. Family planning social services for Guam, Puerto Rico, and the Virgin Islands are available under SSA Titles I, IV, X, XIV, and XVI.

2. On December 24, 1970, the Family Planning Services and Population Research Act of 1970 (PL 91-572) was enacted. This Act was passed to assist in making comprehensive voluntary family planning services available to all persons desiring such services.

3. On October 30, 1972, the Social Security Amendments of 1972 (PL 92-603) was enacted. This Act made it mandatory to inform all recipients of AFDC of the availability of family planning services and to provide or contract for services to all eligible persons voluntarily desiring them. The Act imposes a penalty of one percent per annum on the Federal share of AFDC funds on States which fail to provide these services to eligible persons desiring them. In addition, the Act increases the Federal share of matching for family planning services under Title IV-A -- AFDC -- to 90 percent from 75 percent and increases the Federal share for family planning services under Title XIX -- Medicaid -- to 90 percent from a variable formula with a range from 50 to 83 percent Federal matching.

4. On June 18, 1973, PL 93-45 extended the funding authorizations in PL 91-572 one additional year to June 30, 1974.

5. On January 4, 1975, the Social Services Amendments of 1974 (PL 93-647) were enacted. This law established SSA Title XX which placed major responsibility upon the States to develop their social services programs to be responsive to the needs of the citizens of each State. Title XX continues the requirement under PL 92-603 that family planning services be offered and provided promptly to those AFDC recipients requesting such services. States may also elect to provide family planning services on the basis of income eligibility status. In addition, States must provide three services to recipients of Supplementary Security Income (SSI) payments to the aged, blind, and disabled, of which family planning can be one service. The Federal share of matching continues at the 90 percent rate.

6. On September 7, 1976, PL 94-401 amended SSA Title XX, adding a provision that States may provide family planning services to individuals regardless of their income.

7. Enacted on August 1, 1977, PL 95-83 extends PHS Act Title X through fiscal year 1978.

The two tables that follow list some of the functions carried out by Department of Health, Education, and Welfare (DHEW) agencies.

Table 1 summarizes DHEW family planning programs for delivery of services by function, local delivery agency, and DHEW operating agency with funding and program responsibility.

Table 2 summarizes other DHEW population and family planning programs (research, training, education, and evaluation) by function and DHEW operating agency with funding and program responsibility.

Table 1

DHEW Programs for Delivery of Family Planning Services
by Function, Local Delivery Agency, and DHEW Operating Agency

Function	Local Delivery Agency	DHEW Operating Agency with Funding and Program Responsibility
Medical Services, Information, Counselling, and Referral	Hospitals and Clinic Services	HSA[1/] -- Indian Health Service -- Bureau of Medical Services -- Bureau of Community Health Services HCFA[2/] -- Medicaid Bureau OHDS[3/] -- Administration for Public Services
	Health Departments	HSA -- Bureau of Community Health Services HCFA -- Medicaid Bureau OHDS -- Administration for Public Services
	Voluntary Health Agencies	HSA -- Bureau of Community Health Services HCFA -- Medicaid Bureau OHDS -- Administration for Public Services
	Private Physicians	HCFA -- Medicaid Bureau OHDS -- Administration for Public Services

1/ Health Services Administration
2/ Health Care Financing Administration
3/ Office of Human Development Services

Table 1 (Cont'd)

DHEW Programs for Delivery of Family Planning Services
by Function, Local Delivery Agency, and DHEW Operating Agency

Function	Local Delivery Agency	DHEW Operating Agency with Funding and Program Responsibility
Information, Counselling, and Referral Only	Income Maintenance Agencies	SSA[1/] -- Office of Family Assistance
	Public Social Service Agencies	OHDS -- Administration for Public Services
	Voluntary Social Agencies	OHDS -- Administration for Public Services
	Employee Health Services	HSA -- Bureau of Medical Services

1/ Social Security Administration

Table 2

Other DHEW Population and Family Planning
Activities by Function and DHEW Operating Agency

Function	DHEW Operating Agency with Funding and Program Responsibility
Training Programs for Population and Family Planning	
1. Short-term Pre-Service and In-Service Training of:	
(a) Physicians, nurses, other professional health personnel	HSA -- Bureau of Community Health Services CDC[1/]
(b) Social workers and other public assistance personnel	OHDS -- Administration for Public Services SSA -- Office of Family Assistance
(c) Teachers	OE[2/]
(d) Subprofessional workers	OHDS -- Administration for Public Services HSA -- Bureau of Community Health Services OE -- Adult and Vocational Education
2. Curriculum Development for Above Programs	OHDS -- Administration for Public Services OE
Research Training in Population and Family Planning	NIH[3/] -- National Institute of Child Health and Human Development HSA -- Bureau of Community Health Services CDC

1/ Center for Disease Control
2/ Office of Education
3/ National Institutes of Health

Table 2 (Cont'd)

Other DHEW Population and Family Planning
Activities by Function and DHEW Operating Agency

Function	DHEW Operating Agency with Funding and Program Responsibility
Education Programs	
1. Sex and Family Life Education at Elementary and Secondary School and College Levels	OE
2. Professional Schools	
(a) Physicians, nurses, and other health professions	HSA -- Bureau of Community Health Services
(b) Social workers	OHDS -- Administration for Public Services
(c) Teachers	OE
3. Curriculum Development for Above Programs	OHDS -- Administration for Public Services OE
Research	
1. Reproductive Physiology and Contraceptive Development; evaluation of safety and possible adverse effects	NIH -- National Institute of Child Health and Human Development FDA[1/]
2. Social Research	OHDS -- Administration for Public Services HSA -- Bureau of Community Health Services OASH[2/] -- National Center for Health Statistics NIH -- National Institute of Child Health and Human Development

1/ Food and Drug Administration
2/ Office of the Assistant Secretary for Health

Table 2 (Cont'd)

Other DHEW Population and Family Planning
Activities by Function and DHEW Operating Agency

Function	DHEW Operating Agency with Funding and Program Responsibility
3. Administrative Research	
(a) Utilization studies	OHDS -- Administration for Public Services
(b) Demonstrations in innovative service delivery mechanisms	HCFA -- Medicaid Bureau SSA -- Office of Research and Statistics HSA -- Bureau of Community Health Services
(c) Evaluation methods	OASH -- National Center for Health Statistics
Evaluation	
1. Overall Evaluation and Coordination	OASH -- Office of Population Affairs
2. Medical Services Evaluation	HSA -- Bureau of Community Health Services
3. Social Services Evaluation	OHDS -- Administration for Public Services HCFA -- Medicaid Bureau

II

PUBLIC HEALTH SERVICE

Office of the Assistant Secretary for Health

The Office of Population Affairs (OPA) serves as a focal point for coordination of Department population research, population education, and family planning services activities. The Deputy Assistant Secretary for Population Affairs heads the OPA and has full line authority and responsibility for directing population research and family planning services within the health agencies. PL 91-572, the "Family Planning Services and Population Research Act of 1970," establishes the OPA by statute and delineates the functions of the office as follows:

> The Secretary shall utilize the Deputy Assistant Secretary for Population Affairs--
>
> (1) to administer all Federal laws for which the Secretary has administrative responsibility and which provide for or authorize the making of grants or contracts related to population research and family planning programs;
>
> (2) to administer and be responsible for all population and family planning research carried on directly by the Department of Health, Education, and Welfare or supported by the Department through grants to, or contracts with, entities and individuals;
>
> (3) to act as a clearinghouse for information pertaining to domestic and international population research and family planning programs for use by all interested persons and public and private entities;
>
> (4) to provide a liaison with the activities carried on by other agencies and instrumentalities of the Federal Government relating to population research and family planning;
>
> (5) to provide or support training for necessary manpower for domestic programs of population research and family planning programs of service and research; and
>
> (6) to coordinate and be responsible for the evaluation of the other Department of Health, Education, and Welfare programs related to population research and family planning and to make periodic recommendations to the Secretary.

In addition to its primary program direction activities, the OPA serves as a staff office for the Assistant Secretary for Health. This function involves advising the Secretary, through the Assistant Secretary, on policy and new legislation; participating in legislative and fiscal planning; and preparing reports on departmental and inter-departmental activities for the Secretary and the Congress. The OPA also prepares staff documents for the Secretary and for the White House.

Besides direct coordination of DHEW programs, the OPA works in close cooperation with, and provides leadership to, population research, population education, and family planning activities of other Federal agencies.

A continuing partnership between the Government and other concerned organizations is essential. The past work of private agencies in population-related fields has laid a foundation on which the official agencies continue to build. Therefore, the OPA maintains effective liaison with interested public and private organizations.

The OPA also maintains close communication with the population centers of major universities so that training can be geared to actual needs as they are revealed in ongoing DHEW programs.

In order to stimulate concerned professional and citizen groups to develop family planning resources, the OPA provides leadership at regional meetings, conferences or similar activities.

The OPA is the lead office for population education in DHEW. It is responsible for promoting and coordinating support for population education activities in Federal agencies and for encouraging population education efforts in the non-Federal sector. The primary objective of population education is to provide all sectors of the American public with greater knowledge and understanding of U. S. and world population issues.

The Office of International Health (OIH), a staff office to the Assistant Secretary for Health, is the focal point within the Department for international health relations and for policy development and program coordination relating to international health.

One of the office's responsibilities is the overall administration of the Scientific Activities Overseas (Special Foreign Currency) Program. This Program enables the health agencies to use U.S.-owned excess foreign currency to support selected health research and related activities in designated foreign countries. The countries designated as excess currency countries by the Treasury Department for fiscal year 1978 are Egypt, Burma, Guinea, India, and Pakistan.

There are about 250 active projects within this program at the present time. These include eleven in the field of population and family planning representing a total obligated cost of $3.2 million in foreign currencies. Included among these projects are studies of thromboembolism and oral contraceptives, biochemical tests of sperm in relation to fertility, tryptamine receptors in the isolated rat uterus, and methods of demographic projection analysis.

One study on the epidemiology of birth weight and effects of induced abortion on subsequent offspring was obligated in fiscal year 1977 in the amount of $173,000. A number of new projects have been proposed for development and possible funding during fiscal year 1978 and 1979. These include development of methods for reversible sterilization of men and women and of implantable contraceptive drug delivery systems, establishment of serum baseline levels of reproductive hormones in fertile and infertile couples, studies to determine whether certain steroidal drugs used in oral contraceptives cause damage to reproductive organs, as well as studies directed toward improving family planning services and providing insight into factors which motivate acceptance of family planning.

The office also provides services to the Agency for International Development (AID) on population and family planning programming and facilitates coordination and exchange among concerned U.S. and international agencies. The AID program provides assistance to about seventy developing countries through bilateral or regional projects. Many of these projects are implemented through AID contracts and grants to U.S. institutions and international agencies.

The OIH staff contributes mainly to those AID projects aimed at the development of more adequate systems for the delivery of clinical and educational services and the preparation of manpower. The services provided to AID include problem analysis, project design, identification of technical resources, review of project proposals, program evaluation, planning of training workshops, and guidance on implementation problems. This entails field visits to the AID assisted countries; working with

international organizations; participating in AID task forces, committees, and meetings; and, provision of information and resource materials as requested by AID Missions, AID contractors, and concerned individuals.

Although not directed specifically at population and family planning programming, those areas comprise a significant element of the office's technical consultation services to AID in health planning and health sector assessment. The activities are conducted in a number of underdeveloped countries by OIH staff in cooperation with other consultants, AID Mission personnel, and foreign national officials of Ministries of Health and other health-related national agencies.

The National Center for Health Statistics (NCHS) is responsible for operating a uniform National Reporting System for Family Planning Services (NRSFPS). The NRSFPS was established in order to produce uniform, comparable statistical information on federally-supported family planning programs and, to the extent possible, on other public and private organizations. The NRSFPS has from its initiation in 1969 until June 30, 1977, collected information from all identified family planning service sites on a 100 percent basis. On July 1, 1977 the NRSFPS was converted to a sample survey.

The NRSFPS provides information about the utilization of medical family planning services and about the characteristics of persons receiving those services at family planning service sites throughout the United States and its territories. Annual Summary estimates will be made for the Nation, the 10 DHEW regions and each State.

A second NCHS program for providing information on family planning services, the National Inventory of Family Planning Service Sites, was initiated in 1974. The National Inventory is a comprehensive listing of all sites in the United States that provide family planning services, whether these services are medical or non-medical and regardless of the type of funding support. Unlike the NRSFPS which obtains primarily patient characteristics, the National Inventory, through a periodic census, provides basic characteristic data on the facility. The National Inventory will be used as the base from which sample sites will be selected for the NRSFPS. The National Inventory will also provide the base for any required special studies.

NCHS also operates, on an approximately biennial basis, the National Survey of Family Growth to collect data on factors affecting trends and differentials in the birth rate, family planning, and infant and maternal health. This survey is based upon personal interviews with representative samples of ever-married women in the childbearing ages. Data from the first cycle of the survey (1973-74) have been released, and data from the second cycle (1976) will be released beginning in 1978. Detailed information on the past and current use of family planning methods is secured in this survey.

National Institutes of Health

The research programs of the Department in the population sciences are directed by the National Institute of Child Health and Human Development. Section 444 of the Public Health Service Act authorizes the Institute to conduct and support research and training relating to maternal health, child health, and human development, including research and research training in the special health problems and requirements of mothers and children and in the basic sciences relating to the processes of human growth and development, including prenatal development. Section 1004 of Public Law 95-83 authorizes the Secretary of Health, Education, and Welfare to make grants and to enter into contracts for "...research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population..."

Total expenditures by the Institute in fiscal year 1977 for population research were $59.5 million. They are projected to be $68.6 million for fiscal year 1978. Of the projected expenditures in FY 1978, $65.3 million is applicable under the authority of P.L. 95-83.

Other components of the National Institutes of Health provided approximately $11.8 million in fiscal year 1977 to support a variety of extramural activities with important implications for population research. Research in reproductive endocrinology supported by the National Institute of Arthritis, Metabolism and Digestive Diseases totalled approximately $4.0 million in fiscal year 1977. These studies provide basic information essential in the development of new methods for controlling reproductive processes. The National Cancer Institute's interests in reproductive endocrinology, other reproductive processes, and carcinogenic effects of synthetic estrogens are relevant to understanding normal function and fertility control. In fiscal year 1977, $1.7 million was spent to support these studies.

The National Heart, Lung, and Blood Institute awarded $0.4 million for studies of the effects of estrogens, progestogens, and steroid contraceptives on blood clotting mechanisms and the physiology of circulation. Several studies in reproductive neuroendocrinology, genetic aspects of reproduction, and toxic effects of environmental agents on reproduction were supported by the National Institute of Neurological and Communicative Disorders and Stroke and the National Institute of General Medical Sciences, and the National Institute of Environmental Health Sciences respectively. Support for population research in these three Institutes totaled about $0.5 million in fiscal year 1977. The Division of Research Resources administers approximately $5.2 million in general research support relevant to the population field.

The Center for Population Research (CPR) of the National Institute of Child Health and Human Development (NICHD) is responsible for the primary Federal effort in population research. Support is provided through grants and contracts for:

-Fundamental biomedical research on reproductive processes relevant to problems of human fertility and infertility.

-The development of new and improved methods for fertility regulation.

-The evaluation of the safety and effectiveness of contraceptive methods currently in use.

-Population dynamics research in the behavioral and social sciences on the reproductive motivation of individuals, and the causes and consequences of population change.

-Research on solutions to major problems related to population and reproductive behavior, such as a) high risk pregnancy, especially adolescent childbearing, and b) the relationships between nutrition and reproduction.

Each of these activities is integral to the solution of individual, family, national and international problems. Program emphases, accomplishments, and goals and plans are described according to the substantive areas listed above. In addition, there is a description of CPR efforts to support institutions, develop scientific manpower, facilitate the coordination of Federal population research programs, and communicate research information in the population sciences.

Research Objectives

In the biomedical sciences the objectives are (1) to increase our understanding of all aspects of human and relevant animal reproductive processes in both the female and male; (2) to develop an array of contraceptive methods which are effective, safe, inexpensive, reversible, and acceptable to various population groups; and (3) to evaluate the medical effects of contraceptive methods in use to assure safety and efficacy over short as well as extended periods of time.

The research objectives in the behavioral sciences are (1) to ascertain the social, psychological, and economic determinants of human fertility, since fertility is the single most dynamic factor in population growth; (2) to assess the effects of population size, composition, and distribution so that public policy may be guided by adequate information; (3) to identify the conditions which precipitate migration and to define its consequences, since migration is one of the principal means by which populations adjust to social and economic change; and (4) to increase our understanding of the economic, environmental, social and behavioral consequences of population growth and change.

The program in fundamental biomedical research includes research on female fertility, male fertility, reproductive endocrinology, egg and sperm transport, fertilization, implantation, and animal reproductive behavior. Studies of reproduction in the human and relevant animals are supported in order to increase our knowledge of reproductive processes, the regulation of fertility, and the alleviation of infertility.

The contraceptive development program supports a wide variety of projects aimed at the development of safe and effective methods for fertility regulation in both men and women. These studies involve two broad categories: (1) directed fundamental biomedical research which includes studies in several well-defined areas of reproductive biology and biochemistry that provide the necessary base of scientific knowledge; and (2) product development research which is aimed at the development of new contraceptive methods, utilizing the aforementioned fundamental research, and ranges from laboratory synthesis and testing of new chemicals to clinical trials involving both drugs and devices.

The program in contraceptive evaluation is concerned with studies to evaluate the safety of methods of contraception currently in use. The emphasis in this evaluation, particularly with respect to the contraceptive steroids, is on long-term safety. Modern methods of contraception have come into increasingly frequent use both here and abroad during recent years. The most common method used in this country is the oral contraceptive pill. Intrauterine devices are preferred by several million women. Furthermore, vasectomy has become an acceptable and frequently used technique of male sterilization. The widespread use of these various methods has resulted in a wide range of clinical experience and in the recognition of several complications associated with the use of some of these.

Research on population dynamics in the behavioral and social sciences is concerned with the factors governing variations in the growth, distribution, and characteristics of people and the impact of population changes on the health and welfare of individuals, families, and society as a whole. Such knowledge is essential for the formulation of desirable population goals and effective public policies, as well as other means, to achieve them. Research emphasis is on (1) the social, psychological and economic causes of changes in fertility, since fertility is the single most dynamic factor in population growth in the United States; (2) the effects of population size, composition, and distribution on the lives of individuals and families and on the social and economic institutions in which they participate; (3) the conditions which precipitate migration and the nature of its consequences, as migration continues to be an important element of social and economic change in our country.

Research on problems associated with adolescent pregnancy and childbearing involves efforts to understand the determinants of this phenomenon and its consequences. The continuing rise in the birth rates of adolescent girls is a matter of much public concern. Between the

early 1960s and the early 1970s the birth rate for girls under age 15 rose by 37 percent, the rate for 15-year olds increased by 24 percent and that for 16-year olds by 5 percent. In contrast, rates for older teenagers and for all women over age 20 declined. By 1974, young women who had not yet reached their 17th birthdays were having 122,000 births annually. Most of these young mothers (60 percent) were unmarried. The individual, social, and familial problems associated with this trend are diverse: lost educational and vocational opportunities for the mothers, inadequate care for many of the children, unwelcome burdens of support for many of the parents of teenage mothers, and increased dependency on public resources for medical care, child-care, and living expenses.

Studies dealing with the relationships between nutrition and reproduction include (1) involvement of dietary factors in reproductive processes; (2) the reproductive consequences of malnutriton; (3) the relationship between contraceptive use and nutrition; and (4) the role of nutrition in population dynamics. Research in this area is needed since nutritional factors are known to affect reproductive functions but the interrelationships are poorly understood.

1. Human Fertility, Reproductive Biology, and Infertility

The primary goal of CPR efforts in this area is to enable men and women to have healthy babies in the number and at the times such babies are wanted. To accomplish this goal, the Center will continue to emphasize research on: 1) the development and exploitation of new leads for less hazardous and more effective methods of fertility regulation for use by men and women; and 2) the alleviation of infertility and the amelioration or cure of diseases and disorders of the human reproductive system.

Continued progress in research on substances (releasing hormones) produced in the brain which indirectly control reproduction through stimulation of the pituitary gland has yielded new substances which can block or, alternatively, induce ovulation. In addition, these substances are available to physicians for the diagnosis and treatment of infertility as well as reproductive diseases and disorders. Drs. Roger Guillemin and Andrew Schally, both supported by CPR, recently received the Nobel Prize in Physiology or Medicine for research on the identification, synthesis and mode of action of releasing hormones.

Three recent discoveries have contributed significantly to our understanding of male reproductive processes and, potentially, to the development of new contraceptives for use by men. The first of these is the isolation from Sertoli cells in the testis of the long-sought "inhibin." "Inhibin" appears to be capable of blocking sperm production by the testis as a result of its inhibition of Follicle Stimulating Hormone (FSH), a substance secreted by the pituitary gland and believed to be required for sperm production. "Inhibin" may prove to be useful in the development of a male contraceptive because it neither suppresses the male sex hormone (testosterone) presumed to be involved in libido, nor is it expected to produce undesirable side effects since it occurs naturally in the human body.

The second finding with implications for male contraceptive development also involved the inhibition of sperm production by naturally occurring bodily substances. In this case, sperm production was blocked in experimental animals by the simultaneous administration of an androgen and an estrogen. When combined in a capsule implanted under the skin from which they were released continuously, these hormones blocked sperm production without any apparent effects on the sexual activity of the recipients. Moreover, when the two hormones were administered in combination, only very small (physiologically normal) amounts of each were required for inhibition of spermatogenesis. The requirement for only small amounts of estrogen is important because the potential usefulness of the combination for male contraception is inversely related to the amount of the estrogenic component required for inhibition of sperm production.

The report that has probably the most significant implications for male contraceptive development is based on evidence that a special form of the male sex hormone, testosterone, is capable of suppression of sperm production in men. In exploratory studies, suppression of sperm production was achieved in a small group of men without inducing in them any obvious evidence of undesirable side effects. The Center will support additional studies of this method in an effort to confirm its efficacy and to ascertain if any hitherto undetected problems, such as damage to the liver or other organs, might be caused by use of the testosterone for prolonged inhibition of sperm production in men.

Two recently discovered ovarian inhibitors are being purified and characterized. One inhibitor prevents development of the corpora lutea (part of the ovary which secretes the female sex hormone progesterone) in follicles, and the other prevents the maturation of ova. Either or both of these could be useful in fertility regulation by: 1) interfering with development of the corpora lutea required for maintenance of pregnancy; or 2) preventing ova from developing to the extent required for fertilization.

Progress has been made in increasing our understanding of the underlying molecular mechanisms involved in mammalian ovulation. In order for the ovum to escape the follicle, a layer of the basement membrane must be disrupted. The enzymes involved in this procedure are being identified and characterized. Information will be obtained which may be used to interrupt the release of the ovum.

Knowledge of the transport of sperm in the female reproductive tract is critical for understanding fertilization. Studies in the rabbit show that, contrary to assumptions, sperm do not enter the site of fertilization (lower half of the ampulla) until after ovulation when sperm are released from the lower isthmus of the oviduct. Ovulation, therefore, appears to be a stimulus for sperm transport to the site of fertilization.

Significant progress has been made in research on the precise manner in which sex steroid hormones (estrogens, androgens, progestins) control reproductive processes and events in the body. Of these hormones, the most remarkable progress has been made in the elucidation of the mechanism of action of estrogen. This female sex hormone appears to act primarily by "turning on" or activating one or more genes located in the nuclei of estrogen sensitive cells in the body. Much has been learned about the estrogen initiated sequence of events in the chick that lead to the "turning on" of the gene which governs the production of an important protein (ovalbumin). Since sex steroid hormones are required for reproduction, knowledge of these mechanisms should enable scientists to develop safe and efficacious procedures for the control of fertility and the alleviation of certain types of infertility.

A giant step toward the attainment of this goal occurred recently with the development of procedures for the isolation of large quantities of the ovalbumin gene. Because of this development, it should soon be possible to reveal the precise mechanism of regulation of the ovalbumin gene by estrogen. This significant achievement will mark the first time that a hormonally controlled gene will have been obtained from the cells of a higher organism in sufficient quantities for its widespread use in studies of the mechanism by which its action is controlled.

2. Fertility Regulation

The contraceptive development program supports research endeavors to develop a variety of safe, efficacious, reversible methods that are acceptable to various population groups. Although the major areas of emphasis elaborated upon in the previous report have remained essentially unchanged, the issue of safety of the various methods is becoming more and more important. Consequently, at all stages of method development, there exists a continuous evaluation process the purpose of which is to alert the researcher to potential clinical hazards of the method. Unfortunately, the state of the art is such that even carefully designed animal safety studies may not be predictive to humans. Nevertheless, the overall issue of product and method safety will continue to be in the forefront of the overall commitment in these important research areas.

Research activities to develop a variety of safe fertility regulation methods include (1) continued synthesis and biological evaluation of promising new compounds for the female or male; (2) development of technology for improved drug administration; (3) development of improved vaginal and uterine contraceptives based on chemical or physical methods; (4) continued clinical trials of sex steroids for suppression of sperm production and the consequent development of chemical contraceptives for males; (5) clinical and toxicological evaluation of long-acting progestin as a female contraceptive; (6) laboratory studies and clinical trials to develop and ascertain the efficacy of antifertility methods based on periodic abstinence; (7) studies required for clarification of mechanisms of action of specific drugs.

A. Product Development

Drug Synthesis and Testing. During the past year there was undertaken an extensive laboratory investigation of long-acting androgens (male sex hormones) as possible agents for male fertility regulation. Some of these drugs are much more potent and longer-acting than what is currently available. Consideration is being given to providing supplies of these drugs for toxicological studies and initial clinical studies.

In order to improve the safety of current oral contraceptives for women, considerable animal studies have been conducted on the substitution of synthetic estrogens with naturally occurring ones. Animal data and clinical data from Europe strongly suggest that such substitution can be successfully carried out. The naturally occurring estrogens should be handled more readily by the body, and consequently, present less burden to the liver and the vascular system. Toxicological studies will be initiated in FY 1978. The overall drug synthesis and testing program is being focused on several areas which have shown preliminary beneficial activity.

Drug Delivery Systems and Oral Formulations. Research during the past year has clearly established that new means of drug administration are realistic. The drug intake can be reduced and the potential of using new drugs can be expanded by utilizing factors which deal with drug bioavailability. Goals and plans for this area of research presented in the previous year's Five-Year Plan have been implemented, and the research is currently in progress.

Clinical Trials. Male antifertility trials currently in progress, as discussed above, stress the potential of limiting male fertility with male sex hormones. It has been established that human males do not respond uniformly to therapy and that blood drug levels needed to block spermatogenesis are higher than normally occurring ones. Nevertheless, the basic concept of managing male fertility through such an approach is still valid and strongly suggests that the search for new drugs or drug combinations is in order.

Studies dealing with periodic abstinence methods (Natural Family Planning) are beginning to show trends in favor of one of the methods. Couples utilizing several indexes for determining the fertile period are experiencing fewer pregnancies than couples utilizing a single index of the fertile period. These data are still preliminary but they suggest that a thorough review of the Ovulation Method of family planning is in order. Careful examination of these data is necessary since Congress has directed that the Natural Family Planning methods be made available to the public through HEW supported family planning clinics. Coordination between the research and service components of the Department is being maintained on this issue. Additionally, research findings from other projects that are closely related to the definition of the fertile period are examined for facts which may improve the operation of the main project.

B. Directed Fundamental Research

The major aim of directed fundamental research has been to supply basic information for applied projects. Although this component of the overall program has shrunk considerably, it has been productive and continues to justify the use of the contract mechanism for its support.

During the past year, new findings have clarified the chemical and physical properties of cervical mucus. This fluid changes in composition during the course of the menstrual cycle, and depending on its characteristics influences the passage of sperm through the cervix. Clearly this knowledge of mucus properties can be utilized for the development of contraceptive strategies. Examples of the latter, which are currently being investigated, are clinical trials of abstinence methods and research on intracervical devices which have the potential of rendering cervical mucus impenetrable to sperm.

Research Resources. In the last report, the provision of certain research materials to the scientific community was highlighted. During the past year a collaborative program of drug testing between the World Health Organization (WHO) and NIH has been implemented. Compounds synthesized by WHO contractors are forwarded to NIH for biological evaluation in the Biological Testing Facility. This interaction is beneficial to both organizations in that NIH gains access to potential contraceptive drugs and WHO obtains high quality biological evaluation.

3. Contraceptive Safety

The efforts of the program in contraception evaluation are directed toward attaining improved safety of methods of fertility regulation. This objective is pursued through (1) the identification of health risks associated with various methods of contraception, and (2) the delineation of particular conditions or circumstances which increase risks and provide a basis for counseling. Research into the mechanisms by which complications to various methods of contraception arise is another facet of this program. It is this understanding which will most likely lead to improved safety and further, may prove to be helpful in the development of safer methods of contraceptives.

The program is concerned with the evaluation of hazards associated with oral contraceptives and of intrauterine devices, and also the immediate and long-term risks associated with methods of sterilization for men and for women. In addition, studies are supported to ascertain the possible adverse consequences of pregnancy termination for the health of women, particularly regarding subsequent pregnancy performance.

Among hazards or suspected health risks of steroid contraceptives under investigation are cancer and other forms of tumors, heart disease, hypertension and thromboembolic disease, metabolic and nutritional disorders, birth defects, the identification of new and as yet unsuspected health hazards, and also the understanding of the underlying mechanisms by which known complications arise.

Investigations of women with hepatocellular adenoma (a benign tumor of the liver) has revealed a strong association with exposure to contraceptive steroids. The risks of this tumor increase several hundredfold after more than seven years exposure and are also higher in women over 27 years of age. The risk is related to the dose of estrogen and progestin in the combination pill. The findings suggest that the risk can be reduced by using low dose contraceptive steroids and by restricting their long-term use, certainly in older women. Similar lesions have also been observed in an ongoing experiment involving beagle dogs exposed to medroxyprogesterone.

Preliminary findings from a current project of the risk of myocardial infarction among women on contraceptive steroids confirms the high risk among women who are heavy smokers while using oral contraceptives. Clearly, women should be counseled to give up smoking before starting on contraceptive steroids.

Studies of pregnancies among women who have discontinued contraceptive steroids in order to conceive have indicated a slight increase in non-identical twins in pregnancies conceived within one month after discontinuation of this method of contraception. There also appears to be a slightly lower risk of spontaneous abortion among pregnancies conceived shortly after discontinuation of oral contraceptives.

Numerous possible leads are explored to help in the understanding of the underlying mechanisms by which certain complications arise among women on contraceptive steroids. This includes looking at possible immunological factors to explain the increased risk of blood clots in women on contraceptive steroids, and also the ability of such women to dissolve such blood clots.

Contraceptive steroids affect lipid metabolism by increasing levels of cholesterol and also triglycerides. These effects are known to increase the risk of chronic cardiovascular disease. Research in a specific animal model has shown that these alterations are not due to effects on the absorption of lipids from the gut, their transport in lymph, the rate of secretion of triglycerides by the liver or changes in the lipolytic activity of the enzyme, lipoprotein lipase, but rather to alterations in serum factors which are involved in the activation of this particular enzyme. It remains to be shown whether a similar mechanism is operative in women; however, this lead should be extremely helpful in this regard.

Experimental investigations of the effects of vasectomy among certain animals are continuing. The occurrence of immune complex disease of the testes and kidney has been demonstrated in vasectomized rabbits and also guinea pigs with high antibody levels. In certain animals, there are genetic differences in the development of antibodies after vasectomy. Some strains are nonresponders and others develop high antibody titers after vasectomy. It remains to be determined to what extent these findings in animal models apply to the situation in men.

4. Population Dynamics

Research on population dynamics in the behavioral sciences emphasizes the demographic, social and economic factors which influence the level of the birth rate and the factors which influence variations in family size among individuals and groups. Special attention is given to motivation for fertility regulation, variations in the perceived value and costs of children, changes in the structure and functions of the family, factors affecting the adoption and effective use of contraception on the part of both men and women, and the related effects of changing roles in our society, particularly of women.

Studies which monitor and describe the trends taking place in fertility in the nation are basic to this program because such studies identify changes occurring by age, region and subgroups of the population. A major focus of research will also continue to be the social, economic, and psychological causes and consequences of varying levels of fertility for the population as a whole or segments of it. This research explores the effects of social and economic policies upon the birth rate, changes in family structure, marriage, divorce, and changing roles of men and women in society as these affect fertility and fertility-related variables, such as marriage, divorce, and illegitimacy. It also concerns family decision-making processes which affect the adoption of contraception, selection of contraceptive methods, and the effectiveness with which the latter are used.

Population change results from the balance between births and deaths and migration into and out of any area. Throughout the world, death rates have already been brought low or are being reduced by improvements in public health and the advances in medical sciences, and the values of mankind demand that they remain low. Such urgency as attaches to concern with population growth must therefore be directed toward factors influencing fertility behavior and migration, and their consequences. Research in the behavioral and social sciences has accordingly concentrated upon these latter variables. Primary emphasis has been placed upon fertility, its causes and consequences. Secondary emphasis has been placed upon migration, though the latter must be understood not only because migratory behavior is often related to fertility as both cause and consequence, but also because its causes and consequences have great social, economic, and political significance in the modern world.

The effects of family size and the timing of births upon the health and the social and economic welfare of parents and children are also important because public knowledge of such effects can influence decisions made by individuals regarding age at marriage, timing, and spacing of births and completed family size. Similarly, sound knowledge regarding the consequences of population change for society can provide a foundation for the adoption of public policies designed to affect such change in the future or to make appropriate provisions for adjustment to them.

Research is necessary to create the scientific basis for formulating judicious population policies. In the field of population policy, it is necessary to estimate the influence that socio-economic conditions have on population change so that policy makers can understand how public policy can affect population change directly or indirectly through the diverse elements of our socio-economic system. Often, research is conducted to evaluate how well existing attempts to influence population are operating. Also, some types of population change are virtually impossible to modify through public intervention and in these cases research must indicate how society must adjust to new demographic conditions.

Trends in Fertility. Studies have documented the decline in fertility in recent years among nearly all segments of the population in the United States, urban and rural, among both blacks and whites, and among various religious groups. These declines are correlated with a rise in average age at marriage, greater proportions of men and women single at the younger ages, as well as some evidence of delays for first births and greater spacing of subsequent births. Both the National Fertility Survey of 1970 and data collected by the Census Bureau reveal a reduction in desired family size. While few respondents expect to be childless or to have only one child, an overwhelming majority indicate a preference for no more than two children. In 1975, three-fourths of women 18-24 years of age expected to have no more than two children, as compared to only 45 percent with these expectations in 1967. Moreover, the proportion of women having a child in the first two years of marriage is lower than in the period 1955-1965. The National Fertility Survey of 1970 also reports a marked increase in the use of contraceptives in all groups and increasing utilization of sterilization by both men and women, particularly among those over 30 years of age.

The many studies of U.S. fertility patterns indicate a trend toward the realization of the ideal of controlled fertility. The incidence of unwanted fertility has diminished, indicating an ever increasing level of contraceptive success among American couples. It is also noteworthy that the average age of childbearing has increased rather markedly, raising questions as to whether the dramatic fall of American fertility is a permanent phenomenon or a temporary deferral of childbearing.

In attempting to obtain more understanding of unwanted pregnancies, studies have shown that family planning clinic patients, who experienced contraceptive failures and had unwanted pregnancies, showed less ability to deal with a number of life's problems than successful contraceptors. They had poorer relationships with parents and sex partners, and were more immature and impulsive. Those who had unwanted pregnancies had less ability to plan for the future and were less socialized.

An analysis of contraceptive use at the time of abortion showed that about 57 percent of the women had very good knowledge of contraception but made poor use of it, 25 percent reported good contraceptive knowledge and use but still became pregnant, while about 18 percent demonstrated very poor knowledge and use of contraception.

Determinants of Fertility. A number of studies have examined the effects of economic factors upon fertility. The National Fertility Surveys of 1970 and earlier, as well as Census data, confirm the inverse relation between fertility and income. A study of the black population points to the narrowing gap between blacks and whites in proportions completing the twelfth grade and also improvement in occupation and income among blacks, as contributing to the decline of black fertility. Increasing education and rising occupational levels have also been found to be associated with declining fertility among Spanish-Americans. These studies, along with evidence from another that upward social mobility is associated with lower fertility, suggest that rising aspiration levels for self and children is a key determinant of low fertility.

The relationship between aspirations and income has also been used to account for the very great rise in fertility following World War II and continuing into the 1950s. According to an hypothesis advanced by Easterlin, the post-war increase is attributable to the marked rise in income in that period. The relative increase in income for young people entering the childbearing period, as compared with incomes of their parents when they were growing up, facilitated earlier marriage, earlier childbearing, and eventually larger families. This hypothesis is supported by analysis of census and vital statistics data, using econometric techniques. Fertility, whether measured as desired family size or current fertility, is highly responsive overall to change over time in relative income. Research using data from surveys in the period since 1955, however, has failed to support the hypothesis when interpreted as an explanation for individual behavior in a period of declining fertility. These studies have rather reconfirmed the traditional relationships between fertility and education, income, and other measures of socio-economic status. Further thoughtful research is therefore needed to clarify the relation between fertility and economic trends.

Costs and Value of Children. Increasing understanding of motivations for having children furnishes bases for the analysis of fertility regulation and future trends in population growth. The results of a national survey of parents show that the most important positive motivations for having children are that children satisfy parents' desire for love and a family, and children provide stimulation and joy. In viewing

the negative aspects of having children, parents perceive loss of freedom and restriction of activities as the greatest drawback, with financial costs not far behind. The findings suggest that if economic conditions become more prosperous, there could be a rise in fertility. Another study indicates that significant motivational differences exist between women with no children, one child, and two children. Attitudes toward sex roles undoubtedly influence and are influenced by the perceived costs and value attached to children. One study has indicated that perception of negative aspects of number of children dominate in the decision to limit family size, whereas the motivation to have children may be more a function of idealized expectations of what children are like, or response to felt social pressures and social expectations. Women who themselves have no children evaluate larger family sizes more positively than those who have already borne one or more children. Another study has shown that more women than men see having another child as hindering them from doing the things they like to do and making them less successful at their jobs.

Status and Roles of Women. A number of studies have focused upon various aspects of women's role identities as they affect fertility intentions and behavior. In one study indicators of female status--labor force participation, education, and potential earnings--are strong predictors of fertility variations among groups, and upward trends in these indicators appear to be associated with the decline in fertility between 1960 and 1970. Another study has indicated that women who feel that activities other than motherhood can be gratifying are more likely to postpone a birth and limit their family than women whose definition or womanhood is tightly bound to motherhood. However, a study of new mothers has shown that many young women enter motherhood without clear motivation for the role or desire to have a child at that time. Another has indicated that the role model provided by a girl's mother influences the timing of her first birth.

Research findings also indicate that over the four year period, 1971-1975, women (18-29) became significantly more modern or egalitarian in their sex roles. Those who were more modern in 1971 expressed intentions of having fewer children. During the four year period these women actually had fewer children, longer spacing between their children, and more continuous employment. Another investigator reports that the amount of the wife's potential or actual earnings outside the home exercises a strong negative impact on fertility. It is estimated that the doubling of potential or actual earnings may reduce fertility 25 to 50 percent, depending on the socioeconomic status of the group. A study suggests that the potential psychological gains associated with high female employment opportunity may also be an effective deterrent to high fertility. Furthermore, another investigation reports that the influence of labor force participation of women on fertility is so strong that unless economic conditions create substantial unemployment for these women, fertility rates in the U.S. may continue to fall.

Consequences of Population Growth. Research on the consequences of population growth has been pursued from the standpoint of both societal and individual welfare. Two major studies dealing with the effects of various rates of population growth upon the per capita well-being in the U.S. converge in their findings that, over a wide range of assumptions regarding future economic development, per capita welfare rises more rapidly with slower rather than faster rates of growth.

An important study has found a relationship between fertility and unemployment. This study concludes that changes in fertility rates and the resulting shifts in the population and labor force structure influence the full-employment to unemployment rate but do not influence the actual observed unemployment rate. This study argues that the unemployment goal in this country has been changing in recent years due to demographic pressure and has peaked at 5.5%, implying that this is the lowest possible rate of unemployment without producing increased inflation. Also, this study predicts that as demographic pressures ease in subsequent years, lower rates of unemployment may be possible.

A number of studies deal with the effects of family size on child development and achievement. One is studying the effect of age at marriage and time of first birth on family interrelationships and children's personality and cognitive development. Another is analyzing the effect of birth order and sex of infants on mother-child interaction and on the cognitive and emotional development of infants. Unique findings from this research show that birth order and spacing have affected mother-infant relationships and the child's cognitive performance as early as three months of age. These effects are still present at 12 months, but to a lesser extent.

Research is currently under way on the relationship of age of mother, social setting, interaction, and spacing on the performance and development of children at ages 2 days old through 11 years. One study reports an inverse correlation between intelligence of offspring and family size, even when socio-economic status and intelligence of parents are taken into account. Reduced interaction with parents as family size increases, apparently adversely affects the verbal development and operative intelligence of children. Another study similarly shows that educational achievement is lower the larger the family size, even when income is held constant. Further, the number of siblings that a child has exerts a strong negative influence on completed schooling, even when controlling for parents' schooling and income.

It was found that household crowding, experienced as an increase in the number of persons per room, had adverse effects on a number of characteristics including aspects of mental health as indicated by psychiatric symptoms, and general malaise; social relationships in the home such as marital and parent-child relationships; physical health; and fertility (that the crowded individuals tended to have more children than they wanted). However, there was not much of an effect of household crowding on social relations outside the home.

Two studies concern the effect of family size and childspacing on health. One relates spacing and family size to fetal, infant and early childhood mortality in a rural population, and the other relates the impact of childbearing and spacing patterns on the health of the mother and the development of the child in an urban milieu. Findings from the first show that pregnancies conceived in less than 12 months from the last pregnancy have a higher risk of early fetal death, especially if the last pregnancy resulted in a live birth, and a higher postneonatal mortality rate for live births resulting from less-than-12 month interpregnancy intervals.

Migration and Population Distribution. One study has explored how the absolute level of individual and family income interact with other variables to influence decisions to move, the distance moved, and region of destination. Except for the effect of migration upon progress in school, which is slightly negative, the burden of the findings so far is that migration is economically profitable to migrants. One emphasis in the study has been upon individuals in the United States below the poverty level. Only the West had a net in-migration of people below this level, the other three major regions in the U.S. having more of them emigrated than they gained. At the same time, data suggest that individuals on public assistance are less likely to move than those not on public assistance. An interesting result of the analysis is the determination that black migrants from the South to northern cities have higher incomes than those blacks born or reared in northern cities because the former have higher labor force participation rates.

Another study dealing with economic costs and benefits of migration concluded that benefits outweighed the costs from the standpoint of both migrants and areas of destination. For a number of years, migration was from the rural countryside and smaller cities to metropolitan areas, followed by a sizeable movement to suburbia, and a concentration of blacks within central cities. According to one study, blacks continue to be concentrated in central cities and a few suburbs, but the increasing attitudinal receptivity of whites and the rising economic potential of blacks portend shifts of blacks to the suburbs with increasing residential and educational integration. At the same time, a study on non-metropolitan population changes found that the open countryside in Pennsylvania is attracting more migrants than are the small non-metropolitan towns and cities, and that past and potential migrants appear to prefer non-metropolitan residence, but at sites within comfortable reach of the economic, social and cultural resources of larger cities. These findings are consistent with other research which is showing a change from migration into metropolitan areas to migration to non-metropolitan counties. Many of our central cities are losing population at a large rate which is contributing to a number of urban, social and economic problems.

Several studies indicate that there seems to be an increasing incidence of return migration, i.e., an exact reversal of past migration trends. We have been able to document which areas are losing population (Northeast and Northcentral sections) and gaining population (South and Southwest) due to this phenomenon. Also, certain groups (e.g., the retired) seem to be major contributors to the first wave of the new migration pattern. It is unclear whether the magnitude and composition of this phenomenon will sustain itself in the future and why migration patterns are changing at such a remarkable rate.

It is estimated that international migration, from both legal and illegal sources, accounts for almost half of the U.S. population growth. A significant part of that migration occurs between Mexico and the United States and is a matter of increasing concern to the U.S. public and policy makers. One study reports that 40% of the out-migration from rural locations in Mexico is directed towards the U.S., and that about 70% of this movement is of an illegal nature. The bulk of the migration to the U.S. is of a temporary (about 6-8 months) character. Most of the migrants are married with their families living in Mexico. The Mexican migrants found work in at least 110 different U.S. localities dispersed throughout 19 states. Contrary to popular belief, little use of social welfare programs is made by these migrants; nearly all of the migrants had paid U.S. Social Security taxes. The study concludes that "All available evidence indicates that these migrants paid into the U.S. government treasury in taxes, far more than they collected in the form of benefits from tax-using programs."

Population Policy. In the area of fertility regulation, many studies have documented that, in this country and around the world, the desire to limit fertility is there and the existence of family planning programs can have an effect in reducing the population growth rate. A long term study of Taiwan is an outstanding example of how the existence of a family planning effort coordinated with a vigorous program of economic development can reduce fertility to manageable levels. Similarly, studies in this country tend to find that American families are exercising more control over their fertility. Other studies have found that the success of family planning programs is uneven with respect to age, income, ethnic and social groups. Efforts to date have been least effective for adolescents and low-income minority groups. It is unclear at this time whether an increased family planning program will be necessary to affect the fertility of these special groups.

There are many policies limiting population movement and these policies have attracted increased attention in recent years. For instance, resettlement efforts in developing countries have been adjudged failures in a majority of studies and, similarly, policies designed to prohibit certain types of rural to urban migration have enjoyed only mixed success. In this country, many types of land use restrictions have been used to influence population distribution and movement, and research has not yet produced a definitive evaluation of their efficacy.

Several studies are under way which may eventually delimit the socio-economic pressures on U.S. immigration from Latin America, and preliminary research indicates that much of the migration into the U.S. is in response to short run surges in labor demand in this country. This implies that U.S. immigration authorities may find it exceedingly difficult to regulate this type of immigration during periods of economic growth in the United States.

5. Adolescent Pregnancy

Teenage pregnancy and illegitimacy are causing increasing concern in the United States. Although birth rates are generally declining for all teenagers, rates for those under 17 have risen since the 1960s. In 1975, one in every five births in the U.S. was to a teenage mother. Of these 595,000 births, 233,500 were illegitimate, and 120,000 were to girls under the age of 17.

These developments have serious implications for the well-being of young mothers, who are socially, psychologically and economically less well equipped to assume the responsibilities of parenthood than more mature married women, and for their children. Births to such young mothers run a variety of health risks: the fetal death rate is higher than at later maternal ages, the proportion of children born prematurely or with low birth weight is higher, and the infant mortality rate is higher. Furthermore, women who have their first births at very young ages tend to bear additional children at a more rapid rate, in comparison with women who started their childbearing later. This close spacing of pregnancies brings with it additional health risks to both mothers and children.

Research is emphasized which is designed both to provide baseline data concerning adolescent sexuality and childbearing and to isolate those factors that influence adolescent decisions concerning their sexuality and possible subsequent fertility. Emphasis is also on studies that analyze the contraceptive patterns of teenagers and examine how and why they resolve any subsequent pregnancies.

Research on fertility behavior among teenage women in the U.S. involving nationwide surveys made in 1971 and 1976 has found that unmarried adolescent girls, aged 15-19, have undergone important changes in sexual experience and contraceptive use during the period. For both races and at all ages, there was a 30% increase in the prevalence of premarital intercourse. Knowledge of time of greatest risk of contraception during the menstrual cycle was relatively poor in both 1971 and 1976 but sex education courses did contribute some to this knowledge. Most importantly, the use of contraceptives by teenage women increased significantly between 1971 and 1976 although about a quarter of the sexually active had never used contraceptives. A major change in contraceptive practice since 1971 is the large shift to oral contraception among both black and white teenagers, with about half the teenagers obtaining their original prescription from a clinic. There has been a substantial decline in the use of the three methods - condom, douche, withdrawal - which were most prominent in 1971.

A study of teenagers enrolled in a family planning clinic program revealed that 30 percent dropped out after two to four months. It appeared that prevention of pregnancy was not a matter of high priority to these teenagers.

Among college students, the pill and condom are the most used contraceptives, but there is much more satisfaction with the pill than the condom. However, there is still considerable use of ineffective contraceptives, despite the lack of satisfaction with them.

The social and psychological factors influencing teenage pregnancy to date have had only limited exploration. Research has indicated that rates of premarital intercourse among adolescents have risen, with greater increases for women than for men. Associated with this increase, a study has found that between 1967 and 1975 attitudes of college freshmen toward premarital intercourse have become more favorable, especially among females.

Women who become mothers during their teens are more likely to say that the birth was unplanned or that they regretted the timing of the birth. While teenage mothers seldom report having had strong desires to become pregnant, often there was not strong motivation to avoid becoming pregnant. One study focusing on norms and sanctions surrounding illegitimacy found a possible explanation for higher rates of illegitimacy among blacks in the fact that blacks were more likely than whites to view their environment as supportive of their pregnancies, but whites were more likely to receive support from the baby's father and to marry.

A positive relationship found in one study between mother's and daughter's age at first birth suggests that the mothers serve as role models and thus influence their daughters to accept a similar timing of motherhood even when the pregnancy was not planned. Thus, in an atmosphere of poorly defined goals regarding one's future young women are becoming sexually active at earlier ages than in the past, but showing only sporadic use of contraceptives, at least before a pregnancy. The result is not only a large number of early births, but also a large number of unwanted pregnancies terminated by abortion.

The consequences go far beyond the problems associated with the birth or the abortion experience. Some research suggests that the higher obstetrical risks associated with teenage pregnancy, especially among women over age 15 who have attained physical maturity, may be largely due to the inadequacy of prenatal care which the average pregnant teenager receives and associated factors such as socio-economic status, educational level and social support. Even if adequate prenatal care could be assured, however, research to date shows that a birth during adolescence has significant immediate and continuing effects on the life of the woman.

Approximately 2/3 of the births to teenagers occur within marriage and these marriages later show a higher rate of separation, divorce and dissatisfaction. There is also evidence that women who had a baby out of wedlock as a teenager later experience higher rates of marital disruption. Early childbearing is also associated with larger completed families and closer spacing of births.

Research findings continue to elaborate the extent to which early childbearing is detrimental to educational attainment. The younger a teenager is when she bears a child the greater the impact on her educational attainment. The effect on education is found regardless of the race or family background of the girls and research further shows that young women whose education is interrupted by childbearing rarely make up their deficiency.

Bearing a child as a teenager affects a woman's later occupational attainment and earnings, largely, though not entirely, as a function of her reduced education. As with education, the effect of early childbearing on economic indicators does not get better with time, but rather gets worse. Similarly, although initially more adolescent fathers are working than their classmates and earning more money, a decade later the classmates' investment in education has begun to pay off in higher income and jobs having higher status.

6. Nutrition and Reproduction

Nutritional factors are known to affect reproductive functions, but the interrelationships are poorly understood. Few attempts have been made to correlate nutritional adequacy with problems of hormonal balance that affect fertility. Both overnutrition and undernutrition can result in reproductive malfunction. Nutrition influences the span of reproductive life. Poor nutrition has been related to delayed onset of menarche and premature menopause, and it affects fecundity. Another effect of nutrition is on fetal outcome and infant survival. Nutrition and reproduction also interact in their relation to breastfeeding, which is involved in preventing another immediate pregnancy through the maintenance of lactational amenorrhea.

The research to be emphasized in this area includes involvement of dietary factors in reproductive processes, the reproductive consequences of malnutrition, the relationship between contraceptive use and nutrition, and the role of nutrition in population dynamics.

The function of trace elements, such as zinc and copper, in various facets of reproductive biology is becoming increasingly apparent. It has been known since the 1940s that zinc deficiency in rats leads to atrophy of the seminiferous epithelium of the testes. It has now been shown that a major zinc-binding protein is found in sperm tails, and is identical to a keratin-like protein (similar to hair) that is the major protein of sperm tails. These studies are vital to an understanding of the structural organization of the sperm and its assimilation by the egg after fertilization.

The importance that some vitamins have in reproduction is being investigated in several grants. The role that vitamin A plays in reproductive function is being studied at puberty, during the estrous cycle, and in pregnancy. In vitro experiments have shown that the presence of

vitamin A in steroidogenic tissues is necessary for the formation of steroid hormones. A key question is whether or not Vitamin A deficiency decreases the ability of the gonads to produce their steriod hormones and thus results in increased levels of plasma gonadotropins. Although malnutrition includes a variety of dietary deficiencies, this focus on Vitamin A deficiency may help explain some of the reproductive problems associated with inadequate diet.

A number of ongoing studies assessing the role of Vitamin E in the testis indicate that Vitamin E may have a vital role in the regulation of testicular function (e.g., sperm production). Lipids or fatty acids are essential components of the structure of organs and may have a key role in the metabolism and physiology of the testis. Studies with Vitamin E-deficient rats show that the production of prostaglandins is decreased. Prostaglandins, which acts as regulators of testicular function, apparently need to have Vitamin E present for their optimal production in the testis. The effect of Vitamin E deficiency on lipid synthesis in the testes of normal mice and mice with abnormal testes (essentially no germ cells) is being studied. Knowledge of the role that Vitamin E and fatty acids play in testicular physiology is important to our understanding of fertility in the male.

7. Institutional Development

A. Institutional Programs in Population Research (IPPR's) - Program Projects and Population Research Centers

IPPR grants are awarded to leading institutions in the United States to enable them to establish Program Projects and Population Research Centers on the basis of long term commitments of support for the combination of research projects, services and facilities and research environments required for the establishment and maintenance of interdisciplinary population research programs of high quality. Because of their enormity and complexity, some of the research problems in the reproductive and behavioral sciences cannot be solved by the individual investigator working alone in his discipline or in relative isolation from scientists of other disciplines. For their solution, these problems require the concerted efforts of highly skilled scientists from a variety of disciplines. Ascertainment of the mechanism of action of reproductive hormones or prediction of the acceptability and consequences of widespread use of new contraceptives are examples of population goals that are likely to be achieved only by investigative teams comprised of scientists chosen on the basis of potential contributions from their respective disciplines and their willingness to work together toward common research objectives.

The three IPPR programs are: 1) Program Projects; 2) Population Research Centers; and 3) Specialized Population Research Centers. Program Project grants are designed especially for small groups of investigators who require support for research projects and research resources for the conduct of interdisciplinary research on a specific population problem. Population Research Center grants are awarded to institutions for the support of the organizational framework and research resources required to increase the quality and productivity of ongoing population research projects of high quality. Specialized Population Research Center grants are awarded to institutions for support of population research areas specified by the NICHD. The high priority areas of eligibility for these centers are: 1) fertility regulation, with the development of new methods, the improvement of existing measures, and evaluation of non-contraceptive effects; 2) reproductive neuroendocrinology; 3) mechanisms of action of reproductive hormones; 4) reproductive immunology; 5) control of the ovarian cycle and ovulation; 6) post-puberal male reproductive processes and their control systems; 7) gamete transport in male and female reproductive tracts; 8) mechanisms of fertilization and implantation; 9) methods of fertility regulation not requiring drugs or devices; 10) human population genetics; 11) alleviation of infertility and other reproductive diseases; 12) acceptability of measures for the regulation of fertility; 13) adolescent fertility; 14) economic determinants and/or consequences of population change; 15) sociological determinants and/or consequences of population change; 16) consequences of a stationary population in the United States; 17) antecedents and consequences of legal and illegal immigration in the U.S.; 18) redistribution of the U.S. population; and 19) policies affecting population in developed societies.

A total of 31 Institutional Programs were supported during the 1977 fiscal year and the transition quarter, the period from July 1, 1976 to September 30, 1977. Of these programs, 7 were Program Projects, 16 were Population Research Centers, and 8 were Specialized Population Research Centers.

The recipient institutions and principal research areas of the Program Projects supported during the period from July 1976 to September 1977 are: 1) Columbia University - reproductive biochemistry relevant to problems of human reproduction; 2) The Oregon Regional Primate Research Center - factors which control the events culminating in fertilization in nonhuman primates; 3) The University of Pennsylvania - biochemical, biological, and morphological events in the early processes of reproduction and development prior to implantation; 4) Harvard University - reproductive biology, fertilization, embryogenesis; 5) University of California at San Diego - gametogenesis and reproductive biology; 6) Massachusetts Institute of Technology - migration and migration policies in relation to socioeconomic development; and 7) University of Texas at Dallas - neuroendocrine and behavioral interrelationships.

The recipient institutions and principal research areas of Population Research Centers supported during the same period are: 1) Vanderbilt University - reproductive hormone actions and their molecular controls; 2) The University of Texas at Austin - population dynamics of minority groups; 3) Population Council at the Rockefeller University - fertility regulation and the antecedents and consequences of fertility; 4) University of Wisconsin - demography and human ecology; 5) University of Chicago - molecular biology and human reproduction; 6) Johns Hopkins University - fertility in teenage women, male reproductive biology, and demography; 7) Baylor Medical College - mechanism of hormone action; 8) University of North Carolina - behavioral-social population problems; 9) Columbia University - steroid biochemistry and female reproduction; 10) Princeton University - demography, population economics and statistics; 11) University of Pittsburgh -research in primate reproduction; and 12) Harvard University - reproductive biology and human reproduction; 13) University of Washington - demography, fertility, and population analyses; 14) University of Michigan - fertility, demography, and population clustering; 15) University of Texas, San Antonio - reproductive mechanisms; and 16) University of Pennsylvania - fertility, labor force, migration.

The recipient institutions and principal research areas of the Specialized Population Research Centers supported during the same period are: 1) The University of Michigan - reproductive endocrinology from molecular to physiological levels; 2) The University of Texas at Austin - control mechanisms at molecular to organismic levels; 3) Case Western Reserve University - reproductive biology of events from ovulation to implantation; 4) University of Texas at Houston - male reproductive function; 5) Washington University - hormonal regulation of the reproductive tract; 6) University of Washington - gamete transport in mammals; 7) Mayo Foundation - mechanism of action and molecular biology of estrogen, progesterone and the gonadotropins; and 8) Salk Institute for Biological Studies - neuroendocrinology of reproduction and growth.

B. Population Research Manpower Development

Within the context of the NICHD mandate to facilitate the development and maintenance of population research programs of high quality, the Institute supports the development of highly skilled population research manpower through the following mechanisms: 1) individual postdoctoral fellowships; 2) institutional training grants; and 3) Research Career Development Awards. Individual fellowships are awarded to men and women who have recently obtained a terminal degree with emphasis in one or more disciplines of the population sciences. These awards are made directly to young people, for up to three years of support, to enable them to choose a research trainer commensurate with their interests and to devote full time to the development of expertise in an eligible field of population research. There are currently 52 of these postdoctoral fellowships in effect.

Institutional training grants are awarded to leading institutions in the United States with outstanding trainers to enable them to establish and to maintain an appropriate environment for population research training of high quality. There are at present 30 institutions providing funds for support of predoctoral and postdoctoral research trainees selected by the recipient institutions. Of these institutional training grants, 11 are in the behavioral-social field, while 19 are in the biomedical area.

Research Career Development Awards (RCDA's) are made to selected senior postdoctoral candidates nominated by their universities as having outstanding research potential. The purpose of this award is to enable the candidate selected to obtain release from teaching and administrative responsibilities for five years in order to devote full time to the development of a research program. This program, which at present supports 17 promising scientists, has been successful in launching the research careers of several of the current leaders in the population sciences.

On the basis of its projections of national needs, and developing or extant deficiencies in highly skilled population research manpower, the Institute has designated the following areas of eligibility for population research manpower development: 1) fertility and infertility; 2) fertility regulation; 3) nutrition and reproduction; 4) social and behavioral aspects of reproduction; 5) population change.

The goal is to maintain a population research manpower pool in this country of the size, diversity and competence required for the successful solution of present and future population problems. As it has become increasingly clear that the explanation, prediction, and regulation of population phenomena require sophisticated understanding and analysis, the training of behavioral-social scientists in population research will continue to receive high priority in the future. The primary thrust of this new emphasis will be the support of institutional training grants in behavioral research related to population dynamics.

8. Coordination and Communication

The coordination of Federal population research programs and the communication of research information in the population sciences is carried out through the following activities.

A. Coordination

The Interagency Committee on Population Research (ICPR) coordinates the population research activities supported by Federal agencies and fosters the exchange of information among Federal population research programs. The Committee was established by the Secretary of HEW on October 5, 1970, and is chaired by the Director of NICHD's Center for Population Research. The ICPR is comprised of representatives from the various Federal agencies concerned with research related to human population problems. Significant products of the ICPR include two publications, produced annually with the assistance of NICHD staff: Inventory and Analysis of Federal Population Research and Inventory of Private Agency Population Research.

Close collaboration has been developed by the Center with the population research programs of the Agency for International Development, the World Health Organization, the Population Council, and the Ford Foundation. It involves holding of joint meetings, exchange of progress reports, and staff consultations. Close contact is also maintained with the National Center for Health Statistics, National Cancer Institute, the National Heart, Lung, and Blood Institute, and the Food and Drug Administration. Since the introduction of new drugs and devices in the U.S. is regulated by the FDA, the Center maintains a close liaison with this agency.

B. Communication

Inventory and Analysis of Federal Population Research for fiscal year 1976, combines the Federal Inventory and the Analysis previously published annually as separate publications. It contains (1) a detailed listing of all Federally supported population research projects classified according to the major research category; (2) a statistical analysis with fiscal tables by research areas and supporting agencies; and (3) an evaluative analysis with recommendations for needed population research. The Inventory represents a cooperative effort on the part of each of the reporting Federal agencies which funds projects in population research. The scope of the Inventory encompasses a broad spectrum of research in the biological, medical, social and behavioral sciences and covers all projects--grants and contracts, intramural and extramural--in which population research constitutes a major substantive category.

Federal funds supporting population research in fiscal year 1976 evidenced the largest growth since 1972, even excluding the Transition Quarter (July-September 1976). Funds for population research in FY 1976 grew by 17 percent to a new high of $78.8 million, with an additional $13.9 million awarded in the Transition Quarter. The 17 percent growth in funds for research represents about 9 percent in real growth taking into account current dollars versus constant dollars to adjust for the inflation factor. Nine Federal agencies participated in the support of population research. The Department of Health, Education, and Welfare provided 80 percent of the FY 1976 funds, or $63.3 million, and $44.2 million of this was by the Center for Population Research, NICHD.

Inventory of Private Agency Population Research for 1975, reports information on the population research projects sponsored by the major U.S. private organizations in this field. These three principal organizations involved with research in the population sciences, the Ford and Rockefeller Foundations and the Population Council, have provided the data on their research projects in the same way as the Federal agencies and the information has been published in the identical format as the Federal Inventory.

The 1975 Private Agency inventory shows an overall decrease in both the number of projects and expenditures over 1974. The total of $13 million is 23 percent less in funding while the number of projects funded fell from 462 to 301, a drop of 35 percent. Both The Ford Foundation and The Population Council were responsible for this decrease: the Ford input went from $7.4 million in 1974 to $5.2 million in 1975 while the Council dropped from $5.9 million to $4.3 million. The Rockefeller Foundation population budget as reported in the Inventory remained about the same: $3.7 million in 1974 and $3.6 million in 1975.

The communication of population research information is enhanced through the publication of Population Sciences: Index of Biomedical Research. Approval was received to publish the journal on a monthly basis, and periodic publication began in October 1973. This bibliographic citation journal provides a useful resource to those who wish to be currently informed about the biomedical literature in the field of population research. It is the counterpart of Population Index, a bibliographic journal devoted to population research in the social sciences, which the Office of Population Research at Princeton University publishes and which NICHD has helped support for several years. Population Sciences: Index of Biomedical Research is produced with the cooperation and assistance of the National Library of Medicine and is based on the information contained in the Library's Medical Literature Analysis and Retrieval System (MEDLARS).

Another means for enhancing the dissemination of information undertaken by the Center, is through publication of its Population Research Monographs. These provide a comprehensive review and evaluation of the state-of-the-art in specialized areas of population research in the biomedical or social sciences, a conceptual analysis of the relevant research literature, and indication of future research directions to obtain needed knowledge. The monographs which have been published include: The Walnut Creek Contraceptive Drug Study; Rural-Urban Migration Research in the United States; and Population Psychology: Research and Educational Issues. CPR conferences and workshops in the population sciences also continue to result in publications which constitute a valuable addition to the population research literature.

Food and Drug Administration

Programs of the Food and Drug Administration (FDA) of DHEW are authorized by the Food, Drug and Cosmetic Act of 1938, as amended. The FDA approves contraceptive drugs for safety and effectiveness before they are marketed and maintains surveillance over both contraceptive drugs and "non-drug" contraceptive devices (those which do not incorporate releasable metals or drugs) after they are marketed. The Medical Device Amendments of 1976, enacted on May 28, 1976 provide the FDA with the authority for more extensive regulatory controls over contraceptive devices such as intrauterine devices (IUDs), intravaginal devices, and diaphragms. The agency is currently developing regulations to implement the provisions of the new law. FDA involvement in population research and family planning services lies primarily in:

(1) Sponsoring or monitoring the progress of research necessary to carry out its regulatory responsibilities relating to oral contraceptive safety.

(2) Using its regulatory functions with regard to the safety and effectiveness of contraceptive drugs and devices.

(3) Maintaining a reporting system which serves as a clearing-house for information concerning adverse reactions associated with contraceptives.

The first oral contraceptive agents were approved by the FDA for general use in 1960. By 1978, there were over 60 such agents on the market. Several new drug applications are currently under review, but all are copying products already on the market. In 1976 the marketing of sequential oral contraceptives was discontinued.

Having published its "Second Report on the Oral Contraceptives" in August 1969, the FDA Advisory Committee on Obstetrics and Gynecology continues to assist in activities related to family planning. This Committee has participated in revising oral contraceptive labeling, in updating guidelines for clinical investigations of oral contraceptives, and in evaluating the influence of estrogen content in the thromboembolic action of oral contraceptives. The Committee has also deliberated upon the problem of the tumorigenic action of certain steroidal contraceptives and has assessed the safety and efficacy of certain systemically-administered contraceptives and of IUDs incorporating releasable metal or a hormone.

FDA provides expert advice to the pharmaceutical industry and the academic community in the conduct of studies to obtain data concerning the safety and efficacy of contraceptive drugs. In addition, FDA solicits the views of consumers and other interested parties on proposed consumer information materials to accompany the contraceptive market package.

In order to develop adequate information to assure the safety and effectiveness of contraceptive drugs and devices, the FDA has initiated several research projects. The FDA is supporting an investigation of the carcinogenic and diabetogenic potential of certain oral contraceptive steroids in long-range studies in Rhesus monkeys and beagle dogs at the International Research and Development Corporation in Mattawan, Michigan. These studies follow the protocol prescribed by FDA to the pharmaceutical manufacturers in 1967, and under which already-marketed as well as investigational compounds are currently being evaluated. The dog studies have been completed, and the Armed Forces Institute of Pathology has become the repository for all records, tissues, blocks and slides pertaining to the dog and monkey studies. The monkey studies will be continued for one additional year. The long-range design of the investigations is intended to provide some indication of the possible carcinogenic hazard to long-term human users of the contraceptives, as well as any other possible toxicity to target organs or systems. These studies are intended to be "positive controls" for industrial studies and have resulted in administrative decisions over the past seven years to stop clinical investigations of some products, to stop marketing other products, to restrict the clinical investigation and use of one product, and to permit continued investigation and use of still other products.

Utilizing funds from the PL-480 program in Yugoslavia, the FDA has entered into four Collaborative Programs relating to the safety of oral contraceptives. The first of these was a two-year study of 200 women by scientists at the Institute for Mother and Child Welfare in Zabreb, Yugoslavia. The objective was to study the effects of selected oral contraceptives on carbohydrate and lipid metabolism over a longer period than had been studied before. The final report was dated December, 1975, and confirmed and extended the findings of W. N. Spellacy, et. al., indicating that oral contraceptives can influence glucose tolerance adversely, but not cholesterol, free fatty acids and triglycerides.

A second collaborative study was begun at the University Teaching Hospital for Obstetrics and Gynecology, and the Family Planning Institute, in Ljubljana, Yugoslavia. This study has two different objectives: (1) to determine in a small controlled study (the offspring of 200 mothers) whether congenital anomalies or abnormal karyotypes develop in the offspring of women using oral contraceptives within three months of conception, and (2) to determine in a large

observational study (over 28,000 women have been entered) whether oral contraceptives increase the risk of cervical cancer as compared to users of mechanical devices or no method. Data were collected up to mid 1976, and are now on magnetic tape. Data were analyzed, and a final report was written in 1977.

A third FDA PL-480 project at the Institute of Hygiene and Social Medicine in Sarajevo, Yugoslavia, is expected to continue until 1979. This study also has two objectives: (1) to compare the changes in cervical cytology in 6,000 oral contraceptive users with those in a similar group of women using other family planning methods, and (2) to study all women (7,600) delivering in three population centers to ascertain the possible relationship between abnormal pregnancies and malformed infants and the use of drugs, hormones, and exposure to environmental hazards. A final report of the latter study has been submitted and is being evaluated.

A fourth FDA PL-480 study in Belgrade, Yugoslavia, originally scheduled for completion in December 1974, was extended until June 1976. This four-year study was aimed at investigating the effect of oral contraceptive use on coagulation mechanisms. The report will be submitted pending the completion of data gathering on this project. We expect to receive the final document in two or three months.

Three small intramural projects relevant to population research are being conducted by the Division of Drug Biology, Bureau of Drugs. Hamsters and rats are being used as the test animals. The objective of one of the studies is to test new, proposed male contraceptives for their action on the hypothalamic-pituitary-testis axis, to study applicable protocols and their results and to develop supplemental ones. The second study is intended to assess adverse drug reactions involving protein synthesis on ovulation. The third study involves an investigation of embryo and fetal toxicity and the effects of furosemide and other selected drugs.

In the June 5, 1971 FEDERAL REGISTER (revised and clarified on March 7, 1973), the FDA Commissioner published a proposal to make intrauterine devices (IUDs) which incorporate heavy metals, drugs, or other added substances, "new" drugs. Thus, a "Notice of Claimed Investigational Exemption for a New Drug" must be submitted to the FDA to cover clinical investigations of the safety and efficacy of such contraceptives. Moreover, an approved New Drug Application is required for marketing such devices which currently remain under the jurisdiction of the Bureau of Drugs. As a result of the "Medical Device Amendments of 1976," these IUDs will be transferred to the Bureau of Medical Devices and Diagnostic Products.

Under the "new drugs" procedure, three New Drug Applications (NDAs) have been approved by the Bureau of Drugs for the marketing of "drug" IUDs.

On February 25, 1974, a NDA for Cu-7 (Intrauterine Copper Contraceptive) sponsored by G. D. Searle and Company was approved. On February 4, 1976, an application for Progestasert (Intrauterine Progesterone Contraceptive System) sponsored by Alza Pharmaceuticals Division of Alza Corporation; and on November 4, 1976 an application for Copper T Model T Cu 200 B (Intrauterine Copper Contraceptive) sponsored by the Population Council were also approved.

All approvals were made under the condition that additional studies be performed to collect specific information after marketing. At the present time, the Cu-7 physician's labeling recommends replacement every two years since the contraceptive effectiveness after two years has yet to be established. The labeling for Copper-T states that it must be removed and a new one inserted on or before 36 months from the date of insertion. For the Progestasert, which releases a hormone gradually over a one-year period, the device must be replaced after one year.

The FDA authority, prior to passage of the 1976 Medical Device Amendments, was to prove misbranding or adulteration of non-drug intrauterine devices. FDA continued to maintain surveillance over such marketed devices to ensure their safety and efficacy within its authority.

In June 1974, when the safety of the Dalkon Shield IUD was brought into question, the FDA set up an ad hoc Obstetrics and Gynecology Advisory Committee to evaluate the available data and make recommendations to the Commissioner of the FDA on the safety and efficacy of the IUDs in general and the Dalkon Shield in particular. In addition to evaluating the safety and efficacy of the Dalkon Shield, the Committee endorsed the concept of professional and patient labeling of IUDs to ensure that physicians and patients are fully informed on the safety and efficacy of both drug and non-drug IUDs. Proposed FDA physician and patient labeling was published in the FEDERAL REGISTER on July 1, 1975.

While there is an abundance of scientific literature and research on drug and non-drug IUDs, it is largely uncoordinated and of limited particular value to those who insert IUDs. Therefore, the FDA contracted with the Battelle Human Research Center to assist in updating the 1968 "Report on Intrauterine Contraceptive Devices."

Based on the comprehensive review and analysis of the scientific and clinical data, the updated report represents an attempt to:

1. Identify clinical studies in which there is valid evidence of the effectiveness of both drug and non-drug IUDs.

2. Identify any hazards associated with drug and non-drug IUDs.

3. Identify any physiological and histochemical effects produced by IUDs other than contraceptive effects.

4. Identify the mode of action by which the contraceptive effects are produced.

5. Identify criteria and procedures for use in the selection and insertion of IUDs.

6. Identify the nature of the information which should be made available to physicians and patients.

The contract report was submitted to FDA on August 11, 1975, and is being utilized in developing FDA program responsibilities.

On May 28, 1976, the Medical Device Amendments of 1976 were signed into law giving the FDA the authority to approve devices for safety and effectiveness before they are marketed and maintain surveillance over such devices after they are marketed. The FDA has set up advisory panels to assist in classifying medical devices into three regulatory classes: Class I, General Controls; Class II, Standards; and Class III, Premarket Approval. The following contraceptive devices are tentatively classified into the Premarket Approval category: IUDs, tubal occlusion devices, and hysteroscopic devices for female sterilization. The contraceptive devices tentatively classified into the Standards category are: abortion devices, laparoscopic and culdoscopic devices for female sterilization, and diaphragms.

The FDA is to approve new non-drug IUDs, new tubal occlusion devices and hysteroscopic devices for female sterilization for safety and effectiveness before they are marketed, and maintain surveillance over such devices after they are marketed. The FDA will require the submission of safety and efficacy data on those non-drug IUDs and tubal occlusion devices that are already on the market as well as on new products coming on the market. There will be requirements for post-marketing surveillance for possible long-term adverse effects or failure of these devices.

The FDA will promulgate performance criteria for devices in the Standards category. Technical assistance will be provided to small manufacturers to assist them in complying with statutory requirements in their efforts to introduce new products.

If the FDA determines that a device presents an unreasonable risk of substantial harm to the public health, it has the authority to ban the device, to inform all health professionals, and to require the manufacturer to repair, replace or refund the product cost. In addition, manufacturers are required to keep records on device experience and make reports to FDA.

The FDA will continue its research relating to contraceptive devices in order to ensure their safety and efficacy.

Health Services Administration

The Health Services Administration (HSA) is the major administrative support agency for Federal programs of subsidized family planning services. In the HSA, family planning services activities are administered by the Bureau of Community Health Services (BCHS), the Indian Health Service (IHS), and Bureau of Medical Services (BMS).

Review and approval of services project grant applications is carried out in the DHEW Regional Offices. Regional Family Planning Program Consultants serve as coordinators for family planning activities in each region.

The Bureau of Community Health Services administers family planning activities under two major legislative authorities: the "Family Planning Services and Population Research Act of 1970" (PL 91-572), which established Title X of the Public Health Service Act and was subsequently amended by PL 93-45 and PL 94-63; and Title V of the Social Security Act as amended by the "Child Health Act of 1967" (PL 90-248) and the "Public Debt Limitation Act of 1973" (PL 93-53).

Title X of the Public Health Service (PHS) Act authorizes project grants for voluntary family planning services, grants and contracts for training family planning services personnel, grants and contracts for services delivery improvement research, and grants and contracts for family planning information and education. Categorical project grants under PHS Act Title X represent the major Federal source of direct funding for family planning services.

Title V of the Social Security Act (SSA) authorizes maternal and child health formula grants to assist States in extending and improving their services for promoting the health of mothers and children, especially in rural areas and areas suffering from severe economic distress. PL 90-248 specifies that not less than six percent of the annual appropriations under SSA Title V must be available for family planning services.

The broad purposes of Public Law 91-572 are stated in the law as follows:

1. To assist in making comprehensive voluntary family planning services readily available to all persons desiring such services;

2. To improve administrative and operational supervision of family planning services;

3. To enable public and non-profit private entities to plan and develop comprehensive programs for family planning services.

4. To develop and make readily available information (including educational materials) on family planning to all persons desiring such information;

5. To evaluate and improve the effectiveness of family planning service programs; and

6. To assist in providing trained manpower needed to effectively carry out family planning programs.

Title X of the PHS Act authorizes funds for family planning service projects, training grants and contracts, information and education activities, and services delivery improvement research.

The Bureau of Community Health Services (BCHS) is responsible for allocating Title X of the Public Health Service Act funds to the ten DHEW regional offices. The regional office officials are responsible for making grant awards to individual service providers and for monitoring the grantees family planning activities. BCHS also distributes Title V of the Social Security Act (Maternal and Child Health) funds to the States as prescribed by legislatively mandated formula based on each State's population. The States must use Title V funds for programs of projects which include family planning services as one type of project. BCHS is responsible for monitoring use of Title V funds. The organized family planning service providers funded by Federal, State, and local governments, and non-public agencies are expected to provide services to about 4.5 million patients in FY 1978. Title X funds awarded to 235 grantees will provide at least partial support to agencies which will serve an estimated 3.5 million of these patients.

In 1977 Title X funds ($107.5 million) were a little less than 50 percent of the funds available to organized providers of family planning services. Title V funds ($25 million), indirect Federal funding from Titles XIX and XX of the SSA ($55 million) and State and local governments and non-public agencies ($45 million) were the sources of the rest of the funds.

Family planning services are provided in clinic settings by hospitals, health departments, neighborhood health centers, planned parenthoods and other public and private non-profit agencies and through private physicians under contract to organized provider agencies. In 1978, Title X grantees will distribute funds to over 2,500 delegate agencies which provide services in about 4,900 clinics.

Grantees who receive funds from Title X are required to provide a full range of fertility regulation methods and services and also a wide range of health screening procedures. Since about 3.5 million women receive services through clinics which receive partial support from Title X, these clinics are a significant source of preventive health care for low-income women of child-bearing age.

In fiscal years 1978 and 1979, BCHS will work with regional office officials to expand the level of family planning services established in 1977, and to improve access to services in urban and rural areas for low-income and high-risk individuals, males and handicapped persons. Emphasis will continue on reducing the incidence of unintended adolescent pregnancy through the expansion of services in areas with high teenage birth rates and the improvement of outreach and counseling services. It is recognized that adolescent clients require more extensive counseling and followup than most older patients in order to effectively utilize family planning services.

The training program will continue to emphasize training projects designed to aid service providers, increase knowledge, and update education in order to provide better services to high-risk patients (teenage females and older women), handicapped persons and males. Management training skills in program planning and financial management also are being implemented. The establishment of a Management Institute for Family Planning will provide training for new family planning managers to develop expertise in both specific family planning administration and more general management techniques. The nurse practitioner training program will train an additional 200 nurse practitioners during the coming year and about 11,700 staff will receive general and specialized skills training during fiscal year 1978.

Information and education activities will focus on supporting health providers, State and local agencies, parents, youth agencies and youth themselves in addressing the problems and concerns associated with early childbearing and parenthood. Four regional conferences were conducted in fiscal year 1977 to create an awareness among providers of health, social and educational services for adolescents, as well as State and local officials, of the need for a positive course of action to address the adolescent pregnancy problem. Technical assistance will be available throughout fiscal year 1978 to aid communities in carrying out their strategy. A youth oriented media project in which sports celebrities endorse the concept of responsible sexuality will result in the distribution of public service announcements to teen-oriented radio stations. The National Clearinghouse for Family Planning Information began its second year of operation in 1977 and services will be expanded in fiscal years 1978 and 1979 to better support service provider and client needs. Other activities will include: development of an educational curriculum and film for working with males, assisting parents to become more effective educators of their children through the development of appropriate materials, demonstrating a program for parents and youths focusing on human values and sexual responsibility, and developing and improving materials to inform patients and the general public about available family planning services.

Services delivery research for family planning is funded for operational research studies to assess and test innovative ways of delivering

family planning services. Special studies and demonstration projects are implemented to develop and improve services responsive to family planning program priorities, patient needs, and regional, State, and local variations.

In fiscal year 1978 the focus is on services to the adolescent and four demonstration projects are being implemented to test innovative methods of delivery and information dissemination. In order to understand and improve the delivery of care to this population group, a study to determine patterns of utilization of contraceptive services for teenagers is also being implemented. The report from this study will be disseminated to the 235 grantees for program planning and implementation and will assist the regional staff to assess program performance.

There will be five biregional conferences on natural family planning and also a study on assessment of nutrition information and counseling of teenagers enrolled in family planning clinics. These studies are implemented for the purpose of upgrading the quality of services provided to the family planning patient with emphasis on adolescent health care.

Strategies for alternative approaches for offering and providing technical assistance to grantees and other Bureau programs in reaching males will be developed. The information obtained from this study will increase the ability to assist grantees to develop more effective programs involving males.

The Indian Health Service of the Health Services Administration provides comprehensive health services, including family planning, to American Indians and Alaska natives under P.L. 83-568. The Indian Health Service has been active in the field of family planning since fiscal year 1965. Family planning services are provided in general medical, surgical, and field health clinics rather than in separate family planning clinics.

From fiscal year 1967 through fiscal year 1977, the number of women, aged 15-44, provided services increased by 132 percent. This is approximately a 13 percent increase per year. In fiscal year 1977, 29,070 women received family planning services. Of these women, 5,532 were new patients and 25,238 were continuing patients. The 29,070 who were rendered services during fiscal year 1977 represent approximately one-fourth of the estimated total 121,700 native women, aged 15-44. These women made 55,800 visits during fiscal year 1977, an average of 1.9 visits per program participant. The portion of the population participating and the average number of visits per participant in the program has remained relatively constant over the past four years. From the inception of the program through fiscal year 1977, family planning services have been provided to 76,132 women.

The Department of Health, Education, and Welfare has a legislative mandate to provide direct health care services to specified beneficiaries under provisions of the Public Health Service Act and the Dependents' Medical Care Act. This responsibility is discharged, in part, through the Bureau of Medical Services (BMS) of the Health Services Administration and, within the Bureau, through its Division of Hospitals and Clinics and Division of Federal Employee Health. The program authority of the Bureau's Division of Emergency Medical Services does not encompass the direct delivery of health care services.

The Division of Hospitals and Clinics provides comprehensive health care services to American Seamen, active duty members of the U.S. Coast Guard, members of the National Oceanic and Atmospheric Administration, and to active duty Commissioned Officers of the U.S. Public Health Service. Services may also be provided to retired members of the uniformed services and to dependents of active duty and retired members of the uniformed services under the authority of the Dependents' Medical Care Act.

In addition, the Public Health Service Act permits the providing of limited health services to Federal employees by the Bureau's Division of Federal Employee Health.

Health care services within the Division of Hospitals and Clinics (DHC) are provided by eight general medical-surgical hospitals, one specialized treatment center (Hansen's Disease), 26 free-standing outpatient clinics, and more than 300 contract physicians and hospitals located throughout the United States. This major system constitutes a nationwide network within the Department for the delivery of comprehensive health care services, for training, and for research. In addition, the Division of Federal Employee Health operates 143 clinics in Federal installations across the country.

As compared to fiscal year 1976, total workload increased throughout the system, particularly with respect to ambulatory care visits which registered a 3.3 percent increase during fiscal year 1977.

Funds for clinical research studies are distributed through the Central Clinical Investigations Committee of the Division of Hospitals and Clinics, a formally-constituted body, that is also responsible for monitoring and evaluating research programs. During the year, approximately $250,000 of fiscal year 1977 funds of the Division of Hospitals and Clinics were expended for clinical research, of which $92,080 was allocated to research in family planning. Other studies not related to family planning in PHS hospitals received $279,000 from the National Institutes of Health and $600,000 from the National Center for Health Services Research during fiscal year 1977.

Family planning services provided by the Division of Hospitals and Clinics include the prescription and provision of pharmaceutical

preparations, oral contraceptives, mechanical devices, surgical sterilization and counseling. All USPHS hospitals and outpatient clinics provide family planning services upon request. There were an estimated 7,899 visits to family planning clinics of the DHC during fiscal year 1977. The estimated cost of these services was $211,000 based on an average cost of $27 per visit.

At the USPHS Hospital in New Orleans, which has the only obstetrical service within the Bureau of Medical Services, all postpartum patients are offered family planning information and services as part of the follow-up medical care. Community oriented family planning services are provided at the USPHS Hospital in Boston through an agreement with the Massachusetts State Department of Health. This program continues to be very active with new visits averaging 19 percent of the family planning patient load each month. The program at the USPHS Hospital in Staten Island provides outpatient and inpatient medical services for clients of the Family Planning and Health Clinics (FPHC) of the Staten Island Community Corporation. The FPHC is the only such program on Staten Island. The USPHS Hospital in Staten Island has been told that it performs a particularly valuable service for this clinic, in that the critically needed medical backup expands the scope of services available to enrollees in the family planning program, e.g., the diagnosis and treatment of tuberculosis or surgery for cancer of the cervix.

Center for Disease Control

The Center for Disease Control (CDC) provides training to Epidemic Intelligence Service (EIS) Officers of the U.S. Public Health Service. Some individuals in the EIS program, as well as other CDC career staff, are trained in an epidemiologic approach for evaluating family planning and population programs. Evaluation training is also provided to State, regional, and local family planning program evaluators. The Family Planning Evaluation Division, CDC, provides evaluation assistance to the Bureau of Community Health Services of the Health Services Administration, to HEW Regional Family Planning Program Consultants, and to State and local health agencies in the evaluation of family planning programs. In addition, evaluation assistance is provided to international health agencies and national programs in other countries under an agreement with the AID Office of Population. EIS Officers and/or Public Health Advisors are assigned in New York, Georgia, Minnesota, and California to improve and maintain data processing systems for family planning service statistics, to analyze contraceptive use effectiveness and risks and benefits associated with contraception, to determine the number of women at risk of unwanted pregnancy and the proportion of these women receiving services, and to conduct special studies and analyses based on the above program activities. In addition to these continuing assignments, short-term assistance is given to family planning programs for improving program management, designing and/or improving service statistics systems, conducting clinic flow and cost analyses, evaluating family planning program performance, and conducting contraceptive utilization surveys.

Legally induced abortion has emerged as one of the most frequent surgical procedures in the United States today. To assist in eradicating preventable abortion-related mortality and minimizing morbidity, CDC maintains surveillance of abortion, encompassing the following four general functions: (1) compilation of national abortion statistics, (2) investigation of all abortion-related deaths, (3) study of early medical complications of abortion, and (4) performance of special studies and provision of technical assistance. First, in collaboration with individual States, CDC collects both demographic and technical information on patients obtaining abortion. As the legal status of abortion has changed, the national total has expanded from approximately 22,000 reported abortions in 1969 to 854,853 in 1975. CDC publishes a statistical analysis of reported abortions in its annual Abortion Surveillance Report. The second major activity in abortion surveillance is the monitoring of all maternal deaths related to abortion. The number of deaths has declined from 132 in 1969 to 44 in 1975. CDC investigates each case to ascertain risk factors and elements of preventability, and it disseminates these findings through national meetings and publications. The third major activity in abortion surveillance is the administration of the Joint Program for the Study of Abortion/CDC (JPSA/CDC), a prospective multicenter study of early complications of abortion. Including reports of over 100,000 abortions between 1971 and 1977, JPSA/CDC represents the largest abortion study to date. The series of publications from this work have updated existing knowledge of abortion morbidity and the potential for its

prevention by presenting the safest possible abortion methods for the different stages of gestational age. The fourth major activity involves conducting special studies and providing technical assistance related to abortion at the request of State and local health officials. A recently undertaken study has identified factors influencing women's delay in obtaining abortion. Through these four abortion surveillance activities, CDC strives to minimize the risks to the increasing numbers of women seeking abortion each year. Since 1972, CDC has directly assisted the States of New York, Arkansas, Kansas, California, New Jersey, and Texas as well as the cities of New York, Dallas, Philadelphia, Buffalo, Chicago, and Portland (Oregon) with abortion-related health problems.

Epidemiologic field investigations of the medical consequences of fertility control methods used in family planning programs are being conducted. During 1977, CDC, with cooperation from the Armed Forces Institute of Pathology conducted a field study of the association of oral contraceptive use and development of benign liver tumors. Analysis of data showed oral contraceptive users of seven years or more were 500 times more likely to develop this tumor than were non-users. Because this disease is so rare in non-users, long-term oral contraceptive users have five chances in 10,000 of developing this benign liver tumor.

Currently, more married U.S. couples use surgical sterilization as a method of contraception than use oral contraception. Epidemiologic assessment of surgical sterilization is continuing. In 1974, about 600,000 women of reproductive age had contraceptive sterilization operations, making this type of surgery the fifth most frequently performed in U.S. hospitals. Between 1965 and 1974, there was a fourfold increase in yearly rate of tubal sterilization. Women 25-34 years old had the highest tubal sterilization rate, accounting for over half the operations performed during this time period. In order to describe the medical complications of surgical sterilizations and to assess long-term sequelae, CDC has designed and pilot-tested a study of sterilization complications. Early in 1978, the study will be put into full-scale operation. CDC has also investigated ways of monitoring deaths associated with sterilizing operations in four States. In addition, in cooperation with the National Center for Health Statistics and the National Institutes of Health, CDC is attempting to devise a system to monitor deaths associated with these operations and to assess these deaths for factors of preventability. As these studies proceed, CDC continues to disseminate results through scientific publications and presentations at national meetings.

Health Resources Administration

The Bureau of Health Manpower (BHM), through the Public Health Traineeship program, awards traineeships to earn the Master of Public Health degree in a variety of integrated and interdisciplinary educational programs. Programs have emphasized the training of students to function professionally in areas such as population and family planning which deal with demography, communications, evaluation, program administration, and reproductive physiology.

III

OFFICE OF HUMAN DEVELOPMENT SERVICES

Administration for Public Services

Family planning services are included in the Social Services Programs authorized under Title XX of the Social Security Act for the fifty States and the District of Columbia and under Titles I, IV, X, XIV and XVI of the Social Security Act for Guam, Puerto Rico and the Virgin Islands. The Administration for Public Services has responsibility for the proper administration of these programs by the States.

Family planning services include the provision of information, personal counseling, medical services, referral for medical care, follow-up of medical referrals, and the development of medical resources when none exist.

The Social Security Amendments of 1967 (PL 90-248) require that under Title IV-A of the Social Security Act, family planning services are to be offered to all appropriate recipients of Aid to Families with Dependent Children (AFDC). Acceptance of such services is voluntary and is not a prerequisite for or impediment to eligibility for the receipt of any other service or financial aid.

The Social Security Amendments of 1972 (PL 92-603) require States to offer and provide promptly, upon request, family planning services to all appropriate AFDC recipients and impose a penalty of one percent per annum on the Federal share of AFDC funds authorized for States which failed to carry out these requirements in the previous year. In addition, the Act increases the Federal share of matching for family planning services from 75 percent to 90 percent.

The Social Services Amendments of 1974 (PL 93-647) added Title XX to the Social Security Act. With the passage of Title XX the three major provisions of PL 92-603 continue in effect: (1) Family planning services must be offered and provided promptly upon request to all appropriate AFDC recipients (2) States are penalized one percent of the Federal share of their AFDC funds for failure to provide family planning services to eligible persons requesting them and (3) The Federal share under Title XX continues at the 90 percent rate.

The Social Services Amendments of 1976 (PL 94-401) amended Title XX, adding a provision that States may provide family planning services to individuals regardless of their incomes. As a result, in fiscal year 1977, eleven States planned to provide family planning services without regard to income.

For the most part, family planning services, such as information and referral and some family planning counseling are being provided by the States' local Title XX agencies. Other counseling and medical

services are being purchased from public health agencies, family planning clinics and private physicians. In addition, there is coordination with Title XIX, Medicaid, in the provision of family planning services. In fiscal year 1977, thirty-three States indicated they planned to use Title XIX to purchase family planning services for those individuals eligible for Medicaid.

IV

HEALTH CARE FINANCING ADMINISTRATION

Medicaid Bureau

The Social Security Amendments of 1965 (P.L. 89-97-- approved July 5, 1965) added Title XIX, "Grants to States for Medical Assistance" to the Social Security Act. Under the Federal-State medical assistance program which it established, known as Medicaid, States participating in the program were required to provide medical assistance to all recipients of cash assistance. At State option, they could also finance medical care for the medically needy, i.e., those persons who would otherwise be eligible for cash assistance except that the level of their income is sufficient to sustain themselves, but too low to provide necessary medical care. In addition, States could opt to provide coverage to children under 21 from low-income families.

Under the original legislation, inclusion of family planning services was a State option. However, P.L. 92-603, passed in October 1972, made coverage of family planning services for cash assistance recipients under Title XIX mandatory on the States. In addition, the rate of Federal financial participation for family planning services for both the categorically and medically needy was increased to 90 percent on the date of enactment of the Bill.

Medical assistance for family planning includes payments for appropriate medical examinations, diagnosis, medical counseling and treatment, laboratory services, surgical procedures, drugs, supplies and devices. These services may be provided in doctors' offices, clinics, hospitals (on both an inpatient and outpatient basis), family planning centers, or any other suitable settings.

V

EDUCATION DIVISION

Office of Education

The Office of Education (OE), through its various grant programs, enables educational institutions at all levels to include family life, sex education, and support for innovative family-related projects in their programs. All decisions concerning curriculum, teaching methods, qualifications of teachers, and classroom materials are made by State and local authorities acting within the framework of State law.

Elementary and Secondary Education

The Elementary and Secondary Education Act of 1965 (PL 89-10) and its amendments provide several titles under which family life and sex education activities are eligible for support.

Title I, Grants for the Disadvantaged, assists in expanding and improving educational programs aimed at meeting the special needs of educationally deprived children from low-income families, handicapped children, delinquent or neglected children, and migrant children. Further payments are made to the Secretary of the Interior for grants to benefit Indian children in Federal schools administered by the Bureau of Indian Affairs as well as out-of-state Indian children in elementary and secondary schools. Recipients of Title I grants may use the funds for projects relating to dropouts, preschoolers, teenage unwed mothers, and other approaches for remedying education deprivation. However, the components of these projects which are concerned with family life and sex education are not identifiable per se.

Title III was incorporated into ESEA IV, Parts B and C, by the Education Amendments of 1974; and although Family Planning is supportable under Title IV-C, Support and Innovation, the States and local education agencies tailor programs to their own needs and circumstances. Allocations are made to the States based on proportionate numbers of school-aged children, after deducting one percent for distribution to the outlying areas.

Vocational Education: Consumer and Homemaking Education

Under the Vocational Education Act of 1963 as amended by the Vocational Education Amendments of 1968 (Part F, PL 90-576) and 1976 (Subpart 5, Section 150, PL 94-482), formula grants are allocated to States to support Consumer and Homemaking Education programs. The purpose of consumer and homemaking education is to prepare males and females, youth and adults for the occupation of homemaking including, but not limited to, consumer education, nutrition education and use of foods, family living and parenthood education, child development and guidance. Such programs, services, and activites are designed to improve the quality of personal and family life, and to enhance employability.

For example, consumer and homemaking instructional programs may include parenthood education and family living at all levels from preschool through postsecondary and adult. Such programs enhance skills in the following areas: understanding interpersonal relationships in the light of current social needs; learning to utilize available resources to cope with feelings of frustration and despair; feeding, clothing and nurturing of young children and the aged; understanding concepts related to the home and to family living conditions; and appreciating the contributions of individuals and families in performing the occupation of homemaking. The decision to include family planning within this program is left to the discretion of the individual school system, and only then, when medical personnel are involved in the classes and with parental consent.

Programs for child care/development are available in a variety of school or out-of-school settings. Child care/development programs are concerned with the child's total growth and development including care, guidance, and nurturing of young children to help them cope with their social, emotional, intellectual and physical needs. These programs also assist youth and adults, males and females to improve their skills as parents.

Some specific examples of parenthood education and family living and child care/development programs or activities include:

- Parent Education Programs in Washington State are designed to enable parents to become directly involved in their children's education as well as to assist them in controlling their own education. A Preschool laboratory is supported by Consumer and Homemaking Education funds in cooperation with parents who hire the teacher with the assistance of the local school system. Parents help plan activities and are engaged in a cooperative learning effort with their children.

- Parenting Class at Okaloosa-Walton Junior College, Florida is a joint effort between the College and the County Welfare Department to offer Parenthood classes to parents whose children have been removed from their home due to child abuse or neglect. The children have been placed with approved foster parents until their parents have participated

in classes which assist them in understanding the importance of being a natural parent, the importance of a "good" self-concept as a parent, and the ways of meeting the basic needs of young children, e.g., nutritional meals, nurturing of children of all ages, and the need for adequate rest of the young child. In the meantime, the foster parents are also given classes on child care techniques and principles of child care and growth.

- Ohio Family Life Education Programs are composed of two major types of programs. First, the "Infant Stimulation program" is designed to promote and utilize not only consumer and homemaking education facilities and teachers, but to improve other organizations in assisting parents with infants who have special mental or physical problems. For example the "Infant Stimulation program" has made an impact in Akron, Zanesville, Toledo, and Youngstown. For training purposes, these cities utilize a "well-baby clinic" as well as secondary and adult laboratory facilities. One community has donated a van and driver to transport parents and children to the "Infant Stimulation Center." The second Ohio program involves a series of television programs which reinforce the "Infant Stimulation program." These two programs have benefited approximately 9,039 adults, over 2,300 infants, and 2,063 school age children.

- Enrollment in the two specialized programs, "Parenthood Education and Family Living" and "Child Care/Development" has increased from 160,179 enrollees in 1967 to 290,000 in 1975. An additional 4.5 million were enrolled in the "Comprehensive Consumer and Homemaking Education programs", which include both Child Growth and Development and Parent Education/Family Living.

- Curriculum Development relevant to the needs of Consumer and Homemaking Education enrollees is imperative if quality programs are to continue to be offered. Qualified vocational home economics educators must also be selected since they are vital to the success of these programs.

Adult Education

The Adult education program authorized by the Adult Education Act of 1966, as amended (PL 91-230, Title III, PL 93-380 and PL 94-482), is designed to serve undereducated adults. All adults with less than a high school education are eligible; major emphasis, however, is on those adults with less than an eighth grade education. The program's primary objective is to enable participants to become employable, productive and responsible citizens as well as self-reliant and competent individuals, parents and family members.

Actual cost data on programs and projects involving family planning are not available. However, since there is a growing emphasis on family-related content, inclusion of family planning as a content area and use of family planning materials may be assumed. The following discussion of family-related adult education indicates the broad family-related programs in which family planning content is included.

Parent and family-related education is a major focus in the Utah State adult education program and receives considerable emphasis in other States, particularly California, New York, and Maryland. With a marked increase in home-based adult education, family-related content is receiving more emphasis. In Vermont, approximately half of the adult education program is home-based to reach more effectively the largely rural population. In many communities, the local adult education program provides classes for mothers of children in Head Start and other child development programs.

Under Section 309 of the Adult Education Act, States are required to use not less than ten percent for special projects and for training persons to work in adult education programs. Activities carried out under this provision include curriculum development, experiments with innovative delivery systems, cooperation with other agencies and the establishment of competency-based personnel training. Family-related concerns are reflected in these activities; specific information (funds, time, students), however, is not available.

In 1975, a study known as the Adult Performance Level (APL) project includes family-related data. Under an OE grant to the University of Texas, the APL project is concerned with identifying the "functional competence" of the adult population. It (1) specified competencies for adults which are functional to economic and education success in today's society and (2) developed devices for assessing these competencies in the adult population in the United States. The project raised fundamental questions concerning the need for skills involved in five general knowledge areas of decisionmaking required for daily living: occupational knowledge, consumer economics, health, community resources, government and law. Implications for content highlight education for family decisionmaking within the above categories.

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VI

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
POPULATION RESEARCH AND FAMILY PLANNING ACTIVITIES

Obligations, FY 1975 — FY 1979

Agency and Program	Fiscal Year				
	1975	1976	1977	1978(Est.)	1979(Est.)
Total, Department of Health, Education, and Welfare	$293,735,000	$308,031,000	$343,319,000	$388,644,000	$427,106,000
PUBLIC HEALTH SERVICE					
Office of the Assistant Secretary for Health					
Office of International Health					
Scientific Activities Overseas (Special Foreign Currency Program, P.L. 480)1/	124,000	710,000	173,000	1,000,000	1,500,000
National Institutes of Health					
National Institute of Child Health and Human Development	53,124,000	56,212,000	59,450,000	68,623,000	85,273,000
Health Services Administration					
Bureau of Community Health Services (BCHS)					
Maternal and Child Health					
Formula grants to States	$ 25,000,000	$ 25,000,000	$ 25,000,000	$ 25,000,000	$ 25,000,000
Research	100,000	---	---	---	---
Family Planning	99,826,000 2/	100,046,000	113,626,000	135,000,000	145,000,000
Subtotal, BCHS	124,926,000	125,046,000	138,626,000	160,000,000	170,000,000

1/ Not included in the PHS or DHEW total. All obligations are in U. S. - owned excess foreign currencies.
2/ Includes $409,000 authorized under the FY 1973 continuing resolution, obligated in FY 1975.

Obligations, FY 1975 — FY 1979 (Cont'd)

Agency and Program	Fiscal Year 1975	1976	1977	1978(Est.)	1979(Est.)
Indian Health Service	$ 1,237,000	$ 1,445,000	$ 1,599,000	$ 1,822,000	$ 2,044,000
Bureau of Medical Services	193,000	202,000	211,000	226,000	237,000
Subtotal, Health Services Administration	126,356,000	126,693,000	140,436,000	162,048,000	172,281,000
Center for Disease Control	368,000	524,000	932,000	994,000	998,000
Health Resources Administration					
Bureau of Health Manpower	198,000	320,000	256,000	---	---
Total, Public Health Service	$180,046,000	$183,749,000	$201,074,000	$231,665,000	$258,552,000
OFFICE OF HUMAN DEVELOPMENT SERVICES					
Administration for Public Services	43,177,000	52,029,000[1/]	57,970,000[1/]	61,870,000[1/]	63,600,000[1/]
HEALTH CARE FINANCING ADMINISTRATION					
Medicaid Bureau	56,772,000	71,578,000	83,302,000	93,499,000	103.344,000
EDUCATION DIVISION					
Office of Education					
Elementary and Secondary Education					
Grants for Disadvantaged (ESEA I)	2/	2/	2/	2/	2/
Support and Innovation Services	240,000[3/]	4/	4/	4/	4/

1/ New estimates based on Social Services Reporting Requirements Reports for the third and fourth quarters of FY 1976.
2/ Funds expended for family-related activities which are components of larger projects cannot be separately identified. Allocations are made to the States on a formula basis, and States are not required to report the use of funds according to subject area.
3/ Total shown for FY 1975 was allocated under the Dropout Prevention and the Supplementary Education Centers and Services programs.
4/ In FY 1976, these funds were consolidated under the Support and Innovation grants consolidation program. Dollar amounts are not available.

Obligations, FY 1975 — FY 1979 (Cont'd)

Agency and Program	Fiscal Year				
	1975	1976	1977	1978(Est.)	1979(Est.)
Vocational Home Economics Education	1/	1/	1/	1/	1/
Adult Education	$ 13,500,000	$ 675,000 2/	$ 973,000 2/	$ 1,610,000 2/	$ 1,610,000 2/
Total, Education Division	$ 13,740,000	$ 675,000	$ 973,000	$ 1,610,000	$ 1,610,000

1/ Funds expended for family-related activities which are components of larger projects cannot be separately identified. Allocations are made to the States on a formula basis, and States are not required to report the use of funds according to subject area.

2/ Beginning with FY 1976, estimates are only for family planning rather than for all family-related activities. Family planning activities constitute approximately one to two percent of all family-related activities.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
POPULATION RESEARCH AND FAMILY PLANNING ACTIVITIES

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Formula grants to States	$ 25,000,000	$ 25,000,000	$ 25,000,000	$ 25,000,000	$ 25,000,000
Research	100,000	---	---	---	---
Family Planning	99,826,000 2/	100,046,000	113,626,000	135,000,000	145,000,000
Subtotal, BCHS	124,926,000	125,046,000	138,626,000	160,000,000	170,000,000

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Health Resources Administration					
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Total, Public Health Service	$180,046,000	$183,749,000	$201,074,000	$231,665,000	$258,552,000
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Administration for Public Services	43,177,000	52,029,000[1/]	57,970,000[1/]	61,870,000[1/]	63,600,000[1/]
HEALTH CARE FINANCING ADMINISTRATION					
Medicaid Bureau	56,772,000	71,578,000	83,302,000	93,499,000	103,344,000
EDUCATION DIVISION					
Office of Education					
Elementary and Secondary Education					
Grants for Disadvantaged (ESEA I)	[2/]	[2/]	[2/]	[2/]	[2/]
Support and Innovation Services	240,000[3/]	[4/]	[4/]	[4/]	[4/]

1/ New estimates based on Social Services Reporting Requirements Reports for the third and fourth quarters of FY 1976.
2/ Funds expended for family-related activities which are components of larger projects cannot be separately identified. Allocations are made to the States on a formula basis, and States are not required to report the use of funds according to subject area.
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Obligations, FY 1975 -- FY 1979 (Cont'd)

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Total, Education Division	$ 13,740,000	$ 675,000	$ 973,000	$ 1,610,000	$ 1,610,000

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2/ Beginning with FY 1976, estimates are only for family planning rather than for all family-related activities. Family planning activities constitute approximately one to two percent of all family-related activities.

GENETIC DISEASES

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
National Institutes of Health:					
National Institute of General Medical Sciences	$ 6,500,000	$ 7,000,000	$ 7,900,000	$ 8,500,000	$ 8,555,000
National Institute of Child Health and Human Development	11,000,000	11,500,000	14,665,000	16,760,000	19,600,000
National Heart, Lung, & Blood Institute	19,800,000	22,400,000	25,712,000	26,600,000	26,600,000
National Institute of Arthritis, Metabolism & Digestive Diseases	14,057,000	14,646,000	15,576,000	16,756,000	16,868,000
National Institute of Allergy & Infectious Diseases	-0-	-0-	1,660,000	1,950,000	1,950,000
National Institute of Neurological & Communicative Diseases	7,952,000	8,064,000	8,591,000	9,887,000	10,080,000
National Eye Institute	1,366,000	1,527,000	1,625,000	2,306,000	2,463,000
Total, NIH	60,675,000	65,137,000	75,729,000	82,759,000	86,116,000
Health Services Administration:					
Bureau of Community Health Services	-0-	-0-	-0-	4,000,000	4,000,000
TOTAL, PHS	$60,675,000	$65,137,000	$75,729,000	$86,759,000	$90,116,000

NATIONAL INSTITUTES OF HEALTH

Diseases involving disorders of the hereditary material -- the genes and chromosomes -- are widespread and among the most burdensome of all human afflictions. It has been estimated that 6 percent of the population suffer from severe genetic disease. Studies indicate that about 30 percent of hospitalized children have diseases of genetic origin, that 40 percent of all infant mortality results from genetic factors, and that up to 80 percent of mental retardation which is due to medical organic causes is genetically related.

The costs -- both economic and social -- of genetic disease are enormous. The cost to society of caring for those suffering, for example, from Down's syndrome (also called mongolism), which is manifested by mental

retardation and which has an estimated frequency of one in 1,000 births, is approximately $1 billion annually. The estimated medical bill for a child with Tay-Sachs disease ranges from $20,000 to $40,000 per year for the three to five-year average life span of such a child. Treatment of hemophilia averages about $6,000 per year. Furthermore, regardless of the financial costs, the emotional impact on the family of an affected individual is staggering.

Within the Department of Health, Education, and Welfare, the support of research activities related to genetic disease is primarily the responsibility of the National Institutes of Health (NIH). Because of the vast diversity of hereditary disorders and their effects, all of the various Institutes are involved in relevant research. Each of these efforts is closely coordinated, however, to assure a balanced and effective total effort. By virtue of having the largest formal program in genetics, the National Institute of General Medical Sciences (NIGMS) is the leading coordination unit. Other collaborating units are: National Institute of Child Health and Human Development (NICHD), National Heart, Lung, and Blood Institute (NHLBI), National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD), National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), National Eye Institute (NEI), National Institute of Allergy and Infectious Diseases (NIAID), and National Institute on Aging (NIA).

Unlike many other fields of medical research and health services, the enormous pay-offs already achieved and foreseen for the near future in clinical genetics come not from cures, but from new techniques for diagnosis, prevention, and treatment--overall management of genetic disease. For example, it is now possible to diagnose some 60 serious genetic disorders before birth, and also to identify persons who carry the trait (but who do not actually have the disease) for many of these conditions. These capabilities alone give individuals, families and physicians options for making informed decisions concerning the risk of genetic disease. In addition, a half-dozen or more techniques for treating a number of genetic diseases have recently become available, and more are being developed every year.

While scientific advances have contributed greatly to understanding the causes, control, and therapy of genetic diseases, much remains to be accomplished. No genetic disease has yet been cured, in the strict sense of the word, since this would mean the actual repair of the genetic defect or, indeed, of the defective gene in all the cells of the affected individual. However, in lower organisms, the feasibility of transferring "healthy" genes to deficient cells by a new laboratory technique has been demonstrated, suggesting that the cure of at least some genetic disorders is not conceptually impossible.

GENETIC DISEASES LEGISLATION AND INTERAGENCY COORDINATION

Public Law 94-278, enacted April 22, 1976, amended the Public Health Service Act to contain Title IV, known as the Genetic Diseases Act. This law authorized the Secretary, HEW, to support a national program of both research and services concerning sickle cell anemia, Cooley's anemia, Tay-Sachs disease, cystic fibrosis, dysautonomia, hemophilia, retinitis pigmentosa, Huntington's chorea, muscular dystrophy and other hereditary disorders. To guide the development and implementation of such a program, a Public Health Service Genetics Coordinating Committee was established, consisting of representatives from the NIH, the Health Resources Administration (HRA), the Health Services Administration (HSA), and the Center for Disease Control (CDC). NIH currently chairs this committee.

The first task of the committee was to prepare for submission to the Congress the first annual report required under Sec. 1106 of the Genetic Diseases Act. The report is intended to describe in broad detail the genetic disease related programs and activities of each of the participating Public Health Service agencies.

Another key function of the coordinating group has been to obtain appropriate advice and recommendations from geneticists, clinicians and knowledgeable persons in the public sector, including representatives of numerous foundations, associations and professional societies having major interests and concerns in the development of a national program for genetic diseases. To this end, a two-day public meeting on the need for genetics services was held at the NIH in December, 1977, at which oral and written testimony was presented. Topics addressed included the issues and challenges of genetic screening programs, genetic counseling, professional and public education, and legal and ethical concerns. A summary report on the conference will be presented as part of the second annual report.

NATIONAL INSTITUTES OF HEALTH

National Institute of General Medical Sciences

In 1972 this Institute established a formal program in support of genetic research, encompassing a wide range of basic studies in biochemical, viral, bacterial, insect, and mammalian genetics. In the same year NIGMS established a Human Genetic Mutant Cell Repository, through a research contract with the Institute for Medical Research, Camden, New Jersey. The facility develops, grows, stores, and ships to qualified users, cell lines representative of the many varieties of human genetic disease amenable to study in cell culture. This service has greatly facilitated research in human genetics.

Ten genetic research centers are supported by NIGMS, each of which involves a community of both basic and clinical scientists who have

developed collaborative efforts between these two ends of a continuing spectrum of research. The centers, by virtue of the types of scientists they support and their physical settings, are involved in associated community genetic services, including counseling and amniocentesis procedures. Although, through the center grant mechanism, only the research components are funded, the availability of such service activities provides abundant material for investigation and a setting in which the newest research findings can best be evaluated clinically.

Recent Accomplishments

The NIGMS program in genetics seeks a better understanding of the fundamental processes and mechanisms of inheritance, on the premise that such understanding will yield new concepts and technologies broadly applicable to the prevention, treatment and control of genetic diseases in man. Effective treatment of many of the more than 140 genetic conditions, each marked by a specific enzyme abnormality or deficiency, may be possible as the missing or defective enzyme is identified, synthesized and given therapeutically.

To this end, scientists at Washington University in St. Louis are investigating a set of disorders characterized by lysosomal enzyme deficiencies. These enzymes are required by cells to degrade and dispose of numerous substrate materials which otherwise accumulate and cause disease. As a model, the St. Louis scientists are focusing on the human condition in which a deficiency of the enzyme, beta-glucuronidase, causes excess cellular storage of carbohydrate substances termed mucopolysaccharides, resulting in severe damage to the liver and other vital organs. In cell culture studies of fibroblasts derived from affected patients, it was shown that administration of the enzyme exerted a very positive "corrective" effect, which occurred because the cells absorbed the enzyme through the engulfing process known as pinocytosis. Blood platelets were identified as a very rich source of this corrective enzyme.

The biological properties of the cell receptors for the enzyme are being studied in an attempt to determine which cells are most responsive. These studies are important for the development of effective enzyme replacement therapy.

National Institute of Child Health & Human Development (NICHD)

Research supported by the NICHD in human genetics focuses on problems of normal and abnormal development. Studies are conducted through both the Center for Population Research and the Center for Research for Mothers and Children. Special programs encompass research into the prevention and prenatal diagnosis of genetic disease including inborn errors of metabolism, congenital structural defects, and research into the dietary treatment of genetic diseases. In addition, NICHD Mental Retardation Centers are a national resource for studies into mental retardation and related disorders of genetic origin.

Recent Accomplishments

A recent study of amniocentesis supported by NICHD indicates that this procedure is safe and accurate as a tool for prenatal diagnosis. Amniocentesis is a prenatal diagnostic procedure by which amniotic fluid and cells are withdrawn transabdominally during the midtrimester of pregnancy and are analyzed for the diagnosis of chromosomal aberrations, neural tube defects and inborn errors of metabolism. In this study of over 1,000 pregnant women who underwent amniocentesis compared to an equal number observed through pregnancy upon whom the procedure was not performed, it was shown that amniocentesis does not increase the risk of fetal loss or injury.

NICHD currently supports an interregional cytogenetic registry. This facility provides clinical and cytogenetic information on genetic diseases which will offer better delivery of genetic services and thus better health care. The registry is being developed so that the format can be adopted by other cytogenetic laboratories across the country. The right to privacy of individuals listed in the registry has been carefully considered and the system shown to afford appropriate protection. The registry has the potential for providing information related to risk estimates, natural history of genetic disorders and other clinical, genetic and health care information.

Another NICHD study has developed a major referral center for skeletal dysplasias. Cases of chondrodystrophic dwarfism have been studied and classified and several new disorders elucidated. Through studies of biopsies of bone and cartilage these investigators have been able to provide specific diagnostic and counseling advice, and a new pathophysiological classification of these diseases has been developed. Studies are ongoing of the biochemical abnormalities which cause the human chondrodystrophies.

Other studies supported by the NICHD have begun to illuminate the nebulous area of genetic susceptibility to birth defects. For years it has been known that environmental agents and genetic background somehow work together to determine an individual's chances of being born with a birth defect. The mechanisms responsible for this interaction of genes and the environment are only now becoming known. There are certain proteins called receptors within the mammalian cell which combine with hormones, drugs, and other substances which enter the cell from outside. Once these substances are bound by receptors, they can trigger the action of certain genes which then determine whether the cell will undergo normal or abnormal development. Thus, we may soon be able to determine the exact molecular basis for certain congenital malformations. An NICHD staff scientist has shown that, in certain laboratory animals and also in man, susceptibility to poisons in the environment is determined by a single genetic locus which codes for the enzyme involved in metabolizing these poisonous compounds. This enzyme, acting in concert with recently identified receptors, determines whether poisonous substances entering

the cell will be able to trigger the activity of the gene or not. It appears likely that this receptor system may determine which individuals are most susceptible to environmental toxins, which lead to birth defects, degenerative diseases, cancer, and susceptibility to drug overdose. In the future it may be possible to identify those children at high risk for these disorders.

National Institute of Neurological and Communicative Disorders and Stroke

Research on genetic disorders has as its major focus the study of Huntington's disease, an autosomal dominant gene disorder. Progress in this area has potential application for other genetic and neurologic abnormalities.

Indeed, the significance of this possibility was cited by the Commission for the Control of Huntington's Disease and Its Consequences in the report it made to the Congress late in 1977. The Commission recommended enlarging the research program in this area along broad and basic lines because the knowledge gained will benefit investigations on related illnesses, manifesting hereditary, neurologic, and psychiatric symptoms similar to those of Huntington's disease. Among its several recommendations, the Commission recommended that the NINCDS establish a specimen banking facility of neural tissues to provide samples from Huntington's disease patients and others with neurologic disorders to neuroscientists throughout the world.

Recent Accomplishments

Current investigations on neurotransmitters by the Experimental Therapeutics Branch of the NINCDS show promise for developing a test for the early identification of carriers of the Huntington's disease gene. Symptoms of this disease usually do not appear until between the ages of 30 and 50; therefore, although one-half of the children of an affected parent, on the average, are at risk of developing and transmitting the disease, they are not sure they have the disease until the symptoms appear, usually after they are well into the childbearing years. It is known that the brains of patients with Huntington's disease have substantially diminished levels of a neurotransmitter, gamma aminobutyric acid (GABA). New work suggests that GABA levels also may be low in some individuals who are at risk for Huntington's disease but have not shown symptoms. If this finding is substantiated it could prove useful as a presymptomatic diagnostic test and help in family planning.

Another significant area of research concerns the development of an animal model for the study of Huntington's disease. Past research has been hampered by the lack of an appropriate model for this disorder since the opportunities for human experimentation are necessarily limited. An NINCDS grantee has produced a promising model in rats and monkeys. Injection of kainic acid into the brains of these animals destroys the same cells as those that are destroyed in human Huntington's disease.

Research using these models may provide insight into the biochemical mechanisms involved in the human affliction.

Studies by scientists at the University of California at Los Angeles indicate that an abnormal gene product in patients with Huntington's disease may be detectable by immunologic methods. If confirmed, these findings could have widespread epidemiologic, diagnostic, and therapeutic implications, opening entirely new areas of investigation.

National Institute of Allergy and Infectious Diseases

NIAID has had a longstanding commitment to research on various diseases which are known to be due to genetic defects or which--as our scientific knowledge and technology become increasingly sophisticated--are being identified as having genetic factors. This research is conducted by grantees at various institutions around the country, as well as by intramural scientists.

Recent Accomplishments

Hereditary angioedema (HAE) is an unusual disease caused by an inherited deficiency of the inhibitor of the first component of complement--a series of interacting proteins involved in inflammation and a variety of immunobiologic activities. The disease is characterized by episodes of swelling of the hands, feet, face, abdominal viscera or the airways. Swelling of the last represents a life-threatening situation.

Lacking an effective means of stopping an HAE attack once it occurs, physicians have had to rely on prevention of attacks. Use of drugs for this purpose has been limited by their serious side effects. However, scientists in NIAID's Laboratory of Clinical Investigation (LCI) found that treatment with Danazol--a male hormone with a reduced potential for masculinization--not only prevents attacks from occurring but increases the level of the complement protein to almost normal. Reversal of this biochemical deficiency represents one of the first examples where an inherited abnormality can be treated by drugs.

Another genetic disease to which LCI scientists have made major contributions is the Chediak-Higashi syndrome. Symptoms include partial albinism and central nervous system abnormalities. Most patients who inherit this rare disorder die during childhood due largely to recurrent bacterial infections. NIAID investigators have demonstrated that Chediak-Higashi patients have abnormal white cell functions--possibly due to certain structures in these cells--which delay the movement of these cells to sites of infection. This also delays the killing of bacteria. Using an animal model, the scientists have shown that ascorbic acid (vitamin C) corrects the white cell defects and decreases the animals' susceptibility to infections. The therapeutic value of ascorbic acid is currently being evaluated in patients with Chediak-Higashi syndrome.

LCI scientists are also studying inherited diseases which affect other components of the immune system. Immunodeficiencies--both those known to be inherited and those which have manifested a familial predisposition but for which there is not yet sufficient data to assign a mode of inheritance--are being investigated. One disease which has been extensively studied is chronic mucocutaneous candidiasis, a fungal infection that occurs as a complication of an immunodeficiency disorder. NIAID researchers have shown that the immune systems of most patients with candidiasis are unable to recognize the candida organisms as foreign and do not produce the inflammatory mediators (chemicals) that are important for an immune response. Additional studies have shown that a substance obtained from sensitized white blood cells--transfer factor--can correct this immunodeficiency in most patients. Clinical trials using transfer factor are in progress along with analysis of transplantation antigens and other genetic factors in families in which both a mother and child have this disease.

Recently, scientists at NIAID's Laboratory of Parasitic Diseases have identified a genetic blood group factor which prevents the invasion of human red blood cells by Plasmodium vivax--a parasite which causes one of the four types of human malaria. This factor--the Duffy negative phenotype which indicates the absence of "Duffy a and b" antigens of red blood cells--is found in 90 percent of West African and 65 percent of American Blacks and is now known to be the basis for the fact that they have great resistance to P. vivax infection. Additional studies by these researchers indicate that the invasion of red blood cells by the parasite is a two-step process and that the second step does not occur in Duffy negative cells. Definition of the antigenic determinants involved in the invasion of red blood cells by malaria parasites should facilitate development of a vaccine against this disease which causes the death of one million children annually.

National Eye Institute

Of the approximately 2,000 known human genetic disorders, an estimated 30 percent involve the eye. Of these, half are manifested by anomalies of the eye alone; thus, genetics plays an important role in the etiology of eye diseases. Among the more prevalent hereditary disorders with ocular involvement are macular degeneration, retinitis pigmentosa, sickle cell retinopathy, and retinoblastoma.

Of these, retinitis pigmentosa has been the most widely studied. The first signs of retinitis pigmentosa may appear in the first decade of life in the form of night blindness, but the disorder progressively worsens and may result in legal blindness by middle life. Although reading may still be possible, the absence of peripheral vision makes movement extremely difficult.

Improved diagnostic techniques have led to increased awareness of retinitis pigmentosa in its various forms. The disease usually occurs

as a single entity with bilateral loss of vision; however, it may be part of a series of complex syndromes which can involve obesity, mental retardation, and hearing loss as well as other ocular and systemic defects.

Recent Accomplishments

Much of the fundamental research supported NEI relating to genetic eye diseases focuses on the interrelationship between the retinal photoreceptor cells, the rods and the cones, and the underlying pigment epithelium. These two groups of cells are anatomically attached and are functionally interdependent. Separation of the two (retinal detachment) results in loss of vision. In diseases such as retinitis pigmentosa, there is evidence that the underlying defect may be a failure in the pigment epithelium's normal removal of photoreceptor cellular debris. Current research includes investigation of the selective degeneration of visual cells caused by drugs and poisons, an effect which helps characterize the vulnerability of these cells. There are also indications that light, even at normal levels, may aggravate the destruction of photoreceptors in animals and people with inherited retinal degenerative disorders.

Increased emphasis is being placed on using new diagnostic techniques to improve the classification of various forms of these disorders and to help in the differential diagnosis. The breeding of animals with inherited retinal degenerative diseases is being vigorously pursued, and existing animal models are being studied with great profit.

One particularly important area is the study of the biochemical genetics of ocular disease. An important recent finding is that there is an elevated level of the amino acid, ornithine, in the plasma of patients with an inherited retinal degeneration called "gyrate atrophy". An intensive search for a specific biochemical defect underlying this finding has produced strong indications that a single enzyme, ornithine ketoacid transaminase, is involved. On this basis, rational attempts at treatment have already begun.

National Heart, Lung, and Blood Institute

NHLBI conducts and supports activities concerned with the diagnosis, treatment, and prevention of sickle cell anemia, Cooley's anemia, and other, rarer genetic disorders affecting red blood cells.

Sickle Cell Anemia affects an estimated 50,000 Americans, most of them blacks. These persons are subject to recurrent sickle cell "crises," which may be precipitated in an unpredictable fashion by infections, dehydration, cold exposure, or other stresses. During such crises, many of the normally doughnut-shaped red blood cells assume a rigid, crescent or "sickled" shape. The deformed cells do not pass readily through the smallest blood vessels and may seriously impede blood flow to various organs and tissues. Such crises are excruciatingly painful and may produce extensive, sometimes permanent tissue damage. Moreover, the deformed red

cells are destroyed at an accelerated rate, producing the anemia that is another salient feature of the disorder.

An additional 2,000,000 Americans have sickle cell trait, which rarely produces clinical problems. But when each parent carries the trait there is a one in four chance with each pregnancy that their offspring may inherit a "double dose" of the defective gene and so develop the full-blown disease.

Recent Accomplishments

Since 1971, NHLBI has been the coordinating center for a national program aimed at reducing the frequency of sickle cell anemia and combating illness, disability, and premature death resulting from complications. Program activities include the support of Comprehensive Sickle Cell Disease Centers, Screening and Education Clinics, and a variety of basic and clinical research projects.

The latter include the development and evaluation of various anti-sickling agents for preventing sickle cell crises or for reducing the duration or intensity of such acute episodes. Several such agents, including urea, alkylating compounds, zinc, and cyanate, have shown promise in the laboratory but are not suitable for clinical use. For example, in the case of cyanate, one of the most promising anti-sickling agents, neurological toxicity was a limiting factor when the drug was given orally. However, research is in progress to examine the possibility of using extra-corporeal techniques to treat sickled cells outside the body with cyanate before returning the restored red cells to the circulation. Laboratory and clinical studies of a large number of other potential therapeutic agents are in progress.

Other research is concerned with development of instrumentation and techniques permitting safe, accurate prenatal detection of sickle cell disease. Still other studies are investigating the possibility of stimulating the production of fetal hemoglobin which ordinarily is not made after early infancy. Fetal hemoglobin does not contain the abnormal hemoglobin chain that causes sickling in sickle cell disease, but performs as well in oxygen transport as the adult hemoglobin that gradually replaces it after infancy. Hence increasing the ratio of fetal to adult hemoglobin in the red corpuscles of victims of sickle cell disease offers a potentially effective approach to prevention or amelioration of sickle cell crises.

Information, counselling, and related services provided by Sickle Cell Screening and Education Clinics are increasing awareness and understanding of sickle cell trait and sickle cell disease and are helping disease victims and their families cope with associated problems, psychological and sociological as well as physiological. Such services have helped improve school attendance and scholastic achievement among sickle cell disease patients as well as provide increase opportunities for

safisfying jobs or careers.

Protocols developed at Comprehensive Sickle Cell Disease Centers for dissemination to hospitals throughout the country are resulting in general improvement in the diagnostic and treatment services provided sickle cell disease patients admitted to hospital emergency rooms, where a high proportion of sickle cell crises and other complications of sickle cell disease are initially treated.

Cooley's anemia, or beta thalassemia, affects an estimated 2,500-5,000 Americans of Mediterranean descent (chiefly Italian, Greek, Turkish, Southern French, or North African ancestry). Perhaps as many as 200,000 Americans may be asymptomatic carriers of the genetic trait. As with sickle cell trait, when parents each carry the Cooley's trait there is a 25 percent risk with each pregnancy that the disease will occur in their offspring, and two chances in four that the offspring will be carriers.

In victims of Cooley's anemia, the genetic lesion results in a relative deficiency of one of the proteins required in the assembly of hemoglobin. This results in accelerated red-cell destruction and severe anemia. At present it can be (temporarily) corrected only by repeated transfusions of whole blood or packed red blood cells. The disease and the transfusions required in treating it also lead to the accumulation in various organs and tissues of iron compounds that the body neither tolerates well nor can excrete readily. This iron accumulation (hemochromatosis) may seriously impair normal organ or tissue functions and is a major cause of disabling or lethal complications of treated Cooley's anemia.

Recent Accomplishments

NHLBI studies indicate that regular injections of desferrioxamine, an iron chelating agent that converts iron compounds into forms that are more readily excreted, can prevent further iron overload in Cooley's anemia patients who require regular blood transfusions. Iron excretion is enhanced by using the agent in conjunction with ascorbic acid. Preliminary evidence suggests, however, that the combined regimen may produce some deterioration of cardiac function in patients with excessive myocardial iron deposition. This was not seen with desferrioxamine alone. The reason for this is not clear, but suggests the need for caution in employing ascorbic acid with desferrioxamine in such patients.

Beginning in October 1977, the NHLBI Division of Blood Diseases and Resources launched a series of consultant workshops and studies to: 1) ascertain the size and geographic distribution of the population affected by Cooley's anemia in the U.S.; 2) survey and evaluate resources (including facilities and trained personnel) for delivering care to patients suffering from the disease; 3) develop practical standards for optimal clinical services; 4) assess the impact of Cooley's anemia on patients and their families; and 5) assess the present status of research on the disease and

recommend future basic and clinical approaches to prevention, diagnosis, and treatment.

The report and recommendations resulting from those workshops will be transmitted to the Congress for its consideration and will also be of great value to the Institute both in the evaluation of ongoing programs directed against Cooley's anemia and in future program planning.

Summary

The foregoing reports on progress and accomplishments typify the main thrust of NIH activities in basic and targeted research devoted to the broad gamut of hereditary diseases. In general, research on the complex basic defects that underly these diseases has been and will continue to be emphasized, for only through such knowledge can a rational basis for their prevention and control be reached.

HEALTH SERVICES ADMINISTRATION

Bureau of Community Health Services

GENETIC DISEASES

Title IV of the Public Health Service Act provides authority for the establishment of a national program to provide for basic and applied research, research training, testing, counseling, and information and education programs with respect to genetic diseases, including sickle cell anemia, Cooley's anemia, Tay-Sachs disease, cystic fibrosis, dysautonomia, hemophilia, retinitis pigmentosa, Huntington's chorea, and muscular dystrophy.

Responsibility for administering the authority has been delegated to the National Institutes of Health for the research component and to the Health Services Administration for (1) the award of grants to public and non-profit private entities and contracts to public and private entities for establishing and operating voluntary genetic testing and counseling programs in conjunction with other health programs, including those under Title V of the Social Security Act; and (2) the development of information and education materials relating to genetic diseases and the dissemination of materials to make available the latest advances in testing, diagnosis, and treatment of genetic diseases.

Genetic diseases are a significant health problem. In the United States, one child in every 150 to 200 live births or a total of 15,000 to 20,000 infants each year has a major genetic anomaly. A study in Baltimore indicated that nearly one-third of hospitalized children had diseases that were "gene-influenced."

Currently, 97 percent of new-born infants are receiving genetic screening, primarily for phenylketonuria (PKU). This metabolic disorder which accounts for less than one percent of all genetic diseases causes severe mental retardation if untreated. While in most instances of PKU and a few other genetic disorders, prompt diagnosis and treatment will prevent adverse effects, the reduction of genetic disease is primarily dependent on early identification of carriers of genetic disease traits through genetic counseling and screening. Amniocentesis, for example, can detect or rule out some genetic conditions in fetuses. Provision of genetic counseling based on screening permits individuals to make an informed decision regarding the risks of having a child and/or prepares them for the care of an affected child.

Except for PKU and sickle cell disease screening, genetic screening, diagnostic and counseling services are generally not available to most of the population especially those groups at high risk which are served by the DHEW's health services programs. Laboratory resources required for genetic testing are extremely limited. Even where genetic testing and counseling services are available, they are not linked to the rest of the health care delivery system.

Information on the prevalence of genetic diseases varies considerably. For example, fairly well established figures are available for sickle cell anemia, cystic fibrosis, and Tay-Sachs disease, while almost no reliable figure is available for retinitis pigmentosa; prevalence figures for diseases such as Huntington's chorea and muscular dystrophy vary widely. Similarly, the stage of technological development in screening for carriers of prenatal or early diagnosis also differs considerably for those diseases. Identification of carriers of sickle cell anemia, Cooley's anemia and Tay-Sachs is possible through available screening tests, whereas identification of carriers of cystic fibrosis is still under research, and reports of screening tests for carriers of hemophilia are somewhat controversial. The course of illness and prognosis also vary from Tay-Sachs disease which is usually fatal in the first few years of life to Huntington's chorea which generally becomes manifest only in the fourth decade of life although earlier onset is known to have occurred.

The following is the national plan for implementation of Title IV in 1978:

Interagency Agreements

The National Heart, Lung, and Blood Institute, by an interagency agreement, will support approximately 24 Sickle Cell Screening and Education Clinics for an additional year, thus allowing time to complete development and implementation of a specific plan for integrating this program into a broader genetic diseases service program, while continuing to offer screening, education, and counseling services to 200,000 persons in the at-risk population.

Interagency agreements also will support unique contributions of other DHEW constituent agencies, such as that of the Center for Disease Control (CDC), in developing technical laboratory services, standards, proficiency testing and laboratory bench training. The BCHS also will explore the possible integration of the CDC pilot project which screens older pregnant women, as well as developing and stimulating screening and education programs in selected Public Health Service (PHS) facilities, services of the Indian Health Service, and other Federal programs.

Information and Education Services

A national program focusing on the development of education and information materials aimed at both service providers and the general public will be initiated, utilizing the contract mechanism and workshops designed to elicit input from national organizations focusing on specific diseases.

Grant Program for the Initiation and Development of State-wide Genetic Disease Systems

Grants will be awarded to appropriate entities based on competitive application from all of the 57 health jurisdictions to develop and implement State-wide or, if appropriate, regional systems of genetic care. Applications will be coordinated with existing health service systems and especially with the Maternal and Child Health programs supported under Title V of the Social Security Act. It is anticipated that 10-15 awards will be made initially based on quality of applications and characteristics of targeted populations.

Grantees will collect and document data on the number of persons in the targeted State, area or region, who are at risk of various genetic disorders and describe grantee priorities and methods for screening and education for specific diseases. Arrangements for the delivery of laboratory services and back-up support through State, area-wide or regional Genetic Service Centers will be included in applications.

HEALTH SERVICES ADMINISTRATION

Bureau of Medical Services

GENETIC DISEASES

The Department of Health, Education, and Welfare has a legislative mandate to provide direct health care services to specified beneficiaries under provisions of the Public Health Service Act and the Dependents' Medical Care Act. This responsibility is discharged, in part, through the Bureau of Medical Services (BMS) of the Health Services Administration and, within the Bureau, through its Division of Hospitals and Clinics and Division of Federal Employee Health. The program authority of the Bureau's Division of Emergency Medical Services does not encompass the direct delivery of health care services.

The Division of Hospitals and Clinics provides comprehensive health care services to American Seamen, active duty members of the U.S. Coast Guard, members of the National Oceanic and Atmospheric Administration, and to active duty Commissioned Officers of the U.S. Public Health Service. Services may also be provided to retired members of the uniformed services and to dependents of active duty and retired members of the uniformed services under the authority of the Dependents' Medical Care Act.

In addition, the Public Health Service Act permits the providing of limited health services to Federal employees by the Bureau's Division of Federal Employee Health.

Health care services within the Division of Hospitals and Clinics (DHC) are provided by eight general medical-surgical hospitals, one specialized treatment center (Hansen's Disease), 26 free-standing outpatient clinics, and more than 300 contract physicians and hospitals located throughout the United States. This major system constitutes a nationwide network within the Department for the delivery of comprehensive health care services, for training, and for research. In addition, the Division of Federal Employee Health operates 143 clinics in Federal installations across the country.

As compared to Fiscal Year 1976, total workload increased throughout the system, particularly with respect to ambulatory care visits which registered a 3.3% increase during Fiscal Year 1977.

Funds for clinical research studies are distributed through the Central Clinical Investigations Committee (CCIC) of the Division of Hospitals and Clinics, a formally-constituted body, that is also responsible for monitoring and evaluating research programs. During the year, approximately $250,000 of Fiscal Year 1977 funds of the Division of Hospitals and Clinics were expended for clinical research,

but no funds are presently allocated for research in Sickle Cell Anemia or Cooley's anemia. Other studies in PHS hospitals received $279,000 from the National Institutes of Health and $600,000 from the National Center for Health Services Research during Fiscal Year 1977 for research projects not related to Genetic Diseases.

This report includes information on the Division of Hospitals and Clinics activities related to the genetic diseases stipulated in Title IV of P.L. 94-278. These diseases are: sickle cell anemia, Cooley's anemia, Tay-Sachs disease, cystic fibrosis, dysautonomia, hemophilia, retinitis pigmentosa, Huntington's chorea, and muscular dystrophy. All of the general hospitals and outpatient clinics within the DHC system diagnose and treat persons with these illnesses. However, due to the characteristics of the diseases and the criteria for beneficiaries under the provisions of the Public Health Service Act, the number of people now treated with these diagnoses is relatively limited. In addition, precise data regarding the number and services rendered in these diagnostic categories to persons on an outpatient basis, cannot be obtained at this time. Nevertheless, during the first half of F.Y. 1977, sickle cell anemia was the primary discharge diagnosis in 9 instances, Cooley's anemia was the primary discharge diagnosis in 4 instances and hemophilia in one instance. Patient days involved in these hospitalizations were 61 for persons with sickle cell anemia, 7 for those with Cooley's anemia and 23 for hemophilia, at an estimated cost of $7,991, $917 and $3,013, respectively. The estimated cost is based on an average daily rate of $131.

HEARING AND SPEECH

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
National Institutes of Health:					
National Institute of Neurological and Communicative Disorders and Stroke	$19,276,000	$ 20,360,000	$ 24,320,000	$ 28,387,000	$ 28,840,000
National Institute of Child Health & Human Development	15,453,000	16,521,000	17,569,000	18,656,000	26,583,000
National Institute on Aging	---	---	---	316,000	391,000
National Institute of Dental Research	1,788,000	1,094,000	636,000	510,000	510,000
Total, NIH	36,517,000	37,975,000	42,525,000	47,869,000	56,324,000
Health Services Administration:					
Special Projects	800,000	900,000	900,000	1,463,000	1,463,000
University-Affiliated MR Centers	1,100,000	1,170,000	1,170,000	1,200,000	1,200,000
Research Program Direct Impact	186,000	170,000	170,000	40,000	40,000
Indirect Impact	624,000	600,000	600,000	400,000	400,000
Special Foreign Currency Program	100,000	50,000	50,000	50,000	50,000
Total, HSA	2,810,000	2,890,000	2,890,000	3,153,000	3,153,000
TOTAL, PHS	39,327,000	40,865,000	45,415,000	51,022,000	59,477,000
Office of Human Development Services:					
Rehabilitation Services Administration:					
Basic State Grants	40,800,000	44,659,000	45,158,000	47,149,000	48,699,000
Service projects	581,000	435,000	768,000	879,000	1,600,000
Rehabilitation training	2,672,000	2,805,000	2,519,000	2,570,000	2,570,000
Rehabilitation Research and demonstrations	180,000	180,000	665,000	675,000	545,000
Rehabilitation Research and training centers	500,000	500,000	450,000	550,000	550,000
Special foreign currency program	350,000	300,000	801,000	---	390,000
Total, RSA	45,083,000	48,879,000	50,361,000	51,823,000	54,354,000

Obligations (Cont.)

	1975	1976	1977	1978 Estimate	1979 Estimate
Special Institutions:					
National Technical Institute for the Deaf:					
Salaries & Expenses	$ 8,767,000	$ 10,980,000	$ 14,273,000	$ 16,814,000	$ 18,900,000
Construction	1,981,000	---	---	---	---
Total, NTID	10,748,000	10,980,000	14,273,000	16,814,000	18,900,000
Gallaudet College:					
Salaries & Expenses:					
Gallaudet College	---	---	18,061,000	20,084,000	23,178,000
Model Secondary School	---	---	7,343,000	8,343,000	9,217,000
Kendall Demonstration Elementary School	---	---	3,270,000	3,907,000	4,303,000
Subtotal, S&E	---	---	28,674,000	32,334,000	36,698,000
Construction	---	---	5,033,000	32,812,000	11,105,000
Total, Gallaudet College	---	---	33,707,000	65,146,000	47,803,000
TOTAL	$95,158,000	$100,724,000	$143,756,000	$184,805,000	$180,534,000

NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological and Communicative Disorders and Stroke

HEARING AND SPEECH

The National Institutes of Health supports research on hearing, speech and language primarily through the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) and the National Institute of Child Health and Human Development (NICHD). The National Institute of Dental Research (NIDR) and the National Institute of Aging (NIA) at times support some research in these areas. This special report is coordinated by the NINCDS.

The Communicative Disorders Program of the NINCDS is concerned with research relating to hearing, language and speech. Research to improve the diagnosis, treatment and prevention of diseases and disorders affecting the ear, vestibular system and upper respiratory system, including the nose, sinuses, pharynx, and larynx is another responsibility of the program. In addition, the Communicative Disorders Program supports research on the special senses of smell, taste and touch.

The NINCDS program in communicative disorders presently includes 186 research grants, 21 program projects and clinical research centers, 12 contracts, 75 training programs, and 4 intramural research projects. The allocation of research grant funds for the respective areas of study are as follows: Seven percent for the diseases of the ear and upper respiratory system including the larynx and pharynx; six percent for the vestibular and equilibrium systems; forty-seven percent for normal and disordered functions of hearing; thirteen percent for the basic and clinical aspects of speech and voice; three percent for language disorders; four percent for the auditory effects of noise; six percent for expressive and receptive communicative aids; and fourteen percent for the special senses of vision, pain, touch, smell, taste and multisensory areas. The area of language disorders receives the largest proportion of contract support to fill gaps in this area not covered through research grant support.

The Communicative Disorders Program has expanded its directed research into problem areas which do not receive funding from other Federal agencies. These include improved objective identification of young hearing-impaired children; better measurement, treatment and prevention of speech and language disorders among adults who have experienced stroke or head trauma; effects of noise on children; noise and speech communication; and improved assessment and treatment of language disorders not apparently attributable to sensory impairments. The Program continues to support research on hearing aids and on the extent to which deaf persons are able to integrate electronic analysis of speech as cues, and is implementing clinical trials of the efficacy of treatment for otitis media.

The NINCDS Laboratory of Neuro-Otolaryngology in Bethesda, Maryland, is providing leadership in revealing some of the inner ear functions which were previously not understood. Chief among these is the process of transduction, whereby sound waves (mechanical energy) entering the ear are converted into nerve impulses (electrical signals) for transmission to the brain for processing, utilization, and storage. The Laboratory is studying biochemical mechanisms of the inner ear which are intimately related to the transduction process. Understanding these mechanisms should be an important step toward developing rational methods of dealing with the most prevalent type of hearing loss and the type which has not been amenable to treatment, i.e., sensorineural hearing loss (due to loss of the nerve function of the ear).

The NICHD is primarily concerned with the broad aspects and multi-organ system relationships of human growth, development, learning and behavior as they relate to health. Human communication is an important component of human growth and development. The NICHD has, therefore, interest in the acquisition and development of the human communicative processes and in certain disorders such as developmental dyslexia. It is also concerned with problems of communication related to mental retardation and other developmental disabilities. This Institute also has a strong interest in the prevention of the variety of factors which may lead to hearing, speech or language disorders.

Moreover, the NICHD has identified the area of learning and learning disabilities as requiring special consideration. Included in this priority area is a variety of speech and language-related disabilities such as reading disorders, which affect a large segment of our Nation's children who are otherwise of normal intelligence.

The NICHD currently supports 213 research grants, training programs, individual fellowships and research contracts related to hearing, speech and language. The NICHD also supports 12 Mental Retardation Research Centers which conduct investigations in language acquisition, and in the development and training of the mentally retarded child. Among the handicaps shared by the mentally retarded, language deficiencies are probably the most common.

The National Institute on Aging is currently planning to expand its program in sensory and mobility disorders associated with aging. Research on speech and hearing problems will be conducted under this program.

The National Institute of Dental Research supports research on problems of speech and hearing associated with congenital craniofacial malformation, acquired defects and malocclusion. This research deals with causation diagnosis and treatment of speech and hearing deficit as they relate to the more general craniofacial problems.

Approximately 13 percent of persons over 65 years of age have severe hearing defects due to a variety of age-related changes in the small bones that conduct sound through the middle ear, the sensory endings which receive the sound, the auditory nerve, and possibly the brain itself. The isolation caused by the loss of the ability to communicate normally imposes severe psychological and social problems on the elderly. The defects are complex and not well understood. However, it is well established that many of the elderly cannot understand amplified speech even when it is loud enough to be painful. The Institute will conduct research on the nature of the hearing defects in the elderly and explore the possibilities for creating more effective hearing aids.

HEARING

Definition of the Problem

Hearing impairment is the most prevalent chronic disability affecting people in the United States. Accurate, epidemiologic data for deafness and hearing impairment are not available. Estimates based on the most recent census of the deaf in the United States show that there are 203 deaf patients for every 100,000 population in this country. Of an estimated 14 to 15 million people with impaired hearing, it is projected

that three million have losses severe enough to require habilitation or rehabilitation to communicate effectively with others. The profoundly deaf population is distributed across the age spectrum with the greatest prevalence among those persons over 65 years of age. However, a sizeable group of school-age children (0.6 percent of this population) have hearing losses that require special attention for them to acquire normal language and intellectual skills. Studies have indicated that approximately 20 percent of the school-age population are prone to middle-ear disease which may cause a moderate or intermittent hearing loss during these formative years. Senior citizens with hearing impairments severe enough to require amplification are often denied such help because current medical assistance programs do not provide for the purchase of hearing aids.

Information regarding the actual cost to the Nation of deafness and hearing impairment among the population is scant at best. Conservative estimates, excluding related costs due to the lowered earning power of the communicatively handicapped, are given as $13.4 billion per year.

The ultimate goal of hearing research is the prevention and cure of hearing disorders. The basic mechanisms of hearing, as well as the more complex functions of sound and speech perception, are still not understood. Research has made remarkable progress toward this understanding in the past decade by constructing an increasingly precise description of the anatomic, physiologic and biochemical processes involved. Much of the NINCDS-supported research is directed toward obtaining knowledge about these basic functions. Equally important, however, are clinical studies for improving the treatment of persons already afflicted with hearing disorders.

Research Efforts

Identification of Hearing Disorders

Hearing is perhaps the most important of man's communicative faculties, yet its lack of visibility has tended to delay the search for medical diagnosis and treatment. Early identification and diagnosis of hearing loss is critical not only for the young child, but for all persons whose hearing loss interferes with adequate communication. Accurate measurement of hearing function has been enhanced by the use of recently developed methods and procedures. The NINCDS is currently supporting research to develop reliable screening tests for hearing loss in all newborn children and to refine an objective type of measure of middle-ear function. This latter technique, known as impedance audiometry, provides information regarding the integrity of the mechanisms which conduct sound to the inner ear. Procedures are now being developed to use this technique as an indicator of sensorineural impairment by measuring the responses of middle-ear muscles. The measures provide valuable data for the physician in making his diagnosis, particularly if the patient is unable to be tested by conventional behavioral methods.

Similarly, NINCDS is continuing to support research in several laboratories which are developing electrocochleography, a technique which monitors the neural excitation of the ear by picking up electical impulses produced in the cochlea (the organ of hearing in the inner ear). Brain stem audiometry is also being pursued by NINCDS investigators to identify waves of excitation which are caused by the transmission of nerve impulses from the ear to the processing centers in the brain stem. This technique is proving valuable in diagnosing the changes in neural activity involved with disease at various locations along the auditory pathways. Advancement in these procedures as well as others will continue to be encouraged by the NINCDS to better diagnose hearing disorders.

Congenital Hearing Disorders

Approximately 40 percent of deafness which is present at birth is caused by hereditary defects. More than 40 types of hereditary deafness have been identified, and work in this area is steadily advancing through the identification of specific gene defects. Sophisticated counseling of prospective parents about the genetic nature of various hereditary disorders is now available. NINCDS-supported studies of genetic and prenatal defects which affect the developing ear include techniques which facilitate separate removal of the hearing and vestibular organs from fetal mice and permit laboratory growth and examination. These procedures allow the comparative analyses of normal and genetically defective sensory cells in the organ of hearing and auditory nerves. Animal models of this type have proven invaluable for understanding the human structure and function so that the clinical management of congenitally deaf children may be improved.

In addition to genetic disorders, viral infections also cause congenital deafness. Approximately 10 percent of this type of impairment results from prenatal rubella infection. The NINCDS Collaborative Perinatal Study of 50,000 women and their offspring was in progress during the rubella pandemic of 1964 and showed that about half of the infants whose mothers had rubella during the first trimester of pregnancy subsequently became deaf. The development of the rubella vaccine has considerably reduced the incidence of the disease and the number of impaired-hearing children. It is hoped that further research will provide similar preventive measures to reduce hearing losses attributable to viral diseases and perhaps even genetic disorders.

Otitis Media

Even the child who is born with normal hearing continues to be at risk for hearing loss. Studies from carefully monitored pediatric populations indicate that over 50 percent of all children experience infections of the middle ear. Approximately 20 percent of school-aged populations (at the time of examination) show evidence that they have had significant middle-ear disease during their development. The most common middle-ear disease, particularly in younger children, is otitis

media (inflammation of the middle ear) caused by infection. The inflammation may persist for several weeks to months, with fluid remaining in the middle ear space. This can cause a mild to moderate hearing loss if left untreated.

Serous (or secretory) otitis media was once thought to be a disease separate from acute infectious otitis media. Serous otitis media accounts for the most common surgical procedures required by children. The cost of myringotomy (surgical drainage of the ear), placement of the ventilation tubes, and adenoidectomy performed for this disease amounts to hundreds of millions of dollars per year. Research sponsored by the NINCDS suggests that serous otitis media may be simply one sequela of a long spectrum ranging from acute infectious middle-ear disease to chronic mastoiditis. A great deal of research remains to be done on the epidemiologic factors which may predispose children to middle-ear infection, on the immunologic and infectious aspects in the pathology of the disease, and on better and more effective means of identification and treatment. A major concern in the care of these children is the resultant hearing loss and its effect upon the child's intellectual and educational growth.

NINCDS grantees, in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), have pioneered in the development of animal models for otitis media and in the development and evaluation of vaccines against infectious causes of this disease. NINCDS-supported investigators have reported that even in successfully managed cases of otitis media, there may be permanent hearing loss resulting from the inflammatory process. These initial reports have subsequently been confirmed by other investigators and emphasize the need for further research on the prevention of this very prevalent disease in children. The Communicative Disorders Program is attempting to encourage research needed on otitis media. A Request for Proposal (RFP) has been advertised for the award of a contract to study the efficacy of drugs in the treatment of otitis media. Also in the spring of 1978, the Program will sponsor a small workshop to better define the research that is needed to understand the developmental effects of recurrent or chronic middle-ear disease on young children.

A related concern is the research that needs to be done on the efficacy of and indications for tonsillectomy and adenoidectomy. The impact of this operation on the economy of health care delivery alone mandates that appropriate evaluations of this surgical procedure be accomplished. The NINCDS has funded a planning grant to determine the feasibility of a national multi-center collaborative project to assess the efficacy of and indications for adenoidectomy and tonsillectomy, and a report is expected in the spring of 1978. If a study appears feasible, serious consideration must be given to the desirability and the mechanisms of funding such a large and necessarily costly study. The NINCDS would not be able to fund such a study out of its anticipated allocation in the next fiscal years without severely curtailing other equally important research needs.

Chronic Middle-Ear Disease and Mastoiditis

The end results of recurring middle-ear disease is chronic inflammation and damage to the middle ear and mastoid, with the potential for spread to surrounding vital structures. This once life threatening disease has become surgically manageable with modern otologic techniques. NINCDS has supported basic research on the process of chronic mastoid disease and its ability to destroy bone and surrounding tissues. Major progress has been made by the identification of an enzyme, collagenase, in the tissues of the diseased mastoid which is considered an important factor in the destructive absorption of bone. During the past year investigators participating in this research sponsored a successful International Conference on Cholesteatome (a product of chronic infection causing destruction of the mastoid bone). Their indepth consideration of the biology, etiopathology, and management of chronic middle-ear disease has been published and is now available to the clinicians who must deal with chronic mastoid disease.

Environmental Effects on Hearing

The fact that certain environmental factors can have profound effects on hearing has been apparent to clinicians for many years. Only recently have we begun to understand the mechanisms affected by excessive noise exposure. Large numbers of patients with hearing losses due to small arms and artillery fire during their military service are currently being treated at clinics of the Veterans Administration. In addition, industrial noise exposure is now being recognized as a major health problem which affects about 16 million Americans. Another 10 million urban dwellers are often exposed to harmfully loud noise levels.

Much of the basic work in determining the relationship between the noise level and duration and permanent hearing loss has been supported by the NINCDS. Research findings indicate that there is no simple procedure that will predict which individuals may be most susceptible to noise-induced hearing loss. However, there appears to be a need for (1) education of the public regarding the potential for damage to the ears from excessive noise exposure, and (2) guidelines to protect those individuals who work in noise levels proven to be hazardous. NINCDS-sponsored research has shown that persons who have noise-induced hearing losses appear to be more susceptible to subsequent injury by noise and by other agents toxic to the ear. These persons need to be identified and protected from further hearing damage.

NINCDS participates fully in the Interagency Panel on Noise Effects sponsored by the Environmental Protection Agency. Members of this panel review all government-sponsored research pertaining to noise effects so that important research needs may be identified. NINCDS also coordinates its program with the National Institute of Environmental Health Sciences and the National Institute of Occupational Safety and Health.

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Other Ototoxic Agents

Many drugs used to combat disease can cause damage to the ear and subsequent hearing impairment. Important antibiotics such as streptomycin, kanamycin, gentamycin, and neomycin, and some diuretics such as ethycrynic acid and furosimide, in addition to the more common agents such as aspirin and quinine, have all been studied by NINCDS-supported researchers. They have defined the toxic doses and site of injury for a number of these agents. To facilitate information transfer, the NINCDS has supported the publication of handbooks of ototoxic agents and continues to support several research grants in this important area. Intramural efforts of NINCDS have been instituted to study the toxic effects of some of the cancer chemotherapeutic drugs which are currently being evaluated in the Clinical Center at the National Institutes of Health. Hopefully, all Clinical Center patients on potentially ototoxic drugs will soon be carefully monitored for hearing and vestibular function loss.

The work on environmental factors associated with hearing loss supported by the NINCDS in cooperation with the National Institute of Environmental Health Sciences and the National Institute of Occupational Safety and Health, is being coordinated with other governmental agencies under the auspices of the Environmental Protection Agency and the Interagency Panel on Early Childhood Research and Development.

Rehabilitation

Despite spectacular advances in the medical and surgical treatment of some types of hearing loss, a large portion of the hearing-impaired and deaf population cannot benefit from either medical or surgical intervention. For the hearing-impaired, amplification along with aural rehabilitation can substantially improve their communicative abilities. NINCDS supports investigators engaged in the study of new techniques for rehabilitative training and improved hearing-aid characteristics and selection procedures. One study is evaluating an individualized prescriptive procedure for hearing-aid fitting. Other studies are investigating the effects of reverberation time and compression of the sound signal on the listener's ability to perceive speech. Important basic research is also being supported to define those aspects of sound that are necessary as minimal cues for the understanding of speech.

Tactile aids are also being developed so that vibratory cues may be used by the profoundly deaf to enhance both their speech reception and speech production processes. Without the capability of monitoring his own voice, the deaf individual has great difficulty producing the volume and pitch changes necessary for inter-personal communication. Since there is relatively little information concerning the absorbing capabilities of the skin or the tactile sense in general, NINCDS is supporting basic research in this area in addition to the clinically applied work. Stimulation through the visual sense is another potential means of rehabilitating the profoundly deaf and is being addressed by

NINCDS investigators. An NINCDS-sponsored workshop on tactile and visual aids for the deaf identified pressing research needs and directions, many of which are now being implemented.

Auditory Prosthesis

Scientists have long been intrigued by the possibility that the non-functioning inner ear might be by-passed by a prosthetic device which could decode sound into nerve impulses to be recognized by the brain in a meaningful manner. Pioneering work in this area generated a marked degree of controversy because of our limited understanding of the normal mechanics of the auditory system and the methods by which sound and speech are decoded and encoded. In addition, the effect on normal processes of diseases which cause hearing impairments plus the safety of direct electrical stimulation of the nervous system were all areas of great concern to researchers investigating auditory prostheses. The NINCDS responded to this controversy by sponsoring two workshops devoted to discussions of the feasibility and practicalities of auditory prostheses (or cochlear implants). A majority of the recommendations emerging from the workshops have been undertaken. They include the development and miniaturization of suitable electrodes, the evaluation of long-term effects of stimulation on nerve tissue, and the objective evaluation of patients who have already received an implant device. Through an NINCDS contract, a multidisciplinary team evaluated each such patient over a five-day period and prepared a careful and detailed report (recently published in a widely distributed professional journal). Briefly, the studies indicated that the patients who had been implanted as long as two years appeared to tolerate the implants well. They found that the implants provided primarily time-pattern information of sound, some information on loudness, and very limited information on pitch. This processed information was useful to a few of the implanted patients in improving their ability to speak more clearly and their ability to lip-read. None of the patients were able to understand speech through the device alone. Through training, the implanted patients were able to identify some simple environmental noises. The psychological value of receiving even distorted information about sound through the auditory system, rather than through other sensory systems, appeared to be the chief value of the implant over other currently available rehabilitation techniques.

Research on auditory prosthetic devices for the deaf is in progress at a number of universities, medical centers, and private organizations. The NINCDS is currently spending approximately a million dollars a year for research in this area. Many scientists are convinced that the key to a successful implanted hearing device will come from discovering how the normal ear encodes auditory information and how this information is utilized by the central nervous system. Thus, the potential hope of an auditory prosthesis has provided a stimulus and raison-d'etre for considerable basic research which only a few years ago was thought to be too esoteric to be of any practical value.

The prevailing view is that encoding of intelligible speech, if ever possible, will require multiple channels, and concurrent stimulation of a series of predetermined portions of the acoustic nerve. Toward this end, multi-electrode devices, a second generation from the single electrode devices initially implanted, are now being intensively studied in animals, primates, and a limited number of human volunteers. The expertise required to adequately study this problem requires an unprecedented cooperation of diverse medical and scientific disciplines. A major concern is that primitively conceived and inadequately developed devices will be prematurely implanted by physicians in response to a deaf population eagerly awaiting a new breakthrough. Premature exploitation of the concept of the auditory prosthesis could significantly harm and delay the long-term potential of such devices. The NINCDS will continue to encourage and support research which is carefully and scientifically conceived in this very important area.

Advances in Basic Research

While efforts by NINCDS scientists to understand the physical aspects (anatomy and physiology) of audition have yielded significant advances, "how we hear," remains a mystery. It is clear that the mechanical energy of sound waves must be converted into electrochemical messages before the brain can recognize sound, but the precise site and mechanism of this energy conversion or transduction is unknown. Scientists have demonstrated that the hundreds of microscopic hair cells in the inner ear are the transducers for sound and that the hair cells release transmitter substances which excite the auditory nerve. The electrochemical transduction mechanism is a major area of study for the Neurotology Laboratory in the Intramural Research Program at NINCDS. The Communicative Disorders Program of NINCDS, likewise, supports a number of research projects which are directed toward defining the chemical substances in the inner ear and the auditory portions of the brain that transfer information from one nerve cell to another. NINCDS scientists, using culturing techniques, have worked out new methods for studying the biochemical mechanisms of the hearing organ.

The ability to carry out the necessary basic research on the auditory system has been greatly advanced in recent years by spin-offs from space-age technology. Spectacular advances in computerized ability to quantify and analyze data, in microphysiological and biochemical techniques, and in increasingly sophisticated transmission and scanning electronmicroscopic ultra-structure probes, hold promise for further increases in our understanding of the mechanisms of hearing. Major breakthroughs resulting from basic research are often difficult to predict. However, in recent years, instances of rapid translation to clinically applicable usefulness have been encouraging. The NINCDS hopes to continue the support of important basic research at a level which will provide the necessary knowledge base for an increasingly successful ability to prevent and treat the diseases which cause hearing impairment and deafness.

LANGUAGE AND SPEECH

Definition of the Problem

Individuals must have normal speech and language functions to be able to communicate with others through speaking, listening, reading and writing. In children, language development proceeds hand-in-hand with the acquisition of other forms of cognition and learning. Adequate language development in young children is crucial for their learning new information from others at all stages of development, but particularly during school years.

Approximately six percent of all school-age children (at least three million) have speech and language impairments which require special education and remedial services. The cost of these services cannot be estimated since service delivery systems vary regionally and only recently has funding been accomplished for the diagnosis and treatment of such children. These figures do not include children with other developmental disabilities who also require speech and language services such as those with mental retardation, cerebral palsy or hearing disorders.

In adults, a language or speech disorder can eliminate the possibility of social interaction, gainful employment and self sufficiency. Close to one and one-half million adults in this country have a chronic disabling aphasia, a severe language disorder that results in an inability either to assign meaning to words, to understand speech, and/or to organize words into thoughts, while there are 24,000 persons with laryngectomies (patients who have undergone removal of the larynx as a treatment for laryngeal cancer) in the U. S. today.

Although injury to particular parts of the brain and central nervous system is known to result in various types of language and speech disorders, the neurological bases for normal speech and language development and functioning are not well understood. Also, the etiology and pathogenesis of many disorders such as stuttering, specific language delay, and infantile autism are not known.

Recent Research Advances and Outlook

Normal Language Development

Language is a system in which signs and symbols are combined according to specific rules for conveying meaning. Both the signs and symbols must be known by a speaker or writer as well as the rules for combining them so that others will understand their intended meanings.

The NICHD supports several projects dealing with the acquisition of language during childhood. Because normally developing children learn spoken language as a matter of course, the complexity of language and the acquisition process are frequently overlooked. Scientists from many different disciplines are encouraged to define the major unsolved problems and investigate how children develop language. In the next year, the NICHD will sponsor a conference on the development of speech sounds in young children to determine research needs in this area.

Acquistion of Reading and Developmental Dyslexia

The NICHD has recently undertaken several new projects aimed at determining how reading skills are acquired in the normal population and at improving the detection, diagnosis and treatment of dyslexia, a specific language-related learning dysfunction reflected in reading problems. Scientists are investigating the physiological and psychological functioning of children who are dyslexic. It is not yet understood why children who are of normal intelligence, without sensory impairment, primary emotional problems, or obvious neurological damage and who have received adequate reading instruction, are unable to learn to read.

The NICHD sponsors research studying the relationship of cortical and subcortical areas of the brain on short-term verbal and nonverbal memory and language function. Information from this work will hopefully be useful in improving the abilities of patients with learning and language difficulties such as dyslexia.

The NINCDS supports experimental studies of the auditory, visual and perceptual skills of dyslexic, language impaired and speech impaired children. These investigations are aimed at determining whether relationships exist between the primary impairments of these groups of learning disabled children and their perceptual and cognitive skills. The information derived from this research will provide the knowledge base from which appropriate methods of diagnosis and treatment may be developed.

Developmental Language Disorders

Language development can be hindered or impaired from birth as a result of impaired hearing, mental retardation, infantile autism, or specific brain damage. Children who do not suffer from any of these problems, but still fail to develop normal language skills, often have what is termed a developmental language disability. Almost all of these children continue to be learning disabled throughout school and have significant impairments in reading and writing as adults.

To assure healthier children and adults, the NICHD attempts through research to identify the causes of childhood morbidity so that developmental disabilities can be prevented. While recognizing the importance of early detection of high-risk infants, the NICHD focuses its efforts

on the prevention of those conditions which place children in such a category.

Ongoing research supported by the NINCDS is focusing on the early detection of language impaired children at the preschool age to allow for their treatment prior to entering school. Language screening procedures are being developed for use with Anglo, Black Dialect and Spanish speaking children. Further, language assessment tools are being developed for evaluating the skills of language impaired children and designing improved treatment methods.

Recent advances have been made in teaching language to mentally retarded and autistic children. Investigators jointly supported by the NINCDS and the NICHD determined that such children could often learn to associate concepts with visual symbols more easily than with spoken words. They found that language development could be stimulated by teaching such children signs to represent objects and activities with which they are familiar. Recently, it has been demonstrated that once communication is established, either with visual symbols in the mentally retarded, or with manual signs in autistic children, speech may emerge spontaneously.

Under NICHD support a female chimpanzee, Lana, has been taught to communicate via a computer with man, and recently with another chimp. The information being learned about language acquisition from this and other experiments is being applied to the teaching of retarded children who have previously been unable to communicate.

A long-range goal of the NINCDS is to determine the etio-pathology of developmental language disorders not associated with mental retardation or deafness. This knowledge is needed for future prevention and treatment. Since few high quality researchers are presently addressing this problem, the NINCDS will sponsor a symposium to be held at the National Institutes of Health in January 1978 entitled, "The Neurological Bases of Language Disorders in Children: Methods and Directions for Research." This symposium will draw together scientists from many different fields to address the problem of impaired language development and to determine which research techniques have the greatest potential for providing some answers. The proceedings of the symposium will be published by the NINCDS and disseminated free to neuroscientists to interest them in this area for research.

One language impaired population which has long been neglected is the autistic child. A directed research program on infantile autism is being developed within the NINCDS. A first step will be to study the auditory perceptual skills of these children at different periods in their development and to determine if perceptual disorders are present which could account for their difficulties in developing receptive and expressive language.

Through a research contract, the NICHD continues to provide child development specialists and language scientists with natural and synthetic speech-like stimuli recorded in a precise manner and suitable for a variety of experiments. These recordings are prepared with highly specialized and costly equipment not available to most investigators. As a direct result of this NICHD contract, advances have already been made in speech and language perception which is leading to improved understanding of language and reading disorders.

Adult Language Disorders

In the last decade significant advances have been made in the development of tools for the diagnosis and assessment of language disorders in aphasia following stroke, head injury or surgery. Investigators supported by the NINCDS developed a set of diagnostic tests which classify aphasic patients' language disorders and identify language rehabilitation needs. Other tests measure the severity of patients' impairments in speaking and understanding relative to normal adults of the same age, sex and education. Additional tests can be used to estimate the degree of language recovery which a patient would have during the first six months following the onset of aphasia due to a stroke. Such instruments are useful to the physician and family for planning a patient's rehabilitation program and eventual needs for assistance.

Although significant advances have been made in assessment, until very recently treatment of aphasia has not been promising and received little attention from researchers. In the past three years, work has begun on the learning and memory skills of aphasic patients, studies of their ability to regain speech through alternate communication modes and the development of new types of language therapy.

One group of investigators found that speech intonation is the aspect of language which is best retained by aphasic adults. Subsequently, they developed a treatment program using intonation as the basis from which to retrain sentence production. They administered this treatment to patients who had been mute for at least six months following a stroke with aphasia. With this approach, many patients regained fluent production of meaningful sentences in less than two months.

On an NINCDS directed research project, an investigator has developed a method for recording all the events which occur during treatment sessions with aphasic patients. The coding system provides records of which types of treatment techniques have the best results for improving patients' language skills. This system is already allowing the investigators to develop improved methods of treatment.

NINCDS has also initiated research on the communicative needs of aging adults and aphasic patients. In an effort to determine the everyday needs of aphasic adults, patients living in chronic care institutions, as well as others living at home were observed in their daily lives. It was found that individuals who were aphasic and living

in nursing homes or similar institutions were significantly more limited in their communicative ability in contrast with similar patients who continued to live at home. This research is being continued to examine the effects of aging, living environment, cognition and mild hearing loss on the communicative competence of adults.

Speech Disorders

Speech production is man's most complex motor activity. It requires fine motor control of discrete, rapid and synchronized movements of the lips, tongue, pharynx and larynx simultaneously. Damage to central or peripheral areas of the nervous system which control the speech musculature results in disturbances of speech production called dysarthria. Such disorders accompany almost all neuromuscular and motor disorders such as cerebral palsy, Parkinson's disease, multiple sclerosis, and amyotrophic lateral sclerosis.

Other speech disorders include stuttering, verbal dyspraxia (impairment of needed coordinated movements for speaking) and speech difficulties of the deaf and hard of hearing. Research on speech production disorders which affect approximately eight million persons in the U. S. today, has been scant. One of the reasons for this has been the lack of available technology for objective measurement of each of the motor movements occurring during speech production. Recently, NINCDS grantees have developed new devices which allow experimenters to track movements of the speech articulator, such as tongue, teeth and lips. The output of such devices is digitized by computers and displayed visually allowing patients to observe representations of their articulator movements and self-correct their errors. Systems have been developed which can continuously display the exact positions of the lips and the lower jaw as well as the points where the tongue makes contact with the palate, all at one moment during production of a speech sound. From such displays, the point at which an error occurred in speech production can be located. Although such systems are still in the development stage and only being used with patients in laboratory settings, they have been demonstrated to be far superior to traditional methods for teaching speech to the deaf, and providing patients with dysarthria with biofeedback for self-correcting their speech production.

Approximately three percent of all school children who are without dysarthria or hearing problems have difficulties developing speech articulation skills and require speech therapy. Recently, investigations have begun to determine the process by which normal children learn to perceive speech sounds, begin to imitate them and consolidate their production of them--a process which is complete in normal children by age seven. If the bases for normal and disordered speech development could be determined, the prevention of such disorders might be attained.

Stuttering, which afflicts one million persons in the United States has long been the subject of a great deal of speculation. NINCDS

grantees have recently discovered that during stutterers' speech blocks there is simultaneous and opposing contraction of the muscles which open and close the vocal cords. Additional research has also implicated poor laryngeal control as a basis for stuttering. The NINCDS plans to initiate research on the development of stuttering in young children to determine if certain characteristics of laryngeal functioning can be identified which are precursors to the development of stuttering in childhood.

Laryngeal Disorders

In the United States, at least 4,000 adults undergo a laryngectomy (removal of the larynx which contains the vocal cords) for treatment of laryngeal cancer each year. Recent reports have indicated that the incidence of laryngeal cancer is increasing. Other laryngeal disorders include chronic laryngitis, vocal hyperfunction (strain on the larynx during speaking) and/or poor vocal health. A recent survey indicated that nearly two percent of school children have vocal pathologies and many of these are untreated.

Since it is believed that with early detection and treatment as many as 90 percent of the cancers of the larynx can be cured, the NINCDS has recently initiated research aimed at developing methods for massive screening in high-risk populations to detect early signs of laryngeal pathology. Investigators are evaluating at least three different recording devices and different analysis techniques to determine the most sensitive method for screening large numbers of persons for early signs of laryngeal pathology. In addition, NINCDS is collaborating with the National Cancer Institute to identify factors which are associated with a high incidence of laryngeal cancer. Such information is of importance for determining the cause of the disease and for defining which populations are most in need of screening programs.

Recently, computer based technologies have been developed by NINCDS grantees which provide methods for studying the phsysiological, anatomical and acoustic aspects of vocal pathologies due to laryngeal neoplasms, laryngitis, or neuromuscular disease. The NINCDS plans to bring together scientists and medical practitioners to develop a system of terminology for classifying voice disorders on the basis of several measurement criteria. The development of such a system is long overdue and necessary for developing standardized methods of diagnosis and assessment of these disorders.

Voice Prostheses and Rehabilitation

NINCDS grantees have refined new surgical reconstruction techniques which will provide voice production in patients who have undergone removal of the larynx as a treatment for laryngeal cancer. These techniques were first developed in Europe and allow patients to produce voice without needing to learn esophageal speech or use a prosthesis.

Following removal of the larynx, the upper portion of the patient's trachea is stretched upwards and sutured to the base of the tongue. Usually within a week postoperatively, patients can begin to learn to regulate air flow and the amount of pressure necessary for voice. One disadvantage of the procedure is that patients must learn a new method of swallowing. Although this technique is not applicable to all patients who have laryngeal cancer, its use should eventually become common in this country and should reduce the number of laryngectomics who must rely on voice prostheses.

Non-Auditory Effects of Noise

In 1974, an Interagency Panel on The Effects of Noise reviewed federally supported research on the effects of environmental noise, and concluded that research was most needed on the non-auditory effects of noise. The NINCDS has noted the paucity of knowledge available on the effects of high levels of environmental noise on individuals' language and speech skills. One area of greatest concern is the possible effects on laryngeal health of speaking for long periods in high levels of noise.

Laryngeal hyperfunction due to speaking in industrial or transport noise interference may cause vocal abuse in a high proportion of the persons who must use speech to communicate in such environments. The NINCDS hopes to investigate this possibility to determine if some cases of vocal pathology could be prevented.

Translation of Research Findings To Clinical Practice

As has been mentioned throughout this report, the dissemination of research findings and their application are considered by NIH to be one of its major functions. Each of the Institutes involved in communication research has held conferences and published proceedings.

Recently a task force was formed to address the needs for literature retrieval services for clinicians and researchers in the communicative sciences and disorders. All available systems and publications were reviewed and none were found satisfactory for providing communicative disorders specialists with accurate and up-to-date literature in their field. However, it was determined that most of the medical literature which is relevant to clinicians and researchers in communicative disorders is being stored in the data base of the National Library of Medicine's Medical Literature Analysis and Retrieval System (MEDLARS). This system, however, was found to be less useful than anticipated in the communicative disorders area due to retrieval problems. It was discovered that few indexing terms were being used which were relevant to hearing, speech and language disorders. In the last year, NINCDS staff has been working with the National Library of Medicine to develop appropriate indexing terms in the communicative disorders area. Also, a major objective is to provide clinicians and scientists with instruction on how to retrieve literature from the MEDLARS system. For this purpose

the NINCDS staff is writing an instruction manual which will be disseminated at professional meetings next year. In addition, short instruction courses for users are planned to be given next year at the meetings of the professional societies in the communicative disorders area.

The most recent conference proceedings in the NICHD's Communicating by Language series will be published early in 1978. The book, Speech and Language in the Laboratory, School and Clinic, will highlight the most recent findings from basic research related to speech, hearing and language and the attempts to identify aspects of these findings which may have practical application for speech, hearing or language handicapped persons. The book also will discuss some of the problems associated with the translation of basic knowledge to clinical service in schools and clinics.

Other publications in the Communicating by Language series are: The Role of Speech in Language, Language by Ear and by Eye, The Reading Process, The Genesis of Language, and The Speech Process. Pamphlets highlighting the most recent books in the series are available from the NICHD. They are entitled: "The Relationships Between Speech and Reading," and "On the Relationship of Speech to Language."

In cosponsorship with its Mental Retardation Research Centers, the NICHD has also initiated a series of seminars which will result in state-of-the-art documents for the scientific community on aspects of mental retardation. Recognizing that language and communication are vital elements in the development and performance of the mentally retarded, and that communicative disorders are the most commonly shared handicaps of mental retardation, the first seminar in this series dealt with language and the mentally retarded. The proceedings resulted in the publication Language of the Mentally Retarded. To complement this effort, a second conference was held bringing together basic scientists and clinicians in the field of language. This resulted in the publication of Language Perspectives--Acquisition, Retardation and Intervention. This conference and publication bridges basic research and clinical application. Continuing the major emphasis on communication disorders, coupled with a concern for early detection, diagnosis, and treatment, a third conference on "Early Behavioral Assessment of Communicative and Cognitive Abilities of the Developmentally Disabled" was held in May of 1976. A book entitled, Communicative and Cognitive Abilities--Early Behavioral Assessment will be published in 1978.

HEALTH SERVICES ADMINISTRATION

Bureau of Community Health Services

HEARING AND SPEECH

The Bureau of Community Health Services, Health Services Administration, administers funds appropriated under Title V of the Social Security Act for Maternal and Child Health and Crippled Children's Services. These funds are available as formula grants to State Maternal and Child Health and Crippled Children's agencies, to meet the requirements of Title V, including the requirements for projects for the comprehensive health care of children and youth, maternity and infant care, dental health care, training of professional personnel and for research related to the health of mothers and children.

The Bureau of Community Health Services assists State, local, and community health agencies in planning, developing and evaluating programs of health services for children including those with communicative disorders of speech, hearing and language. These efforts consist of (1) providing technical assistance by staff which is consonant with the national goals and objectives of the HSA and BCHS; (2) initiating, conducting, and supporting efforts by grants and contracts to extend and improve speech and hearing services and the related health services; (3) providing program guidelines and other material relevant to the needs of professionals and parents; (4) reviewing the performance of programs; (5) initiating studies which focus on improving the quality of services, and; (6) supporting the training of personnel, as related to the development and disorders of speech, hearing, and language.

The data in the table accompanying this report represent the obligations and expenditures for speech and hearing services which can be identified in the different categories of project grants. The amounts expended by the States for speech and hearing services under the Title V formula grants are not reported by the States thus the total national expenditure of the Bureau's program for speech and hearing are not identifiable.

The Magnitude of the Problem

Of the 83.8 million children under 21 years of age in the United States in 1970, there were 9 million who were handicapped according to estimates prepared by the Rand Corporation for the Secretary of the Department of Health, Education, and Welfare (R-1420-HEW, May 1974, p.3). Among these there are 2.7 million with hearing and speech impairments. These estimates of the prevalence clearly indicate that communicative disorders are of a magnitude that a significant effort is required in the prevention, detection and treatment of the problems. There are almost a half million children and youth who are hard of hearing or profoundly deaf.

Prevention and Treatment

The etiologies of hearing impairments can be roughly divided into two categories both of which are susceptible to preventive actions, early detection and early treatment. One category includes those conditions related to maternal health, the course of the pregnancy, the delivery and aftercare. This category includes the provision of immunizations including the provision of the Rh anti-immune vaccine and the rubella vaccine as well as others which help prevent diseases which may affect the speech, hearing, and language systems. The other category includes those hearing problems related to malformations and disease or dysfunctions of the upper respiratory system and the middle ear. Both categories require that the hearing problem be detected as early as possible to avoid further medical complications as well as the language and learning problems due to the lack of auditory stimuli. Accurate diagnosis, made promptly so that treatment will be appropriate, is an important aspect of preventive services.

Speech and language problems are caused also by conditions other than hearing impairment, and are frequently related to a wide range of developmental and behavioral problems. A child handicapped in communicative skills is handicapped educationally, socially, and vocationally. While treatment and training may often be directed solely at the child's speech and language impairments, the Bureau of Community Health Services encourages treatment planning which integrates the efforts of multiple disciplines. To meet this need for team oriented clinicians further development of inter-disciplinary training programs and further refinement of standards of quality of care are required.

To increase the effectiveness of care while at the same time reducing its cost requires that one of the national objectives must be to improve the continuity of services. The treatment program for communicative disorders requires coordination between the health service speech and hearing specialists and the school speech and hearing clinicians, and between clinical services and the home. For such continuity to be established and improved, there must be an improved coordination among the programs for speech pathology and audiology services at all levels of the government. Such requirements have led to the formulation of the following general goals.

Goals

The BCHS program for speech and hearing services under Title V, Social Security Act, is guided by the following goals:

1. To assist State and community health agencies to develop additional programs and to extend present programs, especially to infancy and early childhood, for the prevention, identification, diagnosis and treatment of communicative disorders of hearing, speech and language.

2. To increase the availability of manpower and to improve the quality of the personnel and facilities available to serve children with hearing, speech, and language disorders.

3. To identify problems related to providing or improving specialized services and to develop and support studies pertaining to these problems in serving children with communicative handicaps.

State Agency Programs

The services provided in a hearing and speech program in a State Maternal and Child Health or Crippled Children's Service program include medical and surgical treatment, hospitalization and aftercare, audiology and speech pathology services, nursing, social work and psychology services and other health services as required, including the provision of hearing aids. While services for hearing and speech impairments are provided in each of the States, the nature and scope of these services vary among the States and among communities within the States.

In all but six States, either the Maternal and Child Health agency or the Crippled Children's Service agency, or both, employ professionally qualified speech pathologists or audiologists to be responsible for the development and implementation of a program for hearing and speech services. Speech and hearing programs in State Maternal and Child Health and Crippled Children's Services Agencies provide services both directly and indirectly in a variety of different delivery systems.

Casefinding, preventive, and diagnostic services, in many States are provided directly by State personnel at both the professional and supportive personnel levels. Treatment services for both hearing and speech impairments in some States are provided by State employed staff, but most often are purchased from existing hearing and speech facilities and other facilities. Speech services usually are provided as an integral part of the services for children with other handicapping conditions, including mental retardation, cerebal palsy and cleft palate. For fiscal 1975, MCH and CCS has reported testing the hearing of more than seven million children. The number of children who are found by these hearing tests to need medical and other help is, on a national average, approximately 2% to 3% of the total. This national average, however, fails to emphasize the fact that in some geographic areas the prevalence of significant hearing impairments is 15% and in Alaska, for instance, it is above 30%. The number of persons who are profoundly deaf from birth is approximately two per thousand in the general population. In fiscal 1975, the total number of children with cerebral palsy served by the Crippled Children's Service was more than 38,677 and those with cleft lip and palate were more than 23,184. The Crippled Children's Service reported providing services to more than 70,898 hearing impairments; of these more than 27,254 were served for the first time in fiscal 1975.

In 1977 a special initiative was undertaken to develop fifty new sites for testing the hearing of preschool children. Special grant awards totalling $500,000 were made available to State Crippled Chidren's agencies for this purpose. Preliminary evaluation indicates that these stimulation projects have been significant in refocusing attention on the very young child.

Special project grants to State agencies for hearing and speech services include grants to the Colorado Department of Health for demonstrations related to communicative disorders; the Iowa State Services for Crippled Children to explore developments in providing hearing and speech services to mentally retarded children; the Alaska State Department of Health and Social Services to develop a joint program of audiology services with the Alaska Native Health Service.

Bureau of Community Health Services Program

Technical assistance by professionally qualified specialists is provided to State health departments and Crippled Children's Services and to other grantees receiving funds under Title V, Social Security Act, as well as to appropriate voluntary and professional organizations. Financial assistance is provided through grants and contracts for special projects in the area of speech and hearing which are of regional or national significance.

Special training projects in speech pathology and audiology continue to receive grant support at the Howard University, John Hopkins University, University of Iowa, University of Oklahoma Medical School, the New York University Medical School, and Vanderbilt University Medical School. The project at Vanderbilt University includes a cooperative training program with Tennessee State University, a historically black institution. This project, and the project at Howard University, are developing new patterns of professional preparation for speech pathologists and audiologists to serve children whose cultural and linguistic backgrounds are different from that of the specialist.

In addition, speech pathologists and audiologists are included in the more than fifteen health professions which receive support for training in twenty University Affiliated Training Centers. The purpose of this training is to increase the effectiveness and quality of interdiscipinary and multdisciplinary care to handicapped.

Continuing activities in research under the International program include studies of the methods for the early detection of hearing loss. Such studies have been supported with special currency funds in Israel, Poland and in Yugoslavia. A project in Egypt has as its purpose the development of a hospital-based model for delivering speech and hearing services.

One of the aims of the speech and hearing program has been to aid the speech pathology and audiology profession to function effectively in whatever health delivery system may be finally evolved. Financial support for national conferences of leaders in public health, directors of speech and hearing clinical services, and directors of training in speech pathology and audiology has been provided to implement this objective. These meetings included national conferences to consider issues related to guidelines for hearing screening and to the recent nationwide interest in impedance audiometry.

The National Health Service Corps (P.L. 94-484) made scholarship awards to twenty speech pathology-audiology students. These professionals will be assigned to serve in health manpower shortage areas in those States designated as having high infant mortality and morbidity rates. In fiscal year 1978, awards will be made to an additional fifteen students.

The Bureau of Community Health Services has developed guidelines to establish statewide networks of services for handicapped children. The networks will provide comprehensiveness and continuity of health services to those who are handicapped by improving the referral process between the State Crippled Children's agencies and the primary care centers supported with funds administered by the Bureau of Community Health Services. Speech and hearing services will be made available through these networks to the large medically underserved populations served by the primary care projects.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

HEARING AND SPEECH

The basis for national estimates of the total prevalence of speech defects--primarily those related to articulation and language development which could be seriously handicapping are being obtained for the first time among children 4-6 years of age in the present Health and Nutrition Examination Survey program. The evaluation of the speech recordings obtained in the survey is being done by experts in Speech and Hearing including those at the National Institutes of Health.

Among persons 4-19 years of age in this present examination program, hearing levels are being determined through pure-tone air-conduction audiometry as in previous examination programs. From these examination data on speech, hearing and ear pathology it will be possible to obtain national estimates of various types of hearing and speech pathology not previously available.

OFFICE OF HUMAN DEVELOPMENT

Rehabilitation Services Administration

HEARING AND SPEECH

The Rehabilitation Act of 1973 is providing vocational rehabilitation with important new means to reach out and serve men and women with serious communicative disorders. While the history of vocational rehabilitation is replete with sucesses in service to individuals handicapped by deafness and hearing and speech impairments, it was not until this recent legislation that work with the most severely disabled could be initiated. Program development in the area of serious communicative disorders is now making it possible for heretofore unserved or underserved people to achieve their vocational rehabilitation potential.

A summary of the most outstanding ongoing and developing vocational rehabilitative activities that are anticipated to increase the number of deaf, hard of hearing and speech impaired persons rehabilitated annually are presented in this report.

The Problem in General

Americans who are vocationally handicapped by varying degrees and kinds of communication disorders exceed 20,000,000 in number. Some have disorders of the ears, the normal channels for receiving verbal messages. Some have defects in the vocal mechanisms, the main means for sending verbal messages. Some have disorders of the central nervous system which interfere with receiving and sending even though the ears and vocal apparatus are whole. Some have peripheral involvements that curb free verbalization. Some have combinations of causes.

The complexity and variety of the causes frequently obscure the fact that speech and hearing are variables that fluctuate with physical, mental and emotional conditions. Normal ears, normal mentality, normal vocal mechanisms and so on should result in normal hearing and normal speech. One abnormality or more results in abnormal communication. The person permanently affected faces formidable barriers. Fortunately, the condition for many is transitory due to the wonders of medicine and related disciplines. These are not among the above-named 20,000,000 whose disabilities are constant, who continuously search for ways to reduce the handicap of communication limitation.

Vocational rehabilitation workers share with teachers, audiologists, speech pathologists, medical workers, and others the responsibility to create, extend and improve knowledge and resources by which the communicatively handicapped can attain adjustments commensurate with their mental and residual physical capacities.

The Deaf

Our 1.8 million deaf people have very complex problems. Many of them are without useful speech despite years of training. Many have limited language skills. They receive messages principally through their eyes. They send message by combinations of signs, gestures, speech, and writing. Most of them have normal strength, mobility and intelligence. They strive for achievement within the limitations imposed by society. It is primarily a psychosocial problem. It manifests itself in many ways: underinvolvement in the main stream of community life; limited socializing with fellowmen; lack of acceptance among neighbors, employers and fellow employees; severe underemployment. It seldom yields at all to medical intervention such as drugs, surgery or prosthesis. It does yield in approximate ratio to the availability in quality and depth of training and adjustment services that stem from comprehensive, expert diagnosis that may involve the disciplines of psychology, audiology, medicine, and education and to public relations activities that stress the deaf person's strengths.

Two deep-seated problem areas for vocational rehabilitation exist with respect to deaf people. First, the most basic and achievable need of the deaf person, specifically skill in reading and writing, has until very recently been insufficiently emphasized in childhood training. Formal training has generally so heavily emphasized the development of speech skills in the deaf child that speech has erroneously assumed the position of being the equivalent of rather than a vehicle for language. To put it another way, teachers of the deaf have focused disproportionate time and energy upon an outlet (speech) for language rather than power in language itself. Language and speech have been referred to interchangeably, confusing professional and lay workers alike. Hence, the handicapping aspects of deafness have often been intensified by a needless wall of language deficiency. Developing interest in total communication (use of speech, fingerspelling, signs, gestures, reading and writing in combinations verbal by individual children) by parents and educators as a better means for early language development in deaf people is a promising new movement.

Second, an incorrect image of the deaf person's potential in verbal communication skills stems from this heavy emphasis on speech and frequently unrealistic publicity that generates from it. These together create everywhere an expectancy in oral communication performance which very few deaf people can fulfill. Employers and others are, thus, not conditioned to look beyond the poor speech for the hidden, often rich, human resources.

The Rehabilitation Services Administration is attacking the roots of underemployment: (1) By encouraging and assisting in the establishment of rehabilitation centers to diagnose and train deaf people: (2) by extending its training operations (a) to reduce the communication barrier facing deaf people by developing standards and new procedures for speech

conservation, utilization of telecommunications, instruction in manual communication and interpreting, (b) to qualify more professional workers in psychology, social work, vocational rehabilitation, speech therapy and audiology to work with the deaf, (c) to develop better understanding of the potentials of deaf people among vocational rehabilitation workers and others, including employers and community leaders, (d) to improve the understanding among professional and voluntary workers of how they can assist the State vocational rehabilitation agencies in serving the deaf, and (e) to help deaf people and their co-workers develop more productive concepts of community inter-relationships; (3) by encouraging researchers to study and resolve the many economic, social, and psychological problems associated with deafness; (4) by extending assistance in the establishment of post secondary programs for deaf people; (5) by encouraging and assisting universities in opening new professional fields to deaf people through special programs and placement techniques; (6) by aiding parents to become more involved in the rehabilitation of their deaf children; and (7) by bringing into focus the needs and remedial actions that are unique to the civil rights of deaf people.

The Hard of Hearing

The several million hard of hearing pose quite different problems from the deaf, the two groups cannot be treated as one. Whereas the deaf receive verbal communication almost solely through their eyes, the hard of hearing rely principally upon their ears, even though these are defective. The hard of hearing generally have near-normal speech and language. Their disability often had a late onset as opposed to the early affliction of the deaf. Partial hearing impairment is less a psychosocial than a medical problem and often yields significantly and quickly to medical intervention and prosthesis with speedy return to an old job or a new one.

It is known that the number of individuals with partial hearing loss is far greater that those who have lost their hearing completely. How much greater is unknown. More accurate estimates are needed before the full magnitude and vocational significance of this problem can be assessed. Deteriorating job performance, eventual loss of job, and gradual withdrawal from family and society are three of the more obvious results of gradual and progressive hearing loss. Too few of these people request help from their State divisions of vocational rehabilitation.

The problems of the hard of hearing are many; this the State vocational rehabilitation counselor knows. How best to solve them, no one yet knows. Much remains to be accomplished in helping the hard of hearing person retain the skills he had before the onset of his handicap. Better diagnostic methods need to be developed to permit more successful fitting of hearing aids. Abilities which permit a person to speechread (lipread) successfully are, at present, unidentified. And yet, accurate prediction of such ability would have profound effects on the rehabilitation management of hard of hearing and deaf children as well as adults.

Further attention should also be given to ways of helping the person with progressive hearing loss retain his speech intelligibility while he is losing his major sensory pathway for judging the accuracy of his speech production.

Basic to meeting the vocational rehabilitation needs of our hard of hearing are people to provide the highly specialized services that they need and the places to do it. The Rehabilitation Services Administration is aggressively involved in helping the States to find these fundamental resources.

The Speech Impaired

The speech impaired, including the language impaired, necessarily include many of the deaf and the hard of hearing because normal speech production depends to a great extent upon self-monitoring which in turn depends largely upon the speaker's hearing. We hear ourselves and correct as we go along. It is not the same for the hearing disabled. However, there are also millions of speech impaired whose abnormal or absent output stems from organic disorders other than hearing.

The special needs of stroke victims, particularly those with language problems due to aphasia, have received nation-wide attention. Little is known about the actual incidence of the siability, particularly in its more subtle and partial forms. Also, diagnostic techniques to determine the most appropriate treatment program and the outlook for recovery remain crude and inexact. Unavailability of crucial specialized services within the aphasic's home community particularly language therapy, poses insurmountable problems for most aphasics living outside large metropolitan areas. New methods of extending services to those people and/or training other family members to assume the task must receive high priority. Programmed teaching machines represents one partial solution to this problem, but self-teaching programs must be developed and evaluated. The spotlight of attention given to this affliction merely highlights the problems which are as yet unsolved.

Equal attention has recently been given to cancer victims. In great need of rehabilitation are those who have lost their larynx because of cancer, thus, their ability to produce voice. Such a sudden handicap usually results in loss of job and loss of family responsibility. Training procedures now exist to help the laryngectomees learn to use esophogeal speech, but too often those methods fail. Many individuals, therefore, go for the rest of their lives without the ability to speak. Reasons for this failure must be found. Better techniques for identifying those people who will be able to learn esophageal speech--and those who will not--are needed. Programmed learning methods also need to be considered as possible retraining procedures. Pre-surgery personality factors deserve investigation as probable reasons for post-surgery response to rehabilitation efforts.

Stuttering is another wide-spread speech handicap which deserves greater attention. Over 1,000,000 people in the United States suffer from this affliction. The problems of the adult stutterer are particularly damaging and cause the individual to lead a restricted and sterile life. This is true primarily because the speech defect is variable; the stutterer rarely knows when he begins to speak whether he will talk normally or will produce a spasm of muscular tension and an explosion of distorted words. Most stutterers, therefore, remain constantly "on guard" and resort to bizarre tricks and body motions (which themselves attract attention) to avoid stuttering. Some stutterers even pose as deaf to avoid having to speak. Consequently, many stutterers of superior ability accept jobs which require little or no talking and remain at a level of employment far below their aspirations and capacities. Underemployment, self-imposed, may sometimes be the stutterer's handicap.

Usually, these problems are most resistant to change, even though most of the stutterer's speech problem has been learned and can be unlearned. The reasons for the tenacity of stuttering are unknown. What is particularly puzzling is the fact that for a few persons, long-time stuttering can be eliminated with relative ease. Clinical observation has indicated that there are different types of stutterers. We need to find ways of identifying each kind and the critical factors which determine their response to rehabilitation. Also, better ways of helping stutterers achieve and retain more normal speech must be found. To do this, better methods of judging the effectiveness of speech therapy are needed. The goal is doubly worthwhile since, if the stutterer's speech can be improved, most of the associated psychosocial and vocational problems which his stuttering creates will also be eliminated.

The State vocational rehabilitation agencies find that a major problem is the lack of guidelines that enable staff to relate speech impairment to occupational handicap. Moreover, standards of casework performance and progress in therapy are not so closely defined nor apparent in speech rehabilitation as in other areas. The resources that serve the hard of hearing can be effective for the Administration's drive for more hearing and speech centers relates to speech rehabilitation, too. Additionally, special

emphasis is being given (1) to the development of authoritative literature on the handicapping aspects of speech disorders and their treatment and (2) to the fostering of voluntary work for the speech impaired throughout the national community on a level equal to that for the hearing impaired. The development of casework standards as guidelines for vocational rehabilitation counselors serving speech impaired clients has high priority.

Numbers Served by State Vocational Rehabilitation Agencies

The aim of the public vocational rehabilitation program is the preparation of the occupationally handicapped disabled person for suitable employment. The State vocational rehabilitation agencies actually determine eligibility and provide services using grant-in-aid funds administered by the Rehabilitation Services Administration.

All of the resources of the public vocational rehabilitation services are directed toward the occupational adjustment of the person whose disability is a vocational handicap. The media for attaining this end with each client are the case services that are patterned to individual needs. The research, training, and facility development activities of the Rehabilitation Services Administration and the State agencies are carried on for the purpose of strengthening case service techniques, developing new ones, improving the capacities of the case worker and the personnel upon whom he draws, and developing resources for better diagnostic, evaluation, training and restoration services. The dual aim of sharp increases in the quality and quantity of services and persons served permeates the whole program.

The extent to which the State agencies rehabilitated the deaf, the hard of hearing, and the speech impaired in the fiscal year 1975 and the numbers estimated to be rehabilitated in fiscal years 1976 through 1977 are shown in the following table:

NUMBER OF REHABILITANTS OF THE STATE VOCATIONAL REHABILITATION AGENCIES WITH SPEECH AND HEARING IMPAIRMENTS, FISCAL YEARS 1975 - 1979

Estimated and actual number of rehabilitants in fiscal year

	1975	1976	1977	1978	1979
All rehabilitants	324,039	303,328	291,202[1]/	283,000[1]/	277,000[1]/
Number of rehabilitants with major disability of speech or hearing	18,252	18,319	16,875[1]/	16,700[1]/	16,300[1]/
Deaf	6,066	5,936	5,533[1]/	5,400[1]/	5,300[1]/
Hard of Hearing	9,821	10,079	9,129[1]/	9,100[1]/	8,900[1]/
Speech	2,365	2,304	2,213[1]/	2,200[1]/	2,100[1]/

1/ Estimated

The effectiveness of casework rests in appreciable measure upon the joint planning of the counselor and the client. Clients who are hard of hearing or who have serious speech problems of other than hearing origin tax even the most skilled caseworker. Even so, counselor and client do have a line of verbal communication which encourages rapport. They can develop a good rehabilitation plan together. The profoundly deaf client, however, especially that large majority who have serious language deficiencies, are not able to communicate by normal means. This is the crux. There must be communication between counselor and client for effective casework.

The State agencies have recognized this basic factor and are moving to rectify it as qualified workers become available or through special training of current counselors. All of the States now have or are actively recruiting staff who may be classified as expert vocational rehabilitation workers for the deaf since they are trained as professional counselors and are also able to communicate by sign language with deaf clients. Several of the States are searching for and others have already secured additional qualified counselors because their caseloads of deaf clients have rapidly grown beyond the capacities of the special staff as their deaf citizens have become aware that the vocational rehabilitation agency is now able to work more effectively with them. Forty-eight States now have coordinators, too, to oversee and develop their vocational rehabilitation programs for the deaf and hearing impaired. The Rehabilitation Services Administration urges that each State have at least two highly skilled vocational rehabilitation counselors for the deaf and preferably that there be one in each metropolitan area in addition to a coordinator.

A Model State Plan for Vocational Rehabilitation of Deaf Clients developed in 1973 and revised in 1977 is serving as an important guide to the State vocational rehabilitation agencies on manpower development as well as on total program development for deaf and hearing impaired people.

A continuing problem in the area of the hard of hearing through the years has been developing and maintaining adequate channels of referral of hard of hearing persons needing vocational rehabilitation services. Major efforts have focused on encouraging the professional, the medical, and the voluntary worker to refer persons with hearing impairment to State vocational rehabilitation agencies for evaluation and consideration of possible services. The results have been disappointing as witnessed by the relatively small number of hard of hearing clients rehabilitated each year as compared to the many thousands needing or able to benefit from our services. The persistence of this problem has encouraged us to look to other channels by which more persons may become knowledgeable of their entitlements under the vocational rehabilitation service. Accordingly, we have now established formal working relationships with the National Hearing Aid Society, a principal feature of which encourages referrals by hearing aid dealers of persons coming to their attention who may be eligible for the services of our State agencies. If this move is as effective as we expect, the number of hard of hearing rehabilitants each year should increase rapidly into the tens of thousands.

Service Centers

Most of the many hearing and speech centers that have been established in the past twenty years have come into being in universities as training and research facilities, in large hospitals as service units, and in metropolitan areas. They fill vital rehabilitation needs in diagnosis, in evaluation, in training, in lipreading, speech, and listening, and in selection of hearing aids. We may have as many as 900 centers of widely varying levels of effectiveness and uneven geographic distribution. Many thousands of people with communication problems are just too far away from even the least of these service centers and even further from the more technical assistance that they may need. For example, a hard of hearing person who is 50 miles away from lipreading instruction, auditory training, hearing aid evaluation, is not likely to be able to travel this distance several times per week for instruction and service. The Rehabilitation Services Administration is attacking this problem directly through encouragement of projects that bring the basic hearing and speech services that the majority of these disabled people need into the local community at a clost that it can afford to maintain, leaving for the more comprehensive center the intricate services needed by more difficult hearing or speech cases.

In this respect the State vocational rehabilitation agencies are making important contributions to the availability of hearing and speech evaluation services through grants to extend and improve vocational rehabilitation services for the communicatively impaired. In 1969 alone, ten State divisions of vocational rehabilitation established facilities or special programs to improve services to the communicatively impaired. Authorizations under Sections 2, 3, and 4(a)(2)(A) were used in the creation of 25 projects at a total cost of over one-half million dollars.

The practical needs of deaf people are little related to speech and hearing centers. Almost all of them have had several years of intensive, expert training in speech and use of residual sound perception in their special schools. The deaf need the same vocational rehabilitation services as other clients, specifically diagnosis, evaluation, training, counseling, and placement, but in language that they understand. There are very few persons in rehabilitation centers or vocational schools who can communicate with deaf people to the point where a good learning situation may be said to exist. Consequently, the Rehabilitation Services Administration has had to concentrate on developing centers where there are expert professional workers for the deaf. Usually, these have proven to be the residential schools for the deaf. Diagnostic, evaluation, prevocational, and adjustment centers have been established or are planned at the State schools for the deaf in twenty-seven 1/ States.

The programs are serving as needed models for community service agencies and there are growing efforts by established rehabilitation centers to qualify themselves to serve the deaf. Community service centers for deaf people, relieving residential schools for the deaf of counseling responsibility of deaf adults, are located in ten metropolitan areas and being planned in others.

Justification

The provision of comprehensive rehabilitation services for a significant number of deaf people whose maximum vocational potential has not been reached continues to be a challenging and unmet need. These deaf people who have been estimated to number as many as 100,000 are severely limited in their personal, social and vocational adjustment. Appropriate resources for them are just now beginning to be developed. Only a small number of those needing extensive, intensive rehabilitation services are presently being served.

1/ Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Illinois, Indiana, Louisiana, Maine, Mississippi, Missouri, Nebraska, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, Tennessee, Texas, Vermont, and Wisconsin.

Rubella (German measles) eipdemics in the 1960's have resulted in large numbers of deaf children having multiple disabilities. These rubella children have been swamping our schools for the deaf and will soon begin to present a new and demanding challenge to rehabilitation agencies.

Deaf persons whose maximum vocational potential has not been reached, who have not had the advantage of special training, have several characteristics which create difficulties for them in entering and holding gainful employment commensurate with their potentials. Some of these characteristics also account for their inability to qualify for existing post-secondary training programs for the deaf. Their problems cluster around vocational rehabilitation, educational and social underachievement, severely limited skills in communication and adjustment to requirements of daily living and, in some, the presence of secondary physical disabilities.

The majority of these severely handicapped persons have normal strength, intelligence and mobility. Recent research in providing vocational and adjustment training to deaf persons with serious personal, social and work adjustment problems has demonstrated that given proper assistance all of them can improve substantially in their ability to live independently and function more normally in their families and communities. This assistance needs to be provided on an intensive, long-term basis by staff who are able to communicate with them, possess a full understanding of their handicaps, and are skilled in the use of instructional techniques and learning tools for overcoming these handicaps.

The authorization in the Rehabilitation Act of 1973 for special projects and demonstrations to provide vocational rehabilitation service which hold promise of expanding or otherwise improving rehabilitation services to handicapped individuals (especially those with the most severe handicaps) including deaf individuals presents means for long-needed project development for severely handicapped deaf people. The projects will at long last make it possible to provide them with the special type of services they need to become employable or better employed.

Of long concern to the Rehabilitation Services Administration has been the void in vocational training for deaf clients. The accelersting inroads of automation seem to have sharply reduced the number of entry level jobs by which the deaf have gained their footholds in industry. Consequently, more vocational training has been necessary for deaf people who frequently are poorly served or not at all by overcrowded vocational schools. This has intensified the training void for deaf people that exists between the special school system which generally terminates at 9th grade or less and post secondary education, a void which has nurtured and partially perpetuated their serious underemployment. Fortunately, the situation is changing for the better as programs are being developed to meet the various training needs of the deaf adult population.

Accomplishments

The establishment of the National Technical Institute for the Deaf authorized by Public Law 89-36 in 1968 was a very important step toward reducing the underemployment of deaf people. It is contributing vital new concepts in the training of deaf people and through its special job development and placement program opening employment that has not had many or even any deaf practitioners. The State vocational rehabilitation agencies are directly involved with every student.

Great strides are being made in vocational training for deaf people at existing community facilities. Demonstration programs at Delgado College, at Seattle Community College and at St. Paul Technical-Vocational Institute successfully integrated deaf students using support services such as interpreting, notetaking, tutoring and counseling. New and better employment opportunities opened to deaf people as they completed their training. The programs did much to stimulate interest at other schools in providing vocational training to deaf individuals. Currently, approximately fifty community colleges are sponsoring vocational training programs for deaf people modeled on the success of the three demonstration programs. The programs serve as vitally needed training resources for deaf clients of State vocational rehabilitation agencies.

A small but important beginning was made in 1974 in providing services to deaf people who have not achieved their maximum vocational potential. Three special projects funded by RSA were established in Indiana, Washington State and South Carolina to provide comprehensive rehabilitation services to severely handicapped deaf people for whom no programs previously existed. One additional project was set up in 1975 in California, one each in Texas and Maryland in 1976. In 1977, projects were put into operation in Virginia, Delaware, and Florida.

The Communicative Skills Program, a long-term training project funded by RSA now in its eleventh year, continues its work to increase the number of rehabilitation personnel, professionals in allied fields and employers and co-workers of deaf people able to communicate with deaf persons in their sign language. Over sixty universities now offer credit courses in manual communication as a by product of the greater awareness and interest generated by the Communicative Skills Program.

The Registry of Interpreters for the Deaf, a former RSA project, is expanding and accelerating its certification program to meet the critical need of State vocational rehabilitation agencies for an adequate supply of certified interpreters to work with counselors serving deaf people.

The National Interpreter Training Consortium, a long-term training grant program funded in fiscal year 1974 by RSA involving six regional training programs, is expediting the development of certified interpreters needed by State vocational rehabilitation agencies. By 1980, it is expected that each State will have interpreter training programs easing our present acute shortage of qualified interpreters.

DEAFNESS Annual, a document reporting on research and training activities and trends in the area of deafness with a directory of programs and services for the deaf, is an indispensable tool to the State vocational rehabilitation agencies and to professionals serving deaf persons. The American Deafness and Rehabilitation Association, which prepares and publishes the annual report, began this work as a RSA project.

Sixteen States 1/ have developed or are currently developing mental health programs for deaf people. The State of New York which absorbed the pioneering RSA supported demonstration mental health project for the deaf at the New York Psychiatric Institute provides the background for the developing programs. It is anticipated that additional States will commence this much needed work as more mental health workers who are able to communicate with deaf people become available.

1/ California, Connecticut, District of Columbia, Florida, Indiana, Illinois, Minnesota, New York, North Carolina, Ohio, Pennsylvania, South Carolina, Texas, Utah, Washington, Wisconsin.

Rehabilitation Training

Accomplishments

Training grants are available under the rehabilitation training program to support training in the areas of speech pathology and audiology and rehabilitation of the deaf. Since support of rehabilitation training was initiated in 1958, the number of training institutions has grown gradually and commitment of these institutions to train professionals in this specialty has been significant.

The focus in the Rehabilitation Act of 1973 on serving the severely disabled has imposed new demands on the current available manpower providing services to a significant number of communicatively handicapped individuals in this country. Manpower will continue to be needed to serve the deaf and the severely hearing impaired, the stroke patient with aphasia, and the larynegectomee population.

Special attention is being given under the rehabilitation training program to increasing the supply of qualified interpreters for the deaf.

Requirements in FY 1979

Training support in FY 1979 will continue to emphasize the training of skilled interpreters for the deaf to be available to assist state vocational rehabilitation agencies in providing services to severely disabled deaf individuals. Efforts will also be made to improve the manual communication competence of students enrolled in training program disciplines such as rehabilitation counseling and speech pathology and audiology.

REHABILITATION RESEARCH AND DEMONSTRATION

HEARING AND SPEECH

Recent review and analysis of available data indicate that the actual prevalence of speech, hearing, and language disorders in the United States is double previous estimates. Approximately 20,000,000 persons have communicative handicaps, with at least one-third of these suffering either substantial or severe social, education, and economic disadvantage. This relatively large portion of the handicapped population present a continued challenge to rehabilitation. Most communicative handicaps have their origin in childhood from varied causes, such as birth defects or injury, cultural deprivation, untreated disease, etc., but persist into adulthood. However, other causes occur in later life, such as problems of aphasia-related stroke, accidents, or brain injury, and problems of traumatic hearing loss due to excessive exposure to noise. Continued emphasis must be placed on the development of test instruments to assess the communicative behavior problems in order to facilitate rehabilitative and therapeutic goals.

Computer assisted instruction and programmed materials are being developed for clinical rehabilitation use of speech and hearing handicapped persons. The breaksown of communication barriers will allow for increased work potential and thus increased earnings for such individuals. There must be continued development of clinical procedures to assist aphasic patients, laryngectomies, and stutterers in social adjustment as the individual returns to his family and to the work community. Projects concerned with the rehabilitation of the hard-of-hearing, especially in culturally deprived populations and with the older American, will be encouraged. Greater emphasis must be placed on developing the full vocational potential of persons with varying degrees of speech, hearing, and language disorders.

DEAF

Problems areas for members of the deaf community have been found to include (1) basic language disorders underlying the communication handicap; (2) social and cultural deprivation; and (3) lack of awareness of the vocational opportunities which do exist. Our goals include the stimulation of projects concerned with basic rehabilitative procedures in language, with community efforts on behalf of the deaf, and with the expansion of vocational opportunities.

Vocational and technical education opportunities, for deaf persons at the post-secondary education level have been incorporated into regular service programs. There are projects in operation concerned with the development of mechanical aids to assist the teaching of language to the deaf.

Several projects have begun which deal with the intergration of deaf persons into the hearing community; projects concerned with providing mental health services; and projects involved in opening new job opportunities for the under-employed deaf. Data from a national census of the deaf are being utilized in program planning. A major thrust will be projects focusing on social interactivities of the deaf in hearing settings. Continued emphasis will be placed on the assessment of the potential of multipurpose rehabilitation settings to serve the deaf community. An important area of focus will be on provision of improved services to severely disadvantaged deaf adults through facility demonstration including a free-standing residential facility. Development of telecommunications, including cable, and exploration of improved training techniques for deaf people are being throughly explored

REHABILITATION RESEARCH AND TRAINING CENTERS

Hearing and Speech

The New York University Deafness Rehabilitation Research and Training Center provides a continuing framework for research and training in the problems of communication as related to the disabilities associated with the totally deaf; conducts research and training in the evaluation and diagnosis, treatment, counseling, training, and placement of individuals with a wide range of speech and hearing disabilities in addition to their major rehabilitation specialties.

In Fiscal Year 1975, the New York University Deafness Research and Training Center and six other Research and Training Centers conducted a total of 27 speech and hearing related research projects in such areas as technological sensory aids for the deaf, speech therapy in aphasia, social interaction among aphasic individuals, evaluation of speech intelligibility of stroke patients, and input and output measures in aphasia.

In Fiscal Year 1975, the New York University Deafness Research and Training Center conducted 17 short and long-term training courses for 475 rehabilitation workers from all the disciplines involved in the rehabilitation of the deaf. Examples of such training include courses in Principles, Techniques and Problems of Psychological Counseling with Deaf Persons, Disturbances of Communication, Community Service Programs for Deaf Persons, Communication with Deaf Persons, Psychology of Deafness, etc. In addition most of the Research and Training Centers in Medical Rehabilitation offer both short and long-term courses in Speech Pathology, Audiology, Communication Disorders, etc. All the 19 Research and Training Centers have established close working relationships with the Regional Offices as well as with the State Vocational Agencies, and they have addressed their needs in research and training as these pertain to the deaf population.

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NATIONAL TECHNICAL INSTITUTE FOR THE DEAF

HEARING AND SPEECH

Public Law 89-36 authorized the Secretary of the Department of Health, Education and Welfare to enter into an agreement with an institution of higher education for the establishment and operation of the National Technical Institute for the Deaf (NTID). The Rochester (N.Y.) Institute of Technology (RIT) was selected as the sponsoring institution. NTID is a residential facility offering postsecondary vocational education and technical training to deaf persons in order to prepare them for successful employment, a training center for preparing professional manpower to serve the nation's deaf population, and a research and demonstration center to help reduce the economic, educational, communication, personal and social negatives of deafness.

In FY77, NTID reached a full-time equivalent enrollment of 902 deaf students. The current faculty and staff including instructional, instructional support, clerical, administrative, research, and training personnel, numbers 320. NTID's research activities are being heightened in FY78 as a result of what has been learned from operations in the new facilities and the results of students' progress and subsequent job success. In addition, 1700 other persons are being provided with professional training to prepare them to work with deaf people.

The full-time equivalent enrollment of deaf students in FY79 will reach 1070. All students are enrolled in curricula designed specifically to lead them to jobs upon graduation. Of the students served, 215 are expected to graduate during FY79 and be placed in jobs. Training in: 1) sign language programs for personnel who work with deaf students in a variety of capacities; 2) technical subject interpreting for interpreters; 3) graduate internship and in-service programs for graduate students, faculty, and staff; and intensive short-course workshops in which new methods developed and proven at NTID are presented to professionals in the deaf education and related fields. Applied research will focus on questions designed to provide for program enhancement. Projects on the modes, measurements, and improvement of communication skills of deaf students will be carried out as will studies directly oriented to improving the career development process of NTID.

GALLAUDET COLLEGE

HEARING AND SPEECH

Gallaudet College: Gallaudet College, established in Washington, D.C. by an Act of Congress in 1857, has as its purposes to provide a liberal arts undergraduate education program for the deaf, a tutorial school for deaf students who need such training to qualify for college admission, a graduate school program in fields related to deafness, and a continuing education program for deaf adults. In 1976, an estimated 1157 undergraduates and 254 graduate students will attend the College.

In order to promote student development, the College offers a wide variety of learning experiences and instructional options, mediated instruction, significant interaction with the larger society, and experiences which encourage growth toward self-fulfillment, including participation and practice in decision making. In addition, the College offers technical assistance to outside organizations and agencies and services to deaf individuals and persons concerned with the needs of the deaf.

Model Secondary School for the Deaf: Public Law 89-694 provides for the establishment of day and residential facilities for the secondary education of young persons who are deaf in order to prepare them for college, other advanced training or employment. The Public Law authorizes the Secretary, after consultation with the National Advisory Committee on Education of the Deaf, to enter into contruction of such a school. The agreement was signed in May 1969. The school now serves residents of the District of Columbia and nearby states of Virginia, West Virginia, Maryland, Pennsylvania, and Delaware. In 1977, MSSD will have an estimated enrollment of about 169 students.

In one of the boldest experiments in the history of American education, students and staff have come together in a school to seek new ways in which today's young deaf students may be educated toward more productive and meaningful lives. An open laboratory school which employs computer-assisted education, educational television, and individualized instruction, the MSSD is a promise of things to come for schools for the deaf throughout the country. It is expected that the MSSD will provide an exemplary secondary school program to stimulate the development of similarly excellent programs throughout the Nation.

Kendall Demonstration Elementary School: Under P.L. 91-587, Gallaudet College was authorized by Congress to operate Kendall Elementary School as a national demonstration school for the deaf. In 1977 approximately 179 children will attend the school from the Washington, D. C. area.

As a demonstration school, KDES is attempting to develop an exemplary education program for children from the onset of deafness through the age of 15. The School also provides for a diagnostic center and a parent education program. Because of its special focus, Kendall School is also becoming a source of important research on the learning problem of young deaf children.

The obligations for fiscal year 1977-79 for Gallaudet College are as follows:

HEMOPHILIA

"Hemophilia" is a term usually reserved for the two most common forms of hereditary hemorrhagic disease: hemophilia A, or classic hemophilia, and hemophilia B, also known as Christmas disease. The term also embraces, however, some twenty additional disease entities characterized by deficiencies in the amount or activity of certain blood clotting factors--in most cases, factors VIII or IX--that can lead to uncontrolled bleeding. These deficiencies pose a constant threat of hemorrhage, crippling, and premature death in an estimated 18,000 Americans.

National Heart, Lung, and Blood Institute (NHLBI) research programs directed against hemophilia and other hemorrhagic disorders include basic studies of clotting factors in health and disease; development of improved methods of detecting, diagnosing, and evaluating such diseases in their active and carrier states; devising new and improved forms of therapy; basic studies of clinical significance on the nature of clotting factor inhibitors; and research to enhance the safety, effectiveness, and availability of blood and blood products for the prevention and treatment of bleeding episodes.

The National Institute of Arthritis, Metabolism and Digestive Diseases' Clinical Hematology Branch, and the Hematology Service of the Clinical Pathology Department, NIH Clinical Center, also conduct some research on hemophilia.

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
National Institutes of Health:					
National Heart, Lung, and Blood Institute	$ 7,740,000	$ 7,500,000	$ 8,236,000	$ 9,005,000	$ 9,133,000
National Institute of Arthritis, Metabolism and Digestive Diseases	361,000	391,000	455,000	486,000	501,000
Clinical Center	57,000	20,000	20,000	75,000	100,000
Total, NIH	8,158,000	7,911,000	8,711,000	9,566,000	9,734,000
Health Services Administration:					
Bureau of Community Health Services	-0-	3,000,000	3,000,000	3,000,000	3,000,000
TOTAL, PHS	$ 8,158,000	$10,911,000	$11,711,000	$12,566,000	$12,734,000

NATIONAL INSTITUTES OF HEALTH

National Heart, Lung, and Blood Institute

HEMOPHILIA

Background

The coagulation of blood is a complex process involving many steps and the participation of at least eleven blood clotting factors. For a number of these clotting factors, there are hereditary deficiencies or defects that may result in bleeding tendencies ranging from mild to very severe.

Known collectively as the hemophilias, these hereditary hemorrhagic disorders include:

- classic hemophilia, hemophilia A, the result of a deficiency in functional factor VIII (antihemophilic factor, or AHF).
- hemophilia B, also called Christmas disease after the patient in whom the defect was first detected, caused by a deficiency of functional factor IX (Christmas factor).
- von Willebrand's disease, formerly known as "pseudohemophilia", recently shown to involve a defect in the factor VIII molecule distinct from that in classical hemophilia A.
- other, less common forms, such as hemophilia C, a rarely encountered deficiency of factor XI that afflicts primarily people of Jewish ethnic origin.

An estimated 14,000 Americans suffer from moderate and severe hemophilia. About 11,000 of these have hemophilia A; some 3,000 hemophilia B. An undetermined number have von Willebrand's disease, which usually is a relatively mild bleeding disorder, but may be more common than all other hemophilias combined. In fact, clotting factor deficiencies are mild and of no clinical significance in many hemophiliacs and, as no overt bleeding tendency exists, often go undetected. In others, clotting defects are detected only after an automobile accident, dental extractions, surgery or other major trauma elicit excessive bleeding.

Both hemophilia A and hemophilia B affect males almost exclusively, but both are transmitted by female carriers. In these sex-linked forms of hemophilia, if a male hemophiliac begets children, his sons will be normal, but his daughters will be carriers. If the daughters bear children their sons have a 50-50 chance of being hemophiliac and their daughters a 50-50 chance of being carriers. Hemophilia can occur in women, but this is rare because it requires a union between a hemophilic male and a female carrier. Daughters born of this union have a 50-50 chance of being hemophiliacs and those who escape the disease will be carriers.

Unlike hemophilia A and hemophilia B, von Willebrand's disease can affect, and be transmitted by, either sex, though it tends to occur more frequently in women.

About 30 percent of all cases of hemophilia apparently occur de novo, with no previous family history of the disease. Some of these cases probably represent errors or omissions in reconstructing the victim's family tree, but others may represent recent genetic mutations.

In victims of hemophilia, the chief threat to health or life is not excessive blood loss from surface cuts, abrasions, or related injuries. Bleeding from such causes can usually be staunched even if the coagulation defect of hemophilia remains uncorrected. The real threat is internal bleeding into organs, soft tissues, and joints. Such episodes may occur with no apparent reason in severe hemophilia and are very likely to follow even seemingly minor trauma. The only effective means of controlling them is to supply the specific clotting factor needed to correct (temporarily) the victim's coagulation abnormality.

The major causes of death among hemophiliacs are cerebral hemorrhage and severe internal bleeding due to trauma. The major causes of permanent disability in these patients are orthopedic problems resulting from repeated hemorrhages into joints. These may result in progressive muscular atrophy, unstable joints, and related conditions that may eventually prove crippling.

Current NHLBI programs directed against hemophilia include basic research on antihemophilic factor and Christmas factor, their precise role in coagulation, the normal molecular structure of these factors, and genetic alterations occurring in hemophilia that cause them to perform poorly or not at all in clotting. Other research seeks possible means of stimulating the production or slowing the metabolism of normal factor VIII or IX in hemophiliacs, or finding other substances with procoagulant activity that might be modified to substitute effectively for the normal clotting factors in victims of the diseases.

Applied research is concerned with improved techniques for extracting concentrates of factor VIII and factor IX from whole blood or plasma, finding means of eliminating hepatitis virus or other dangerous organisms from these concentrates, and improving techniques for detecting female carriers of hemophilia before they give proof of it by bearing hemophilic sons. A major cooperative study is seeking basic data on and effective means of dealing with "antibodies" against factor VIII that arise in some hemophiliacs, possibly as a result of repeated infusion or transfusion therapy. Such inhibitors may complicate the management of bleeding episodes in such patients.

Diagnosis

Severe hemophilia usually becomes clinically manifest early, and most cases are diagnosed during the first year of life. Mild or moderate hemophilia is more often diagnosed later. The victim may have

sufficiently high clotting factor levels to prevent spontaneous bleeding episodes or other clinical manifestations of the disease under normal circumstances, and his bleeding tendency may not be detected until he bleeds excessively after trauma, a tooth extraction, or a surgical procedure.

Reliable coagulation tests have been developed that are practical for the routine screening of candidates for surgical procedures, and which cover the gamut of clotting factor defects or deficiencies. Any abnormality in the results of these tests indicates that a clinically significant bleeding tendency exists. They do not pinpoint the specific clotting-factor defect or deficiency responsible. However, this can be done by adding aliquots of plasma or plasma fractions known to be deficient in specific clotting factors to samples of the abnormal plasma, then repeating the coagulation tests. If the addition of plasma with the known clotting factor deficiency fails to correct the abnormal test, the patient's plasma is also deficient in that factor.

Other procedures for determining plasma concentrations of functional antihemophilic factor (AHF) are useful both for the detection of hemophilia and for assessing the severity of the disease. For while AHF levels may vary widely among hemophilic patients, the lower the AHF level in the individual patient the greater his bleeding tendency. These assay procedures are also of great value in monitoring the effects of AHF infusions to prevent or control bleeding episodes in hemophiliacs.

Treatment

The prevention and treatment of serious bleeding episodes in hemophiliacs improved dramatically during the sixties with the introduction of clotting factor concentrates. Administered by intravenous infusion, these can temporarily restore normal coagulability to blood deficient in AHF or AHF activity.

This formerly had to be done with transfusions of fresh whole blood or fresh or freshly frozen plasma. To raise functional AHF levels sufficiently to achieve hemostasis or to "prime" the hemophiliac for necessary surgery or tooth extractions and to sustain these levels during healing frequently required so much plasma that the patient's circulation might be dangerously overtaxed.

The first AHF concentrate to become widely available was a "cryoprecipitate" prepared by a technique developed by Dr. Judith Pool and associates at Stanford University. They found that, when fresh frozen plasma was slowly thawed in the cold, an AHF-rich precipitate was formed that contained, in concentrated form, upwards of half the AHF originally present in the plasma. The precipitate could easily be separated and could be stored for extended periods at very low temperatures until needed. Almost any hospital blood bank can prepare AHF concentrates by this method.

Other AHF concentrates are prepared by using neutral amino acids, such as glycine, to precipitate AHF from plasma. Some of these use pooled batches of cryoprecipitate as the starter material and yield highly concentrated AHF. Some concentrates can be lyophilized, or "freeze-dried," to a stable, powdered form that can be stored under normal conditions for prolonged periods.

The increased availability of the powdered concentrates and cryoprecipitates has permitted extensive use of home therapy as the mode of health care delivery to hemophiliacs. The patient or members of his family can be trained to administer AHF infusions at home at the first sign of bleeding. Experience has shown that this approach reduces costs, decreases physicians' visits, diminishes hospitalization time (when required for severer bleeding episodes), and permits the hemophiliac to pursue a more normal lifestyle. Home treatment can nearly always be initiated more rapidly than is possible when the victim must first be brought to the hospital emergency room, and this may also reduce the threat of permanent damage to joints or other tissues affected by the bleeding episode.

Most hemophiliacs receive episodic or "demand" treatment: that is, AHF is infused only when bleeding episodes occur or else to "prime" the patient for some anticipated dental or surgical procedure. In prophylactic care, AHF concentrates are infused on a regular schedule to sustain sufficiently high plasma AHF levels to prevent most bleeding episodes. As yet the advantages of prophylaxis over episodic care have not been fully evaluated.

Complications of Therapy

Transfusions of whole blood or plasma or infusions of clotting factor concentrates carry some presently unavoidable risks for the hemophiliac.

Acute or chronic hepatitis are common medical problems among hemophiliacs. The availability of techniques for identifying the presence of hepatitis B virus in blood and blood products has helped some, but there is presently no technique for removing or destroying hepatitis virus in most blood products that is not also destructive of vital components of the blood products themselves.

The use of commercially prepared AHF concentrates, rather than individual units of plasma or locally prepared cryoprecipitates, compounds the hepatitis risk. Commercial AHF concentrates offer the advantages of reliability of dosage, ease of transportation and storage, and the ease and rapidity with which they can be prepared and administered. But the AHF extraction procedures employed in making commercial concentrates require starting with large batches of pooled plasma, usually well over a thousand units, most of it obtained from paid donors rather than volunteers. Even though these donors are now continually screened for hepatitis B, studies have shown that plasma pooling and use of paid donors both increase the risk that the final product will be contaminated with hepatitis virus.

The use of pooled plasma may also contribute to another problem that occasionally attends AHF therapy, especially when large amounts must be infused. This problem is destruction of sometimes substantial quantities of the recipient's red blood cells (hemolysis). This may occur because commercial AHF concentrates may contain small quantities of blood-group or related antibodies that are hostile to the red cells of recipients, because plasma is pooled without respect to the blood groups of the donors (since it is usually the cellular components of blood that figure in transfusion reactions).

Another problem that appears to occur with greater than expected frequency among hemophiliacs is hypertension. The reasons are not clear, but some scientists suspect that repeated exposure to blood and blood products (and their antigens) may produce subtle kidney damage in hemophiliac recipients. The damage may neither produce overt clinical symptoms nor show up in conventional renal function tests, yet contribute to the elevation of blood pressure. And, for obvious reasons, renal biopsy (like liver biopsy for suspected but unconfirmed liver damage) is too hazardous to contemplate in most hemophiliacs.

Some hemophiliacs develop antibodies specifically directed against infused AHF. These may greatly increase the amount of AHF concentrate required to control any given bleeding episode and may also lead to anaphylactic reactions to AHF infusions. The prevalence of significant AHF antibody titers among hemophiliacs is not known. Nor is it clear how and why such antibodies arise (antigenic substances in blood and blood products are suspected, though it is also thought that some hemophiliacs may be genetically predisposed to produce AHF antibodies). The value of ancillary therapy (immunosuppressive agents) is also debated. The use of prothrombin complexes to bypass the AHF-requiring step in coagulation offers a promising but as yet controversial approach. A controlled trial of prothrombin complex will begin in January 1978, as part of the NHLBI factor VIII inhibitor study.

Seeking answers to these and related questions, the Institute has awarded contracts for pertinent laboratory and clinical studies among more than 1300 hemophilic patients at 10 participating clinical centers.

The Institute is also gearing up for a large-scale, retrospective autopsy study of hemophilia patients to evaluate pathologic changes (if any) in various organ systems resulting from hemophilia and to ascertain whether more or less organ damage has resulted from increased use of the more highly purified therapeutic products developed during recent years. Information expected from this study may improve the detection and clinical management of complications of hemophilia as well as possibly contributing to development of improved blood products for the prevention and control of bleeding episodes.

NHLBI research also continues apace on means of improving the safety of blood and blood products for all clinical uses. Special

emphasis has been placed on the development of more reliable, more sensitive tests for detecting the presence of hepatitis or other potentially dangerous contaminants in blood products. The quest also continues for means of removing hepatitis virus from blood products and for protecting patients exposed to hepatitis against development of the disease.

A nationwide system of Hemophilic Comprehensive Care Centers has been established. The NHLBI maintains a close working relationship with the Health Services Administration, and has served as scientific consultant in the evaluation of over twenty such centers.

Research

With the goal of increasing the availability of AHF concentrates and reducing their cost, NHLBI continues to support research concerned with improving the efficiency of present methods of extracting AHF from plasma. Other research is concerned with the development of effective substitutes for human AHF, such as animal sources, and with the quest for other substances with procoagulant activity.

Another approach involves bypassing AHF altogether by activating a subsequent step in the blood coagulation process. This approach has shown promise for controlling bleeding episodes in patients with factor VIII inhibitors.

The factor VIII molecule is so large and complex that laboratory synthesis of this clotting factor appears unlikely. However, research on the structure of factor VIII molecule indicates that it is composed of several smaller sub-units. One or more of these sub-units may be responsible for the procoagulant activity of the factor VIII molecule. The sub-units may be more amenable to precise structural determination and to synthesis in the laboratory.

The large size and complexity of the factor VIII molecule also provides a plausible explanation for the great variety of hemophilic states encountered among different families afflicted with hemophilia A. Structural defects may occur in a number of different sites within the molecule, with each defect affecting blood coagulability in a different way.

Similarly, in von Willebrand's disease, a major portion of the factor VIII molecule is missing, and this gross molecular defect correlates with the abnormal platelet function and distinctive clotting disorder seen in patients with this disease.

Prevention

The female carrier of hemophilia is usually asymptomatic. In many cases, it is not possible to be certain, on historical grounds alone, whether she is normal or carrier. Laboratory tests are helpful, but in some subjects the results of standard coagulation

assays are equivocal. Carrier detection in hemophilia thus presented a formidable scientific and clinical challenge.

Recently, however, NHLBI grantees have developed immunochemical methods that, in combination with standard coagulation tests, may identify carriers with an increased accuracy. This procedure is being studied in a collaborative study organized and sponsored by the NHLBI and the National Hemophilia Foundation. The rationale for this procedure is as follows:

- Hemophiliacs synthesize both functional and nonfunctional AHF. The abnormal variant, which does not participate normally in clotting--and which does not show up in functional coagulation tests--may comprise 90 percent or more of the total in moderate to severe cases. Immunochemical techniques employing antibodies against factor VIII do not distinguish between these forms, i.e., the factor is present in normal amounts by antigenic criteria.

- Similarly, carriers of hemophilia also synthesize both types of AHF. But the functional clotting factor comprises a considerably higher percentage of the total, so that functional coagulation tests may yield results within the normal range. If, however, the results of these tests are combined with those of the immunochemical tests, the presence of significantly high levels of nonfunctional AHF will identify the hemophilia carrier. The combination of functional plus antigenic criteria in potential carriers has increased diagnostic accuracy from a previous level of 50-percent to 90-percent or more.

Conclusion

The lot of the hemophiliac is much better today than it was only a few years ago. Unfortunately, it is still a difficult one for the victim and for his family. It seems unlikely that the disease can be eradicated, nor are the expectations very bright for a cure during the near future. However, through continued research and the fullest possible application of new knowledge gained through such efforts, we can continue to reduce the physical, emotional, and financial burdens presently imposed by the disease.

HEALTH SERVICES ADMINISTRATION

Bureau of Community Health Services

HEMOPHILIA

Title XI of the Public Health Service Act, as amended by P.L. 94-278, authorizes the award of project grants for Comprehensive Hemophilia Diagnostic and Treatment Centers.

With participation by the Bureau of Community Health Services (BCHS), which administers the project grant program, the National Heart, Lung, and Blood Institute initiated a study to estimate the prevalence of hemophilia in the United States and to determine the supply and demand of plasma products required to treat this population.

The results of the study estimated that the number of persons with hemophilia was around 14,000 (previous estimates were between 100,000 to 140,000). The study also estimated the prevalence rate of hemophilia A to be 1:10,000 males and hemophilia B to be 1:40,000 males. In 1975, there were 10,514 cases of hemophilia A and 2,629 cases of hemophilia B. The difference in Hemophilia A and B, which are the two main forms, is the specific types of clotting protein missing in the blood. Both forms result in similar symptoms, but each form requires a different treatment.

The findings further indicated that the supply and demand for blood components are in balance and will continue to be until at least 1980.

Of the 14,000 estimated hemophiliacs, approximately 7,300 are considered mild to moderate cases, while 6,700 are severe. The yearly cost of treatment, which must continue throughout the patient's life, ranges from $3,400 for mild cases to $25,000 for severe cases.

Too often, only emergency care, primarily injections of blood derivatives, are provided for acute hemophilia conditions; patients are not provided the continuing medical care and information they need to help avoid the recurrence of such acute problems. In the Federally-assisted centers, emphasis has been placed on educating the hemophiliac to obtain continuous preventive care and control of bleeding rather than the alternative of episodic, emergency care.

In 1978 and 1979, the Bureau of Community Health Services will continue support for the 21 Federally-assisted centers that have the capability of contributing to a nationwide network of centers, particularly in areas with limited or no facilities.

The centers are comprehensive and interdisciplinary and provide for high quality diagnosis, treatment and long-range management to meet the multiple needs of the patient with hemophilia. The centers provide a range of services, depending on the needs of the patient, and are establishing relationships with private physicians and other providers. Most of the centers are part of some other health facility. A majority are in University Medical Centers and the balance are affiliated with teaching hospitals and State health departments.

While the goal of maintenance care and the control of bleeding and orthopedic problems will continue, the significant psychosocial problems facing the hemophiliac and his family also must be addressed. Services will be expanded to provide careful and effective counseling to address the social problems of the hemophiliac and his family regarding education and occupational training and goals.

HYPERTENSION (HIGH BLOOD PRESSURE)

High blood pressure (hypertension) affects at least 23 million American adults. Of these, about 14 million have hypertensive heart disease (chiefly heart enlargement) resulting from the elevated blood pressure. The prevalence rate of high blood pressure among U. S. blacks is about twice as high as among whites, and the prevalence rate of hypertensive heart disease among black males is nearly three times that of white males. Over 15 million Americans with high blood pressure are under age 65 and more than 4 million are under 45.

Probably due to the availability and widespread use of effective drugs for blood pressure control, the U.S. death rate from high blood pressure has declined by 80% or more since 1950. But the disease still causes over 20,000 deaths a year directly and contributes to hundreds of thousands of other deaths from heart attacks, strokes, heart failure, and kidney failure.

High blood pressure alone roughly doubles the risk of heart attacks and other manifestations of coronary heart disease. This risk increases apace with rising blood pressure levels. In addition, the threat is amplified by the presence of other risk factors. For example, if the person with high blood pressure is a cigarette smoker, the risk from coronary heart disease is increased by a factor of 3.4. If, in addition, blood fats are elevated, the risk is more than 10 times that of persons with none of these risk factors.

Obligations for Programs in Hypertension

	1975	1976	1977	1978 estimate	1979 estimate
National Institutes of Health: National Heart, Lung, and Blood Institute....	$39,254,000	$52,250,000	$58,794,000	$66,896,000	$67,854,000

NATIONAL INSTITUTES OF HEALTH

National Heart, Lung, and Blood Institute

When the physician determines blood pressure with the familiar blood pressure cuff, two numbers are recorded. The higher of the two (expressed in millimeters of mercury) is called the systolic blood pressure. This is the pressure developed in the major arteries by contraction of the heart (systole). The lower number represents the pressure persisting in the arteries while the heart relaxes and refills between beats (diastole) and is called the diastolic blood pressure.

Most investigators consider a diastolic pressure of 90 to be the upper limit of normal and a diastolic pressure that persistently exceeds 95 as hypertension. Most experts agree that persons with blood pressure above 140 systolic and/or 90 diastolic should be referred to a physician for evaluation of their condition.

What Causes High Blood Pressure

In only about 10 percent of persons with hypertension can any specific organic cause be identified to account for their elevated blood pressure. These persons are said to have "secondary hypertension." The remaining 90 percent are said to suffer from "essential" or "primary" hypertension. The cause of essential hypertension is not known.

Many victims of essential hypertension develop the disease during their thirties. During the early stages of the disease, it seldom produces any symptoms perceptible to the person who has it, and the absence of noticeable symptoms may persist until the disease is well advanced. If undetected and untreated during its early or middle stages, the disease may enter an accelerated phase, sometimes called "malignant hypertension," in which the victim's blood pressure, previously elevated but stable, climbs sharply to levels that pose an immediate threat to survival. The accelerated phase usually occurs when the disease has already produced some blood vessel damage in the kidneys.

High blood pressure is usually considered a disease of adult and middle life. But current evidence indicates that it may be possible to spot much earlier--perhaps even during childhood or adolescence--persons at high risk of developing hypertension later on.

An important program initiated by NHLBI during 1976 is concerned with identifying forerunners of hypertension that may be identifiable in young people, possibly long before the onset of the clinical disease and when it may well be preventable. This program will study genetic, environmental and psychological factors in the development of high blood pressure; "tracking" of blood pressure levels (the concept that one's blood pressure, relative to others of the same age group, is fixed early in life and tends to remain in the same "track" unless treated); certain factors during infancy and pregnancy that may be predictors of hypertension during adult life; and diverse other precursors or correlates of elevated blood pressure including aspects of diet, psychological characteristics, growth patterns, demographic factors, and hemodynamic, physiologic and biochemical factors.

Treatment of High Blood Pressure

When hypertension is secondary to a tumor in one of the adrenal glands (a pheochromocytoma) or, more commonly, to severe damage to one of the kidneys, surgical removal of the abnormal gland or kidney may actually cure the hypertension. Even in essential hypertension, some cases can be handled effectively without drugs; by restricting dietary sodium (table salt) and, in the obese, by reduced caloric intake and supervised exercise

programs. In the vast majority of hypertensives, however, drugs must be taken--usually for the remainder of their lives--to achieve and maintain the desired blood pressure levels.

The specific drug or drug combination used by the physician varies with the severity of the disease and also with the patient's response to the medication prescribed. No single agent is uniformly effective in all patients or against every phase of hypertension. But where one drug fails, another drug or drug combination will usually succeed, so that only in rare instances does it prove impossible to control the patient's blood pressure.

These agents are not without side effects, especially in higher doses. With some drugs, the side effects are relatively mild and work no hardship. They neither impede the patient in his job nor in other pursuits. However, all of the most potent antihypertensive drugs may cause some undesirable side effects.

Fortunately, side effects can usually be minimized by the physician. One means of doing this is using several agents in combination, each in relatively low doses. Minimizing side effects is important because even relatively mild side effects can become bothersome to patients faced with the prospect of remaining on medication indefinitely. They may be especially annoying to the patient with high blood pressure who had experienced no symptoms until treatment was initiated.

The benefits of therapy in reducing illness and mortality from stroke, heart failure, and kidney failure have been convincingly demonstrated among patients with moderate to severe hypertension. Evidence from epidemiologic studies indicates that even mild hypertension increases the individual's risk of coronary heart disease, stroke, and other cardiovascular disorders. The benefits of blood pressure control are probably equally valid in such patients, though more difficult to verify.

National High Blood Pressure Education Program

High blood pressure is easily detected in the physician's office. Yet, because the disease in its early stages seldom produces symptoms that send the afflicted person to a doctor, many American adults with high blood pressure do not know that they have it. Others who know about their high blood pressure may not be taking any treatment for it or else may take prescribed medication too sporadically or haphazardly to maintain adequate blood pressure control.

In an effort to combat some of these problems, NHLBI has coordinated the National High Blood Pressure Education Program since 1972. Its goals include alerting health professionals and the general public to the wide prevalence of hypertension; to the fact that it produces few symptoms or none at all and thus may often be present but undetected; to the health hazards of untreated hypertension and to the fact that the disease can easily be diagnosed and readily controlled by a physicians, with corresponding health benefits for the patient.

The Program currently supports a variety of research efforts to determine cost-effective ways of achieving high blood pressure awareness or behavior change in the public, patients and health professionals. Particular emphasis has been placed on effective patient education to promote adherence to treatment. In addition, the Program supports several projects to evaluate hypertension control at the work site. Employee health programs offer a unique opportunity to identify hypertensive persons and to help them remain under the needed long term therapy. For every employee dying from an industrial accident, some fifty die from cardiovascular disease, so the effort has significant promise in helping control escalating health benefit costs.

Program services include the High Blood Pressure Information Center. This Center responds to public inquiries; develops and evaluates educational materials; distributes, free of charge, educational materials produced by the NHBPEP and other organizations; operates a Speaker's Bureau for local, state and national meetings; and manages a vigorous exhibit program. It distributes over 1 million information pieces in response to over 25,000 requests annually.

Recent survey data indicate that since the program began operations, total patient visits to physicians for treatment of high blood pressure have increased 49-percent (8% during 1976 alone); new patient visits for HBP treatment have increased 46-percent (13% during 1976); and the percentage of hypertensives unaware of their disease has dropped from 49-percent to 29-percent. The number of patients under treatment for HBP has increased sharply, as has the number of treated patients whose blood pressure is under adequate control.

During 1977, NHLBI also initiated several statewide demonstration projects in hypertension education, screening, treatment and control. The aims are to:

- alert the general public and health professionals throughout the participating state to the wide prevalence of hypertension; its hazards to health or life; that the disease, if present, can be easily detected and readily controlled by a physician, provided that the patient adheres faithfully to the treatment prescribed; and that adequate blood pressure control confers substantial health benefits;

- reach out to all parts of the State to identify people at risk because of previously unsuspected or inadequately treated hypertension and assist these people in getting on and staying on effective drug regimens;

- identify people with "borderline" blood pressure levels that are higher than normal, but not so high as to justify drug treatment. Provide surveillance services so that treatment can be initiated promptly if their blood pressure subsequently climbs into the hypertensive range;

. collect baseline data on the prevalence and incidence of hypertension and "borderline" high blood pressure within the state, together with percentages of these people who are aware of their high blood pressure and/or are under treatment for it. Similar baseline data will be collected on illness and mortality from stroke, hypertensive heart disease, and other hypertension-related disorders. These data will provide one of the yardsticks against which achievements of the hypertension control efforts can be measured.

To this end each of the participating states will mobilize resources and manpower from state and local health departments; medical and dental societies; voluntary health agencies, such as state and local American Heart Associations; and other agencies and groups--public or private, statewide or local--who desire to participate.

There are grounds for expecting that such coordinated, statewide efforts against hypertension can reduce the number of strokes occuring in the State, can sharply reduce illness and mortality from congestive heart failure, and can reduce cases of kidney failure. The Institute is hopeful that it will also bring about significant reductions in morbidity and mortality from acute heart attacks, far and away the leading killer among the cardiovascular diseases.

Current Research Efforts

The National Heart, Lung, and Blood Institute (NHLBI) currently supports more than 200 research projects at universities and medical centers all over the country concerned with etiology, pathogenesis, prevention, diagnosis and treatment of high blood pressure, and with related subjects, such as kidney disorders and physiology. The Institute also conducts research on hypertension in its own laboratories at Bethesda.

Principal research areas in the hypertension program include:

. The search for causes of essential hypertension, and identification of genetic and environmental factors that increase susceptibility to the disease or aggravate its clinical course. Without such knowledge, cures or effective means of prevention are unlikely.

. Evaluation of drugs and other therapeutic procedures for blood pressure control and assessment of the effects of these measures in reducing illness and death from hypertension and such complications as heart attacks, strokes, congestive heart failure, and kidney failure.

. The role of the nervous system, hormones, and other biologically-active substances in regulation of blood pressure.

. Physiology and pharmacology of vascular smooth muscle in normotensive and hypertensive conditions.

- Diagnosis and treatment of hypertension secondary to kidney disorders, endocrine disorders, and certain tumors.

- The kidney mechanisms operative in maintaining fluid and electrolyte balance, and disturbances in these mechanisms that may underlie or result from hypertension.

- Identification of innovative methods of educating professionals and the general public about all aspects of hypertension (National High Blood Pressure Education Research Program).

The Institute also supports specialized centers of research on hypertension at Cornell, Vanderbilt, Boston and Indiana Universities. These centers are conducting research on problems which include:

- interactions between the sympathetic nervous system, renin-angiotensin, aldosterone, renal function, and sodium metabolism in the etiology and maintenance of hypertension;

- studies of inheritance of hypertension, and measurement of biochemical parameters;

- comparison of surgical and medical treatment of renovascular hypertension;

- isolation, purification, and characterization of renin;

- pharmacology of propranolol and role of kallikrein, kinins, and prostaglandins in hypertension;

- the role of new mineralocorticoids in human and experimental hypertension;

- the role of renin-angiotensin system and other humoral factors in the development of hypertensive vascular disease;

- the identification and typing of hypertensive patients using endocrine profiles related to electrolyte metabolism;

- development of treatments for hypertension based on specific physiologic alterations.

Clinical Trials

Other definitive information will be provided by the NHLBI Hypertension Detection and Follow-up Program, established in 14 clinical centers. Approximately 11,000 patients age 30 to 69 with diastolic pressure exceeding 95 at initial screening are being followed. The goal is to assess the effectiveness of anti-hypertensive therapy in controlling high blood pressure and the extent to which disability and death from its complications can be reduced. An important secondary goal is to overcome problems in motivating patients with high blood pressure to seek treatment and to adhere

faithfully to the prescribed therapeutic regimens. Over 157,000 persons were screened to obtain 11,000 participants. Among those observed one year or longer, 73 percent have achieved their goal blood pressure: between 80 and 90 for the diastolic blood pressure, depending upon baseline blood pressures.

High blood pressure often co-exists with other cardiovascular disease risk factors, and such combinations can sharply escalate the threat to the life and health of affected persons. It has been estimated that 80 percent of death and disability from cardiovascular disease occurs among persons having one or more of the following: high blood pressure, elevated blood fats, and the cigarette smoking habit. Persons with two or more of these risk factors run 3 to 10 times the risk of those with none. Now underway is the NHLBI Multiple Risk Factor Intervention Trial, which will evaluate the effectiveness of countermeasures against these three risk factors among 12,000 high-risk males age 35 to 57. The clinical phase of the trial will be finished in 1981.

Conclusion

Although medical science can neither prevent essential hypertension nor cure it, research over many years has yielded a large body of information about blood pressure control mechanisms and some of the derangements that occur. It has led to the development of many drugs for controlling high blood pressure of all degrees of severity and agreement that such drugs can save and prolong lives among patients with moderate to severe high blood pressure. It has yielded effective means for identifying potentially curable secondary forms of high blood pressure and for searching out persons most likely to benefit from surgery or other definitive therapy. Continued research may yield even safer, more effective drugs and help eliminate high blood pressure as a major cause of illness, disability, and death in the United States and around the world. In the meantime, ongoing public and professional educational activities of the National High Blood Pressure Education Program will increase application of our current knowledge toward the control of hypertension, so that growing members of hypertensives will become aware of their disorder and motivated to adhere to prescribed treatment regimens.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

HYPERTENSION

The total prevalence of hypertension in the U. S. population 6-74 years of age was determined in the Health and Nutrition Examination Survey of 1971-1974 with further data on hypertensive heart disease obtained on adults 25-74 years of age.

In the present examination program on the probability sample of the population 6-74 years, the prevalence, severity and person's awareness of their hypertensive condition is again being determined as an aid to the National Hypertension Control and Research programs in monitoring progress in the control of this condition.

IMMUNIZATION

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Center for Disease Control:					
Grants	$ 6,200,000	$ 4,960,000	$17,000,000	$23,000,000	$35,000,000
Direct operations	1,339,000	1,384,000	1,494,000	1,770,000	2,770,000
Total, CDC	$ 7,539,000	$ 6,344,000	$18,494,000	$24,770,000	$37,770,000

CENTER FOR DISEASE CONTROL

Since 1963, project grants have been awarded to State and local health agencies to assist them in planning, developing, and conducting immunization programs. Initially, grants were awarded to assist health agencies in developing and implementing mass immunization programs against poliomyelitis, measles, and rubella shortly after licensure of live vaccines against these diseases. These programs were generally oriented toward a single disease and accounted for substantial reductions in morbidity and mortality from the diseases.

As the large numbers of susceptibles for poliomyelitis, measles, and rubella were individually reduced, comprehensive immunization programs directed toward all of the major vaccine preventable diseases of childhood were supported to maintain the decline in morbidity and mortality which had begun.

By calendar year 1974, reported cases of measles, rubella, and poliomyelitis had reached what was then all-time lows — 22,094, 11,917 and 7 cases respectively. As a result, concern for immunization programs began to relax and support declined. In 1975, reported cases of measles began to increase, and by the end of 1976, had approximately doubled the number of cases reported in 1974. Reported cases of rubella also began to increase in 1976. During 1977, larger increases in cases of measles and rubella were reported. In addition, data from the 1976 U.S. Immunization Survey indicated that the numbers of children susceptible to measles, rubella, mumps, diphtheria, pertussis, and tetanus were also increasing and had reached 13.7 million for measles, 14.4 million for rubella, 18.8 million for polio, 25.0 million for mumps, and 13.0 million for diphtheria, tetanus, and pertusis. Data also indicated that the number of doses of vaccine being distributed and administered was decreasing.

With these needless increases in reported cases of measles and rubella and the decline in immunization levels, the Secretary announced a major Immunization initiative which included two fundamental goals: "To seek to immunize the millions of children who today are inadequately protected against all preventable childhood diseases..." and to "seek to establish a permanent system to provide comprehensive services to the three million children born in America each year." The objective of the Immunization Initiative is to raise the immunization levels of our children to 90 percent by October 1, 1979.

To reach the high goals established by the Initiative, a new Immunization strategy was developed and is being implemented in fiscal year 1978. It specifically requires the active support, and total commitment of Federal, State and local health authorities, the various arms of organized medicine, and a variety of voluntary organizations. Major progress has been made in creating public awareness of the needs and a motivation to action, and in molding a coalition of government agencies and volunteer groups into a unified thrust toward achieving the goal. Procedures have established for the systematic identification of incompletely immunized children as evidenced by the increase in vaccine administration.

Present technology in surveillance/outbreak control will be strengthened. Reporting systems, school systems, child caring facilities, and active participation of private physicians in reporting disease and vaccine reactions, will be reexamined and changes made to insure greater sensitivity and prompt reporting.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

IMMUNIZATION

In April 1977, the Secretary of Health, Education, and Welfare, announced the initiation of a mass vaccination program for the nation's school-age children to begin in October 1977. The National Center for Health Statistics plans to establish a monthly reporting system to produce national estimates of the level of immunization in the population. This system will provide timely information needed to monitor the nationwide children's immunization program.

KIDNEY DISEASE

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
National Institutes of Health:					
National Institute of Arthritis, Metabolism, and Digestive Diseases	$21,077,000	$19,798,000	$26,059,000	$28,091,000	$28,856,000
National Institute of Allergy & Infectious Diseases	996,046	1,159,109[1/]	1,005,543	1,106,097	1,216,707
Total, NIH	22,073,046	20,957,109	27,064,543	29,197,097	30,072,707
Health Resources Administration:					
Regional Medical Programs	5,224,000	103,000	-0-	-0-	-0-
TOTAL, PHS	27,297,046	21,060,109	27,064,543	29,197,097	30,072,707
Office of Human Development Services:					
Rehabilitation Services Administration:					
Research and Demonstration	-0-	-0-	105,182	65,000	190,000
TOTAL	$27,297,046	$21,060,109	$27,169,725	$29,262,097	$30,262,707

1/ Includes transition quarter figures.

KIDNEY DISEASE

Kidney and Urinary Tract Disease and Artificial Kidneys

The kidneys are vital organs which play a critical role in the maintenance of body functions. As blood passes through the kidneys, at a rate of 18 gallons per hour, a complex system of filtration, excretion, and reabsorption removes impurities and excess fluid from the blood and sends the wastes to the bladder. These versatile organs also perform a number of other essential physiologic, metabolic, and endocrine functions. When the kidneys are no longer able to remove the body's metabolic wastes sufficiently and to perform their usual work of maintaining homeostasis (a stable internal environment) of the body, the body's ability to achieve a normal balance of water, salts and metabolic products is greatly disturbed. Retention or imbalance of water, salt and waste products occurs. Some of the waste substances produce toxic effects, and unless they are removed, normal metabolism is deranged by this altered chemical and fluid balance. The clinical condition which results from this build-up of metabolic waste products and changing homeostatic balance is known as uremia.

Each year, the lives of approximately 5,000 new patients with end-stage renal disease are saved and prolonged by treatment with dialysis by artificial kidneys or with kidney transplantation. In 1977 the Federal Government spent over a billion dollars for these treatments, primarily with MEDICARE and MEDICAID funds, and at present 36,000 patients are being kept alive with maintenance dialysis treatments. The National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) is the lead Institute at the National Institutes of Health which supports research on kidney and urinary tract disorders as well as for research on improving artificial kidney treatment. It shares additional responsibility for certain specialized aspects of kidney research with the National Institute of Allergy and Infectious Diseases and the National Heart, Lung and Blood Institute.

NATIONAL INSTITUTES OF HEALTH

National Institute of Arthritis, Metabolism, and Digestive Diseases

KIDNEY AND URINARY TRACT DISEASE RESEARCH

The total research effort of the NIAMDD related to kidneys and urinary tract and their disorders amounted to over $25 million in Fiscal Year 1977. The many patients with chronic uremia and end-stage kidney disease represent but one facet of the many and diverse disorders of the kidney and urinary tract. Urinary tract infections, obstructive uropathy, and kidney stones are major causes of disability that affect at least 12 million people annually in the United States and are responsible for about 20 percent of the deaths from kidney and urinary tract diseases.

Benign prostatic hyperplasia (BPH) is a major medical problem which affects more than 50 percent of men by age 50. By the time they are 80 years old, more than 90 percent of men develop BPH with varying degrees of bladder neck obstruction and urinary retention. The disorder can result in many other physical problems, as well, which include chronic urinary tract infection, bladder dysfunction and kidney disease. Although the procedure known as prostatectomy is generally effective in relieving such obstruction, many aging men are very poor risks for this surgery, and the costs involved in this approach could be greatly reduced if an effective medical treatment could be found. If such a treatment can be discovered, researchers believe it will result in major medical, economic and psychosocial benefits. Scientists are also pursuing studies aimed at prevention of BPH, at identifying demographic variables that may be linked to increased risk, and at determining the possible relationship of the disease to the development of prostatic cancer. Research so far indicates that unusually large numbers of men with coronary heart disease, hypertension, diabetes mellitus and cirrhosis of the liver develop BPH, and investigators say that long-range epidemiologic studies are necessary.

Investigators supported by the Kidney Disease and Urology Program of the NIAMDD are seeking new methods of preventive therapy, earlier diagnosis and more effective treatment through expanded knowledge and understanding of the basic mechanisms and causes of the various renal and urinary tract disorders. Research in this area includes basic studies of the kidney and urinary tract and research on diseases caused by variations in immune responses resulting in kidney disorders such as glomerulonephritis, interstitial nephritis and pyelonephritis. Fundamental research is conducted into diseases and disorders such as urolithiasis (kidney stones), nephrosis, benign prostatic hyperplasia, polycystic kidney disease and diabetic nephropathy, drug-induced kidney damage, and congenital malformations.

Treatment of Kidney and Urinary Tract Stones

More than a million people each year are hospitalized in the United States for the treatment of kidney and urinary tract stones. Only five percent of these patients have a known underlying cause for stone formation while the remaining 90-95 percent of these stones are of as yet uncertain origin. Kidney stones can cause urinary tract infection or can arise as the result of infection. Approximately 20 percent of kidney stones may be the consequence of urinary tract infection. Morbidity and mortality from infection-induced stones, moreover, are considerably higher than from other forms of stones.

Studies over the past 50 years have implicated urea-splitting bacteria as the primary causative agent in the occurrence of infection-induced stones. Recently, Dr. Donald P. Griffiths and associates at the Baylor College of Medicine and Dr. Stuart Feldman and his associates at the University of Houston have been studying the efficacy of acetohydrozamic acid (AHA), an inhibitor of the bacterial enzyme urease, in treatment of patients with infection-related stones.

Dr. Griffiths and his associates are conducting a long-term clinical study to attempt to halt growth of stones with AHA in patients who chronically form them. In another group of patients who have had stones removed surgically, but who harbor chronic, recalcitrant urea-splitting urinary bacteria, AHA is being administered to determine its effects on further stone formation. The researchers report that patients who have taken AHA for periods of 6-18 months can tolerate doses of 1 gram per day, that both urinary ammonia and pH are reduced in these patients, and that thus far none of them has experienced a recurrence of urinary stone growth.

Aspirin-Induced Depression of Renal Function

Effects on the kidney of chronic use of large doses of aspirin, although recognized abroad for 60 years in association with non-medical abuse of aspirin and related analgesic drugs, have rarely been noted to cause significant problems for the clinical management of patients. Recently, however, Drs. Robert P. Kimberly and Paul H. Plotz of the NIAMDD's Arthritis and Rheumatism Branch noted striking changes in renal function concomitant with administration of therapeutic doses of aspirin in some patients with systemic lupus erythematosus (SLE), a rheumatic disorder. This observation prompted the investigators to study aspirin's effect on renal function in patients with SLE or rheumatoid arthritis, as well as in normal volunteers. These studies have shown that therapeutic doses of aspirin can in fact diminish renal function significantly. The investigators report that aspirin, and other nonsteroidal anti-inflammatory agents, can have a major, though reversible, effect on renal function that may influence the interpretation of clinical data. The investigators state that care should be taken to assess renal function in patients regularly taking aspirin or similar drugs that may alter functioning of the kidney.

ADVANCES IN KIDNEY TRANSPLANTATION

The NIAMDD is one of several Institutes of the National Institutes of Health supporting research aimed at improving transplantation procedures for kidneys and other organs. Transplantation is a desirable means to treat patients with end-stage renal disease, but the frequent rejection of transplanted organs makes this surgical approach far less consistent in the results obtained than treatment with artificial kidneys. Overcoming the problem of rejection of grafted kidneys continues to be one of the most serious obstacles to a predictable outcome in the use of transplantation, although there has been progress in this area in recent years. In general, patients who receive well-matched organs from closely related donors have the best chance of success among recipients of transplants and of a consequent return to a more normal existence.

Kidney Preservation

Successful transplantation of donor kidneys is often dependent upon their preservation and transportation to distant locations. Research is continuing on ways to preserve the viability of donor organs during transportation. NIAMDD grantee Dr. Folkert Belzer and his associates at the University of Wisconsin have conducted studies of kidneys preserved by perfusion with plasma at a temperature between 4 and 10°C. They compared the biochemical and physiological changes that occur during this process in the donor kidney with that of normal kidney tissues. The researchers identified at least two defects in the perfused kidneys that could explain the adverse effects of prolonged organ preservation. These are: imbalance in the distribution of cellular water and a loss of total adenine nucleotides (TAN), a constituent necessary to maintain the function and structural integrity of the cortex cells of the kidney. To maintain the level of TAN in the perfused kidney, the researchers added a number of compounds that are involved in the synthesis and breakdown of TAN, and were able to raise TAN levels in some instances, but the results of these studies are inconclusive. Their experiments into the cause of the water imbalance and methods to alter the TAN levels are in preliminary stages, but are encouraging in terms of the possibility of improving organ preservation techniques.

Managing Transplant Patients with Viral Infections

Cytomegalovirus (CMV) infections are known to cause significant secondary illness in renal transplant patients and those with bone marrow transplants as well as other disorders associated with suppressed natural immunity. Grantees of the NIAMDD, Dr. Henry H. Balfour, Jr., and his associates at the University of Minnesota, after conducting prospective studies, have suggested that the finding of leukopenia (reduced number of white cells in the blood) is significant in early recognition of CMV infections in renal transplant patients. The study has revealed that onset of such infections is usually in the second month after kidney transplantation, that it is often accompanied by a reduced number of leukocytes (white blood cells), and that early recognition of such infections may be very helpful to the transplant surgeon in the management of the patient's immunosuppression regimen.

The investigators also say that if differences among CMV strains can be detected by serologic techniques, it will be possible to trace a single virus type from patient to patient, from donor to transplant recipient, or from patient to hospital personnel. The researchers have now undertaken a CMV infection screening program among the members of the transplantation service at the University of Minnesota, and they anticipate that this surveillance study over the next four years will provide answers to important epidemiologic questions.

ARTIFICIAL KIDNEY-CHRONIC UREMIA PROGRAM

Irreversible and potentially fatal kidney failure confronts over 40,000 patients in the United States each year. For the past 15 years, maintenance hemodialysis has been the main technique used in treating end-stage renal disease and is now used in 36,000 patients in the U.S. It has successfully maintained life in patients whose outlook was otherwise hopeless. Although transplantation offers an attractive alternative when compatible donor organs are available, hemodialysis has remained the single most important treatment modality.

Long experience with maintenance hemodialysis has demonstrated that many difficulties may arise during the course of treatment. These problems may be associated with the uremic state, regardless of present treatment, or may arise from the treatment itself. Specific examples are: neuropathy (primarily impaired sensation or muscle strength in arms or legs) in some patients, osteodystrophy (decreased mineral content of the bones), and anemia. In addition, the well-being of patients on hemodialysis is impaired by occasional muscle cramps, hypotension and post-dialysis fatigue, especially when large amounts of fluid have been removed during dialysis treatments, which are given three times each week. The mortality rate among maintenance dialysis patients is about nine percent a year regardless of sex or age; this figure must be viewed in contrast with a certain 100 percent mortality for patients with non-functioning kidneys if dialysis is not available for treatment.

Advances in Hemofiltration and Hemodialysis

In recent years, new and improved treatment procedures have been devised and are under careful investigation. One of them is hemofiltration, a process pioneered under the sponsorship of the Institute's Artificial Kidney-Chronic Uremia Program. It is a method of filtering blood through porous membranes which quickly remove large quantities of fluid together with uremic waste products (as well as necessary salts). Necessary chemicals and controlled amounts of fluid are then returned to the body by continuous infusion. Experience to date indicates that hemofiltration is well tolerated by patients and appears to result in better control of hypertension and to lessen other side effects by comparison with conventional hemodialysis. Studies are now under way to elucidate these preliminary findings and to assess the clinical and economic potential of this method.

Recently, Dr. William Stone, Jr. and Dr. Paul A. Cantor and associates of the National Institute of Scientific Research in Los Angeles, supported by NIAMDD funds, reported the results of clinical evaluations of a new dry polycarbonate membrane that is unusually suitable for hemofiltration procedures, and which also offers high permeability, physical strength and potentially rapid, safe conventional hemodialysis of patients. The membrane can be heat-sealed through many layers and is relatively rigid when wet, a combination of features that makes it possible to produce disposable hemodialyzers that are small, light and comparatively inexpensive.

Diet Therapy for Uremic Patients

Elevated levels of plasma triglycerides ("neutral fats") in conjunction with renal failure may increase the risk of developing atherosclerotic heart disease. Studies by Dr. Robert S. Swenson and associates of Stanford University, supported by NIAMDD, have therefore been conducted to define triglyceride levels during moderate to severe chronic renal failure, and to determine if these levels might respond to modification by dietary manipulation. Results indicate that hypertriglyceridemia indeed occurs in patients with moderate to severe chronic renal failure, and that dietary modification promptly reduces triglyceride levels over an 11 day period. This research suggests that a prolonged period of hypertriglyceridemia occurs in the natural course of chronic renal disease, and that a defect in removal of very low-density lipoproteins (combinations of fats and proteins) is responsible for the disorder. Because this condition has been linked to accelerated development of atherosclerotic heart disease in end-stage renal disease and maintenance dialysis patients, it seems reasonable to attempt to lower triglyceride production rates and, consequently, triglyceride levels, by a safe and physiologic approach -- dietary modification.

Research Progress in Peritoneal Dialysis

The technique known as peritoneal dialysis utilizes the lining of the abdominal cavity (the peritoneum) as the membrane through which uremic waste products are filtered. Blood is not removed from the body as in hemodialysis. Instead, a sterile wash solution is repeatedly introduced into the abdominal cavity and withdrawn from it through a small tube that is permanently implanted in the abdomen. Each time the wash solution is left in the abdomen for about 20 minutes during which toxic substances are removed through the peritoneal membrane by osmosis.

Peritoneal dialysis is not used nearly as much as hemodialysis. One reason is that until recently it took longer. High cost and increased risk of intra-abdominal infection had also been reasons for the relatively infrequent use of this technique in the past, but these disadvantages seem now to have been virtually eliminated through research sponsored by the Institute. Particularly important was the development of automated, closed-cycle, peritoneal dialysis machines which make their own sterile flushing solution; they have greatly decreased the cost and risk of infection in this treatment method.

This type of dialysis, moreover, has specific advantages. It is more efficient than hemodialysis in removing some toxic uremic substances, and it is safer since it does not involve removing blood from the body and manipulating it. It also eliminates the need for administering blood-thinning drugs (anti-coagulants), and it is simpler to teach patients to dialyze themselves with the aid of the new peritoneal dialysis machines, either at home or in a dialysis center.

Dr. Morton Maxwell and his associates at Cedars-Sinai Medical Center in Los Angeles, have been working under contract to the NIAMDD to develop a simple, inexpensive, safe peritoneal system which utilizes sorbent chemicals to regenerate peritoneal dialysate, thus allowing the dialysis to be conducted with a small volume of dialysis solution. Animal studies of this system have shown that it may be possible to increase dialysis efficiency by 100 percent or more using techniques of continuous flow peritoneal dialysis, and the investigators say the system offers the potential not only of reducing dialysis time, but of miniaturization and development of a wearable peritoneal dialysis system. Human patients are now being dialyzed successfully with the system for periods up to 12 hours with biochemical results identical to those obtained with standard dialysis techniques.

Continuous Ambulatory Peritoneal Dialysis

Another improvement in peritoneal dialysis technique is currently under investigation by Dr. R. P. Popovich of the University of Texas, Dr. J. W. Moncrief of the Austin Diagnostic Clinic, and Dr. K. D. Nolph of the University of Missouri Medical Center. With NIAMDD sponsorship, these researchers are studying the technique of continuous ambulatory peritoneal dialysis (CAPD) to determine the longterm effects of what seems to be a simple and potentially inexpensive form of therapy which liberates the patient from having to come to a dialysis center three times weekly for his dialysis treatment.

Patients in CAPD therapy maintain about two quarts of dialysis solution in their peritoneal cavity 24 hours per day, except for short periods of drainage and installation of fresh solutions several times during their waking hours. This treatment method is so new that only a small group of patients has had experience with it to date. Their enthusiastic acceptance and the potentially reduced cost of this therapy, however, make it a promising new approach to maintenance treatment of end-stage renal disease patients.

Suitcase Artificial Kidney

Hemodialysis patients have limited flexibility and some difficulty in rehabilitation because of the need to conform to the schedules of treatments in a dialysis center. The introduction of home dialysis has permitted greater flexibility in patients' scheduling of daily activities. Patients are still limited in travel, however, and in other pursuits because of their need to reach a center every two or three days.

To increase mobility of home hemodialysis patients, Dr. Eli A. Friedman and his associates at the Downstate Medical Center in Brooklyn, with NIAMDD contract support, have developed a portable, lightweight hemodialysis system that is transportable in a small suitcase and flight bag. With this equipment, which will soon be commercially available, a patient can travel and dialyze himself wherever he likes, as long as he has access to running warm water and an electrical outlet. This "suitcase kidney," which is computerized, is simple and safe to operate, and has been well-accepted by patients who have used it experimentally in travels throughout the United States and abroad. The investigators say that once it is widely used, it is expected to result in improved patient morale and that greater rehabilitation may be achievable through this less burdensome and restrictive therapy.

The National Institute of Allergy and Infectious Diseases Research Effort in Kidney and Urinary Tract Diseases

One area of great interest is urinary tract infection (UTI). Dr. John P. Burke of the University of Utah is searching for ways to prevent and control hospital-acquired UTI. These infections, which account for about 40 percent of all those acquired in the hospital, often occur after the use of indwelling bladder catheters. The use of closed sterile drainage systems has sharply reduced the incidence of these infections, but they remain a serious problem.

Dr. Burke's studies indicate that patients most at risk are those whose periurethral areas are colonized with pathogenic organisms, such as gram-negative rods or enterococci. In related studies, Dr. Burke and his colleagues showed that, contrary to current belief, twice daily cleansing of the urinary meatal area did not decrease the chances of infections and, in some cases, increased the likelihood of infection from indwelling catheters.

Urinary tract infections are also common outside of hospitals and particularly in women. Dr. Thomas Stamey, Stanford University, has been studying women with recurrent UTI. The results of his studies suggest that the susceptibility to infection found in particular women is related to a defect at the cellular level that encourages bacterial adherence to the external vaginal mucosa. The bacteria found colonizing this area are usually those responsible for subsequent UTI in women with recurrent infections.

Another area of interest to many NIAID investigators is glomerulonephritis, an inflammation within the kidney tissue caused by antigen-antibody complexes lodging in the kidney's filtering bed (the glomerulus). This inflammation can occur in acute, subacute, and chronic forms.

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One of the earliest clinical observations of glomerulonephritis was in association with streptococcal infections. The streptococcal products act as antigens, generating circulating antibody and resulting in injury to the kidney. Dr. Gene H. Stollerman, University of Tennessee, has been studying streptococcal antigens in human urine, serum, and kidneys of patients with poststreptococcal acute glomerulonephritis (AGN). He and his colleagues found that although 90 percent of AGN patients excrete antigens that cross-react with streptococcal antisera, this same cross-reactive antigen is also found in the urine of approximately 20 percent of patients with non-streptococcal glomerulopathies. It appears likely that these antigens are of host rather than streptococcal origin.

Pyelonephritis, usually caused by bacterial infection of the pelvis of the kidney, is being studied by several NIAID-supported investigators. One of them, Dr. Gerald J. Domingue of Tulane University, hopes eventually to prevent this infection with a vaccine. He is purifying enterobacterial common antigen (ECA) and has used it in the rabbit to stimulate antibodies. These antibodies are protective in animals against experimental pyelonephritis. The isolated and purified ECA may eventually have unlimited application by serving as a useful immunogen effective against a variety of enterobacterial infections.

Outlook

For years NIAMDD has sponsored a broad and productive research effort in diseases of the kidney and urinary tract. The largest proportion of this effort is devoted to acquisition of a broad fund of basic and clinical knowledge which hopefully will result in more effective ways of dealing with the health problems related to man's urinary tract. It is of great importance that this research effort continue unabated and increase in scope so that eventually improved methods of management of kidney diseases and urinary disorders will evolve. It is to be hoped that a maximal number of these diseases can actually be prevented and that the number of patients confronted with end-stage kidney disease each year (currently over 40,000 patients annually) will diminish in the future. At the same time the Institute's more applied research effort related to treatment of patients with irreversible end-stage renal disease is relied upon to provide them with extended life of maximal quality and productivity at a minimum cost.

HEALTH RESOURCES ADMINISTRATION

Regional Medical Programs

KIDNEY DISEASE

The RMP program, Title IX of the Public Health Service Act, has been terminated. As part of the phaseout process, Congress appropriated a final $10 million at the end of FY 1976 to complete exemplary RMP projects or to permit their temporary continuation until other funding could be developed. Six projects for end-stage renal disease activities in the amount of $103,000 were funded under the final Title IX appropriation. No further funds are expected under this authority.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

KIDNEY DISEASE

Kidney disease and its treatment have major implications for such programs as the Health Maintenance Organizations, National Health Insurance, Medicare, Medicaid and comprehensive health planning at the Federal, State and local levels. The present National Health and Nutrition Examination Survey is obtaining for the first time national estimates among persons 12-74 years of age the total prevalence of kidney disease for kidney disease prevention and control. In addition to the standardized physical examination, medical and family history related to hypertension and kidney disease, the examination includes urine analysis and serum creatinine tests for assessment of kidney function.

OFFICE OF HUMAN DEVELOPMENT SERVICES

Rehabilitation Services Administration

KIDNEY DISEASE

End- Stage Renal Disease

There are, currently, five going research grants in the area of end stage renal disease which are partially supported by the Rehabilitation Services Administration. George Washington University has been given an extension of their proposal to explore the vocational potential of the end- stage renal disease patient through analysis of the relationships between the medical factors of end- stage renal disease and alternative job placement strategies. Now in its second year, a project at the University of Washington, Seattle, is studying electronics measurement of patients with end stage renal disease. The Milton S. Hershey Medical Center, Hershey, is bringing to a close their work on the development and implementation of a professional client and family education and training program and its impact on improving the rehabilitation of persons with end stage renal disease. Emory University, has just completed its research study on "Renal Rehabilitation Success Determination" and has presented the results at a seminar in Atlanta in mid-January. Emory University has been given a new grant to continue to study the medical, psychosocial and vocational evaluation of kidney transplant and dialysis patients.

LEAD-BASED PAINT POISONING

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
Center for Disease Control	$9,885,000	$3,500,000	$8,500,000	$10,250,000	$10,250,000
Health Services Administration:					
Bureau of Community Health Services	1/	1/	1/	1/	1/
TOTAL, PHS	$9,885,000	$3,500,000	$8,500,000	$10,250,000	$10,250,000

1/ Obligations not identifiable.

CENTER FOR DISEASE CONTROL

LEAD-BASED PAINT POISONING

Since 1972, grants have been made to assist communities in developing childhood lead-based paint poisoning prevention programs. These programs are designed to identify children with undue lead absorption and to provide appropriate medical and environmental followup services. In addition, they coordinate the lead screening and medical followup services provided by the other child health programs and supplement these activities by providing an active outreach effort in older deteriorating neighborhoods where lead-based paint is often accessible to children.

Lead seriously affects the body in many ways and can produce irreversible effects on the central nervous system. Studies have indicated that levels of lead absorption previously thought tolerable can result in metabolic disorders, mild neurologic disabilities, and educational underachievement. The Childhood Lead-Based Paint Poisoning Prevention Programs serve as the focus within the community to provide the intensive outreach and followup necessary to identify and protect children at risk of the disease before irreversible neurologic damage or death can occur.

In fiscal year 1977, 58 grants were made to those programs which continued to document a significant problem and which had developed productive programs. These programs screened approximately 380,000 and identified approximately 28,000 children requiring pediatric management for undue lead absorption. Coordinated program efforts with the other federally funded child health programs have been intensified. In fiscal year 1977, 14,700 children were detected with iron deficiency and referred for care by the other pediatric providers. Similarly, 15,400 children were referred to the lead poisoning prevention projects for medical and environmental followup.

The fiscal year 1978 appropriations will be used to continue support to approximately 65 grants, including 8 new starts which are faced with the most severe lead poisoning problem. With increased State and local support, increasing awareness of the lead poisoning problem by the medical community, and with full implementation of the erythrocyte protoporphyrin screening procedure, approximately 500,000 will be tested. It is estimated that 42,500 children with undue lead absorption will be identified. The Center will continue to encourage the other child health programs to incorporate lead poisoning prevention services into their ongoing operations.

The Center for Disease Control, in addition to the administrative, technical, and consultative services, will continue to maintain a laboratory proficiency testing program and assist local communities without a lead program to assess their needs. The Center has established two demonstration programs where the personnel from the other child health programs can receive a practical orientation into the proper care of children with undue lead absorption.

HEALTH SERVICES ADMINISTRATION

Bureau of Community Health Services

LEAD-BASED PAINT POISONING

Excess exposure to lead among children, largely from lead paint on old dwellings, but also from other environmental sources, remains a major health problem in many areas. Maternal and Child Health Grants to States support Children and Youth projects which continue to screen their population for undue lead absorption and lead poisoning. In recent years, the number of cases of severe or overt lead poisoning among children has diminished, but undue lead absorption is still common, especially among the young. Studies in the last few years have increasingly suggested that neuropsychological impairments, including learning disorders and hyperactivity, may occur in young children unduly exposed to this toxic element who are otherwise "asymptyomatic." One study suggested an association between excessive prenatal exposure to lead in drinking water and mental retardation. In view of these findings, the upper limit of normal blood lead level for young children and pregnant women has recently been revised downward from 40 ug/100 ml to 30 ug/100 ml.

The issue of "low" level lead toxicity in the young (born and unborn) is far from clear-cut and is a source of considerable controversy. However, it deserves considerable attention because undue lead absorption is common among children, the findings so far carry very serious implications and the problem is preventable. Further research to clarify the toxic effects of lead in the very young is needed. In the meantime, health workers and the public should be educated and/or reminded continually about the many hazardous lead sources which include not only lead paint on houses, but also contaminated dust and dirt, and drinking water conducted through lead pipes in older homes, particularly if the water in the area is soft.

The effects of undue lead exposure in the pregnant women and their offspring have gained considerable attention recently as more women enter the labor force and take jobs with occupational lead hazards. In addition to the study linking prenatal lead exposure to mental retardation mentioned above, some preliminary reports have suggested increased obstetrical complications in women unduly exposed to lead.

The Bureau of Community Health Services has continued its efforts in educating health workers and the general public on the problem of lead poisoning through its many publications. It has also continued to provide technical assistance and consultation upon request to various government and non-government agencies on the problem.

LONG-TERM CARE

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
Alcohol, Drug Abuse and Mental Health Administration:					
National Institute of Mental Health.....	$ 250,000	$ 250,000	$ 250,000	$ 250,000	$ 250,000
Health Resources Administration:					
Health Planning and Resources Development: 1/					
Medical Facilities Construction and Loan Program.....	5,095,000	21,511,000	2,780,000	5,966,000	2,660,000
Bureau of Health Manpower:					
Special Projects Program.....	835,496	1,155,689	1,707,158	29,502	---
Total, HRA	5,930,496	22,666,689	4,487,158	5,995,502	2,660,000
Office of the Assistant Secretary for Health:					
National Center for Health Services Research:					
Grants & Contracts....	3,627,000	987,000	1,293,000	800,000	100,000
Bureau of Health Manpower.....	1,203,000	---	---	---	---
Emergency Medical Services Research.....	278,000	---	---	---	---
Total, OASH.....	5,108,000	987,000	1,293,000	800,000	100,000
TOTAL, PHS.....	11,288,496	23,903,689	6,030,158	7,045,502	3,010,000
Health Care Financing Administration: 2/					
Research and Evaluation..	---	---	1,012,531	1,725,000	2,760,000
TOTAL.....	$11,288,496	$23,903,689	$ 7,042,689	$ 8,770,502	$ 5,770,000

1/ Obligations also included in material on "Aging."
2/ General Funds Only. HCFA now has responsibility for the Medicaid program. Most of the Medicaid money goes to nursing homes, and physicians, while most of the Medicare money has gone to hospitals; therefore, R, D, and E in the nursing home area are significantly increased in order to support our new medicaid responsibility.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health

LONG-TERM CARE

Since 1964, the resident population of State and County mental hospitals has dropped from about 500,000 to less than 193,000 today. Several factors contribute to the steep decline, including rising costs of hospitalization; influence of court decisions; availability of psychoactive drugs; increasing availability of community alternatives; and the opportunity for State mental health agencies to save money by transferring costs of long-term mental health care to Federally subsidized programs.

Nursing homes have been replacing State hospitals as the primary locus of long-term care for elderly, mentally impaired persons. In 1974, the total number of elderly nursing home residents with a chronic condition of mental disorder was 273,000, almost 85 percent greater than the equivalent category of residents in 1969. At the same time, the number of aged in State mental hospitals decreased 51 percent between 1969 and 1975. 1974 data indicate that approximately 25 percent of the patients in nursing homes have a primary diagnosis of mental disorder or senility.

Nursing home care is now the largest single locus of care for the elderly mentally ill, repesenting 29.3 percent or $4.2 billion of the total estimated direct costs of mental illness in 1974. State and other public mental hospitals accounted for only 22.8 percent of the total direct care costs of that year. There are now 1.2 million nursing home beds in the United States, more than twice the number of surgical hospital beds.

Most nursing and boarding facilities have little or no staff trained to work with mentally disabled persons. Many instances of exclusion, neglect, and abuse of rights have been reported and documented in such community facilities. There has been a back-lash in some communities, reacting against the placement of large numbers of mentally disabled persons for whom few appropriate services are available. At the same time, scattered programs in various communities have continued to demonstrate that a carefully planned network of small community-based facilities and services is preferable to the large, remote facilities of public hospitals.

NIMH Efforts

In 1974 the NIMH Division of Mental Health Service Programs began a concerted effort to develop policies and programs relative to services to the chronically ill. While long-term care is to be avoided wherever possible, the practice of unrestricted deinstitutionalization without regard to the availability of appropriate alternative facilities is at least equally undesirable.

NIMH sponsored a series of working conferences to obtain and synthesize advice from a broad range of leaders from state and local agencies, universities, citizen and consumer advocate groups, other Federal agencies, and national organizations concerning both policy and program development strategies in the area of deinstitutionalization. Through this conference series, a consensus has emerged to shape NIMH policy along the following lines. First, deinstitutionalization is no longer seen as a goal in itself, but rather a complex phenomenon which happens for a combination of reasons. This phenomenon calls for better coordinated efforts among agencies at all levels of government if it is to be a viable alternative to long-term care, and benefit the individuals involved. Second, NIMH is now focusing attention on development of comprehensive community support systems for persons with mental disabilities. Components and guiding principles for such systems have been conceptualized, defined, and validated in the conference series. Third, a consensus has emerged on the necessity for mental health agencies at Federal, State and local levels to play a leadership role in working with human service agencies such as housing, social services, vocational rehabilitation and others to assure that mentally disabled clients returned to the community have access to, and receive, services appropriate to their needs.

Opportunities for collaboration between NIMH and other Federal agencies which share responsibility for community support systems have been explored. A formal interagency agreement is being developed between NIMH and the Rehabilitation Services Administration.

Clarification has been obtained from the Department of Housing and Urban Development on the eligibility of mentally ill for a wide range of types of Federal housing assistance. A manual is being prepared to help state and local mental health agencies work with housing programs to develop community living arrangements for deinstitutionalized clients.

In other areas, a monograph series on effective models of community-based service to the chronically disabled adult psychiatric client is in preparation. Individuals have been designated in each Regional Office, either formally or informally to work on community support issues.

Nursing Home Improvement Program

For several years, the NIMH has addressed the problems of the quality of long-term care through its Nursing Home Improvement Program.

Following a statement of Presidential support on nursing homes in August 1971, NIMH staff began development of approaches to the creation of short-term training programs in mental health for staff of the Nations nursing homes. The program was developed through the mechanism of contracts with appropriate educational institutions, professional organizations, and service agencies. This represented the first time that nursing homes per se were made the focus of a specific mental health training program. Because of limited resources, the immediate concern was

to develop a program that could have maximum impact in a relatively short period of time, and on as large a segment of the population as possible. At the same time, the program was intended to assure a sound basis on which long-term planning could be built. It was decided that the concern should not be as much with development of training materials or curricula, as with the development of mechanisms for transmitting knowledge of principles and methods of practice which would promote the mental health of patients (and personnel) in nursing homes, and minimize impairment of function caused by mental disorder. For maximum efficiency and impact, it was necessary to call upon existing resources rather than attempt to develop new ones. As a result, the program drew on existing organizations and established "models" of collaboration which could be tested, modified, and then put into operation around the country.

During the past year, the Nursing Home Improvement Program awarded a contract to develop a model continuing education and consultation program to assist mental health, aging and long-term care personnel to establish community mental health services for the elderly in urban and rural settings. An existing contract was extended to further refine an innovative model of a continuing education program in gerontology for mental health professional personnel.

During the current year the Nursing Home Improvement Program plans to provide technical assistance and consultation in order to strengthen linkages between and among personnel of nursing homes, community mental health centers, state institutions and the educational centers in the area of continuing education for personnel working in long-term care. Joint funding of programs will be undertaken between NIMH and the Division of Long-term Care, Health Resources Administration.

HEALTH RESOURCES ADMINISTRATION

Health Planning and Resources Development

LONG-TERM CARE

Long-term care facilities have been an important element since the early years of the Hill-Burton program. From the mid-1950's until the signing of P.L. 93-641 in January 1975, long-term care facilities were assisted under separate "chronic disease hospitals" and "skilled nursing homes" appropriation categories or a combined "long-term care" category. Long-term care units of hospitals were included in these categories. As of September 30, 1977 1,868 long-term care projects had been assisted with $581.0 million in grant funds. State agencies have reported that 354,000 long-term care beds need to be modernized or added.

Public Law 93-641, signed on January 4, 1975, extended and extensively revised the Hill-Burton program. Nursing homes are no longer being aided under a separate long-term care formula grant category. However, they are eligible under two priorities of formula grant assistance: (1) modernization of health facilities, and (2) construction of new inpatient medical facilities in areas which have experienced recent rapid population growth. The same facilities are also eligible for loans or loan guarantees with interest subsidy. Another type of grant assistance is project grants for construction and modernization projects designed to prevent or eliminate safety hazards in publicly owned medical facilities and to assure compliance with State or voluntary licensure or accreditation standards. Grant and loan assistance from 1976 and 1977 appropriations/authorizations (except Section 1625 grants) are awaiting the publication of regulations for Title XVI. At that time, $39.9 million in formula grants and $250 million in loan guarantee authority will be available for the priority projects in each State. Section 1625 public facility project applications have already been approved for the $11.4 million available.

HEALTH RESOURCES ADMINISTRATION

Bureau of Health Manpower

LONG-TERM CARE

Over one-hundred projects were awarded in 1977 to up-grade the quality of patient care in long-term care facilities. This educational program prepares long-term care faculty and state agency personnel with the basic knowledge necessary to improve services to the elderly and to understand the intent of Federal and state regulations pertaining to long-term care.

Currently, five nursing homes are participating in a longitudinal study to test the validity of an instrument for measuring job performance of R.N.'s and nursing aides. The long term goal of this research is to validate performance evaluation procedures that can be generalized for comparable nursing positions in different nursing homes.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Services Research

LONG-TERM CARE

The National Center for Health Services Research, which has as its mission the development of research efforts to improve the health status of the total population, has included as an integral part of its program, health services research issues relating to both acute and long-term care for the aged. The National Center defines long-term care to include all forms of services required by people with chronic health conditions. Such conditions may be experienced at any age as recurrent or persistent sumptoms, illnesses, disabilities or impairments which are either incurable or which last for prolonged periods (e.g. 3 months or more).

Over the past few decades, people with chronic health conditions have turned increasingly to health care providers for assistance with their diverse health and social problems. Unfortunately, the health sector has been organized primarily to deal with discrete, acute health problems. For people requiring prolonged multiple services, medical care has often been fragmented, inadequate, and impersonal. As the elderly population increases and as more people of all ages with chronic health problems survive longer, public decision-makers are under increasing pressure to expand or reorganize long-term care assistance programs. Yet, they are acutely conscious of the escalation in medical care costs and of the growing economic burden of long-term care. Despite recognition of the need for improvements, there is no consensus as to a course of action that would make adequate long-term services available without exorbitant expense to those who need them.

Comprehensive Service Planning. Individuals who have chronic health conditions frequently experience a broad range of problems in social, economic, psychological, and physical functioning. They are likely to suffer from more than one chronic health problem, as well as from the constant threat of further physical deterioration and the prospect of decreasing ability to function. Physical dependency and mobility impairments are often accompanied by job loss, decreased social interaction, and severe psychological stress. All of these problems are likely to have significant impact on their families as well. Information is currently being produced that will contribute to the planning of effective and economically feasible programs of comprehensive service, by enhancing the general understanding of the health and social problems usually experienced by people with chronic conditions, the types of services already available to them, and the costs and outcomes of alternative service configurations.

Institutional Services. Skilled nursing homes and extended care facilities are by far the major providers of long-term care in this country, and their costs are borne largely by taxpayers through Medicare and Medicaid. NCHSR is supporting a number of projects to describe the structure and behavior of the nursing home industry, particularly in response to public regulation and reimbursement policies. Another area of special interest is in the development of methods of prospective reimbursement that offer equitable compensation for differences in patient case mix.

Home and Community Services. The predominance of nursing homes as suppliers of long-term care stems largely from the structure of existing financing mechanisms. Their position is not a function of proven superiority in clinical efficacy, efficiency, or attractiveness. NCHSR is therefore devoting substantial resources to the exploration of additional strategies for non-institutional long-term care programs. These include homemaker services, adult day care, and special types of supportive living arrangements. Particular emphasis is being given to such approaches because they not only represent potentially useful alternatives to institutionalization, but may also have substantial rehabilitative impact in some types of cases.

HEALTH CARE FINANCING ADMINISTRATION

LONG-TERM CARE

The Long Term Care Research, Demonstration, and Evaluation Program in the Health Care Financing Administration, HCFA, is conducted by the Office of Policy, Planning, and Research, OPPR, in the Division of Long Term Care Experimentation. This Division was created within the Office of Research, Demonstrations, and Evaluations by OPPR, to give special emphasis to the delivery of health care to the chronically ill and disabled of all age groups as specified under Section 222 of Public Law 92-603. Analysis of LTC financing, developing alternatives to institutionalization and studying the impact of alternatives, including nonmedical services, is being emphasized.

The law stipulates that research should determine the relative advantages and disadvantages of prospective reimbursement to skilled nursing facilities and other providers of services and care under Title XVIII of the Social Security Act and under State plans approved under Titles XIX and V of the Act.

The long term care research program is primarily concerned with the delivery of health care and other appropriate services to the chronically ill and disabled of all age groups; the elderly comprise the highest proportion of the population in need of these services. Promoting community care alternatives to institutionalization for the chronically ill and disabled who want and are able to function outside of institutions can have an important effect upon the lives of the elderly and that of their families.

Two demonstrations and an analyses of community-wide coordinated health and social service delivery programs were initiated. The major thrust of this effort is to determine the quality of care and reduce costs for delivering long term care to the chronically ill and disabled. The projects are in the operational stage. One, in the State of New York, entitled "Demonstration of Community-Wide Alternative Long Term Care Models," is testing the feasibility of developing community-wide, population-based models for the organization, delivery, and financing of care within Monroe County, New York. The second project, in the State of Washington, "Community-Based Care Systems for the Functionally Disabled--A Project in Independent Living," is an effort to examine the effects of focusing State social services on coordinating health and social service delivery in order to prevent unnecessary institutionalization and improve the quality of care for high-risk populations. Each of these projects is an attempt

to provide care plans for the population-at-risk which contribute to the maintenance of integrity and self-sufficiency through appropriate services and placements fitting the functional capacity of the individuals concerned. Each will attempt to develop a link to the continuum of care important for this population as well as links with service providers for care delivery. In each of the projects, costs will be tracked and evaluation of effectiveness undertaken through comparison with a control community. Two additional projects funded in FY 1976 are also contracted, one in Georgia, "Cost Effective Alternatives to Nursing Home Institutionalization," and Vermont, "Long Term Care Proposal."

Two new community care projects were funded in FY 1977, Maine "Adult Day Health Center," and Colorado, "Community Care Organization," as well as an Information and Referral System in Michigan.

A research project primarily concerned with exploring the feasibility and cost effectiveness of delivering services to the chronically ill and disabled in settings other than day care centers, nursing homes, and long term care hospitals is expected to have several additional products. The project, "The Feasibility and Cost Effectiveness of Alternative Long Term Care Settings," was completed at the Stanford Research Institute. It produced a number of case studies on long term care programs outside of nursing homes and long term care hospitals. In addition, a bibliography on studies of long term care providing systematic information on developments in this field and a report on the effects of legislative, regulatory and/or administrative programs has been prepared. (A companion investigation of day care centers has been undertaken by the Health Resources Administration.)

Another project provided a comparison of costs. This comparison will be useful for participants of similar functional capacity in nursing homes and the alternative settings with the same geographic area. It has developed a method of comparing services provided by different settings to individuals with similar functional mental status.

The Utah Long Term Care Payments System project is a Statewide experiment designed to link reasonable cost reimbursement with the quality of care within skilled nursing facilities. It is not only designed to respond to the requirements of Section 249 of P.L. 92-603 but to add to the system a structure which will increase nursing home accountability for appropriate services to the patients as well as to provide an opportunity for the type and level of care extended to individual patients to be a component in the cost reimbursement system.

In California, Colorado, Texas, Wisconsin, and Maine projects are demonstrating the effect of social services, including day care and homemaker services, in keeping the elderly in their own homes instead of in intermediate care facilities and nursing homes. A project in New York City, "Project Monitor in Day Hospital in Rehabilitation Medicine," is testing the efficacy and cost of day hospital care in lieu of 24 hour hospitalization.

During FY 1978, LTC demonstrations will be designed to test alternative systems of LTC. The objective will be to demonstrate the effectiveness and efficiency of comprehensive organization for delivery of services; including coordination, needs assessment, and management of care. Long Term Care Research will focus on the characteristics, health status, and services to residents of domiciliary and/or congregate care facilities; the impact of regulations on the cost and quality of LTC and the impact of Medicare and Medicaid funding patterns on the use and availability of LTC.

MATERNAL AND CHILD HEALTH

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
National Institutes of Health:					
National Institute of Child Health & Human Development....	$ 73,314,000 1/	$ 79,661,000 1/	$ 85,661,000 1/	$ 97,820,000 1/	$113,658,000 1/
Alcohol, Drug Abuse & Mental Health Administration:					
National Institute of Mental Health.....	78,601,000	71,864,000	92,238,000	102,964,000	114,303,000
Health Services Administration:					
Bureau of Community Health Services.....	303,970,000	318,119,000	345,044,000	361,854,000	374,854,000
Health Resources Administration:					
Bureau of Health Manpower.....	5,946,159	2,448,451	3,161,185	3,010,683	2,142,922
Center for Disease Control:.....	2/	2/	2/	2/	2/
TOTAL, PHS.....	$461,831,159	$472,092,451	$526,104,185	$565,648,683	$604,957,922

1/ Represents obligations for Research for Mothers and Children only. Although certain Population activities do relate to Maternal and Child Health, their costs are more appropriately included in the Population Research Special Report.

2/ Funds are reported under the categories of Lead-Based Paint Poisoning and Immunization.

NATIONAL INSTITUTES OF HEALTH

National Institute of Child Health and Human Development

MATERNAL AND CHILD HEALTH

The National Institute of Child Health and Human Development (NICHD) is the Federal Government's major research arm concerned with the health and well-being of mothers and children. The mission of the NICHD is to seek out opportunities for early prevention of disease and disability, using the tools of the biomedical and behavioral sciences, together with demographic, biometric and statistical techniques. It fosters a steady expansion of knowledge on child and maternal health, human development, fertility regulation, and the many factors determining the adaptation of individuals and populations to various economic and evironmental conditions. In addition, the NICHD serves as the scientific focal point for a number of Federal agencies concerned with improved health for mothers and children and with family planning.

Among the disorders addressed by research at the Institute are many of the most significant and costly health problems of our society.

An estimated $1 billion alone is expended yearly for intensive care of premature and low weight infants. Seventy percent of all neonatal death is associated with prematurity and low birth weight; twenty-five percent of those who survive are subject to life-long morbidity from such disorders as mental retardation and impaired lung and nerve function. One fifth of all infants born of diabetic mothers die. Seven percent of infants born each year suffer from a congenital defect; more than 50 percent of spontaneous abortions show gross fetal malformation. Each year, two infants of every 1,000 born are victims of the Sudden Infant Death Syndrome. Learning disorders affect an estimated 26 per 1,000 children enrolled in school. Conservatively, at least one in every hundred Americans is a victim of mental retardation. Recent data suggest that one of every five births is unwanted. It is estimated that approximately 2,000,000 couples who want children are unable to have them.

In 1975, 595,000 or 19 percent of all births occurred to adolescents; of these, twenty percent occurred to women less than 17 years of age, the young population at highest risk for complications of pregnancy and the most economically vulnerable.

These problems cannot be addressed by research on a single organ or isolated event in time. Rather, a multidisciplinary approach is required that spans the period of life during which aberrations of reproduction and development occur.

To this end, the NICHD has developed a research strategy based upon an interdisciplinary mix of studies in reproductive and developmental biology.

This research strategy, which was initiated by the Institute in its 1979-1983 Forward Plan process, has demonstrated significant promise for new and important

medical advances. For example, the Institute's support of basic studies on hormonal receptors focuses primarily on contraceptive development and cures to infertility. These same studies, however, by determining the role of hormones in triggering intercellular events in embryonic development, may provide needed answers to problems of birth defects and spontaneous abortion. Recent research at the Institute has shown that genetic make-up determines the ability of the fetus to respond to hormones and foreign chemicals reaching it by way of the placenta; the fetal response in turn determines immunity to toxic substances and the occurrence of a congenital defect.

The assurance of a healthy infant population, in large part, will be effected by advances in fetal and perinatal medicine and in the population sciences. Optimal prevention of childhood disease and disorder may derive from research that not only permits the physician to anticipate the birth of a distressed baby and thereby prepare for corrective treatment upon delivery, but also provides him with techniques and methodologies that make possible correction of deficiencies and problems in utero. The degree to which research can enhance the development of safe, acceptable, and effective methods of fertility regulation will have a direct impact upon unwanted and unplanned births, the frequent sequelae of which are prematurity, mental retardation, and the perpetuation of poverty.

In FY 1978, the NICHD will implement an initiative on alternatives to abortion by increasing research activity in the following program areas:

HIGH RISK PREGNANCY

Specific emphasis within the Institute's program of research on high risk pregnancy will be directed to (1) adolescent pregnancy and, (2) diabetic pregnancy.

Pregnancy in the young adolescent constitutes a significant problem particularly when the mother-to-be is single and less than seventeen years of age. The Institute plans to undertake research to define and explain the physiological antecedents of toxemia in the pregnant adolescent. Investigations will be supported that can contribute to an understanding of the mechanisms by which maternal infection, such as herpes and cytomegalovirus, affect fetal growth, maturation, and function. Studies will also focus on the maternal and fetal contribution to the premature onset of labor.

Research will continue to be supported that concentrates on the social and behavioral factors influencing teenage sexual activity and contraceptive usuage, and on the impact of early childbearing, not only on the teenage mother but also on the child, the father, and other family members who share responsibility for care of the child. Age of parents at first birth has been found by several investigators to have a significant direct effect on educational attainment. This effect holds even when background characteristics are controlled, and is felt by both males and females, but the effect on women is stronger and increases over

time. Young childbearers are also likely to express regret over their educational careers. The effect of adolescent childbearing on education is especially important since it is the mechanism by which occupation and earnings are affected. Women who bear their first child during their teens are also likely to suffer lowered occupational prestige and earnings. Early family formation forces males into the labor force at an early age, and a decade later they have jobs at lower pay and prestige than classmates who did not begin their families so young. A decade after high school women who became mothers early were more likely to be working than their classmates, but in jobs of lower pay and prestige and with less job satisfaction. Several studies have shown that pregnancy at an early age affects occupational attainment since it often results in reduced education and, to a lesser extent, an increase in family size.

Maternal diabetes constitutes a significant risk to both the pregnant woman and her fetus. Research supported by the Institute focuses on factors of diabetes in pregnancy that contribute to congenital anomalies and metabolic disorders in the fetus. Using the rat as an animal model, one investigator's studies suggest that the high incidence of birth defects in infants of diabetic mothers is due to hypersecretion of insulin by the fetal pancreas in response to maternal hyperglycemia in spite of insulin treatment of the mother. If further studies confirm that the teratogenic effect of maternal diabetes exerts its effect in the rat at 8-10 days of gestation, this would suggest that in the human the teratogenic effect is exerted before the 8th week of intrauterine life. This period of pregnancy is usually ignored in the care of pregnant diabetics, but may in fact be critical for teratogenesis. These findings may lead to a change in current therapy so as to emphasize the danger of hyperglycemia during the first 8 weeks of gestation. This could then result in a significant reduction in fetal anomalies.

NUTRITION

An important area that requires further development is that of fetal nutrition. It is essential that optimum maternal nutrition be defined in order to enhance the potential for normal fetal development or to ameliorate abnormal development by correcting disorders in utero. Additional research activities will focus on the development of techniques to accurately assess the nutritional status of pregnant women and to understand the total nutritional needs of the mother and fetus, and of nutritional interventions that can be applied during pregnancy to prevent permanent physical and mental handicaps.

A new research initiative will permit the study of feeding patterns and developmental factors related to the later appearance of obesity and of diabetes mellitus in genetically predisposed infants. Research will be supported to determine how best to feed low birth weight infants so that their ability to achieve normal physical and intellectual development is improved.

CONGENITAL DEFECTS

The etiology is unknown for 69 percent of congenital defects that occur in seven percent of all live births. In FY 1979, the NICHD will initiate a major effort toward prevention of congenital defects. Investigation of genetically caused congenital malformations will be pursued so that prospective parents may make more informed decisions about their reproductive activity. High priority will also be given to elucidating the metabolic treatments that ameliorate genetic disorders. Attention will focus on the degree to which congenital defects are caused by the interaction of environmental factors, such as infectious agents and over-the-counter drugs, with genetic factors.

MENTAL RETARDATION

Emphasis is being given to the support of basic research on primary prevention of Down's syndrome. Included in the effort will be studies on normal and abnormal development of germ cells, and the relationship of chromosomal abnormalities to structural and functional defects. Research will also focus on secondary prevention of Down's syndrome and other forms of mental retardation through studies on genetic counseling, prenatal treatment of conditions diagnosed antenatally, and amelioration of genetic diseases through such techniques as drug administration.

FERTILITY-INFERTILITY

Studies on male and female infertility are being supported which involve clinical research on hormonal disturbances in women who fail to ovulate, the relationship of infectious agents to infertility, behavioral and physiological factors in the treatment of infertility, and on the fertilizing capacity of human sperm.

CONTRACEPTIVE SAFETY

Projects will be initiated to ascertain the mechanisms by which oral contraceptives produce serious health defects, particularly adverse cardiovascular effects, in women as a function of age, weight, family health experiences, smoking history, or specific biochemical and physiological complications. These studies are supported to provide knowledge on safer oral contraceptives and also to predict women at high risk of health hazards from the pill so that they may be advised on other forms of contraception.

The Institute plans to maintain initiatives in the following program areas:

SUDDEN INFANT DEATH SYNDROME

The Institute's broadly based, multidisciplinary research effort on the sudden infant death syndrome (SIDS) will continue. Emphasis will be given to the development of indices of risk for SIDS, particularly in low birth weight infants, and on preventive approaches such as instrumentation for monitoring cardiorespiratory function on infants in the home. Research is planned to better define the time and type of developmental insult that results in SIDS with particular attention to antecedents in fetal life.

As a result of Institute supported investigations of SIDS between 1972 and 1977, there is now a growing body of evidence that the victims of crib death are not completely healthy and their deaths not as inexplicable as was once thought. It appears that these infants have subtle physiological defects of a neurologic, cardiorespiratory, and/or metabolic nature. It is also evident that the pathogenesis of the syndrome is not through a single mechanism as previously believed. Instead, a number of developmental, environmental, and pathologic factors appear to be involved which under a complex set of circumstances interact in such a way as to rapidly set up a sequence of events that produces a sudden, unexplained, and unexpected infant death. A summary of the NICHD SIDS research effort is presented in a recent Branch publication entitled "The Sudden Infant Death Syndrome Research Program of the National Institute of Child Health and Human Development."

HUMAN LEARNING AND RELATED BEHAVIOR

An impediment to the acquisition of meaningful data on developmental dyslexia is the lack of standard procedures to define subject populations.

The Institute has undertaken, through the contract mechanism, to develop a reading achievement test designed to assess directly the major components of reading. Such a test would permit a better definition of reading problems in those individuals now labeled "developmentally dyslexic."

MAJOR RESEARCH PROGRAM GRANTS

In fiscal year 1977, the Institute initiated the establishment of Major Research Programs (MRP) to address specific aspects of health problems affecting pregnant women and children. MRP grants have been awarded which focus on the premature initiation of child-birth labor, diabetic complications of pregnancy, and the sudden infant death syndrome. MRP grant applications pending review are concerned with developing a risk index for low birth weight infants and the biosocial aspects of adolescent pregnancy.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health

MATERNAL AND CHILD HEALTH

The number of individuals under the age of 18 needing the attention of mental health professionals is estimated at 7 to 10 million (12 to 15 percent of the total child and adolescent population through age 17). Analyses of case utilization data indicate that 85 to 90 percent of these young people will not receive the services needed.

In 1975 (the year for which we have the most recent data), there were 597,840 reported psychiatric admissions of people under age 18 years to the combination of community mental health centers, free-standing outpatient clinics, State and county mental hospitals, and private psychiatric hospitals. (No figures are available on the number treated in private out-patient settings.) These figures refer to individuals who are identified through the mental health system. They do not include a large number of individuals who have problems that might be helped to some degree by mental health professionals but are dealt with in the general health care system because of chronic physical and physiological stigmata or are dealt with in the criminal justice and alternative services systems because of different forms of social deviance. The NIMH finds that psychological dysfunction is, to varying degrees, related to detrimental conditions. Such conditions are: disturbed parents; disturbed parenting; institutional parenting; poor nutrition; overcrowding and poverty; racism. The problems dealt with by the mental health system include: psychopathology related to mental retardation; organic brain syndromes; schizophrenia; depressive disorders; other psychiatric disorders; transient situational disturbances; behavior disorders; and social maladjustment without manifest psychiatric disorder. Only 21.4 percent of the identified patient care epidodes in the mental health system as traced by NIMH fall within the category of the classic psychopathologies (schizophrenia, depressive disorders, behavior disorders, organic brain syndromes). The remainder seem to fall in a category which is more derivative of developmental, socioeconomic, and family disturbances.

Research

The NIMH has very active research programs in child and adolescent mental health. These programs are found in many parts of the Institute but are primarily located in the Division of Extramural Research Programs, the Intramural Research Programs and at the Mental Health Study Center in Adelphi, Maryland. In fiscal year 1976, 18.1 percent of the Extramural Research Program dollars and 10.8 percent of the Intramural Research Program dollars were spent on child and adolescent mental health research. In fiscal 1977, the Division of Extramural Research Programs supported 202 grants with child mental health as the primary emphasis. The 13 million dollars expended represented one-third of the entire Division of Extramural Research Program budget. This divisional support accounts for

approximately 70 percent of the Institute's entire extramural expenditures on child relevant research. Of the Extramural Research Program projects primarily involved with child and adolescent mental health, 57 percent focused on basic biological, psychological and social development processes and behaviors while the remainder were largely devoted to the dysfunctional child (psychoses and autism, neuroses and severe behavioral disorders, sociopathy, and general social and behavioral problems). An analysesby broad substantive areas provides the following breakdown: (a) biological antecedents and behavioral correlates together with the study of underlying biological mechanisms account for 18 percent of the projects; (b) traditional psychological aspects of behavior (covering cognitive, perceptual, and emotional processes, learning, language, personality, and motivation) comprise 33 percent; (c) social and cultural correlates of behavior (incorporating studies of family, groups and community structures and dynamics, socialization, values and attitudes) account for 27 percent; (d) research on treatment and prevention account for an additional 11 percent. The remaining supported projects include studies of methodology, investigations bearing on service delivery systems and studies aimed at development and improvement of early screening and prognostic indicators as well as of diagnostic and therapeutic procedures.

The establishment of a new program for Clinical Research Centers has been a major Division initiative this past year. Public announcements and communications regarding this program emphasize the need for and the importance of establishing Clinical Research Centers which would focus on mental health problems of childhood and adolescence. Of the eight new Centers actually funded in fiscal year 1977, one is devoted entirely to childhood psychosis and autism. Components of several other Centers deal with a variety of biological and behavioral dimensions of mental illness among children and adolescents.

Some highlights of the Division's activities last year follow. Under a Division contract, a comprehensive and critical review was undertaken of the literature on concepts, measurement, and factors related to premorbid adjustment. This report was published in Vol. 3, Number 2, 1977 of the Schizophrenia Bulletin. A two-day workshop was convened as a followup to examine critical stages of child development as predictors of adult social competence and mental illness. One major recommendation was on the need to consider premorbid adjustment in the context of social systems, coping strategies and life events of developmental stages. Another recommendation stressed the need for new measuring instruments of premorbid adjustment which would take normative data into account as well as the interrelationship between the biologic and behavioral variables. In another subject area, over a years preparation went into the convening of a conference in March of 1977 which comprehensively and critically considered existing knowledge on dyslexic disorders, etiologies, early detection, prevention, and remediation, identifying both needed and promising research directions from the perspectives of such disciplines as neurology, neurophysiology and neuropsychology, psychiatry, psychology and

education. The results of this conference and the papers commissioned for it are scheduled to be published as a volume in 1978 to be entitled "Dyslexia--An appraisal of Current Knowledge". Conclusions reached in the assessments and the papers presented at the conference will also be presented in an invitational three hour symposium of the 1978 meetings of the Association for Children with Learning Disabilities. Concerning adolescence, the Division continues its activities in this area. It held a workshop on the biological and behavioral interactions of adolescents during the month of April, 1977. This workshop brought together steroid chemists, neuro-endocrinologist, pediatric endocrinologists, demographers, sociologists, psychologists and psychiatrists to concentrate on problems of adolescent sexuality, aggression, and depression.

Several interesting findings have been reported by Division grantees. One project (MH-25235) has been able to verify that there is a subgroup of autistic children who are responsive to vitamin B-6 therapy and that autistic symptomatology and behavior controlled by such medication reappear with the momentary cessation of that treatment. Another grantee (MH-21795) has found that children with mental retardation from a number of different etiologies have qualitatively different information processing deficits. In another area, an investigator has completed development of a multidimensional assessment profile methodology for monitoring trends in television programming violence as well as of other content; this project has demonstrated the feasibility of such measuring techniques. One organizational change has occurred. The Juvenile Problems Research Review Committee was renamed the "Developmental Problems Research Review Committee".

Activities in the Intramural Research Programs are focused in three parts of that program: the Laboratory of Developmental Psychology; the Biological Psychiatry Branch; the Laboratory of Clinical Sciences. There are three major areas of ongoing research in the Laboratory of Developmental Psychology; these areas include the emotional-social development of children; the studies of child psychopathology; and the interfaces between organic conditions and child behavior.

In the research on early emotional development, studies have focused primarily on empathy and altruism. These studies are being conducted from the point of view of examination of emotional responses in the contexts of parent techniques, and in the context of the behavior and levels of arousal of children, and in the context of cognitive development. Studies are also being done which examine interpersonal behaviors involving nurturing, gentleness, stoicism, assertiveness, emotional expressiveness. This Laboratory also has studies into the psychological consequences of major stress in the lives of children whose mothers have engaged in crime and are imprisoned. Finally, in this particular sphere of research is an ongoing program studying mother-infant relationships.

Concerning studies of psychopathology, the Developmental Psychology Laboratory has a program directed toward the development and testing of standardized measure of adaptive and maladaptive behaviors in children and

adolescents. Field trials are being conducted of a Child Behavior Checklist that has already been developed. Concerning studies of organic conditions in child behavior, this is a new direction of research in the Laboratory. One group of projects deals with serious illness (cancer) in children. The objectives of the study are to elucidate (a) how illness and treatment effect the cognitive affective, and social functioning of the child, and (b) how the functioning of familial and medical-care networks is associated with psychological adaptations of the child. Physiological and neurological changes which appear to be a result of treatment are also being related to children's psychosocial status. A second study of children with cancer is investigating the cognitive characteristics of survivors of leukemia who have undergone intensive central nervous system treatment (irradiation and chemotherapy) as a prophylactic measure for sustaining remission. So far it has been found that the patient's level of functioning on both verbal and nonverbal abilities was significantly lower than the siblings who had not had such treatments. There also is evidence at this point that the more time that has elapsed between central nervous system treatment and intellectual evaluation, the greater the difference between patients' and siblings' scores. This suggests that central nervous system treatment may indeed effect the children's conceptual abilities and capacities to assimilate and integrate new information. The degree of deficit in the patients is in the process of being correlated with computerized tomography records obtained by research staff. The entire study is also being repeated with a prospective design in collaboration with the Hematology-Oncology Service of the Children's Hospital in Los Angeles. In another area of clinical research, studies are being conducted into high risk infants. These are the approximately 6 percent of all infants born in the United States before the 38th week of gestation. Data gathering is underway concerning the premature infant's sensory capacities and capacities to interact with caretakers.

Another project is concerned with the relations between the physiological conditions and behavior of children under conditions of chronic malnutrition. Studies are being planned to investigate how nutritional supplementation will affect chilren's cognitive, social and emotional development.

Many other studies by this active Laboratory could be presented if further information is desired.

Concerning the other parts of the Intramural Research Program, there are projects involving extensive behavioral and physiological investigation into children with the hyperkinetic syndrome. This research has as its purpose the extension of our knowledge into the neurobiochemical functioning and behavior, as well as the cognition and motor activity of such children. In addition, highly specific pharmacological studies of drugs used in the treatment of such

children are being carried out. Another project involves studies of depression by looking at children of parents who have been hospitalized for major affective disorders on NIMH's inpatient service at the Clinical Center in Bethesda, Maryland. A third project involves the study of enuretic (bed-wetting) children. These children are being studied from the point of view of their peripheral and nervous system through a combination of behavioral, sleep physiological, and pharmacological studies. Among adolescents, two disorders in particular are being studied, anorexia nervosa and Gilles de la Tourette Syndrome. The first is being studied simultaneously with regard to its behavioral and metabolic aspects while assessing unique pharmacological approaches to treatment. The second is also being studied through a multidisciplinary approach involving behavioral, psycholinguistic, neurobiological, and pharmacologic investigations.

At the Mental Health Study Center, a clinical research project is underway studying infants whose normal development is in jeopardy for a variety of reasons: existing significant handicaps; predispositions for severe pathology; and/or maladaptive maternal environments. This project has as its purpose the development of evaluation, treatment and family assistance techniques which show effectiveness over time. The study has a group of National advisors who also form the nucleus for a communications and information network among the outstanding clinical infant programs working on infant-parent research. Plans are underway to develop a small series of clinical infant research and training programs in various parts of the country. This project is further described under the Services paragraph.

Training

The NIMH sponsors programs for training in clinical services and research. Clinical training activities include child psychiatry, psychiatry, behavioral pediatrics, psychiatric nursing, psychology, social work, continuing education programs, parsprofessional programs, and experimental and special programs. These efforts include the training of pediatricians as primary care physicians in the understanding and management of manifest and potential psychiatric problems in childhood; an interdisciplinary endeavor "to train child mental health personnel for assessment and service roles in small towns and rural areas with limited professional resources". Research training activities are in the biological, psychological and social sciences. Research training highlights include a program to train Ph.D's and Ed.D's as early childhood development research specialists; and another program which combines training in anthropology with developmental psychology and human development.

Services

A wide range of projects relating to the delivery of mental health service for children is being supported by NIMH. These include

projects focused on a variety of preventive activities and on identification of incipient problems, as well as programs for children and families where problems already exist. One prototype project is exploring methods for increasing systemization in research and development programming for children.

During the past year major service-related research activity has focused on preventive services for children and their families. Work has proceeded on the development of a screening instrument that can be utilized by those without extensive training and on program activity with parents and teachers aimed at enhancing communication to facilitate the development of children. The child's admission to a hospital for an operation or physical illness can have significant implication for the child's emotional well being. With this in mind, work is being directed to this important area. The coexistence of minority and poverty status can increase vulnerability to mental health problems. Therefore, a project of this nature has considerable preventive implications.

Deinstitutionalization, an issue for children directly, and through their parents, provides an example of another area of service-related research activity. A newly awarded grant will test a program that involves simultaneous interventions to rehabilitate recently institutionalized mothers and aid the development of their children. A recently completed study demonstrated that a community care program has the potential for reducing state hospital admissions for children.

Some of the other major child-related activities of the Institute concern the financing of children's services. These have included an analysis of voluntary health insurance coverage for children's services and study of financing of children's services in residential treatment centers under the CHAMPUS program.

The NIMH Mental Health Study Center is currently proceeding with work on establishing a national infant mental health center. This is aimed at forming the nucleus for a communications and information network among outstanding clinical programs focused on vulnerable infants and their families. In addition, Study Center staff continue their work on a broad spectrum of studies relating to children; these range from projects concerned with infant, and daycare programs to studies relating to adolescent mental health needs. Specific examples of programs underway include the following:

1. Clinical Infant Development Program: The Clinical Infant Development Program at the Mental Health Study Center, in establishing a substantiative clinical research study, will provide a range of services for families and infants where, for a variety of reasons, there are interferences in the infant's development. The clinical research staff will provide for the observation, evaluation, develop-

mental facilitation, treatment, and follow-up of the children, and appropriate evaluation, guidance, and treatment for parents and families in a center-based and outreach program. The results of our studies are expected to have major implications for infant health and mental health programs on a national and international level.

2. Cognitive and Educational Development: Cognitive and educational development studies at the Mental Health Study Center have resulted in an important paper detailing the relationship between two types of predictive equations, including the prediction of whether a student will be a dropout or graduate from high school; and the prediction of the grade level in which dropouts leave school. The theoretical implications suggest a reconceptualization of the dropout phenomenon. Evidence of this and other studies show that prediction of high school dropouts is similar to, and on the continuum with, prediction of whether or not an individual will attend college. There is also a correlation with prediction of the eventual level of education a person will attain.

Related Efforts

The Institute's Division of Biometry and Epidemiology is responsible for much of the existing data on mental illness and the utilization of mental health treatment facilities. Data in terms of the child and adolescent population is now being tabulated by such variables as age, sex, race, psychiatric diagnosis, education, source of referral, type of treatment received, referral and discharge, and principle source of payment, as well as trend data. The Division has finished through a contract with the University of Rochester School of Medicine and Dentistry a feasibility study on the role of pediatricians in the detection, treatment and referral of patients with emotional, behavioral and school problems. This pilot project is now in the process of being developed into a full study of pediatrician's practices in Monroe County, New York, a county which has the most accurate mental health and pediatric registry in the country. Some of the provisional findings from the pilot project indicate that about 5 percent of children under 18 years of age (over 8 percent of those in ages 5 through 17 years) were detected by their pediatricians to have an emotional, school or behavioral problem. The small sample of pediatricians in this study referred over one-third of such children for care elsewhere. Data has been gathered now on the mental health treatment given to people of all ages through two health maintenance organizations and one neighborhood health center. During the coming months, this data will be analyzed for the child and adolescent population in terms of age, sex, diagnosis and type of psychiatric treatment, duration of visit and clinical specialty of the professional providing the treatment. The Division also supports through grant mechanisms a series of nine research projects relevant to children. Amongst these are five projects focused on specific conditions. One of these projects is a longitudinal study on the

factors involved with mental retardation. Two of the projects involve studies of autism; one concerning its manifestations among non-Western people and the other concerning viral diseases as a possible etiology. Another project is studying the long-range psychosocial effects of early hyperkinesis. A fifth project is studying life stresses and psychosocial factors in automobile accidents among young drivers. Another project is involved with developing screening methods for use in preschool children in determining the prevalence of behavioral, emotional and cognitive dysfunction in four-year-olds. Ongoing projects include a longitudinal study of stress and related factors in the incidence of mental and behavioral problems among 1000 urban children; a longitudinal study of childhood factors predicting occupational success, criminality and psychiatric disorders; a study of college students and the impact on their emotional health of residence hall environments. A new project involves the study of the prevalence of behavior problems among three-year-old children living with their parents.

The NIMH Division of Scientific and Public Information answers inquiries on mental health issues from the general public and press. Of the 94,612 information requests received from the general public in FY 1977, 5 percent concerned children. Technical information services indicate an even higher proportion of user interests, as 13.8 percent of the 14,109 computer-generated bibliographies prepared by the NIMH National Clearinghouse for Mental Health Information were child related. Among the eight professional groups most often served by the Clearinghouse, all, with the exception of physicians, asked for information about children more often than about any other topic. The Division's Mental Health Studies Branch is working on almost a dozen program reports about children. These reports are based on NIMH-supported research. They deal with such varied topics as childhood depression, the effects of labelling on children, training foster parents and teaching children altruism. Planned are a number of program reports including a piece on runaways, a longitudinal study of abused children, and other publications under the general heading of family mental health. The Division also has been producing information concerning the interrelationship of the physical and emotional factors as they effect children. These publications include topics such as the psychosomatic aspects of diabetes for children and their families, the tie between physical and behavioral irregularities in children, and styles and temperament and their effect on behavior.

The NIMH Division of Special Mental Health Programs is made up of a number of units, each dealing with a different social problem of major public concern. The Division's activities during the past year which have major relevance to children and youth include the following:

The Center for Minority Group Mental Health Programs is funding several research projects investigating the lifestyles and coping patterns of different kinds of minority families, including urban

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Native Americans as well as Black and Puerto Rican single parent families. The Center is also supporting research on child rearing practices and development of minority children.

The Center for Studies of Child and Family Mental Health is funding three pilot programs to develop innovative services for abused and neglected adolescents. Several Center-funded monographs are being prepared for publication; the subjects include learning-disabled children, parent-infant interactions, stepparenting, and parent-infant enrichment programs. The Center is funding the preparation of a monograph on public policy and child care and mental health programs. Jointly with the Mental Health Disaster Assistance Section, the Center is funding the development of an instrument to measure family coping capacity.

A major program focus of the National Center for the Prevention and Control of Rape is child sexual assault. The Center is currently funding several projects to improve the treatment of victims of this kind of abuse, and has recently joined with the Law Enforcement Assistance Administration and the National Center for Child Abuse and Neglect (part of HEW's Administration on Children, Youth and Families), ACYF, to support projects in this area. The Center is also funding a research project on the effects of incest early in life.

During FY 1977, the Mental Health Disaster Assistance Section has had four contracts funded to provide disaster counselling services to victims of major national disasters. In all of these communities, young people under 18, and especially children under 10, comprise a significant proportion of the impacted population requiring mental health services post-disaster. The communities and the percentage of children being served are as follows:

		Age	% of Total
1.	Logan-Mingo Counties, West Virginia	0-18	26
		0-10	46
2.	Harlan, Bell, Knox Counties, Kentucky	0-6	14
		7-12	13
		13-17	13
3.	Cambria, Bedford and Somerset, Pa.	0-20	10.6

4. McDowell County, West Virginia
   The average number in the client households is 3.86; strategy is being developed to reach the children in need of services through the school system.

The Center for the Study of Metropolitan Problems is currently funding research on the effects of women's employment on children and family life. Another project is studying the effects of residential density on the

well-being of low-income children.

The Center for Studies of Crime and Delinquency currently funds several research projects involving children and youth. Examples include: a study of the interactions between mothers and their premature or full-term infants which seeks to establish some of the antecedents of child abuse; a study of the relationship between sex roles of adolescents and their patterns of involvement in delinquency; an attempt to identify social-psychological typologies of delinquents.

HEALTH SERVICES ADMINISTRATION

Bureau of Community Health Services

MATERNAL AND CHILD HEALTH

Under Section 501 of Title V of the Social Security Act, the Maternal and Child Health Program provides formula grants to the States to extend and improve health services for mothers and children, including crippled children. Emphasis is placed on the reduction of infant and maternal mortality and morbidity. A full range of health services addressing the needs of unserved and underserved populations are provided.

Title V also authorizes under Section 505: (1) special project grants to State health agencies to provide pre- and postnatal health care to mothers and infants, necessary intensive infant health care and family planning services, with the aim of reducing the incidence of mental retardation and other handicapping conditions associated with childbearing: (2) special project grants to State agencies to promote the health of children and youth of school or preschool age; (3) special project grants to State agencies to promote the dental health of children and youth of school or preschool age; (4) under Section 511, project grants to support training programs in institutions of higher learning and affiliated organizations, which provide specialized health professionals with expertise in health services delivery for mothers, children and crippled children; and (5) under Section 512, research grants to identify methods for improving services and services delivery systems providing care for mothers, children and crippled children.

I. Formula and Special Project Grant Programs

In 1979, the focus of the formula grant programs will be on developing State-based systems of care which will provide States the capability to identify mothers and children requiring Federally supported services. The States will coordinate existing health resources and develop new ones to ensure that needs are met. The State-based systems will emphasize the development or expansion of the capacity to provide comprehensive health care services.

In 1979, the Adolescent Health Services and Pregnancy Prevention Initiative will be one of the priority areas for targeting Maternal and Child Health services. Through the State-based systems of care, which will focus on five areas: Family Planning, Prenatal Care, Perinatal Care, Child Health Care, and Adolescent Health, 82,000 additional adolescents will be provided pregnancy prevention and other comprehensive health services.

In 1979, pre- and postnatal care will be provided to 656,500 mothers; comprehensive health services will be provided to 178,400 infants; nursing services will be provided to 2,143,000 women; dental services will be provided to 1,033,200 children; 21,479,300 children will receive visual, audiometer, and dental screenings: 10,952,300 children will be provided immunizations for polio, rubella and diphtheria and 582,600 crippled children will receive physician services.

Family Planning

Approximately 9.4 million adolescents, ages 15-19, and women, ages 20-44, comprise the priority target group, those at risk of unwanted pregnancy, for family planning services. Family planning services are provided as part of a comprehensive health care delivery system with priority given to improving the quality and comprehensiveness of services and to expanding access to services for high-risk low-income persons, especially adolescents.

Prenatal Care

Approximately 30 percent of pregnant women who give birth to 2 million babies annually do not receive prenatal care until after the first trimester or have no prenatal care at all. The goal of the Maternal and Child Health Program in this area is to increase the number of high-risk women enrolled in continuous care programs early in their pregnancy, especially in the first trimester.

Perinatal Care

Approximately 900,000 women and their infants need perinatal care. In 1979, priority will be placed on States which have the highest infant morbidity and mortality and the highest number of births among adolescents with the aim of identifying high-risk women, and developing referral for continuous and follow-up care. Eleven additional, for a total of 34, Improved Pregnancy Outcome Programs will be developed in 1979.

Child Health Care

In 1979, emphasis will continue to be placed on preventive health services to ensure the health and well-being of children. Preventive

health services will be provided including immunizations, screening and counseling, accident prevention, alcohol abuse, drug abuse, child health, nutrition services, parenting education, and habilitative services for children with handicaps.

Child abuse and battering, which has become the leading cause of death of children under 5, will be emphasized within the preventive health services.

Adolescent Health

Through the Adolescent Health Services and Pregnancy Prevention Initiative, emphasis is being placed on providing comprehensive health care services to adolescents focusing on prevention of pregnancy, venereal disease, drug and alcohol abuse and emotional disorders and on providing services such as family planning education, sexuality and parenthood counseling, pre- and postnatal counseling and primary health care.

Each year approximately one million teenagers become pregnant; 600,000 give birth. Adolescents are nearly twice as likely as older women to give birth to low-weight infants, who run high risk of death and developmental defects. In addition, approximately 44 percent of adolescents who give birth to their first child will be pregnant again within one year and adolescents who give birth and keep their children are very likely to drop out of school, be unemployed and dependent on public welfare, and suffer family break-up.

II. Training Grant Program

Training of health professionals to provide quality Maternal and Child Health services continues to be an essential complementary component of the Maternal and Child Health Program. Section 511, Title V of the Social Security Act, provides authority for project grants to carry out the training program. In 1979, the 11 Pediatric Pulmonary Centers will provide training to 159 persons who treat children suffering from such illnesses as asthma, chronic bronchitis and cystic fibrosis. In addition, 21 university-affiliated centers will provide training to 240 health professionals who care for mentally retarded and multiply-handicapped children.

III. Research Grant Program

The Maternal and Child Health research program, authorized under Section 512, Title V of the Social Security Act, focuses on improving Maternal and Child Health and Crippled Children's services and services delivery systems. High priority is given to research related to mental retardation, especially in the prevention, intervention and improvement of handicapping conditions and the functioning of the handicapped child. In 1979, 55 research projects will be continued to conduct research studies of regional and national significance applicable to programs delivering services to mothers and children and crippled children.

HEALTH RESOURCES ADMINISTRATION

Bureau of Health Manpower

MATERNAL AND CHILD HEALTH

One of the primary goals of the health manpower programs is in expanding the role of the health professional. In the area of maternal and child health, educational programs for experienced registered nurses to be trained as nurse practitioners or nurse-midwives have been a major focus of the health manpower nursing program. Grants have been awarded to institutions to provide specialized educational training of nurses in Pediatrics, Obstetrics and Gynecology. These nurses are able to deliver specialized care to women and children in hospitals, nurseries, newborn intensive care centers, community health settings, and rural areas where there is a shortage of physicians.

Additionally, a study is currently being performed to test the effectiveness of psychological preparation for children (and their families) who are undergoing major elective and emergency surgeries.

CENTER FOR DISEASE CONTROL

MATERNAL AND CHILD HEALTH

Immunization:

The Center for Disease Control has provided project grant and technical assistance to State and local health agencies in support of their childhood immunization programs since 1963. Initially, support for immunization programs against polio, diphtheria, pertussis, and tetanus was funded. Later, as new vaccines became available, support was focused toward the control of measles, and then rubella. As backlogs of unprotected children were reduced for these diseases, support for more comprehensive immunization programs were funded.

These efforts have had a beneficial impact on children's health. Reported measles cases declined from 261,904 in 1965 to a record low of 22,094 in 1974, and reported rubella cases declined from 57,686 in 1969 to 11,917, also a record low, in 1974. As a result, concern for childhood immunization began to relax and support declined. In 1975, reported morbidity for measles had increased to 24,374 and reported cases of rubella had reached 16,652. In 1977, reported cases of measles and rubella had increased to 54,847 and 20,045 (preliminary data). Reported cases of mumps decreased from 38,492 in 1976 to 20,123 (preliminary data) in 1977 and reported cases of polio (20), tetanus (70), and diphtheria (84) continue to remain very low during 1977 (preliminary data).

Data from the 1976 U.S. Immunization Survey indicated that the number of children susceptible to the childhood diseases were increasing and had reached 13.7 million for measles, 14.4 million for rubella, 25.0 million for mumps, 18.8 million for polio, and 13.0 million for diphtheria, tetanus, and pertussis. Because of the concern over an increasing number of cases of measles and rubella and the large numbers of children susceptible to childhood diseases, the Secretary announced a major Immunization Initiative which included two fundamental goals: "To seek to immunize the millions of children who today are inadequately protected against all preventable childhood diseases..." and to "seek to establish a permanent system to provide comprehensive services to the three million children born in America each year." The objective of the Immunization Initiative is to raise the immunization levels of our children to 90 percent by October 1, 1979.

CENTER FOR DISEASE CONTROL

MATERNAL AND CHILD HEALTH

Lead-Based Paint Poisoning Prevention:

It has been estimated that 600,000 children each year suffer from undue lead absorption. Of these, 6,000 may suffer permanent neurological damage.

The children, most at risk of lead poisoning are generally from lower socio-economic urban areas where deteriorating older housing contains many layers of lead-based paint. During fiscal year 1977, 58 communities received federal grant support under the Lead-Based Paint Poisoning Prevention Act to conduct lead poisoning prevention programs designed to identify children with undue lead absorption and to provide appropriate medical and environmental followup services. Through these programs approximately 380,000 children were screened and 28,000 children were identified as requiring pediatric management for undue lead absorption. The intensive outreach activities of the Childhood Lead-Based Paint Poisoning Prevention Program have been instrumental in increasing the participation of children in the ongoing child health care delivery system.

Childhood Lead Poisoning Prevention Program activities are coordinated with, and have generally become an integrated part of the Maternal and Child Health Services provided by health departments and Neighborhood Health Centers.

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
Alcohol, Drug Abuse, & Mental Health Administration:					
National Institute of Mental Health:					
Budget Authority	$418,023,000	$368,110,000	$451,754,000	$502,885,000	$545,181,000
Obligations	(434,236,000)	(486,621,000)	---	---	---
Saint Elizabeths Hospital: 3/					
Budget Authority	49,673,000	57,002,000	68,835,000	74,171,000	75,824,000
Obligations	(71,382,000)	(77,081,000)	(87,558,000)	(95,595,000)	(98,792,000)
Total, ADAMHA:					
Budget Authority	467,696,000	425,112,000	520,589,000	577,056,000	621,005,000
Obligations	(505,618,000)	(563,702,000)	(87,558,000)	(95,595,000)	(98,792,000)
Office of Human Development:					
Rehabilitation Services Administration:					
Basic State Grants	161,160,000	164,951,000	174,713,000	178,711,000	183,797,000
Innovations and Expansion	5,214,000	3,893,000	4,012,000	3,995,000	4,399,000
Special Projects	---	---	112,700	426,000	687,000
Research	---	---	300,000	330,000	363,000
Special Foreign Currency Program	---	---	149,000	---	450,000
Training	175,000	175,000	194,585	275,000	275,000
Total, RSA	166,549,000	169,019,000	179,481,285	183,737,000	189,971,000
TOTAL	$634,245,000	$594,131,000	$700,070,285	$760,793,000	$810,976,000

1/ Includes $16,213,000 in FY 1973 court released funds.
2/ Includes $118,511,000 in FY 1973 court released funds.
3/ Parenthetical amounts denote total obligations including reimbursements for patient care.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health

GENERAL MENTAL HEALTH

Almost all Americans are touched by the problems of mental illness, either personally, or through friends or relatives. Direct care for mental illness now costs the American people approximately $15 billion annually. The total cost of mental illness within the United States, including indirect costs for disability, loss of productivity while under treatment, and death, was conservatively estimated at $36.8 billion for 1974. Since this estimate does not take into account losses due to underemployment of the untreated mentally ill, this figure tells only the partial story of the real economic cost.

In terms other than economic, the cost of mental illness is incalculable. During 1977 approximately 6.7 million Americans, or 3.7 percent of the population, encountered one or more epidsodes of care for a mental illness, either in an organized mental health care setting or in the office of a private practitioner. An additional 18 million Americans will seek services in the general medical sector. Current estimates are that at least 15 percent of the population, or 32 million persons per year, will have a mental disorder that may require some type of mental health services.

Federal leadership in the effort to reduce the toll of mental illness has been placed with the NIMH, which has the Congressional mandate for the planning, direction and coordination of Federal efforts in the areas of research, training and services. Among the major problem areas addressed by the NIMH are the following:

1. Mental Health of the aged: 5 percent of the Nation's aged live in institutions. Of these about 12 percent are in mental hospitals, with the remainder in nursing and other types of homes for the aged and chronically ill. The elderly comprise 7 percent of additions to State and county mental hospitals, and 28 percent of the resident patients. Approximately 80 percent of patients aged 65 and older who live in nursing and personal care homes have some degree of mental impairment. Only 3.8 percent of outpatient psychiatric service admissions are aged 65 and over. An estimated 10-25 percent of the aged in the community have some degree of mental impairment. The death rate for suicide among the elderly is highest at age 55 and over (19.9 per 100,000 as compared with 12.7 per 100,000 for all ages). Approximately 44 percent of all male additions to inpatient services of State and county mental hospitals with primary diagnosis of alcohol disorder are aged 55 and over. NIMH conducts studies relevant to the mental health of the aging including projects which deal with the etiology, diagnosis, and treatment of mental disorders; the development and delivery of mental health services; and the prevention of mental disease. The Institute's goals are carried out through grants and technical assistance, directed toward stimulating and encouraging (a) research into areas in which knowledge is needed; (b) incorporation of mental health consideration in programs for aging in which mental health

components have been neglected; (c) development and evaluation of innovative programs for the delivery of mental health services to the aged; and (d) development and dissemination of information about mental health of the aging.

2. Mental Health of children: Approximately one-third of the total U.S. population, or 70,220,000 people, are under 18 years of age. It has been estimated that 10 percent of this group, or some 7,000,000, is in need of psychiatric services, and that some 90 percent of that group, or 6.3 million, have unmet mental health needs. Approximately 6% of all admissions to state and county mental hospitals are young persons under 18 years of age. The suicide rate among young people has been growing since 1950. In 1964, it ranked fourth as the major cause of death among the age group 15 - 24. Between 1962 and 1975, there has been almost a doubling of the suicide rate. The NIMH is addressing this problem through its combined efforts of research, training and services. Studies are underway dealing with the biological, behavioral, and socio-cultural aspects of the major mental illnesses among children. Work is also being undertaken with respect to the major behavior disorders, and the mental health dimensions of dyslexia and learning disorders. The institute is creating opportunities for work across disciplinary lines, and promoting research training in areas relating to child mental health. NIMH is actively promoting public mental health education, seen as a primary prevention device, especially in the psychosocial dimension of severe mental illness, chronic physical illness, learning disorders, child abuse, and child an adolescent development. The requirement and provision for consultation and education services by the Community Mental Health Centers under Public Law 94-63 gives NIMH the opportunity to further extend its primary and secondary prevention activities through the CMHC program.

3. Crime and delinquency: Serious crime in the United States increased by 37 percent in the period 1972-1976, while population increased by only 3 percent. Violent crimes increased by 18 percent, and property crimes by 39 percent. The murder rate decreased by two percent since 1972, but the rates for aggravated assault and forcible rape increased by 21 percent. During the same five-year period, arrests of juveniles for violent crimes increased by 28 percent. Risk of becoming a victim of serious crime increased by 33 percent. The annual cost of crime is estimated in excess of $35 billion a year. The focal point for NIMH activities related to these problems is the Center for Studies of Crime and Delinquency which seeks to develop improved means of understanding and coping with problems of mental health reflected in criminal, delinquent, and violent behaviors -- and in the effects of such behaviors on victims. The Center also develops and evaluates new types of community-based treatment and rehabilitation programs as alternatives to institutionalization of offenders. Critical issues in the area of law and mental health interaction -- e.g., competency of offenders to stand trial,

"dangerousness" as a ground for involuntary commitment, right to treatment -- are another Center concern. The Center's program is conducted primarily through the means of research grants which are awarded on a competitive basis to applicants. Training grants are also awarded to develop and test new educational models for researchers and practitioners in the crime and delinquency field. The NIMH Director serves on an advisory council for the National Institute for Law Enforcement and Criminal Justice (LEAA).

4. Depression: Depressive illnesses are the second leading cause of hospital admissions for psychiatric care in the United States. Of approximately one million hospital admissions, roughly 294,000 represent depressive illness. This proportion (28 percent) was about the same as that for schizophrenia (27 percent) and surpassed that for alcoholism. The great majority of people suffering from depressive illness are not admitted to a hospital, but rather they are treated as out-patients. As a result, the foregoing statistics must be regarded as extremely conservative. Rough estimates of the prevalence of depressive illness point to a rate of between 2 - 4 percent of the population or 4 - 8 million Americans. It is further estimated that one out of five who are clinically depressed receive treatment, one of fifty is hospitalized, and about one in two hundred depressed persons commit suicide. A recent survey indicates that during any given year, 15 percent of all adults between the ages of 18 and 74 may suffer significant symptoms of depression. Unlike most categories of mental illness, the depressive illnesses may be fatal. Suicide, with an official mortality rate of 11.9 percent accounts for over 24,000 recorded deaths per year in the United States. It is the eleventh leading cause of death and the fifth leading cause of death among the most potentially productive members of our society (ages 25 - 44). Due to the stigma often associated with suicidal deaths, these figures are regarded as under-estimates. The current major NIMH research emphasis in the depressive illnesses is focused on psychobiology, in an attempt to elucidate the basic physiological derangement underlying the abnormal behavior which is recognized as depression. Genetic studies are undertaken to understand the family aspects of some depressive illnesses, and suicide studies are aimed at clarifying this tragic outcome of depression for some. Programs in psychopharmacology address the issue of discovering newer and more effective modalities of drug treatment. Psychotherapeutic studies are seeking to discover treatments for the milder forms of depression.

5. Minority mental health: Approximately 39 million Americans are members of ethnic and racial minority groups (one person out of 5). Of this total 24.1 million are Blacks, 11.1 million are Hispanics; 1.2 million are American Indians and Alaskan Natives; and 2.5 million are Asian Americans.

Of the 3.3 million people admitted to State and county mental health facilities, 17 percent were non-white admissions. This is a rate of 2,010 per 100 thousand population, as opposed to 1,523 per 100 thousand for

Whites. The non-white admission rate is 32 percent higher than that for Whites.

The NIMH Center for Minority Group Mental Health Programs was established to increase the Institute's response and capabilities to meet the special mental health needs of minority groups. The Center focuses on mental health problems of 4 groups: Blacks, Hispanics, American Indians and Alaskan Natives, and Asian American. A multidisciplinary staff with minority group membership provides consultation on research, training, services, contracts and grants procedures. The review committee of the Minority Center is interdisciplinary and has representation from the four minority groups specified above. Currently six Research and Development centers are funded by the Center which include: 2 centers for Blacks; 2 centers for Hispanics; 1 center for American Indians and Alaskan Natives; and 1 center for Asian Americans. During FY 1977, three Institute-wide Minority Research Workshops were convened focused on 1) Clinical and Behavioral problems and 2) Social and Behavioral Problems among minority group populations.

6. Schizophrenia: It is estimated that at least 2 percent of persons born in 1960 will have an episode of schizophrenia some time during their life time. The affliction strikes hardest at those in the most productive years of life. Of the total schizophrenic additions to State and county mental hospitals in 1975, 51 percent were between the ages of 25 and 44, and an additional 23 percent were persons less than 25 years of age. Although the number of hospitalized schizophrenics continues to decline, half of the beds of mental hospitals throughout the Nation are occupied by schizophrenics - a number which has approximated 93,000 in State and county mental hospitals. Current NIMH efforts in schizophrenia involve a diverse, in-depth examination of the many components of the disorder. Because of the difficulties engendered by the lack of a reliable,valid and widely applied diagnostic system for research in schizophrenia, much recent work in this area has attempted to address these diagnostic difficulties. Current research in schizophrenia is also focused on several key questions, including what can be predicted, based on current data, about the rate of occurrence of schizophrenia over the next decade. Based on these predictions, the Institute addresses the problem of what kinds of facilities should be planned; what effect has the community orientation in treatment had on patterns of facility used; and what is the true population prevalence of schizophrenia. Despite the impressive data that have recently accumulated from a variety of genetic studies, the basic questions of genetic transmission remain unresolved. Current studies suggest a genetic predisposition to schzophrenia, but at the same time make clear that genes alone are insufficient to produce schizophrenia. This suggestion, in turn, has generated new interest of studies of genes - environment interactions. Basic neuroscience studies have contributed greatly to the understanding of the neural mechanism underlying normal and abnormal functioning of the human brain. Applica-

tion of rapidly developing technology from the basic sciences to clinical populations may soon permit testing of current and newly developing biological hypotheses of schizophrenia. The NIMH is also addressing the problem of schizophrenia through research in the areas of psychological functioning, studies of high-risk population, childhood schizophrenia and autism, and the family.

Research

The problem areas described in the preceding material are dealt with through the combined efforts of research, training, and services. The operating programs within each of these activities are described in the material which follows:

1. Intramural Research: The NIMH Intramural Research Program consists of three Divisions, two of them located on the campus of the National Institutes of Health (and at the NIH Animal Center in Poolesville, Maryland), and a third at St. Elizabeths Hospital. The major operating unit in the Intramural Research Program is the laboratory or branch, of which there are now seventeen. The Program endeavors to study those problems in psychiatry, the neurosciences, chemistry, pharmacology, and the behavioral sciences that are important for its categorical mission and that can be effectively attacked in the special facilities provided by the NIH biomedical complex. Within these disciplines the best criterion for choice of problem is long-term relevance to mental health. More specifically, the Program includes clinical studies and basic research in a mix that varies some from time to time. Currently it is about 70% basic and 30% clinical or applied.

The research program of the seventeen laboratories and branches can be analyzed as to the subject matter of the research into the following broad categories: neurosciences, behavioral sciences, biochemistry and pharmacology, and psychiatry. Though all such classifications are approximate, a useful estimate of IRP program content is given by the fact that 19% of salaried staff members work in the neurosciences, 16% in the behavioral sciences, 29% in biochemistry and pharmacology, and 36% in psychiatry. Research in psychiatry is both basic and clinical.

Currently the Program employs approximately 370 full-time permanent employees. If projected plans are realized, 40 employees will be added in FY 1979 to study the mental health problems associated with aging.

2. Extramural research: The Institute's extramural research programs are both process and problem oriented. Among the research categories receiving support are the following:

a. Behavioral sciences: This program supports research in the broad areas of personality and cognition, experimental psychology, neuropsychology, and social sciences.

In the areas of personality and cognition; research is supported on human personality structure and development, cognition, intelligence and higher mental processes, including learning and language disabilities, human motivation, relationship of personality to perception and learning, emotional processes, attitudes, values, problem-solving, thinking, and creativity.

Experimental psychology programs are supported, which deal with basic studies of animal and human behavior in areas of learning, conditioning, memory, perceptual and sensorimotor processes, comparative and physiological psychology, behavioral genetics and animal ethology.

Research is supported in neuropsychology, psychobiology, and psychophysiology with emphasis on the relationship of behavior to the central nervous system including both the effect of behavioral change on central nervous system function and the effect of change in the central nervous system on behavior.

Social sciences research support is provided for projects with mental health relevance in anthropology, sociology, and social psychology in such areas as culture and personality, cross-cultural factors, social perception and attitudes, socialization, sex role behavior, social structure and dynamics, social change, family studies, and group processes.

b. Psychopharmacology: In the preclinical area, support is provided for studies of the sites and mechanisms of action of psychoactive drugs, research on biochemical processes and mechanisms related to drug action and the etiology of mental disorders. Under this rubric are projects in physiology, biochemical pharmacology, neuropharmacology, drug metabolism, and related fields. Included are studies on drug development and synthesis, toxicology, and pharmacogenetics. Projects also involve the synthesis of chemicals needed in research. Work is supported to develop better methods of drug screening to provide psychotropic compounds or assays of psychotropic compounds and metabolites needed in research on drugs which seem potentially of value in therapy.

In the clinical areas, studies evaluating the efficacy and safety of drug treatments in a variety of psychiatric patient populations are supported. These include the early testing of drugs for preliminary indications of safety and efficacy, as well as controlled studies evaluating drug efficacy in comparison with placebo, other standard drugs, or other psychiatric therapies. Also supported are long-term studies of drug maintenance as well as prediction studies of differential response to drug therapy. Patient populations both inpatient and outpatient, include schizophrenics, depressives, neurotics, patients with character disorders, and patients with psychiatric disorders of childhood or advanced age.

c. Applied research: In the area of juvenile mental health, the range of concern extends from the impact of experience in infancy to

problems of college stress, and includes studies of various milieu, e.g., home, school, day care, and of relationships, e.g., familial, peer. Research on intellectual stimulation and cultural enrichment procedures for children, early identification and intervention techniques with emotionally disturbed children, and the myriad problems of adolescence and young adulthood are also topics of interest. The social problems area is concerned with the nature of the nuclear family, including such phenomena as trends in marriage patterns and impact of divorce. Studies are also supported on changing roles of men and women, generational differences, aging, sexuality including sexual dysfunction, mobility, and occupational stress.

d. Clinical research: Schizophrenia and depression are core problem areas of clinical research. A broad-based program of psychiatric, psychological, biological, and sociocultural studies is supported on the two major mental illnesses. Special emphasis is placed on studies of the biological, psychosocial, and clinical aspects of the depressive disorders through collaborative research with several major clinical centers and investigators. Other disorders studied include organic brain syndromes, psychoses (including autism), neuroses, psychosomatic and psychophysiological disorders, and character and personality disorders. In addition to research on normal and clinical populations, research with animals (e.g., animal analogs of clinical phenomena) is also supported by the program. The development and evaluation of psychological and social approaches to the treatment and rehabilitation of mental disorders and also methods and procedures for the description measurement and classification of these disorders are central goals.

e. Clinical research centers: Full scale and "developmental" Clinical Research Centers were initiated in 1977 to foster and expand current biological research on the nature, mechanisms and etiology of various mental disorders, further develop the knowledge base of psychological and social influences on the etiology and treatment of mental disorders and to stimulate research and research training in highly critical, but neglected areas, e.g., childhood psychoses, social rehabilitation of schizophrenics, the severe neuroses. Clinical and community-based research environments are expected to enhance the opportunity for excellence in research productivity where scientists and clinicians interact in an effort to solve problems of classification, etiology, psychosocial and/or psychopharmacologic treatment and prevention of severe mental disorders. Gradual development of these Centers through the provision of stable support for multidisciplinary integrative research is to allow the emergence of some 8 to 12 regional or national resource laboratories, each uniquely prepared to deal with specific areas of mental health concern.

f. Minority mental health: The minority mental health program serves as the focal point for institute activities which bear directly on improving the mental health of minority groups, and on increasing the number and competence of minority group members engaged in mental health

projects. This program supports research designed to increase knowledge of minority group cultures, their relationships to other groups and the particular mental health problems associated with these cultures.

g. Metropolitan mental health: The Metropolitan mental health program deals with the impact of urban life on human well-being and mental health, emphasizing contemporary social issues and the relationship of urban social structure to individual family and community functioning. This program identifies, analysizes and evaluates current research and related program developments in the metropolitan mental health area, directing this information to citizens, administrators, and policy makers as an aid for assessment of local program needs.

h. Crime and Delinquency: The crime and delinquency program analysizes and evaluates current research and related program developments relating to the mental health aspects of criminal, delinquent, and individual violent behavior.

i. Services research and development: Mental health services research and development is directed toward the continued improvement of the effectiveness and efficiency of services delivery. The goal is achieved through assessing problems; analyzing and synthesizing already available knowledge not fully used; planning and supporting research studies to provide needed knowledge; and fostering the diffusion and utilization of research knowledge through specific programs of technical assistance.

j. Epidemiology: The Division of Biometry and Epidemiology conducts research on the operation of the mental health system in the United States; including research on the efficiency, effectiveness, cost and staffing of speciality mental health settings and the provision of mental health care in primary care/general medical sector. This program also supports research and demonstrations pertaining to determining the scope of mental disorders in the population and the distribution of mental disorders in different population groups. This program supports the public health research approach to mental illness. It contributes to improved methods which enable us to determine the scope of mental disorders in different population groups and the factors associated with that distribution. Of major concern are the causes of new emotional problems and conditions affecting their early detection and appropriate treatment. This grant program has overall responsibility for development of mental health statistics at the national level.

k. Research Scientist Development: The research scientist development program is designed for the support of research investigators working on mental health problems. Its function is to stabilize careers of research scientists and to ensure continuity of effort in research programs. Research Scientist Development Awards are made for 5-year periods, and may be renewed for one second term, following competitive review. Two types of awards are made, one for persons with research

potential but who require experience in a research environment, another for those who are functioning as independent investigators but who need additional research experience to realize their full potential. Research Scientist Awards support more senior scientists who are well qualified to conduct research independently and make significant contributions to the research programs of their sponsoring institutions. These awards are also made for a 5-year period and may be renewed for up to two additional 5-year terms, with competitive review.

The 1979 budget will reflect on increase in total research effort, in accordance with the recommendations of the President's Commission on Mental Health, in its preliminary report of September 1, 1977. The preliminary report of the President's Commission points out two major trends affecting mental health research funding. First, despite some increase in total dollars appropriated since 1969, inflation has caused a decrease in buying power. Second, other health research and general Federal research and development funds have increased substantially. In order to remedy the imbalance, the President's Commission recommended a 1979 research budget increase of approximately 20 percent over the current base. The increases requested in 1979 fall into the four broad categories of Mental Disorders and Maladaptive Behavior; Basic Biological and Developmental Studies; Social and Cultural Issues and Problems; and Mental Health Services Research.

Training and Manpower Development

The purposes of the training and manpower development activity are to train personnel for clinical service and for research, to support research and development related to mental health manpower, and to assist State and sub-State entities to increase their capacity for manpower planning and development.

1. Basic mental health education: Since 1948, NIMH has provided grant support for training in the four core disciplines of psychiatry, psychology, nursing, and social work. The purpose of the program has been to promote the quality and adequacy of mental health professional education, in order to meet the need for mental health services. Efforts have been made to strengthen the educational capability in the core discipline fields, foster experimental and innovative approaches to the problems of professional education and manpower planning, and promote special projects dealing with educational standards and curriculum development. Funds requested will make it possible to maintain the capacity of training and educational institutions to continue producing mental health professionals in the core disciplines of psychiatry, psychology, social work, and psychiatric nursing. Projects funded will be expected to (1) interact or collaborate with training institutions and service delivery authorities to identify and support the need for the kind of manpower to be developed; (2) be specifically targeted to service priorities; and (3) include explicit, systematic plans for evaluating the outcome of program objectives. In addition, the Institute will be implementing its new services manpower initiatives.

2. NIMH services manpower initiatives: During the current year, the National Institute of Mental Health is further implementing the redirection of its clinical or services training programs. Mental Health education programs have been refocused to emphasize the preparation of professional and paraprofessional mental health personnel for practice in targeted areas of service need: underserved geographic areas; underserved populations such as minorities, the aged, and children; and understaffed public clinical facilities such as community mental health centers, State mental hospitals, correctional institutions, etc. Increased attention is being given mental health education of primary health care providers.

In accordance with the preliminary recommendations of the President's Commission on Mental Health, 1979 funding for clinical training activities will be maintained at the 1978 level. This will make possible the continuation of the Institute's redirected efforts in the areas of services manpower development and core discipline training.

3. Mental health research training: This program provides funds to train personnel for research in the field of mental health through grants to institutions and fellowships to individuals under the National Re-

search Service Award Act. Research training is supported in areas identified by an ongoing, annually reported study of national needs conducted by the National Academy of Sciences, which also recommends the numbers of trainees and levels of support (pre- or postdoctoral) needed. The proposed budget would support 77 new institutional awards and 204 new fellowships. Additional programs started at the predoctoral level will emphasize the support of minority researchers in the social and behavioral sciences while, at the same time, continuing the Institute's general trend toward more postdoctoral awards.

Services

Funds provided under this activity heading are used for the improvement of the organization, allocation, and delivery of mental health services. In 1977, the Public Health Service Act (P.L. 94-63) was amended by P.L. 95-83 and is the primary mechanism for Federal support of community mental health services. Title III extends and amends the Community Mental Health Centers Act, and Title I requires plans to eliminate inappropriate institutionalization of the mentally ill, and to improve the quality of care for those who do require institutionalization. Together, the two Titles spell out a long-range strategy for Federal, State, and local efforts to meet the entire range of mental health service needs. P.L. 94-63, as amended by P.L. 95-83, strengthens the Community Mental Health Centers Program in a number of respects, and continues six grant mechanisms, which are discussed in the material which follows. In addition, the National Institute of Mental Health continues to provide support for those staffing and child mental health grant projects initiated prior to the new legislation. Grants are authorized under various provisions of the Community Mental Health Centers Act as follows:

1. Programs under P.L. 94-63:

a. Planning: Section 202 authorized funds for grants designed to (a) assess need for services; (b) design a center based upon such an assessment; (c) assemble financial and professional assistance and support for the proposed center program; and (d) initiate and encourage continuing community involvement in development and operation of the program.

b. Operations: Section 203 authorized appropriations to finance the cost of operations grants. This authority replaced staffing support under the old Community Mental Health Centers (CMHC) Act.

c. Conversion: Under Section 205, funds are authorized to enable centers to meet additional costs associated with converting existing centers to add services to the elderly, children, alcoholics, and drug abusers; assisting courts in screening residents recommended for referral to State mental hospitals; follow-up services; and transitional halfway house services.

d. Consultation and Education: Separate grants are authorized (Section 204) to provide consultation and education services to centers which have completed four years of Federal support, and to entities which meet the definition of a community mental health center.

e. Distress: Section 213 authorizes financial distress grants to centers terminating final Federal staffing support if, without this support, there will result an inability to provide, or a significant reduction in, the types or quality of services required under the new Act.

f. Facilities Assistance: These grants are authorized to enable a center to acquire new facilities or remodel the existing plant. Also included are authorities to lease, construct, and initially equip such facilities.

2. Old Legislation: Funds provided under this category are used to provide continuation support for CMHC staffing and child mental health grants awarded prior to June 30, 1975, and which have not changed to support under the new authority, 203d. The authority to continue these awards is in Section 203e.

NIMH Efforts

In 1974 the NIMH Division of Mental Health Service Programs began a concerted effort to develop policies and programs relative to services to the chronically ill. While long-term care is to be avoided wherever possible, the practice of unrestricted deinstitutionalization without regard to the availability of appropriate alternative facilities is at least equally undesirable.

NIMH sponsored a series of working conferences to obtain and synthesize advice from a broad range of leaders from State and local agencies, universities, citizen and consumer advocate groups, other Federal agencies, and national organizations concerning both policy and program development strategies in the area of deinstitutionalization. Through this conference series, a consensus has emerged to shape NIMH policy along the following lines. First, deinstitutionalization is no

longer seen as a goal in itself, but rather a complex phenomenon which happens for a combination of reasons. This phenomenon calls for better coordinated efforts among agencies at all levels of government if it is to be a viable alternative to long-term care, and benefit the individuals involved. Second, NIMH is now focusing attention on development of comprehensive community support systems for persons with mental disabilities. Components and guiding principles for such systems have been conceptualized, defined, and validated in the conference series. Third, a consensus has emerged on the necessity for mental health agencies at Federal, State and local levels to play a leadership role in working with human service agencies such as housing, social services, vocational rehabilitation and others to assure that mentally disabled clients returned to the community have access to, and receive, services appropriate to their needs.

Based on these assumptions, NIMH initiated in late FY 1977 and early FY 1978 a pilot program -- the Community Support Program (CSP) designed to stimulate States and communities in developing and improving opportunities for the chronically mentally disabled. CSP is supported through a reprogramming of funds previously allocated to the Hospital Improvement and Hospital Staff Development Programs.

CSP operates through contracts (not grants) with State mental health agencies, and sub-contracts to a variety of local agencies. Pilot projects have been initiated in 16 States. The projects are designed to try out and evaluate a wide variety of administrative arrangements for organizing and funding "comprehensive community support systems," making maximal use of State mental health funding and the resources of numerous Federal, State and local non-categorical "mainstream" programs such as vocational rehabilitation, housing, employment, Supplemental Security Income, social services and others.

In the first year of the pilot program, it has been possible to establish focal points of responsibility in 16 States; to identify and develop more than a dozen local "models" of a community support system; to establish a communication network among responsible program planners and policy makers at Federal, State and local levels; to identify a number of Federal policy obstacles to appropriate community care and channel this information into the HEW "Deinstitutionalization" Task Force; to begin establishing a baseline of information on the costs and distributions of costs among agencies cooperating in serving the mentally disabled in the community. An evaluation of the program has been initiated, to document the implications for policy and practice at Federal, State and local levels.

An adjunct to the CSP pilot projects is an intensified effort by NIMH to collaborate with other Federal agencies involved in community programs for the mentally disabled. A cooperative agreement has been developed with the Rehabilitation Services Administration, which led to planning for a number of joint initiatives for research, training and

services development. Informal collaboration continues with the Department of Housing and Urban Development, and it has been possible to remove barriers to inclusion of the mentally ill in HUD programs, to develop new opportunities, and to develop a technical assistance manual for agencies serving the mentally disabled. Collaborative efforts with ACTION and Labor are in the early stages of exploration.

The Development and Implementation of Standards

NIMH has actively engaged in the past three years in activities associated with the development and/or implementation of standards for psychiatric facilities. Most recent activities encompass the following areas:

1. Community Mental Health Centers:

a. Since 1974 the NIMH has supported the development of CMHC standards under contract to Joint Commission on Accreditation of Hospitals (JCAH). In 1976 the standards were published and subsequently, JCAH has been field testing their standards in CMHCs.

b. National standards for CMHCs were developed by NIMH and submitted in a Report to Congress, January, 1977.

In addition, Grants for Community Mental Health Centers Proposed Implementation was published in the Federal Register on Tuesday, November 2, 1977. It outlines the special requirements for CMHCs under Section 201 and 206 of P.L. 94-63.

2. Psychiatric Hospitals: Since 1970, under contractual agreement with Bureau of Quality Assurance and Standards, Health Care Financing Administration (HCFA), NIMH has provided technical assistance to Regional Offices/HCFA and State Medicare agencies through the utilization of NIMH consultant teams to survey psychiatric hospitals (upon request of the State agency) for the determination of compliance with the Medicare standards for psychiatric hospitals (Two Special Conditions of Participation).

3. Other Activities:

a. Completion of a contract with SREB on "Standard Setting and the Law." Monograph will be forthcoming.

b. Under contract with SREB, NIMH has published three publications entitled: "Applying State Mental Health Standards: Management Uses," "Setting and Monitoring Standards in a State Mental Health Agency," and "State Mental Health Standards: How To Do It."

c. NIMH continues to work with HCFA on the revision of Medicare standards for "Psychiatric Facilities" and "Inpatient Psychiatric Units of General Hospitals."

Development of Quality Assurance Systems

A variety of efforts have been undertaken by NIMH to ensure a high level of quality in CMHCs. Major areas of activity are briefly outlined below:

1. To fulfill requirements of CMHC amendments of 1975 that CMHCs establish an ongoing quality assurance program, program guidelines have been prepared by NIMH, along with a manual, "Assessing and Assuring Quality in Community Mental Health Centers" in 1976.

2. Program guidelines to evaluate the effectiveness of CMHC services (under the A.D. Little contract) have been developed and a manual on CMHC evaluation has been completed.

3. Ongoing efforts in terms of NIMH acquainting CMHCs with PSROs and relationships continue with the designated Federal PSRO agency. Contract effort will be forthcoming in FY 1978 on the "Development of a Model Relationship Among A PSRO Organization, A CMHC and Non-Physician Mental Health Care Practitioners." Its focus will be to determine the feasibility of establishing the essential elements of a prototype working relationship for the three areas outlined above.

4. Through site visits from Regional NIMH offices, with assistance from Central Office NIMH staff, CMHC programs are being monitored to determine their compliance with P.L. 94-63 and its regulations, and the NIMH policies and requirements. The CMHC monitoring package was approved by OMB and was published August, 1977. FY 1978 will witness an increased and concerted effort by NIMH in this activity.

In addition NIMH continues to engage in activites related to the development and implementation of standards for CMHCs which include activities related to Quality Assessment and Quality Assurance.

Special Institute Efforts

The NIMH is organized to deal with a variety of current social problems having mental health implications, and to provide support activities having general application to the total mental health field. Among these programs and activities are the following:

1. National Center for the Prevention and Control of Rape: Part D, Title III of P.L. 94-63 authorized the establishment in NIMH of a National Center for the Prevention and Control of Rape. The Center is mandated to conduct a continuing study of rape, including investigation of the following:

a. The effectiveness of existing Federal, State, and local laws dealing with rape;

b. The relationship, if any, between traditional legal and social attitudes toward sexual roles, the act of rape, and the formulation of laws dealing with rape;

c. The treatment of victims of rape by law enforcement agencies, hospitals or other medical institutions, prosecutors, and the courts;

d. The causes of rape, identifying social conditions which encourages sexual attacks, and the motives of offenders;

e. The impact of rape on the victim and family of the victim;

f. Sexual assaults in correctional institutions;

g. The actual incidents of forcible rape as compared to the reported incidents of forcible rape and the reasons for any differences;

h. The effectiveness of existing private and local programs designed to prevent and control rape.

The Center is responsible for compilation, analyses and publication of summaries of the continuing studies enumerated above, and for support of research and demonstration projects. The Center is also charged with the responsibility to develop and maintain an information clearinghouse dealing with the subject of rape prevention and control, and for the compilation and publication of training materials for personnel who are engaged or intend to engage in programs for rape prevention and control. The Center also gives assistance to Community Mental Health Centers and other entities in conducting research and demonstration projects in this field, and provides assistance to Community Mental Health Centers in meeting and promoting community awareness of specific locations in which sexual attacks are most likely to occur.

2. Center for Studies of Mental Health of the Aging: The NIMH Center for Studies of Mental Health of the Aging was established in August 1975. Although the mental health of the elderly has long been an NIMH priority, it was given additional emphasis with enactment of Public Law 94-63, which directed the Secretary of Health, Education, and Welfare to appoint a committee on mental health and illness of the elderly. The Center has been actively involved in the establishment of this committee. The Center on Aging also coordinates research, training, and services for the prevention and treatment of mental illness among this group of citizens. Since persons 65 years of age and older now constitutes approximately 10 percent of the population and display the highest incidence of new cases of psychopathology, it follows that a significant portion of the NIMH effort should be directed toward their problems and needs. The Center closely coordinates its activities with the National Institute on Aging, NIH.

3. Disaster Assistance: The Disaster Relief Act of 1974 (P.L. 93-288) recognizes a Federal responsibility toward mental health problems associated with disasters. Staff of the NIMH Division of Special Mental Health Programs are made available to provide counseling and technical assistance to communities which have experienced major disasters. Contract funds for post-disaster counseling services and training of crisis personnel are also available through Section 413 of the Act.

4. Center for Studies of Child and Family Mental Health: The NIMH Center for Studies of Child and Family Mental Health plans and administers special research and demonstration programs in child, youth, and family mental health such as child advocacy, runaway youth, and child abuse. The Center coordinates these programs with other Federal, State, and local agencies and organizations, and provides related technical assistance. This organization also analysizes and evaluates current research and program development in child and family mental health.

5. National Clearinghouse for Mental Health Information: The National Clearinghouse for Mental Health Information (NCMHI) collects scientific, technical and other information on mental illness and health from sources outside the Institute, including international, national, State and local agencies, and private, professional, and lay organizations. The NCMHI classifies, stores and retrieves data for dissemination to the biomedical community, and to private and lay organizations, as well as other components of Government. NCMHI also responds to public inquiries by abstracting appropriate information from available literature, transmitting publications, or providing syntheses of available information.

Accomplishments and Objectives

Research

A total of 556 new and competing awards will be funded during 1978. Areas of study included rape prevention and control; services development; depression; schizophrenia; minority and metropolitan mental health problems; and female crime and delinquency. The intramural program addressed problems of schizophrenia and depression at the more basic level, and examined drug treatment of hyperkinetic children. The latter effort sought to develop methods of more accurately gauging optimum dosage levels for individual children.

A total of 829 new and competing awards will be supported in 1979. The NIMH will move forward with collaborative research on psychological, psychosocial, and cultural factors which influence the development and cause of depression, as well as research into the causes and prevention of rape. Programs of basic psychological, biomedical, and genetic research into the causes of schizophrenia will be continued. Child mental health research will be directed toward studies of hyperkinetic disorders, mental health dimensions of learning disorders, and problems of early adolescents. Intramural research efforts will address the development of treatment for mental disorders of children, and will attempt to develop an early diagnosis and treatment procedure for potential depressives.

Training

In 1978, a total of 272 new and competing clinical training grants will be awarded, along with 17 research training institutional awards, and 130 fellowships. NIMH has implemented a redirection of the clinical training program, with the objectives of linking the training of mental health manpower more closely with service delivery needs by (1) improving the psychosocial and psychiatric components of curriculum for primary caretakers; (2) moving toward a research and development model which emphasizes short-term Federal invovlement; and (3) providing technical assistance to States, to help them develop capacities in the areas of manpower planning, training, and administration.

In 1979, within the same dollar total, 270 new and competing clinical training awards will be made. In the area of research training, the NIMH will make approximately 77 new institutional awards, and support 204 fellowships.

Services

Accomplishments in 1978: The 1978 appropriation will support a total of 73 new awards, including 43 operations grants, 26 conversions, and 4 distress grants. The CMHC program in total has supported 704 centers. Of this total, 647 will be operational by the end of FY 1978,

and approximately 2.3 million patients will be treated during this year.

Objectives for 1978: No new awards will be made under this program in 1978. Funds are requested to support continuation costs of awards made through September 30, 1977.

The FY 1979 budget allows for meeting all continuation costs and providing Federal support to assist all centers funded in 1979 to meet currently mandated service requirements through converted staffing or conversion awards. There is no prohibition against making new awards if they can be made within the current budget level. To the degree that funds become available and eligible centers use non-Federal funds to provide mandated services, NIMH will support new centers.

Community Support

As the previous Hospital Improvement and Hospital Staff Development programs are gradually phased out, the funds released will be applied to the Community Support Program (CSP). The FY 1979 budget maintains the CSP at the 1978 dollar level.

Saint Elizabeths Hospital

The National Institute of Mental Health has responsibility for the operation of Saint Elizabeths Hospital, which provides mental health treatment, care and rehabilitation services for approximately 2,200 inpatients and 3,100 outpatients. The Hospital operates a security treatment facility and a community mental health center which serves District of Columbia residents in the Southeast quadrant of the city. Saint Elizabeths also conducts a clinical research program, and provides multidisciplinary clinical training for professional and related personnel.

The Administration has made a major change in policy regarding the transfer of Saint Elizabeths Hospital. In light of the fact the District of Columbia will not accept a disaccredited Hospital supplemental funds will be requested for renovation of the Hospital and to upgrade patient care. With the appropriation of these funds, and the development of plans for the outplacement of medical domiciliaries patients, it is expected that the Hospital will be reaccredited. It is anticipated that an accredited Hospital providing high quality patient care can then be transferred to the District.

The Hospital will treat an estimated 9,489 patients during 1979. A total of 4,000 is expected to be admitted, and a total of 4,000 is expected to be discharged from the rolls. In terms of daily averages, the inpatient load is expected to average 2,200, in addition to an outpatient load of 3,100.

OFFICE OF HUMAN DEVELOPMENT SERVICES

Rehabilitation Services Administration

GENERAL MENTAL HEALTH

It is estimated that there are about 20 million people in the United States suffering from some form of mental illness who could benefit from psychiatric treatment. On any one day, approximately 760,000 of these people are patients in mental hospitals or psychiatric wards of general hospitals. The magnitude of the problem is also reflected in statistics for the State-Federal program of vocational rehabilitation, which indicate that about one quarter of the total number of disabled people rehabilitated by the State rehabilitation agencies have a mental or emotional disorder as their primary impairment. In FY 1979, an estimated 61,600 people in these disability categories will be rehabilitated. With the mandate in the Rehabilitation Act of 1973 to afford service priority to the severely disabled, State rehabilitation agencies are directing their attention increasingly to people with severely-incapacitating psychiatric conditions, particularly those in the psychotic and neurotic diagnostic groups.

The Community Mental Health Center Amendments of 1975 stress the need for providing community support services, as well as treatment resources, for people with severe mental illness. Since these Amendments were passed, the Rehabilitation Services Administration has been represented on a Community Support Work Group established by the National Institute of Mental Health to identify roles and responsibilities of the various agencies participating in the development of support-service programs for the mentally ill. A formal Statement of Principles of Cooperation between NIMH and RSA is expected to serve as a basis for fostering closer working relationships among State rehabilitation agencies, community mental health centers, and institutions for the mentally ill. Activities with NIMH are expected to continue at a high level.

The Innovation and Expansion Grant program authorized by Sections 120-121 of the Rehabilitation Act of 1973 has proven a useful resource in developing programs to meet the multiple rehabilitation needs of people with severe mental illness. Initiated by State rehabilitation agencies, projects under this authority often involve cooperative programming with community mental health centers, institutions, and other components of the mental health system. A project at the San Pedro Residential Center, California, for example, serves a population of the chronically mentally ill who are not only unready for competitive employment but also educationally deprived and disadvantaged by a poor work history. Another California project, located at the West Oakland Health

Center, administers an industrial therapy program for people so severely disabled by mental illness that, in their present condition, there is not a reasonable expectation that they can become employable, and who have been unable to work for at least a full year. A grant to the Massachusetts Association for Mental Health supports an intensive, vocationally-oriented Day program of pre-vocational and vocational training for former patients at Worcester State Hospital. A project at the Southwest Community Mental Health Center, Columbus, Ohio; focuses on the shared responsibility of the State rehabilitation agency and the community mental health center in team planning for patients about to be released from public and private mental hospitals in a catchment area. At Winter Haven, Florida, a project assists the mentally ill toward independent living by affording a semistructured environment in a halfway house based on "therapeutic community" concepts that is utilized in the deinstitutionalization process or as an alternate to hospitalization.

The Rehabilitation Services Administration has made good use of its Training authority to develop manpower skilled in the provision of vocational rehabilitation services for the mentally ill. Three long-term training grants are supporting special courses in psychiatric rehabilitation for personnel employed by State rehabilitation agencies, one at Nebraska Psychiatric Institute; another administered by the Human Services Training and Research Council, Inc., Charlottesville, Virginia, and the third administered by the Massachusetts Rehabilitation Commission for personnel of the New England States. RSA also supported a training course on Alternatives to Institutionalization in Los Angeles, November 1977, conducted under a grant to the International Association of Psycho-Social Rehabilitation Services.

Rehabilitation Research

Research and Evaluation projects concerned with the rehabilitation of the ex-mentally ill client have shown the efficacy of a rehabilitation program coordinated with the psychotherapeutic intervention program. A recently completed project has demonstrated that positive rehabilitation outcomes can be achieved through the use of such techniques as transitional employment; transitional living siutations; group placement; and extended post-placement follow along services. The basic concepts and approaches developed and tested in this project have been utilized in at least 36 other rehabilitation facilities throughout the country servicing the ex-mental patient.

In FY 1977 RSA funded two research projects directed toward this category. One project area is to investigate, systematically, the array of services necessary to place the client on a job, and the other project will be to determine the array of services necessary to maintain the client on the job.

The Special Foreign Currency Program is also involved with research projects in this area. A project is ongoing in Pakistan which is replicating the domestic project mentioned earlier but in a totally different cultural setting. One new project in Egypt has been funded in FY 1977 and another is in the planning stages in Pakistan. The three projects are envisioned as a cross-cultural consortium of projects to augment and complement those planned for domestic programs.

Number of People Rehabilitated:

Fiscal Year	All Rehabilitants	Person Rehabilitated With Mental Illness
1975	324,039	73,550
1976	303,328	67,705
1977	291,202 1/	65,288 1/
1978	283,000 1/	63,200 1/
1979	277,000 1/	61,600 1/

1/ Estimated

MENTAL RETARDATION

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
PUBLIC HEALTH SERVICE:					
National Institutes of Health:					
National Institute of Child Health and Human Development	$22,034,000	$23,946,000	$25,370,000	$26,201,000	$30,729,000
National Institute of Neurological and Communicative Disorders and Stroke	5,326,000	6,294,000	5,579,000	6,455,000	6,570,000
Total, NIH	24,360,000	30,240,000	30,949,000	32,656,000	37,299,000
Alcohol, Drug Abuse and Mental Health Administration:					
National Institute of Mental Health	1,966,000	2,157,000	2,014,000	2,173,000	2,566,000
Health Resources Administration:					
Health Planning and Resources Development:					
Medical Facilities Construction and Loan Program	---	---	---	200,000	---
Health Services Administration:					
Bureau of Community Health Services	1/	1/	1/	1/	1/
TOTAL, PHS	$26,326,000	$32,397,000	$32,963,000	$35,029,000	$39,865,000

1/ Obligations not identifiable.

MENTAL RETARDATION

Obligations

OFFICE OF EDUCATION:

	1976	1977	1978 Estimate	1979 Estimate
Education for the Handicapped				
Education for the Handicapped Act, Part B.....	67,000,000	80,000,000	90,000,000	139,000,000
Education for the Handicapped Act, Part C, Section 623.....	1,000,000	1,000,000	1,000,000	1,000,000
Education for the Handicapped Act, Part D.....	6,100,000	6,100,000	6,100,000	6,100,000
Education for the Handicapped Act, Part E.....	3,769,000	3,000,000	3,000,000	3,000,000
Education for the Handicapped Act, Part F.....	3,000,000	3,000,000	3,000,000	3,000,000
Total, Education for the Handicapped.....	80,869,000	93,100,000	103,100,000	152,100,000
Other				
Library Services and Construction Act (LSCA, Title I).....	2/	2/	2/	2/
Vocational Education Act, Part B.....	1/	1/	1/	1/
Total, Office of Education.....	80,869,000	93,100,000	103,100,000	152,100,000

1/ Amounts expended for mental retardation activities cannot be separately broken out from funds going to the States for regular vocational education activities.

2/ Amounts expended for mental retardation activities cannot be separately broken out from funds used to support LSCA services to the handicapped and to residents of State-supported institutions.

MENTAL RETARDATION

SOCIAL SECURITY ADMINISTRATION

Estimated Benefit Payments to the Mentally Retarded

Activity	1977	1978 Revised Budget Estimate	1979 Budget Estimate
Income Maintenance:			
Estimated Benefit Payments from RSI-DI Trust Funds.....	$471,000,000	$504,000,000	$562,000,000
Trust Fund Obligations Incurred to Adjudicate Claims of Beneficiaries.	7,402,000	7,774,000	7,991,000
Sub-total, Trust Funds....	478,402,000	511,774,000	569,991,000
General Fund Payments for Supplemental Security Income 1/.....	625,000,000	685,000,000	735,000,000
General Fund Obligations Incurred to Adjudicate Claims for Supplemental Security Income.....	54,291,000	57,085,000	61,722,000
Sub-total, General Funds..	679,291,000	742,085,000	796,722,000
Total Social Security Administration.....	$1,157,693,000	$1,253,859,000	$1,366,713,000

1/ Includes Federal contributions toward State supplementation (hold harmless).

MENTAL RETARDATION

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
OFFICE OF HUMAN DEVELOPMENT:					
Rehabilitation Services Administration:					
Basic State Grants..$	---	$ 87,878,000	$ 93,279,000	$ 97,340,000	$ 101,324,000
Facility Improvement Grants.....	---	300,000	314,800	312,500	312,500
Research and Demonstrations.....	---	669,000	1,657,000	1,500,000	1,500,000
Special Foreign Currency Program...	---	100,000	---	---	---
Training.....	---	70,000	85,400	85,400	126,600
Total, RSA.....	---	89,017,000	95,336,200	99,237,900	103,263,100
Developmental Disabilities: 1/					
State Grants.....	---	---	33,058,000	33,058,000	49,880,000
Special Projects....	---	---	19,617,000	19,567,000	5,557,000
University Affiliated Facilities....	---	---	5,250,000	6,500,000	6,500,000
Total, DD.....	---	---	57,925,000	59,125,000	61,937,000
TOTAL, OHD.....	---	89,017,000	153,261,200	158,362,900	165,200,100
HEALTH CARE FINANCING ADMINISTRATION:					
Medicaid Bureau.....	---	339,000,000	395,000,000	441,000,000	490,000,000
Office of Policy Planning and Research:					
Health Care Trust Funds.....	---	---	100,000	125,000	150,000
TOTAL, HCFA.....	---	339,000,000	395,100,000	441,125,000	490,150,000
TOTAL OBLIGATIONS FOR MENTAL RETARDATION....	$26,326,000	$541,283,000	$1,832,117,200	$1,991,475,900	$2,214,028,100

1/ Funds indicated are the amounts appropriated for all developmental disabilities included in the Developmental Disabilities Services and Facilities Construction Act, as amended.

MENTAL RETARDATION

Mental retardation ranks among the nation's most pressing social and health problems. Persisting from infancy through maturity, it ranks foremost among conditions of chronic disability. Well in excess of 200 causes of mental retardation have been identified and additional causes are being discovered regularly through research investigations. The costs of mental retardation to the Nation have been estimated at between $6.5 and $9.0 billion annually in care, treatment, and lost, productivity. The Department of Health, Education, and Welfare alone spent $1.7 billion on the problem of mental retardation in FY 1976. The greatest hope for mastery of the problem lies in its prevention, and, when this is not possible, in the promotion of the individual's maximum skills through a wide-range of habilitative and restorative procedures. Within the National Institutes of Health, these efforts are major concerns of the National Institute of Child Health and Human Development, the National Institute of Neurological and Communicative Disorders and Stroke and the National Institute of Allergy and Infectious Diseases.

NATIONAL INSTITUTES OF HEALTH

National Institute of Child Health and Human Development

The NICHD, within the NIH, has primary responsibility for research on mental retardation. This interest is expressed categorically through the Institute's Mental Retardation and Developmental Disabilities Branch (MRDD) of its Center for Research for Mothers and Children (CRMC). The MRDD Branch supports research into the biological, behavioral and social processes which contribute to or influence the development of retarding disorders. Of primary concern are studies concerned with finding causes and means for preventing mental retardation. Support for research pertaining to prevention of mental retardation also derives from activities of other branches of the CRMC. The Institute employs research grant mechanisms, and supports special research facilities, disseminates scientific and public information, and provides contract support of research to accomplish its goals. The Institute's research programs and resources provide research knowledge and understanding applicable not only to mental retardation but to other closely related developmental disabilities as well.

Research into the causes, means of prevention, and methods of amelioration of mental retardation serve many of the research requirements of developmental disabilities including autism, epilepsy, cerebral palsy and special learning disabilities. Children with these conditions often present with symptoms of mental retardation. With the exception of special learning disabilities, mental retardation is frequently associated with the other disabilities.

These developmental disabilities are a frequent consequence of reproductive casualty resulting from genetic defects, disorders of pregnancy, complications of birth, and maternal ill health. The Institute, because of its assigned responsibility for research in maternal and child health, has a major research concern for these disorders. All of the Institute's programs, both Extramural and Intramural, make significant contributions relating to these issues.

Research Activities

The Institute's broad program of research embraces the full range of problems associated with mental retardation. Its research attack relates to each of the over 200 identified mental retardation syndromes with concern for both the preventive and ameliorative aspects of the problem. The Mental Retardation Research Centers (MRRCs), constructed under the authority of P.L. 88-164 and administered by the Institute's Mental Retardation and Developmental Disabilities Branch, are major contributors to the national research effort on mental retardation. The scope of the problems attacked and progress toward their solution are indicated in the reports of research activities that follow.

Down Syndrome (Mongolism) and Genetics

It has been estimated that between 5 and 6 percent of the population suffer from some form of serious genetic disease at some time of life. When the newborn population is examined it is found that between 2-4 percent has some type of genetically based birth defect. The birth defects detected postnatally represent only a small proportion of all genetic aberrations because most of them result in early spontaneous abortion. Chromosome abnormalities occur in about 5 percent of still-born infants and in 0.6% of all newborns. Down syndrome is the most common and readily identifiable genetic condition associated with mental retardation. Despite its recognition as a distinct clinical entity over a century ago (and the first condition in which an association with a chromosomal defect was firmly established), several fundamental issues concerning this syndrome continue to elude scientists. But recent research findings and technological development have contributed much to our understanding of the disorder. The maternal-age effect on its incidence is well established. It was one of the first clinical entities to be diagnosed prenatally. In an effort to provide fundamental information which is necessary for our basic understanding of the condition, the MRDD Branch will soon publish an RFP (Request for Proposals) which will solicit research contracts dealing with the development of animal models which will hopefully provide some insight into our understanding of Down syndrome. Restraints imposed upon research using human subjects, particularly those who cannot give informed consent including mentally retarded and young children, have blunted efforts needed to solve a number of medical problems, including genetic disorders. Development of animal models for human diseases will help alleviate this dilemma. By using animal models, including selective breeding of mice heterozygous for one or more metacentric chromosomes, chromosomally unbalanced gametes can be produced. Animal models will help elucidate the mechanism of nondysjunction and the biochemical (i.e. gene-dose effect), developmental and phenotypic consequences of trisomy.

Prenatal diagnoses of chromosomal, biochemical, and morphologic disorders have been demonstrated to be both feasible and safe. The number of conditions diagnosable in utero will undoubtedly increase and prenatal diagnosis is likely to become a common procedure for women at increased risk of producing defective

offspring. It has been estimated that in 1974 among women who should obtain prenatal diagnoses, through amniocentesis, for various indications only about 5 percent received the benefits of this procedure. Several reasons have been proposed for this low compliance rate, including insufficient number of laboratories and technically qualified personnel to meet the demands. To help alleviate the backlog of requests for cytogenetic evaluation, the MRDD Branch will soon initiate a field trial of two computerized systems, to be used in tandem, for automated chromosome preparation and automated karyotyping.

Inborn Errors of Metabolism

In order to dtermine the effectiveness of a low phenylalanine diet, a collaborative suty of children treated for Phenylketonuria (PKU) was initiated in 1967 and continues to the present time in 15 medical centers across the United States. The results of a comparison of the intellectual performance of 36 PKU patients at an average age of 50 months and their non-affected siblings showed that the patients scored a mean IQ of 94 while the non-affected siblings obtained a mean IQ of 99. Although this five-point average difference was statistically significant, when compared to untreated PKU patients who are generally severely handicapped, this achievement is considered to be a remarkable addition to the medical armamentarium. The successful treatment of PKU in early childhood has raised other problems, such as the question of when the diet should be terminated. The Collaborative PKU Project, through a grant from NICHD, is studying the problem by terminating the low phenylalanine diet in one-half of its subjects, selected at randome, at six years of age. The The developmental and biochemical consequences of diet-discontinuation are being monitored closely.

A second problem relates to the observation that infants of PKU mothers, most of whom would not be expected to have PKU, are almost always retarded and may, in additon, have physical abnormalities. The question remains unanswered whether or not women with PKU, who have obtained normal intelligence as a result of early treatment, can be protected from having retarded offspring by maintaining a low phenylalanine diet during pregnancy. This problem will be addressed by the investigators in the collaborative project funded by NICHD.

Lead Poisoning

Except in certain high-risk areas, lead poisoning is not generally recognized as a medical problem and screening is not done routinely. The importance of this problem, however, is attested by the fact that the number of children with elevated blood lead levels is estimated at 600,000. Studies of the effects of low level lead expousre in children have in the past been of limited validity because of small sample size, poor indices of lead exposure, and lack of sensitive outcome measures. Advances in this area have recently been made by investigators at the Mental Retardation Research Center, Children's Hospital Medical Center, Boston.

The lead concentration in shed deciduous (baby) teeth has been developed as a useful marker of lead exposures in older children by the Boston MRRC investigators who have analyzed the lead content in 2,200 teeth from first and second grade children. Children with high and low tooth lead levels were then given detailed examinations in a neuropsychological laboratory. After controlling for social class and other variables, the investigators found that children with high tooth lead levels did less well on measures of intelligence, attentional and language functions than children with lower levels of lead in their teeth. In addition, when teachers' ratings of 789 first and second grade children were compared, children with high tooth lead levels were found more than twice as likely to display nonadaptive classroom behavior than low tooth lead children.

Maternal Alcohol Intake

Behavioral scientists at the University of Washington Child Development and Mental Retardation Research Center in Seattle have been studying the effects of maternal alcohol intake during pregnancy on the development of offspring. Earlier, these investigators had identified a Fetal Alcohol Syndrome (FAS) associated with chronic alcohol consumption by pregnant women. More recently, they have shown that maternal consumption of alcohol prior to and during pregnancy appears to have a significant influence on the behavior of newborns, even when the amounts consumed are far below those of alcoholic women. Moreover, the combined effects of drinking and smoking are worse than expected--that is, infants exposed prenatally to both alcohol and nicotine suffer more deleterious effects than would be expected from merely adding the effects suffered by alcohol and nicotine separately. The long-term effects of maternal drinking and smoking are not yet known, but are being studied by repeated evaluations of the sample through school age. To date, the findings suggest that alcohol ingestion during pregnancy, in amounts considered to be "social drinking" has potentially negative effects on the behavioral development of children.

Educational Placement

A study completed by researchers at the University of California at Los Angeles, Mental Retardation REsearch Center has demonstrated what happens to borderline-retarded children who are taken out of the special segregated classes for the educable mentally retarded (EMR) and returned to the regular school program. As a consequence of civil rights litigation based upon disproportionate representation of minority California chidlren who were labeled EMR and placed into such programs, the federal courts mandated changes in identification practices. As a consequence several thousand children, orginally identified as EMR because of classroom failure, were returned to regular class. To determine how well they got along, the investigators looked into the school success of these "decertified" children, sampling in 12 representative California school districts. The results showed that students remained seriously behind their age peers in reading and mathematics, but also showed that most could adjust reasonably well to the regular class again, given some kind of assistance. Their rate of

leaving school was not much different from that of the regular class students of the same ages, ethnic backgrounds, and sex, and was, in fact, lower than that of students who had not been taken out of the EMR special class. Thus, returning the students to regular class did not overcome their inital academic difficulties, but could be regarded as a partial success based upon their acceptance by peers and teachers. It is clear that such children, if educated by "mainstream" methods, must receive more direct assistance than was provided by the California "transition" program, and that their regular teachers must also be provided with special help.

Early Education

Researchers at the Kennedy Mental Retardation Research Center, George Peabody College for Teachers, Nashville were among the early pioneers of early educational intervention programs for children from disadvantaged families. These investigators have now examined the long-term effects of early education. Follow-up of children who participated at ages 4 and 5 years in a project for early education of children from low-income familes, now 15 years from its beginning, has revealed the following positive effects (or at least correlates) of early educational intervention: (a) Significantly fewer children in the treatment groups (those who received the educational intervention) have been placed subsequently in segregated special education classes; (b) There have been significantly fewer instances of school failure among the children in the treatment groups than among those in the control groups; (c) Among girls, although not among boys, there have been significantly fewer school dropouts, and a higher percentage of school graduation (i.e., they are not still in school having failed a grade) than among children in the control groups. Some effects of educational intervention at 4 and 5 years of age with children from low-income faimilies can still be detected, including a reduction in the number of such children who are classified as mentally retarded and consequently are placed in special education classes.

Adolescent Pregnancy

Studying the effects of adolescent pregnancy on mother-infant relationships, Kennedy Mental Retardation Research Center researchers at Peabody College have found that the provision of comprehensive child care to low-Socio Economic Status (SES) mothers appears to eliminate much of the risk typically associated with teen-age pregnancy. In cases in which comprehensive child care and prenatal care have been provided to teen-age mothers, the differences between this group and somewhat older mothers usually found (in favor of the older mothers) have disappeared, both in social development and in the area of obstetric risk across a number of measures. Thus, aside from the purely humanitarian reasons for providing prenatal and comprehensive child care for teen-age mothers, the evidence suggests that such care may reduce reproductive casualty and enhance social development.

Neonatal Brain Damage

Two of the most prevalent causes of neonatal brain damage associated with mortality and severe neurobehavioral developmental disability are kernicterus and intracranial hemorrhage. Analysis of the experience in the Kennedy Mental Retardation Research Center's Neonatal Clinical Research unit at Albert Einstein College of Medicine has identified two previously unsuspected factors implicated in the pathogenesis of kernicterus and intracranial hemorrhage. Kernicterus is usually related to excessively high bilirubin levels that are often present in premature infants. There is, however, a poor quantitative correlation between level of hyperbilirubinemia and neurobehavioral deficit. The investigators have found that the concurrent presence of culture proven septicemia has been a necessary condition for the development of autopsy demonstrated kernicterus. It appears that the infectious process may damage the blood-brain barrier and permit abnormal transport of bilirubin into the susceptible brain regions, even at blood bilirubin concentrations that would not ordinarily produce brain damage.

In another study of premature infants with neonatal mortality attributable solely or in part to intracranial hemorrhage, it was found that all infants had received exchange transfusions for hyperbilirubinemia. Following transfusion these infants had abnormally high blood sodium levels, a presumptive cause of germinal plate hemorrhage in prematures. The elevated sodium concentration was traced to anticoagulants utilized in banking the blood for transfusion. Elimination of these additives may be expected to reduce the incidence of fatality and brain damage due to intracranial hemorrhage in premature infants receiving exchange transfusions.

Research Training

In FY 1977, the Institute provided research training support for a total of 24 mental retardation training grants in the amount of $1.778 million. Of the training grants, 16 were in the form of institutional training grant awards and 8 were postdoctoral fellowships. The institutional training grants provide primarily for predoctoral training and are the major means for providing a continuing flow of competent behavioral sciences researchers serving the research needs of mental retardation. There continues to be a need for behavioral scientist investigators and investigators trained in the conduct of interdisciplinary research.

NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological and Communicative Disorders and Stroke

Data collected in the Collaborative Perinatal Project of the National Institute of Neurological and Communicative Disorders and Stroke are being analyzed to determine the primary and contributing roles of biological and environmental factors in mental retardation in a population of 40,000 white, black and Puerto Rican children followed from the prenatal period to age seven. The identification of early signs of mental retardation will facilitate prevention, diagnosis and treatment, and will add substantially to current knowledge that has been derived largely from small retrospective studies of institutionalized retardates.

Mental retardation was defined as an IQ of 70 or less on the Wechsler Intelligence Scale for Children, or, for the relatively few children who could not be tested according to study protocol, equivalent IQs from other tests or reliable clinical judgments of retardation. Since children with IQs under 70 form a heterogeneous group, they were subdivided into four major categories consisting of those with severe retardation (IQ under 50) with and without signs of central nervous system damage, and those with mild retardation (IQ between 50 and 69) with and without such signs. Specific neurological diagnoses were obtained from the neurological examination given at age seven. The four groups were further subdivided by ethnic group and sex. Comparison groups are composed of children with IQs in the borderline, average and superior ranges.

The incidence of severe retardation (0.5%) did not differ by ethnic group in this study population, but mild retardation was more frequent among non-whites (5%) than whites (1%). The incidence of mild retardation, and to a lesser extent severe retardation, decreased as social class increased. Among the severely retarded children, three-fourths of the whites but only one-half of the non-whites had major neurological problems. Among mildly retarded children 6% of non-whites and 14% of whites had major neurological problems. In general, the proportion of retarded children with major neurological involvement increased as social class increased. Early predictors of retardation include signs of perinatal anoxia and psychomotor test scores in infancy.

In a special study, fifty children with marked neurological abnormality manifested by moderate or severe motor disability and severe mental retardation were compared with a large control population with respect to prospectively-ascertained perinatal characteristics. None of 60 prenatal factors distinguished the affected group from controls. In labor and delivery, lowest fetal heart rate in the second stage of labor, arrested progress of labor, and use of midforceps discriminated between the two groups. Neonatal characteristics of children who were later severely handicapped differed from controls, particularly with respect to difficulty

in initiating and maintaining respiration, intracranial hemorrhage, neonatal seizures, low birthweight and small head circumference, low hemoglobin or hematocrit, and overall neurological status. Multivariate analysis, including factors from the pre- and perinatal periods, indicated that intracranial hemorrhage and neonatal seizures were the strongest independent discriminators between the neurologically-impaired children and controls. A comprehensive report on all of these data is being prepared for publication.

As part of a broader program to identify and assess the relative importance of developmental factors associated with mental retardation, follow-up studies of two groups of children in the NINCDS Collaborative Perinatal Project are planned: those who showed large changes in intelligence test scores in early childhood, including those who shifted in or out of the retarded range; and the large sample of twin and sibling pairs which is ideally suited for the study of genetic and environmental factors affecting intellectual development.

Mental retardation associated with metabolic disease is under study by NINCDS intramural scientists. Enzyme replacement therapy for Gaucher's disease pioneered by NINCDS intramural scientists has now been repeated and confirmed by another U.S. group and also by a British group. Large scale commercial production of the enzyme is now ongoing. The possibility of producing an animal model of Gaucher's disease is under active investigation. Such a model would be invaluable for detailed evaluation of enzyme replacement therapy. Other experimental animal studies have already demonstrated the feasibility of utilizing techniques for temporary opening of the blood-brain barrier to deliver systemically-administered enzymes into the central nervous system.

There is increasing interest and concern over the cytomegalovirus (CMV) as a major cause of postnatal neurological deficit. With development of sensitive specific tests for CMV, it has been demonstrated that 3 percent of all pregnant women excrete the virus (and the percentage rises to 8 among lower socio-economic groups). Moreover, one percent of all newborn babies are excreting CMV at the time of birth, thus signifying infection in utero, and up to 10 percent of these babies exhibit some abnormality (ranging from full-blown CMV-inclusion disease in 1:20,000 pregnancies to the more frequent conditions such as mental retardation and high-tone deafness. The need for further work, particularly on vaccine development, is obvious.

In addition, through research grants, the NINCDS is currently supporting 57 extramural studies on the metabolic basis of mental retardation. Toxic, metabolic and deficiency disorders are being investigated including kernicterus, phenylketonuria and Tay-Sachs disease.

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases (NIAID) is particularly concerned about those infectious diseases which, as a result of their transmission by an expectant mother to the fetus or her newborn child, lead to mental retardation and other birth defects. Such viral, bacterial and parasitic diseases cause a significant amount of mental retardation.

Although it is possible for transmission to occur transplacentally, it is estimated that 75 percent of infections are acquired during birth or shortly thereafter.

Among the herpes simplex group the problem of genital or type 2 herpes is the most significant. Almost half of the diagnosed cases of herpes in children are of this type. Physicians know that, as in gonorrhea, the infant may contract herpes as it passes through an infected birth canal. Such an infection may lead to a disseminated form of meningitis which is often fatal or causes severe permanent disabilities of the nervous and sensory systems.

Genital herpes is not a reportable sexually-transmitted disease and estimates of its incidence vary. Of full-term newborns with herpetic infections, 62 percent die, 24 percent survive with neurologic and other disorders, and 14 percent survive without any problems. There is no effective treatment. NIAID is evaluating the efficacy of adenine arabinoside (ara-A) in the treatment of some herpes simplex infections. This evaluation is a multi-institutional project coordinated by the University of Alabama. The Institute also has two grants concerned with the basic studies of metabolism of herpes-infected cells.

Cytomegalovirus (CMV) is a member of the herpes virus group. In the United States CMV infections occur in 1 percent of all newborn infants. Of these births at least 10 precent will eventually manifest significant damage. Compared to normal children, those born with CMV-IgM antibody (indicating infection), will have 2.7 times the risk of school failure. For each infant with recognized symptoms, at least ten do not have recognizable symptoms. These "silent" infections often lead to mental retardation.

There is no specific therapy available for congenital CMV. Basic research is exploring the pathogenesis of CMV infection, immunology and virus-host cell interactions. NIAID is evaluating the efficacy of ara-A in the treatment of CMV infections. Limited contract-supported studies have been done to evaluate the efficacy of the antiviral substance -- interferon -- in the treatment of CMV.

Congenital rubella is one of the most important causes of mental retardation. Some years ago NIAID played a major role in the development of an effective vaccine for the prevention of rubella (German measles). The emphasis now is on immunization programs that will protect pregnant women against the disease. The vaccine is recommended for all preschool age children because they are the major source of dissemination of the rubella virus. Only under the most careful supervision is the vaccine used in post-adolescent females.

Bacterial infections can also damage the very young. Important organisms are Hemophilus influenzae, Streptococcus pneumoniae, and Neisseria meningitidis. Hemophilus influenzae is responsible for 80 percent of meningitis cases in children 2 months to 5 years. Most of the remainder are due to Streptococcus pneumoniae and Neisseria meningitidis.

NIAID-supported research has led to the establishment of efficacy in children for vaccines against N. meningitidis, group A and S. pneumoniae. No vaccine is available for group B meningococcus and group C vaccine is not effective in young children. Although an experimental H. influenzae vaccine has been found safe and effective in youngsters over the age of two, it is not effective in young children where most of the disease occurs. NIAID is now supporting research on a new candidate H. influenzae vaccine which shows promise in animal studies of being immunogenic in the very young.

Group B streptococcus (GBS) acquired from the birth canal of the mother during delivery is often responsible for the early onset of meningitis. The mortality rate is near 50 percent and of those who survive, 20 percent to 50 percent develop mental disabilities and other birth defects.

There is no treatment at present which removes GBS from the birth canal. NIAID has approximately 19 grants in the general area of streptococcal disease and immunology of group B strep infections. There are also two contracts directed towards the development of a vaccine for group B streptococcal infections.

Toxoplasmosis is a parasitic infection that is found throughout the world. It is most dangerous when a woman acquires a primary infection during pregnancy. Fetal infection may then result from transplacental passage of the organism. The risk of infection to the fetus during active maternal infection is about 35 percent. It has recently been reported that children with subclinical congenital toxoplasmosis may have intellectual deficits that only become evident 3 to 4 years later.

Many animals harbor the toxoplasmosis parasite in their tissues and organs. Research findings by NIAID scientists and grantees have shown that cats may be a major reservoir for human infections. NIAID is supporting three major grants in this area which provide for a general look at toxoplasmosis infection and the immune response.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health

MENTAL RETARDATION

The National Institute of Mental Health has been involved in the field of mental retardation for approximately 25 years. In 1962, the National Institute of Child Health and Human Development (NICHD) was established as part of the National Institutes of Health, and assumed responsibility for the major mental retardation research activities. At that time, funding for some of the developmental research previously supported by NIMH was transferred to NICHD. In 1967, leadership for retardation programs was turned over to the Social and Rehabilitation Service (SRS), and funding for NIMH-supported mental retardation and relevant hospital improvement grants were shifted to SRS. For several years, the unified effort headed by SRS absorbed many of the NIMH mental retardation programs. This was particularly true with respect to demonstration projects, in-service training, and basic research in child development.

Research

One research project concerns the development of skills for solving logico-conceptual problems. The aim is to identify and to chart the age-based progress of behavioral processes involved in forming and using class-type concepts for the normal child; then to contrast this developmental sequence with similar assessments of performance in both disadvantaged and mentally-retarded children. Another project centers on the utilization of known facts and skills, combining to form what are commonly called strategies, in complex conceptual tasks. The emphasis is on studying the efficiency of information processing by adult subjects. Another study is being conducted of developmental learning and cognition aimed at deterimining the processes whereby children (especially normal but also including familially retarded) with mental ages 4 to 14, solve problems. Children with learning disabilities will also be studied at a later stage.

Research on socioaffective development in infancy involving normal and mentally retarded children which previously concentrated on the first year of life is being extended to cover the first two years of development. In the context of general studies on early parental attachment, an ongoing study of interrelationships of parental grief, attachment, and early infant affect expressions will continue at the clinical-descriptive level. A new investigation will involve study of Down's syndrome infants. A total of 20 infants with Trisomy 21 will be studied longitudinally over the course of their first two years of life. Children are to be observed and filmed during the first three months of life and mother-infant interactions are to be observed at regular intervals through age 24 months. Bayley Scale and EEG data will be obtained periodically as will be photographs and films of facial expres-

sions and behavior on a "visual cliff". Special attention is being paid to the processes of parental attachment and their relations to the development of affective expressions in the Down's syndrome infant.

Another project deals with discrimination; remembering and forgetting; attention; learning perception and transfer processes in mentally retarded children.

The NIMH is funding a project to develop laboratory procedures to supplement clinical techniques for describing, predicting and modifying the behavior of severely mentally retarded persons, especially children. Subjects are mentally retarded children under 16.

Also being supported is a study of autistic schizophrenic children, including retardates, and treatment employing social reinforcement of verbal behavior which imitates that of adults.

Two projects underway involve studies of biological factors. In the first, the principal investigator focuses on an understanding of the effects of brain injury in infancy through the use of psychophysiological methods and theory. The problems under study are: (1) whether two generalized arousal systems, differentially affecting stimulus processing, can be distinguished; (2) whether one of the systems, the "orienting reflex", is relatively difficult to elicit when higher brain centers are not functioning optimally; (3) whether manipulation of early stimulation can affect development of this system. Subjects of study are undergraduate college students, normal and premature infants, and mental retardates.

Temporal distribution is being studied, as well as the behavioral and subjectively experienced correlates of telemetered, continously recorded intermittent electroencephalograph (EEG) abnormalities. Adult and child subjects with Epilepsy, mental retardation, schizophrenia, or childhood behavior disorders whose EEG's are distinguished by paroxysmal slow or spike transients, but who do not have overt seizures, are hospitalized and investigated over periods of 24 hours.

Intramural scientists working on phenylketonuria (PKU), a disease long associated with mental retardation, have identified the metabolic fault, have proposed and tested innovative corrective measures and in doing so have discovered a new variant of the disease. From knowledge growing out of these findings, they have developed a replacement therapy for the deficiency which characterizes the variant and have tested its efficacy in a small number of subjects. It is clear now that the treatment cannot reverse the neurological deterioration associated with the deficiency once it occurs but there is evidence that it stops the progressive downward course of the disease that ends in death.

Training

Several NIMH training programs relate, either directly or indirectly, to mental retardation. The NIMH supports a training program for predoctoral interns in a hospital which has both adult and child patients. The trainees gain experience in dealing with child mental illness, with their families, and with the health needs of the community. Training in diagnosis, treatment, counseling, mental retardation, research and group therapy is given.

In another developing program, training in mental retardation is being offered as a supplement to the training of the general psychiatric resident as well as to child psychiatrists. Trainees receive instruction in biochemistry, genetics, neurology, and communicative disorders, and in problems relating to retardation. Each trainee also treats two retardates and their families.

One NIMH training project is designed to provide intensive one year field training for psychologists in the schools. Assignment to 3 Long Island school systems provide diversified population, preschool to adult in the study of emotionally disturbed, retarded, gifted, culturally disadvantged, handicapped children. Opportunity is given for group dynamics with student, leaders, and administration.

An NIMH-supported grant involves the development of a series of four institutes to provide a broad orientation in mental retardation for psychiatric and pediatric residents. Each of the institutes consists of a two-week period of 100 instructional hours and trains 25 participants. Lectures, seminars, and individual assessment of assigned cases constitute the basic teaching methods. Demonstrations focus on retardates with inborn errors of metabolism and on encephalopathies. Seminars cover a wide range of topics, and field trips give special emphasis to management of retardates in the community. Lectures on prevention, genetic counseling, and treatment also are included in the curriculum.

Another grant has, as one of its objectives, the teaching of adolescent psychiatry to medical students through student participation in the Adolescent Service of the Neuropsychiatric Institute. The training program also offers training experience in mental retardation, child psychoanalysis, and forensic psychiatry.

Services

In the services area, two projects relate, in a significant portion, to mental retardation.

South Carolina State Hospital is establishing a treatment program to serve 300 emotionally disturbed, psychotic, retarded, delinquent, or hyperactive patients under 18 years of age. Most of the children and adolescents were previously placed in adult units and treatment pro-

grams. Staff is being trained in the use of behavior modification techniques. Close liaison is maintained with community mental health centers and community clinics, since they refer patients to the hospital and provide care after release. An outside consultant aids in evaluation of the program, which involves pre-test and post-test data on a broad-based behavioral measure, the Devereux Child Behavior Rating Scale, as well as other measures such as school attendance, grades, behavioral ratings by parents, and arrest records.

Through its affiliations with multiple neighborhood child care agencies and educational facilities, the Hahnemann Community Mental Health/Mental Retardation Center (HCMHMRC) is developing an early detection, intervention, and facilitator network of services to reach the young, high-risk children in this ghetto catchment area. The new staff positions funded by this grant are created for home agency facilitators and school facilitators. The Home Agency Facilitator staff includes a pediatrician with a psychiatric background, a child development specialist, and a social worker, all of whom train and supervise the nine outreach paraprofessional workers. The professional school facilitator staff includes psychoeducational specialists, a social worker and a mental health technologist. The target area is not only the poorest section of Philadelphia but has the highest state poverty rating. The population of 130,000, of whom 56 percent are black, has a multiple array of mental health and economic problems including unemployment, broken homes, low educational level, and alcoholism and drug abuse. Two-thirds of the homes are headed by a single parent, and over one-third of the residents are under 19 years of age. Because only one percent of the 1,300 children treated by HCMHMRC last year were under six years of age, the new focus on early detection and intervention is considered essential if later childhood and adolescent pathology is to be decreased.

The linkage network is a coordinating council, consisting of representatives from day care centers, law enforcement agencies, child health and mental health centers, preschools, the public school system, and foster home placement services. This council through the home agency and school facilitator staff, seeks out children under seven years of age who are physically, emotionally, and/or culturally vulnerable, handicapped, or abused. The home agency workers act as counselors to families in their homes, as facilitators of appropriate educational, health, and/or social welfare referrals, and as representatives of the community to the linkage network council. The school facilitators are diagnosticians and consultants to teachers. They also coordinate teams who assess a child's disabilities and secure appropriate remedial services. A data bank collects information, monitors the overall project, and assures continuity of care without duplication. Evaluation is based on parental reactions to quality and availability of services, and a comparison of behavior patterns of children who have received help with those who have not.

HEALTH RESOURCES ADMINISTRATION

Health Planning and Resources Development

MENTAL RETARDATION

Mental retardation facilities have been eligible for and have received construction assistance from the Hill-Burton program since its inception 30 years ago. Up until the passage of the "Mental Retardation Facilities Construction Act" (1963) - P.L. 88-164, Title I, the Hill-Burton program was the primary source of Federal assistance for retardation construction, and administered the Act after enactment until August 1967. Since the advent of the specific construction programs for mental retardation facilities, the Hill-Burton program has been acting primarily as a back-up resource for construction aid. A total of 109 mental retardation projects have been assisted with $56.7 million in Federal funds since the Hill-Burton program began. Hill-Burton personnel in both the DHEW Regional Offices and in the State Hill-Burton agencies have provided expert consultation to the mental retardation facility programs and to many mental retardation project sponsors or potential sponsors. Hill-Burton consultation is especially valuable where mental retardation services are to be provided in a comprehensive health care facility or in any combination with other health services.

Public Law 93-641, signed on January 4, 1975, extended and extensively revised the Hill-Burton program. Mental retardation facilities are eligible under two priorities of formula grant assistance: (1) modernization of health facilities, and (2) construction of new inpatient medical facilities in areas which have experienced recent rapid population growth. The same facilities are also eligible for loans and loan guarantees with interest subsidy. Another type of grant assistance (Section 1625) is project grants for construction and modernization projects designed to prevent or eliminate safety hazards in publicly owned medical facilities and to assure compliance with State or voluntary licensure or accreditation standards. Grant and loan assistance from 1976 and 1977 appropriations/authorizations (except Section 1625 grants) are awaiting the publication of regulations for Title XVI. At that time, $39.9 million in formula grants and $250 million in loan or loan guarantee authority will be available for the priority projects in each State. Section 1625 public facility project applications have already been approved for the $11.4 million presently available.

HEALTH SERVICES ADMINISTRATION

Bureau of Community Health Services

MENTAL RETARDATION

Through a program emphasis on mental retardation, initially mandated by Congressional earmarkings of funds for the Maternal and Child Health and Crippled Children's programs under Title V of the Social Security Act, specific balanced and coordinated models of prevention and services for retarded and handicapped children and their families have evolved.

The activity is dependent on the use of a combination of basic formula grants, special project grants to States and Institutions of Higher Learning, and a major interdisciplinary training effort and programmatic research grants to achieve this program emphasis. The coordinated program linking State health agencies, medical centers, and universities is helping achieve movement toward the realization of our two national goals in mental retardation - prevention and deinstitutionalization.

Section 508, Title V, Social Security Act, authorized grants for projects to help reduce the incidence of mental retardation and other handicapping conditions caused by complications associated with childbearing and to help reduce infant and maternal mortality by providing necessary health care to high-risk mothers and their infants.

Starting in FY 1975, each State was required to incorporate such project in its State plan and provide the services either directly or through grants and contracts. The percentage of women seeking care in the first trimester of pregnancy in these programs increased from 14.5 percent in 1967 to 32 percent in 1975. The ultimate long-range impact on prematurity and the presumed decrease in the number of damaged infants produced by these women will be studied.

Phenylketonuria (PKU), an inborn error of metabolism, has in the past been responsible for one percent of the severely retarded population in

State institutions. By detecting families with the condition and by screening newborn infants (43 States have enacted mandatory requirements for such screening), the damage can usually be prevented by placing the infants on a special diet.

Approximately 97 percent of the live newborn infants in this country are screened for PKU and other conditions. State Health Departments, working closely with medical centers, have developed the necessary laboratory and clinical facilities to screen, diagnose, and manage these infants on the special diets.

As a means of monitoring the outcome and effectiveness of newborn infants detected and treated for PKU, some 16 clinics have been participating in a MCH supported collaborative follow-up of their patients. Preliminary findings thus far indicated that:

> Children in the study sample appear to be developing normally on the diet in terms of physical and neurological examinations performed at diagnosis, one, two, three, four, and six years of age.
>
> The age of dietary inception appeared to be a significant factor influencing future cognitive ability, beginning in the second month of life. Children treated after 31 days of life appear to have a slightly lower mean IQ score than those treated prior to one month of age.

A second phase of this collaborative effort is beginning to explore the point in time at which the special dietary treatment might be discontinued, with a third phase focusing on management of potential pregnancy occurring in females with PKU who were treated as infants.

A number of metabolic conditions which can result in progressive damage or death of an infant after birth can be detected through a newborn screening program. The same newborn blood sample being collected for PKU screening can be used to test for an increasing number of these conditions. Two State Health Departments (Oregon and Massachusetts) have set up Regional Centers designed to screen for multiple conditions from all of the States in the region. Better quality control is maintained on a regional basis and the sample are screened for six conditions at a lower cost than what the individual States had paid to screen for PKU alone.

The State Health Departments through their Children and Youth Projects are continuing to screen their populations for lead poisoning which is still considered as a major public health problem.

Reports of "subclinical" effects of lead on children without overt evidence of lead poisoning, but with psychological and other functional

impairments, continue to appear. It has also been suggested that the interaction of lead with other metals and pollutants is further complicating the problem.

While the issue of low lead toxicity in children is far from clear-cut, the implications of many of the positive findings are grave. Systematic joint efforts with local units of the National Association for Retarded Citizens and Cerebral Palsey Groups, in the education of risk populations in preventive measures, are being carried out.

The use of MCH formula funds by State Health Departments to provide Rh immunoglobulin in their maternity services for Rh negative women at risk, has increased the utilization rate of this preventive procedure and contributed to the general decline of Rh Hemolytic Disease in the past.

The liberalization of State abortion laws and the recent dramatic increase in the early termination of pregnancies, however, may well be negating some of this progress. An Rh negative woman can become immunized by the spontaneous or induced abortion of her Rh positive fetus if she is not protected by the administration of Rh immunoglobulin. Utilization rates of RhIG after abortion have been far from ideal. This is an area of prevention which will require particular attention.

The number of children with suspected and confirmed Congenital Rubella Syndrome being cared for by the MCH supported Special Clinics for Mentally Retarded Children and by the Crippled Children's Program has shown a considerable decrease. The general decline in immunization levels in our population, however, again creates the potential for the recurrence of significant numbers of infants with Congenital Rubella Syndrome.

Clinical services for mentally retarded children operating in all but two States provided diagnosis, evaluation of a child's capacity for growth, the development of a treatment and management plan, interpretation of findings and counseling of parents, and folow-up care. Mental retardation clinic services were provided for over 75,000 children, through 360,000 visits made to 166 clinics supported by MCH funds.

Children are being seen at these special clinics at an earlier age as a result of multiple screening procedures carried out by the State Maternal and Child Health Programs. 40 percent of the new patients seen in these clinical programs were under 5 years of age; 39 percent were 5-9 years old; and 15 percent were ages 10-14.

These clinical programs fulfill a major function of "labeling" children referred as presumably mentally retarded. Among new patients classified, one-third were found not to be retarded and were referred to other appropriate treatment resources.
The programs likewise played a significant role in preventing institutionalization by providing parents with alternatives in terms of management help, treatment, and access to community resources.

CENTER FOR DISEASE CONTROL

MENTAL RETARDATION

Immunization:

In 1970, the Center for Disease Control provided project grants and technical assistance to State and local health agencies to support an intensive rubella immunization program. This massive effort was initiated because of the following: (1) a rubella epidemic occurred in the United States in 1964-65 and resulted in an estimated 30,000 cases of congenital rubella syndrome (severe birth defects) and left nearly 15,000 babies mentally retarded, deaf, or blind; (2) a new live-virus rubella vaccine had just been licensed for use in the United States, and (3) based upon past epidemiologic data, an epidemic of rubella, similar to the one in 1964-65, was predicted for the early 1970's. By the end of 1972, over 30 million doses of rubella vaccine had been administered in public programs. Through the end of 1977, over 81 million doses of rubella vaccine had been distributed and protection levels against rubella had reached those of measles.

As a result of rubella immunization programs since 1970, reported cases of rubella decreased from 56,552 in 1970 to a low of 11,917 in 1974. Since 1974, reported rubella cases have increased to 20,045 in 1977. In addition, 14.4 million children remain unprotected against rubella. Rubella is one of the childhood vaccine preventable diseases included in the Secretary's Immunization Initiative. One goal of the Initiative is to raise immunization levels against rubella to at least 90 percent by October 1, 1979.

Lead-Based Paint Poisoning Prevention:

Mental retardation, neurological damage, and behavioral and learning disabilities have been attributed to the ingestion and absorption of lead. Approximately 6,000 children per year suffer some neurological damage from undue lead absorption.

The ubiquity of lead in the child's living environment, particularly under conditions of housing deterioration and flaking and peeling of lead-based paint, accounts for the increasing problem of undue absorption among children.

Project grants and technical assistance are provided by the Center for Disease Control for detection, treatment, and hazard reduction activities in local communities throughout the United States which have demonstrated the existence of a lead poisoning problem.

During fiscal year 1977, 58 community programs tested approximately 380,000 children and identified 28,000 with evidence of undue lead absorption. Medical and environmental services were provided to protect these children from the effects of overt lead poisoning.

OFFICE OF EDUCATION

MENTAL RETARDATION

Education for the Handicapped

Programs dealing with handicapped children in the Office of Education have been placed under the administrative direction of the Bureau of Education for the Handicapped. This is consistent with the efforts of the Office of Education to provide maximum educational programming for all children. The Bureau of Education for the Handicapped (BEH) is responsible for supervising and implementing current and new legislative authorities to provide funds for projects and programs relating to the education and training of and research on handicapped children and youth. These children include those who are mentally retarded as well as those who are hard of hearing, deaf, speech impaired, visually handicapped, seriously emotionally disturbed, crippled, or other health impaired and require special education.

The overarching goal for Federal efforts in the area of education for the handicapped is to equalize educational opportunities for handicapped children. Only a bit more than 58 percent of the Nation's more than six million schoolaged handicapped children receive needed special education services.

The main issues surrounding the Federal role in education for the handicapped are:

1. How can the limited available Federal resources be used in a catalytic and stimulative manner to bring quality educational services to the greatest proportion possible of the unserved 42 percent of the target group?

2. What is the best use of Federal resources in preventing identifiable handicaps from becoming serious disabilities in school and adult life?

3. What educational techniques and methods can be developed, introduced and adopted to insure handicapped children job skills to enter adulthood with a high probability of participation in society in a meaningful manner?

Six objectives have been adopted for the Federal programs for education of the handicapped:

I. National Commitment

To insure that every handicapped child aged 5 to 17 is receiving an appropriately designed education by 1978, and that all handicapped children aged 3 to 21 will receive an appropriate education by 1980.

II. Increased Services

To assist the States in providing the appropriate educational services to the handicapped by 1980.

III. Career Education

To assure that by the year 1978, every handicapped child who leaves school has had career educational training that is relevant to the job market, meaningful to his career aspiration, and capable, of bringing him up to his fullest potential.

IV. Manpower Development

To assure that all handicapped children served in the schools have a trained teacher competent in the skills required to aid the child in reaching his full potentials.

V. Early Childhood Education

To secure the enrollment of preschool aged handicapped children in Federal, State, and local educational and day care programs.

VI. Severely Handicapped

To encourage additional educational programming for severely handicapped children to enable them to become as independent as possible, including reducing their requirements for institutional care, and providing opportunities for self-development.

In order to efficiently implement the program and carry out the Federal mandate, the Bureau is administratively organized into four major divisions under the Office of the Deputy Commissioner. Each of the major Divisions -- Personnel Preparation, Assistance to States, Media Services and Innovation and Development -- functions as an integral element in the total Bureau program for handicapped children. The following pages describe the functioning of each division as it relates specifically to mentally retarded children.

Services

Division of Assistance to States

Under this Division, there are two branches. One administers the Aid to States programs and the second operates the severely handicapped programs, which includes the Deaf-Blind program.

Aid to States Branch Programs

A. Branch Purpose

The Aid to States Branch is responsible for administering and monitoring programs of assistance and also providing technical and developmental assistance to States in the design, development, implementation and review of State plans for the education of the handicapped. The Branch also serves as a clearinghouse of information concerning novel and/or effective approaches to special education in other States.

B. Historical Development

The purpose of Title VI, Part B, Education of the Handicapped Amendments of 1974, P.L. 93-380 was to provide funds to the States for the initiation, expansion and improvement of special education and related services for handicapped children at the preschool, elementary and secondary school levels; and may be used for the early identification and assessment of handicapping conditions in children under three years of age. Beginning in FY 1975, the State plan must include a goal of providing full educational opportunities to all handicapped children and provide for a procedure to assure the accomplishment of this goal, with priority for expenditure to funds going to serve children who are not receiving an education. The State plan must also provide for procedural safeguards concerning the identification, evaluation and educational placement of the children. With the passage of P.L. 94-142, "The Education for All Handicapped Children Act", the focus of this program changes from being primarily a catalytic or technical assistance effort to one of stringent implementation. The new law mandates that the Federal government administer all of these programs under the requirement that the States set in motion plans and procedures to provide a free appropriate education to all school aged handicapped children by 1978. The responsibilities of the Federal government to enforce this law requires that the compliance of the States and local agencies must be monitored to determine that the States adapt extensive child identification, due process, confidentiality, least restrictive placement and individual child planning procedures in support of their timetable to provide a free appropriate education for every handicapped child.

C. Impact on Mentally Retarded

During fiscal year 1977, $37.5 million was obligated for the Part B program. Of this amount about $12 million was expended in the area of mental retardation, providing direct services to 64,000 mentally retarded children. In 1974 the Part B

appropriation increased to $47.5 million; $15 million of which provided direct services to 80,000 mentally retarded children. During 1975 we are estimating that we shall be serving the same numbers of mentally retarded children. During 1976 $67 million will be allocated to the mentally retarded resulting in 350,000 children being served. Approximately $80 million will be allocated to the mentally retarded during 1977. The 1978 allocations will total $90 million serving 972,000 children and 1979 will reach 990,000 children at an approximate cost of $139 million.

The purpose of the P.L. 89-313 Amendment to Title I of the Elementary and Secondary Education Act is to provide assistance to the States for the education of handicapped children in State-operated and State-supported schools. A new provision, beginning in fiscal year 1975, requires that if a child is transferred from a State-operated or supported school to one operated or supported by a local school system that the P.L. 89-313 funds follow him there.

During recent years, as local facilities for the handicapped have increased, State schools have found the composition of their resident populations changing from the mildly handicapped to large percentages of children who are severely mentally retarded, and those who have serious handicaps in addition to mental retardation.

Model and pilot programs for these types of children have been conducted under P.L. 89-313 in many States.

These funds have enabled institutions and agencies to develop programs for children who have not previously been considered capable of responding to educational or rehabilitative services. The results in many instances have been encouraging and special educators and staff in residential institutions and day classes have raised their levels of expectations for such children. While this program originally had a relatively limited funding, significant results have been realized, especially in terms of planning for comprehensive services.

During fiscal year 1973, of $75.9 million expended, about $46.9 million was in the area of mental retardation, serving about 98,760 children. During fiscal year 1974 about $85.8 million was appropriated for this program. Of this amount, about $52.5 million went to mental retardation, serving about 103,000 mentally retarded children. In fiscal year 1975 $87.8 million was appropriated for this program to supplement the special educational services of approximately 179,000 handicapped children with $54,828,432 being used for 111,600 mentally retarded children. During fiscal year 1976, almost $96 million was allocated for this program to serve 188,078

handicapped children with 18,030 of such children being served in local educational agencies. Of the amount allocated for fiscal year 1976, $57,633,060 was used to serve 113,000 mentally retarded children.

In fiscal year 1977, we estimate that we will be serving 118,000 mentally retarded children in institutional programs and in programs operated and supported by local educational agencies. Our estimation for fiscal year 1978 is that approximately 131,500 mentally retarded children will receive services.

Special Services Branch - Programs for the Severely Handicapped

A. Purpose

Programs for Severely Handicapped Children and Youth provide for the funding of projects which would provide in conjunction with relevant public and private agencies and organizations within a State; (a) a plan for comprehensive services designed to meet identified, developmental needs of severely handicapped children and youth; (b) a model demonstration program providing direct educational and/or training services for these children and youth which can ultimately be replicated State-wide and throughout the Nation; and (c) dissemination strategy whereby information about exemplary program activities or elements will be made available to persons interested in the education/training of severely handicapped children and youth.

B. Assessment Needs

It is estimated that nearly one million severely handicapped children and youth are totally excluded from the educational system of our Nation. At least 300,000 others are not receiving adequate services.

The principal problems delimiting the delivery of effective educational/training services to severely handicapped children and youth in those areas where such services are mandated or supported include: (1) extensive deficiencies in personnel with expertise and experience; (2) lack of adequate, functional facilities; (3) general void of appropriate curricula, methodologies, and education/training programs; (4) scarcity of specialized materials and equipment; (5) limited child and youth identification; diagnostic, prescriptive and placement services; and (6) a general apathy or lack of concern for the needs of such persons, as well as the near nonexistence of advocate groups organized and functioning on their behalf.

The extreme shortage of adequate facilities, staff, and programs, has in many instances limited placement options for severely handicapped children and youth to already overpopulated institutions where, with a lack of funds, facilities, and staff, it has been impossible to provide little more than custodial care. Under more fortunate circumstances there may be more appropriate programs as institutions, and a variety of education/training service capabilities in home communities through mental health clinics, group home, halfway houses, and interim care placement centers. The States of Washington and New York are among those implementing some of these techniques. The "Rosenberg Report", a study in New York State in 1969, found that almost one-third of the retarded children and adults institutionalized by the State could be placed in the community if there were appropriate mental health and day-school facilities for them. At the present time, adequate facilities for such placements are very limited.

Among the most isolated of all severely handicapped children are those who reside in the Nation's "training schools for the retarded and mental hospitals for the emotionally disturbed." Many of these institutions are located far away from any developed community; often those in larger cities are in relatively isolated or inconvenient locations. Children in these institutions rarely leave the grounds of the facility and are almost never given the opportunity to participate in the educational programs of the local school district.

Despite programs administered under legislation such as P.L. 89-313, amendment to Title I, ESEA, which helps to serve nearly 175,000 children in State-operated and State-supported educational programs, tens of thousands of children are left on their own to pass their days without constructive educational programs or social therapy. Such critical personnel shortages exist, that often when services are provided, these services constitute little more than routine custodial care.

C. Current Activities

The Special Services Branch funded for continuation ten (10) programs and five (5) telecommunication activities for severely handicapped in fiscal year 1975. Seven new programs totaling $795,573, were funded, each directing attention to specific areas of the severely handicapped such as auditorial, visual, and orthopedic impairment, severely emotional disturbance and severely/profoundly retarded. The seventeen programs, totaling $2,826.00, will serve as model demonstration programs to be replicated throughout the States. The five telecommunication efforts, totaling

$1,328,779, deal with Telecommunications for Severely Handicapped Children and Youth Who Are Homebound. Telecommunications can be a link between severely handicapped children and the improvement of their social skills and enrichment of their general life situation.

D. Historical Overview and Future Goals

The Bureau of Education for the Handicapped has been interested in launching a concerted effort on behalf of the severely handicapped because of the demand and apparent need for services to this population, the difficult financial position of local and state governments, and the extent of successful activities conducted in the programs for deaf-blind children, funded by the Bureau over the past several years.

Through the BEH objectives and activities addressed to the needs of severely handicapped, we will undertake cooperative planning with related Federal agencies and with State departments of special education to target resources at this population. There will be a program of technical assistance to State education agencies to improve both their management and planning techniques so as to make maximum use of all Federal resources that can be dedicated to the needs of the severely handicapped.

The specific strategy proposed for implementation by BEH during fiscal year 1976 as a sustained thrust toward meeting the educational/training needs of severely handicapped children and youth is: to develop and refine a national compact between BEH and selected States on the education and training for the severely handicapped. A tentative plan for such an agreement has been drafted to incorporate the major service delivery problems that will have to be considered, resolved and funded from State and Federal resources. The intent is to discuss this plan in whole and in the broad spectrum encompassed by its several parts with selected States. The objective of this activity is to engage in a dialog with these States to determine the feasibility and possible deficiencies of the task required to launch the implementation stage of such a national plan. In furtherance of the intent of this activity, it is visualized that we would pursue this effort along two lines; (a) a technical assistance colloquy with the several States to explore various areas of mutual concern, and (b) the development of bench-mark data to be tentatively in a preliminary assessment of the scope, quality and breadth of the plan.

E. Impact on the Mentally Retarded

As it is reflected in current data 41% of the children served in this program were considered to be severely mentally retarded. In terms of money expended the data reflects approximately: 2,300,000 to be expended on behalf of severely mentally retarded.

Centers and Services for Deaf-Blind Children

A. Program Purpose

The purpose of this program is to "provide through a limited number of model centers for deaf-blind children, a program designed to develop and bring to bear upon such children, beginning as early as feasible in life, those specialized, intensive professional and allied services, methods, and aids that are found to be most effective to enable them to achieve their full potential for communication with and adjustment to, the world around them, for useful and meaningful participation in society and for self-fulfillment."

These centers will develop and provide services to children who are deaf-blind and have been deprived of their major avenue of learning and contact with the every-day experiences of life.

B. Historical Background, Legislation and Funding

Public Law 90-247 was signed on January 2, 1968. This legislation was in response to the rubella epidemic (German Measles) that swept the nation and left many children with auditory and visual impairments, as well as other handicapping conditions including mental retardation. Approximately 5064 children were left deaf and blind. There were no programs in existence for such children at that time. In 1969, the first eight regional deaf-blind centers were started. From 1975 to 1978 there have been a total of 10 Regional Deaf-Blind Centers serving deaf-blind children in all 50 States and U.S. Territories.

Total funding approved for Centers and Services for Deaf-Blind Children is as follows:

1970	2,000,000.00
1971	4,500,000.00
1972	7,500,000.00

1973	10,000,000.00
1974	14,055,000.00
1975	12,000,000.00
1976	16,000,000.00
1977/78/79	16,000,000.00

4387 deaf-blind children are in various types of educational programs located in public and private institutions and State hospitals for the mentally retarded. Some of the types of services offered by the Deaf-Blind Program are as follows:

1. Full and part-time education services (both residential and day.)
2. Diagnosis and Evaluation
3. Parent Counseling
4. In-Service Training
5. Short-term program (summer school, respite care)
6. Pre-vocational programs

C. Impact on Mental Retardation

Children born with rubella have many handicapping conditions; many of the children are mentally retarded or show evidence of mental retardation. 800 of our deaf-blind population are receiving services in State hospitals for the retarded. Many more of these children who are deaf-blind and mentally retarded are in programs at public and private institutions. Between 50-85% of children in deaf-blind programs have also been diagnosed at having some degree of mental retardation.

Division of Media Services

Under the Division of Media Services there are three major activities: Media Services and Captioned Films, Recruitment and Information, and Regional Resource Centers.

Recruitment and Information

The recruitment and information program comes directly under the purview of the Deputy Commissioner.

A. Program Purpose

(1) to link parents of handicapped children and youth with needed and appropriate educational and related support services through information and referral to State and local resources; by reaching through mass media, parents of handicapped children who have failed to find appropriate services for these children, to respond to public inquiries generated by media and by assisting local groups in their efforts to meet information and referral needs of parents; (2) to assist States and local planners in providing adequate and appropriate services to handicapped children by supplying valuable consumer feedback to the service delivery system; and (3) to encourage regular education teachers to pursue careers to become teachers of the handicapped.

B. Historical Development

The National Special Education Information Center is now almost six years old. In the past it has directed its greatest efforts to making direct responses to parents by answering telephone inquiries and responding to mail inquiries. It has advertised its services on radio and television and in newspapers. It has also sponsored talk shows by special educators on radio and television.

Currently it is continuing these major efforts, but expanding on them through surveys of existing services, support of local parent groups and provision of feedback to the State and local delivery systems.

C. Impact on Mental Retardation

The Center provides comprehensive information on needs, rights and services for handicapped children. It has answered a quarter of a million letters and more phone calls from concerned parents and provided information to hundreds of parent organizations, and to Federal, State and local agencies, which have passed along the information to individual parents. While its efforts have not targeted on any individual handicapping condition, the Center has had a great impact on the provision of services to the mentally retarded.

Media Services and Captioned Films

A. Program Purpose

This program, authorized under Part F of the EHA provides the handicapped learner with specific educational materials directed at his (her) educational needs. This purpose is

being advanced through the operation of Centers for Educational Media and Materials for the Handicapped. Another major purpose is the captioning and distributing of motion picture films and other media to the deaf and hearing impaired population.

B. Historical Development

During 1974 and 1975 more than 4363 groups of hearing impaired persons, representing an audience of 3.0 million people, were reached through the Media Services and Captioned Films program. Of these, 1541 were schools or classes for the deaf. The total audience for theatrical films numbered over 1.6 million with a monthly average of 4,000 showings.

The program circulated more than 700 different captioned educational films through its 60 film depositories.

In 1976 the number of groups of hearing impaired persons reached exceeded 4,800 (1,600 schools and classes for the deaf). The captioned theatrical and cultural films reached a total audience of 1.8 million persons with a month average of 5,000 showings.

800 captioned educational film titles have reached an audience of 1.7 million hearing impaired children, with classroom showings averaging over 4,000 per month.

Support of the National Theatre for the Deaf is continuing, and a daily captioned evening news broadcast over the national PBS network is continued. The development of an electronic coding system to provide captioned television programming to a potential audience of more than 13 million hearing impaired Americans is expected to be operational in two years.

C. Impact on Mentally Retarded

The Centers on Educational Media and Materials for the Handicapped and one of the specialty centers associated with the Centers are actively working with the States in the development of media and materials for the mentally retarded and other handicapped learners.

Regional Resource Centers (RRC's)

A. Program Purpose

The Regional Resource Centers (RRC's) were established under Part C of EHA. Presently, there are sixteen (16) RRC's serving their respective regions by supporting assistance to

States in developing an intrastate capacity in regard to the following educational services and to provide said services to the States' service-clients within service rules which are clearly reinforcing of local and State capacity; appraisal of handicapped children, diagnosis of learning disorders and prescription of educational programs of handicapped children. The RRC's are concentrating their efforts on development of resources and services for the unserved, underserved and difficult to serve segments of the handicapped population, i.e., poor inner city and rural populations including a high percentage of the ethnic minorities.

B. Historical Development

In fiscal year 1973, in conjunction with State and local education agencies, the program provided specific diagnostic, evaluative, prescriptive remedial or supportive services. Program strategies were designed to achieve the catalytic effect of influencing practices to enable more children to be placed in regular school programs.

In 1974, the major concern of the centers was to improve the effectiveness of on-going practices and of developing and implementing the use of new techniques where none existed. The major objective was to assure that all geographical areas covered by RRC programs had access to services directly or through cooperative efforts. Coordination of planning activities with the National Media and Materials Center is to bring about a dynamic, interrelated resource system.

In 1974, approximately 40,000 handicapped children received comprehensive services from six Regional Resource Centers. Approximately 200 State education agencies and 6,000 local education agency personnel received training through workshops, special institutes, and technical assistance activities. Also, 2,000 severely and multiple handicapped children received services in addition to the 40,000 children mentioned above.

In 1975, considerable emphasis was being placed by the RRC's serving their 57 client States on developing the SEA's "Master Plan" for special education services to handicapped children as the plan relates to appraisal and programming.

C. Impact on the Mentally Retarded

By the end of 1978 it is estimated that 74,000 mentally retarded children will receive services as a result of this program. In addition, support will be provided to 400 State educational service agencies and 16,000 local education agencies who provide services to the Nation's handicapped children.

Training

Division of Personnel Preparation

A. Purpose

The Division of Personnel Preparation of the Bureau of Education for the Handicapped initiates, maintains and improves programs for the preparation of professional leadership and teaching personnel so that the States can reach the goal of properly servicing handicapped children and youth by 1980. Divisional programs which are designed to respond to this goal are four-fold in their attack in that they must provide: (1) classroom, supervisory, consultative, and administrative personnel for State and local special education programs; (2) personnel for higher education institutions responsible for preparing administrative and classroom personnel; (3) paraprofessionals for special education programs; and (4) training for regular educators to work with handicapped children.

B. History

In 1958, Public Law 85-926 was passed by Congress authorizing an appropriation of $1 million per year for the preparation of professional personnel in the education of the mentally retarded. This initial piece of legislation was directed at preparing college and university personnel to staff the then existing programs, and much needed new programs for preparing personnel to work with the handicapped in State and local school systems. Between academic years 1959-60 and 1963-64, 692 graduate traineeships were granted to 484 individuals who became college and university professors while 208 others became State and local special education leadership personnel.

On October 31, 1963, P.L. 88-164 was signed into law. Section 301 of this Act amended P.L. 85-926 to: (1) expand the program to include not just the area of mental retardation, but also the areas of the visually handicapped, deaf, crippled and other health impaired, speech and hearing impaired, and the emotionally disturbed; (2) allow for the preparation of teachers and other specialists in addition to leadership personnel at the graduate level; (3) extension downward into the senior year undergraduate levels; and (4) increase the monies authorized for these purposes.

Public Law 85-926 was further amended with the passage of Public Law 89-105 and 90-170. These amendments expanded and extended the program through fiscal year 1970, authorizing appropriations at 29.5 million for fiscal year 1967; $34 million for fiscal year 1968; $37.5 million for fiscal year 1969; and $55 million for fiscal year 1970.

These appropriated funds have been used as stipends for students as well as to support colleges, universities, and State education agencies. Since P.L. 85-926 was passed in 1958, approximately 109,000 traineeships have been awarded to individuals preparing to work with mentally handicapped children. This included both short-term and full academic year awards.

State Education Agencies have received approximately $6,000,000 in recent years to provide short term training in their respective States. This money has been largely used to provide for inservice training of special educators.

Training Awards in the Area of Mental Retardation Fiscal Year 1960 -1977

Fiscal Year	Number of Traineeships	Number of Higher Ed. Institutions Participating	Number of State Ed. Agencies Participating	Total Amount Obligated
1960	177	16	23	$ 985,222
1961	164	18	41	993,433
1962	160	20	46	997,000
1963	163	19	48	996,433
1964	2,357	108	50	6,419,332
1965	2,506	153	50	6,569,815
1966	3,110	162	52	7,658,002
1967	3,816	177	53	8,891,072
1968	4,521	177	53	8,493,668
1969	6,366	193	53	9,382,084
1970	6,171	200	55	10,391,341
1971	4,909	207	55	8,955,355
1972	5,100	210	56	8,955,355
1973	4,830	215	56	8,476,181
1974	5,835	225	56	10,240,450
1975	2,050	225	55	6,100,000
1976	2,050	225	55	6,100,000
1977	2,050	225	55	6,100,000

This program has enabled a great number of colleges and universities to develop and/or expand their teacher training programs in mental retardation. A current analysis of the more than 300 institutions requesting funds in the area of mental retardation indicates that more than 170 of them have on their faculties former trainees of the program.

Under current awards policy, which give more authority to universities to administer their own program according to local needs and requirements it is difficult to report discrete number of teachers being trained for mental retardation. However, it is our best judgment from review of proposals received that the number of teachers being trained for mental retardation has not diminished. Although only 2050 students enrolled in training programs in the area of mental retardation and funds allocated have been reduced, emphasis is now being placed on training teachers to serve the more severely retarded child. Institutions are changing training programs to fit this demand.

C. Cooperative Activities

The Division of Personnel Preparation in an effort to utilize all resources in the provision of quality educational pro- programs for all retarded children has entered into cooperative funding or working arrangements with other personnel training programs in the Office of Education and the Social and Rehabilitation Service. The following are three examples of the Division's cooperative efforts:

University Affiliated Facility Program

The Division of Personnel Preparation in cooperation with the Division of Developmental Disabilities, Rehabilitation Services Administration (SRS) provided support monies to special education components in unviersity-affiliated facility programs for fiscal year 1976. The extent of the Division's support ranged from approximately $20,000 to $30,000 with a total expenditure of $396,000.

The Division supports a special educator on the university affiliated facility core faculty. The special educator is responsible for instructing medical students, psychologists, social workers, and other related medical personnel as well as students majoring in special education. He serves to effectively integrate special education concepts into the overall interdisciplinary training program of the university affiliated facility.

The institutions receiving support through this program for recent years were: Georgetown Unviersity; University of

California at Los Angeles; Johns Hopkins University; Indiana University; University of Miami (Florida); Ohio State University; University of Cincinnati; University of Tennessee (Memphis); Children's Hospital (Harvard); University of Oregon; University of Alabama (Birmingham); Utah State University; University of Wisconsin; Georgia Retardation Center (Georgia Department of Public Health); University of Kansas; the University of Michigan; University of North Carolina.

D. Special Projects

The special Projects program in the Division of Personnel Preparation, Bureau of Education for the Handicapped, is designed to provide an opportunity for conceptualizing and implementing on a trail basis, approaches to personnel preparation for the education of the handicapped children which are basically new or which are significant major modifications of existing personnel preparation and facilitate innovative approaches to the solution of major training problems.

Currently there are approximately 40 operational Special Projects funded by the Division of Personnel Preparation. Approximately one-fourth of these projects are concerned with the preparation of personnel to educate retarded children. Most of these projects are primarily concerned with the most severely handicapped. During fiscal year 1976 approximately one-fourth of the 3.7 million dollars invested in these projects was specifically targeted for the mentally retarded.

E. Future Goals

The goals of the Division of Personnel Preparation are to:

1. Increase the number and quality of personnel for education of the handicapped with special attention to early childhood education, vocational education, the urban and rural poor, paraprofessionals and to train regular classroom teachers to teach the handicapped

2. Increase the amount and quality of technical assistance to agencies and institutions training professional personnel.

3. With State departments of education and institutions of higher education effect cooperative planning for the training of personnel in special education.

4. Develop a systematic data collection program upon which to monitor current efforts and to base future efforts.

Research

Division of Innovation and Development

A. Purpose

The Research Program of the Bureau of Education for Handicapped promotes and supports research and related activities which show promise of leading to improvement in educational programs for handicapped children. Support is available for research, dissemination, demonstration, curriculm, and media activities.

B. History

This program now administered by the Research Projects Branch, was initiated during fiscal year 1964 with appropriation of one million dollars authorized under Title III, Section 302 of Public Law 88-164. This authorization has been continued, through the ensuing years and the scope and flexibility of the program have been expanded. In April 1970, the various acts of legislation that pertained to research were incorporated into P.L. 91-230, Education of the Handicapped Act. The latest Act, P.L. 95-49 provided for authorization through fiscal year 1982. An increasing proportion of research funds have been allocated to projects which impact more generally on the education of handicapped children. In general, such "non-categorical projects have tended to equal or exceed the amount of activity directed specifically at the field of mental retardation, and may be assumed to have virtually as much an impact on programming in the field of mental retardation as do those projects which relate to problems specific to the mentally retarded.

C. Impact on the Problem of Mental Retardation

It is frequently difficult to assess the direct impact of research activities on educational programming since the lag between the discovery of new knowledge and consequent changes in educational practices obscures the relationship. However, a number of suggestions regarding program impact are available. As of the end of 1974, supported projects had resulted in the distribution of over 500 project reports relating to education of the mentally retarded through the ERIC system, and at least an equal number

of publications in professional journals. In addition, validated curriculum materials designed specifically for mentally retarded groups have been developed and are now availabe in the area of social learning, arithmetic, science, physical education, and self-help skills. Special education instructional materials centers and regional resource centers for the handicapped which began as development/demonstration projects supported through the research program have now become institutionalized service operations providing services to the mentally retarded as well as other handicapped populations.

D. Current Activities

A number of research and research related activities relevant to the education of mentally retarded children are currently being supported by the Research Projects Branch. A major applied research program is involved in a series of studies relating to the effects of teacher behavior on pupils, and on ways of establishing more effective teacher behaviors. Another major program is investigating methods of optionally matching learning characteristics of retarded children with various teaching methods and environments. Development of additional specialized curriculum materials for the mentally retarded continues with particular emphasis on development of new materials for severely retarded children.

Additional efforts of a more general nature also have particularly important implications for the retarded. Among the most important projects currently being conducted is an investigation of reintegration of handicapped children into regular education programs. A second major effort involves a series of eleven demonstration projects involved in the investigation of techniques for integration of a wide variety of community services available to retarded and other handicapped children.

E. Future Goals

In order to stimulate more effective programming for handicapped children the research and development program is structured to link research and research-related activities more directly to the support of special education services. Major areas of emphasis are:

1. Assessment of the effectiveness of special education curricula and procedures.

2. Development of new curricula, materials, and techniques.

3. Encouragement of the broadest possible diffusion, utilization, and implementation of effective procedures.

Of particular importance in the area of mental retardation are: continued attention to development of curriculum and materials, investigation of the effects of integrating retarded children, and increased attention to the problems of severely and profoundly retarded children. Across all these activities attention will be concentrated on problems of early education and career education for the retarded.

RESEARCH PROJECTS IN MENTAL RETARDATION

Year	Number	Amount
1964	9	$ 238,270
1965	14	520,905
1966	39	1,110,089
1967	32	1,084,429
1968	31	1,608,076
1969	29	2,184,921
1970	16	1,601,709
1971	10	4,413,863
1972	7	2,204,723
1973	10	3,020,347
1974	14	2,599,405
1975	27	2,706,927
1976	18	3,768,943
1977	15	3,000,000
1978	15	3,000,000

Other O.E. Programs Providing Services to the Mentally Retarded

Library Services

In recent years public libraries have recognized mentally retarded citizens as another of the special groups requiring individualized attention and services. Creative, innovative and generally non-print oriented programs, especially adapted to suit the mentally retarded patron's developmental and social needs, are being sponsored by local libraries utilizing Federal funds available under the Library Services and Construction Act (LSCA), Title I. Several of the legislative priorities under Title I (Library Services) have significant implication for mentally retarded persons. Included among these funding priorities: grants to establish and improve libraries in residential institutions operated by or substantially supported by the State (Training Schools for Educable Mentally Retarded, Schools for Developmentally Disabled, etc.); funds to provide specialized materials and services to blind and physically handicapped persons who are unable to utilize conventional print material; and grants to extend and improve public library services where inadequate.

Whether residing in private homes or State institutions, mentally retarded persons of all ages are benefitting from the public library's increased awareness and responsiveness to their needs. There is growing evidence to show that mentally handicapped persons can receive pleasure, gain social skills, and actually acquire some necessary life-coping skills from specially designed library programs.

In the past year numerous States have expended LSCA funds to sponsor in-service training programs for librarians. These institutes and workshops provide a much needed forum for discussion about service to this special group and help impart the information, techniques, and skills local librarians will need in order to deal effectively with their mentally retarded patrons.

Such in-service programs are especially important in light of the recent Federal requirement that public school systems provide for an "individualized educational program" for each handicapped child. Public libraries are a major source of support to school systems, serving both the professionals who need specialized information and the students who use the library to supplement their formal learning program. Libraries are, therefore, being increasingly called upon to assist schools in giving mentally retarded children the proper educational programs they require. Indeed, libraries can and do augment the schools' special education programs in a unique way. As a community institution, public libraries provide a "real life" environment into which the mentally retarded person can be successfully mainstreamed. Also, the activities carried on in a library can involve the handicapped child in a way that stresses individual effort and abilities and provides opportunities only for success and achievement, not failure.

Activities for mentally retarded patrons often include storytelling, poetry reading, arts and crafts "do-it-yourself" programs, use of audio-visual materials (cassettes, films, filmstrips, etc.), puppet shows, etc. These activities enhance a child's performance in regular school programs by providing another constructive environment for learning. Library programs provide mentally handicapped persons with:

a) aesthetic experiences through art projects in which the mentally retarded person can use his imagination to create and need not fear failure

b) physical therapeutic experiences through arts and crafts projects which involve repetitious use of manipulative skills such as holding crayons, grasping scissors, etc.

c) vocational experiences through use of audio-visual materials which require following verbal instructions and through story-telling and response activities which increase listening skills; and

d) social experiences through interaction with "outsiders" in a normal setting.

With the increased use of audio-visual materials, media, toys, educational and skill-building realia, etc., libraries are often successful in reaching mentally handicapped persons and attracting them to the library individually and in groups. Libraries are also developing special collections for these persons and sponsoring programs to meet their specialized needs. In State residential schools for the mentally retarded, library-centered bibliotherapy sessions assist the handicapped residents in relating to the world around them. Equally important, libraries are helping the surrounding community to better relate to them by providing:

a) factual books on retardation in library collections;

b) vital information and referral services for parents, teachers, etc.;

c) presentations to community groups on problems of handicapped, thus serving as public educators;

d) inspirational materials;

e) parenting education and information; and

f) structured "interest centers" within the library, equipped with audio-visual aids for use by special patrons.

Although it is difficult to enumerate the actual number of public library programs reaching out to serve the mentally handicapped (projects are often subsumed under broader services such as outreach or summer reading programs for handicapped children), the following examples of LSCA-funded projects illustrate the diversity and effectiveness of library services to the mentally retarded:

In Pennsylvania, "Project L.I.F.E. (Libraries Initiate Freeing Experiences)" serves mentally retarded and learning disabled individuals of all ages and ability levels. The project's multi-faceted approach involves close cooperation with the schools and agencies serving this population. A collection of multi-media materials is available for circulation among the mentally retarded. Programs in which these handicapped patrons can participate and find enjoyment and stimulation are presented in the library, thus providing a situation in which they can relate to other patrons and become better integrated with community. Serving parents, teachers, and professionals, the project also provides a resource collection, an up-to-date information and referral service, and given presentations on relevant topics including parent workshops to demonstrate use of skill-building toys.

A Massachusetts public library program focusses on the speciaized advice, information, and materials needed by parents of children who are mentally retarded or learning disabled. In cooperation with the local schools, the library has organized a resource center for the parents of children with special needs. Housing a select collection of books, instructional materials and audio-visual aids, the Center offers a wide range of services and opportunities for parents to actively help their handicapped children. Consultant services provided by special education teachers, parent-teacher meetings, lecture programs, films, and demonstrations are all available at the Center, along with parent groups assembled to exchange ideas and share unique parenting experiences.

In one New Jersey project, the library, working in conjunction with hospital staff, produced a video-tape series to help mentally retarded adults acquire such daily life skills as shopping, meal preparation, riding public transportation, etc. This project resulted in mentally handicapped adults who were trained and capable of living independently.

Many State institutions have specially equipped libraries provided by LSCA funds and designed specifically to serve the residents who cannot take advantage of public library services. One such institution library is the innovative multisensory library for the mentally retarded at the Wrentham State School in Massachusetts. This library features films and story hours, puppet shows, high-interest/low vocabulary books, talking books, and other media to stimulate both mind and senses, thus helping to develop the residents' feelings of educational achievement and emotional satisfaction.

Vocational Education Act

Under the Vocational Education Amendments of 1968, States are required to use at least 10% of their basic grant money to support vocational education programs for handicapped persons. For FY 1979, this represents a set-aside of at least $55 million in Federal dollars with State dollars matching approximately $1.16 to every Federal dollar.

Although State vocational education reports in the past did not give data by category of handicapping conditions, deaf, blind, crippled, emotionally disturbed, and mentally retarded educable and trainable were all listed among the categories being served. Unvalidated national information indicates that the largest single category is still the mentally retarded with more than half of the enrollments being so diagnosed.

The Vocational Education Amendments of 1976 established a new vocational education data system. Under this system, the problem of lack of data on categories of handicapped individuals being served in vocational education programs is being addressed. NCES has developed a means of identifying by category of handicap, occupational area, and educational level (secondary, postsecondary, and adult), all handicapped persons being served in vocational education programs. The reporting system being developed is currently undergoing feasibility studies and it is hoped that this segment will be retained.

Estimated total handicapped enrollments are:

	1975	1976 EST.	1977 EST.	1977 EST.	1979 EST.
Total handicapped enrolled in Vocational Education: (in thousands).....	263	290	335	363	385
Secondary.....	201	210	235	250	265
Postsecondary.....	32	45	55	60	65
Adult.....	30	35	45	53	55

The number of mentally retarded served was addressed in a project entitled an Assessment of Vocational Education Programs for the Handicapped Under Part B of the Vocational Education Amendments of 1968, performed by Olympus Research Corporation in 1976. This report indicates that in a representative sample of vocational education programs for the handicapped in 19 States, 84% of students diagnosed as handicapped were categorized as mentally handicapped: 66% were educable mentally

retarded; 12% were trainable mentally retarded; 4% were learning disabled; 1% were emotionally disturbed, and 1% were educationally handicapped; 15% were physically handicapped and 1% were multi-handicapped.

Under vocational education, the mentally retarded are being served in special classes in State schools, in local educational agencies, and in regular vocational education programs in vocational schools. In most programs, the objective is to provide those services and program modifications which will assist the mentally retarded person to become employable at the highest level of which he/she is capable. We are finding that the potential of many handicapped persons has been underestimated and we are now modifying approaches to provide more individually prescribed instruction and better assessment of potential through use of Vocational Rehabilitation/Vocational Assessment programs and other assessment tools.

As a part of this effort, inservice training of vocational education instructors to enable them to better serve the handicapped has been supported at the national level and is being offered in all States under State Department of Education, Vocational Education Division. Teacher Training Institutions for Vocational Education Leadership are becoming increasingly active in providing preservice and postgraduate education for vocational education instructors concerned with handicapped students.

At the national level, two projects were funded by the Bureau which were designed to assist State and local teacher education efforts to respond to the need for in-service and preservice education for teaching students with special needs. Additional efforts to reach all vocational instructors to teach handicapped students are being made at the State level.

SOCIAL SECURITY ADMINISTRATION

MENTAL RETARDATION

Purpose

The basic purpose of the social insurance programs (Old-Age, Survivors, and Disability) is to provide cash benefits to replace, in part, earnings that are lost to individuals and families when earnings stop or are reduced because the worker retires, dies, or becomes disabled. This program is contributory and self-supporting. Benefits are wage-related and entitlement to benefits is an earned right. In January 1974, the Supplemental Security Income Program was added to those SSA administers. It provides payments to the needy aged, blind, and disabled, is noncontributory and is financed entirely out of general Federal revenues.

Historical Development

In 1935, when the original social security law was passed, the program was to have provided only retirement benefits to aged workers. In 1939, benefits for dependents and survivors were added and benefits became payable in 1940. Protection against long-term total disability--not only for disabled workers, but also for adult sons or daughters (who became disabled before age 18) of disabled, retired, or deceased workers--was provided by the 1956 amendments. The 1967 amendments provided benefits for disabled widows and widowers age 50 and over. Since 1958, there have been seven general benefit increases in recognition of the fact that prices and wages have gone up. In 1972, a section of P.L. 92-336 provided for an automatic benefit increase when the cost-of-living rises by 3 percent or more. Effective January 1974, payments under the Supplemental Security Income Program began to qualified aged, disabled, and blind persons, including the mentally retarded.

Economic Impact

Old-Age, Survivors, and Disability Insurance (Title II Programs)

Mental deficiency is a major factor in about 78 percent of cases involving dependents or survivors who have been continuously disabled since childhood. In fiscal year 1977, an estimated 289,000 mentally retarded adults, disabled in childhood, and retarded workers received $471 million in benefits.

The regulations contain guides as to the level of severity required in disability cases involving mental retardation. These regulations (published in 1968) have the effect of law and are available to the public and the medical community.

The number of mentally retarded children under age 18 who receive social security insurance payments as dependents of retired, disabled, or deceased workers is unknown, since their benefits are payable regardless of disability. Under social security's "Childhood Disability" provisions, lifetime monthly payments can be made to a person age 18 or over who has been disabled by mental retardation--or other impairments--since childhood. In many cases, the monthly benefits enable the retarded childhood disability beneficiary to be cared for at home instead of in an institution. Furthermore, as more and more retarded people outlive their parents, the program offers reassurance to fathers and mothers who know that financial help for their disabled child will be forthcoming even after their death. About 56 percent of the childhood disability beneficiaries are age 35 and over and 32 percent of them are age 45 and over.

If the parents are dead, a relative who has demonstrated a continuing interest in the beneficiary's welfare, a welfare agency, or a legal guardian may be chosen as representative payee to handle the benefit funds and to plan their use on behalf of the beneficiary. Each representative payee is held accountable for the way in which he uses the benefits.

Supplemental Security Income (Title XVI)

An estimated 400,000 retarded individuals who are not entitled to benefits under the Title II Disability Insurance Program were receiving payment under the Supplemental Security Income Program by the end of calendar year 1977.

Activities and Achievements

Since 1970, the Social Security Administration has conducted biennial on-site reviews in State mental hospitals and schools for the retarded. The program focus is an in-depth examination of the way in which these institutions are managing social security benefits on behalf of patients who receive their checks through an institutional official serving as "representative payee."

The observations and conclusions resulting from a State review are, after analysis, communicated to the State Commissioner for his use in the development of improved practices in the State's system. Findings also serve as a basis for SSA program and policy evaluation. The on-site approach is expected to strengthen relationships with the States, improve their understanding of their responsibility for optimum use of benefits when serving as representative payee, and open new channels for the discussion of problems and practices affecting the well-being of all beneficiary-patients in State mental institutions.

SSA has participated in the Special Program for Employment of the Handicapped to employ the mentally retarded since its inception in 1964. It also has tried to generate interest in the program by private employers and other Federal agencies. In SSA, mentally retarded persons are successfully performing in such positions as mail and file clerks, messengers, operators of printing, xerox, card reader machines, and key punch machines. An experiment with the color coding of file cabinets and cartridges of microfilm has proven highly successful in broadening employment opportunities for the mentally retarded to an area of work which requires a very high degree of accuracy.

In cooperation with the Bureau of the Census, the Social Security Administration conducted surveys in 1971 and 1972 of noninstitutionalized adults who had been reported as disabled in the 1970 Census or had become disabled since the 1970 Census. The data collected included demographic characteristics; employment history and present work situation; disabling conditions; job limitations and adjustment; functional limitations and mental health ratings; use of medical care and rehabilitation services; family participation and relationships; and economic resources. Mentally retarded persons age 18 and over who were not institutionalized at the time of the survey are included in these studies.

The available reports summarizing the data are:

(1) First Findings of the 1972 Survey of the Disabled: General Characteristics, published in the October 1976 SSA Bulletin;

(2) Impact of Disability on the Family Structure, published in the May 1977 SSA Bulletin; and,

(3) Disabled-Worker Beneficiaries Under OASDI: Comparison with Severely Disabled PA Recipients, published in the August 1977 SSA Bulletin.

OFFICE OF HUMAN DEVELOPMENT

Rehabilitation Services Administration

MENTAL RETARDATION

Under the public rehabilitation program, grants are made to State vocational rehabilitation agencies to assist them in providing rehabilitation services to mentally and physically disabled individuals who have substantial employment handicaps and who can reasonably be expected to be rehabilitated into gainful employment. Among the services provided by State vocational rehabilitation agencies are comprehensive medical, psychosocial and vocational evaluation; physical restoration; counseling; personal adjustment, prevocational and vocational training; maintenance and transportation during the rehabilitation process; placement in suitable employment; services to families of handicapped people when such services contribute substantially to the rehabilitation of the handicapped client; and follow-up services to assist handicapped individuals in maintaining employment.

In relatively-recent years, there have been dramatic advances in the provision of vocational rehabilitation services to mentally retarded individuals. Approximately 12% of all the handicapped people rehabilitated by the State agencies have mental retardation as their primary disability. In 1977, about 35,500 mentally retarded individuals were rehabilitated, and in 1978 this figure is expected to be nearly 36,000.

Basic to the vocational rehabilitation effort has been the growing reliance on counselors and other vocational rehabilitation staff who work exclusively with mentally retarded clients. This specialized staff may be assigned to local vocational rehabilitation offices, schools, institutions, sheltered workshops, or other facilities serving the mentally retarded. By concentrating their attention on the mentally retarded clients, these counselors are successfully developing rehabilitation plans based on the special problems of the retarded, and are able to be broadly responsive to the needs of both the client and his/her family.

The specialized vocational rehabilitation staff working with the mentally retarded has been particularly effective in the development of cooperative vocational rehabilitation-special education programs designed to assist the retarded young person make a satisfying transition from school to work. These cooperative programs are found in many communities throughout the country and have greatly strengthened both special education and vocational rehabilitation efforts with the mentally retarded. The cooperative program structure varies from State to State, and the variety of approaches is extraordinary. In some States, program administration is Statewide and in others there are separate agreements with individual school districts. Some programs function only to serve the mentally retarded, while others include youth with all kinds of disabilities. In some States, only vocational rehabilitation and special education are administratively involved, while in others representation includes vocational education.

Most cooperative arrangements have brought about the development of vocationally-oriented curricula within the schools. All of them, however, provide comprehensive evaluation of the retarded young person's vocational rehabilitation potential, personal adjustment and pre-vocational training, counseling, on-the-job training and work experience, job placement, follow-up and related vocational rehabilitation case services. These cooperative programs have proven themselves effective in reducing the school dropout rate of retarded youngsters and have provided a technique for continous service to youngsters during the school years when they are best able to benefit from them.

Another emphasis of State vocational rehabilitation agencies has been the establishment of rehabilitation facilities, such as comprehensive rehabilitation centers, evaluation centers, occupational training centers, workshops, half-way houses, and other specialized facilities serving the mentally retarded. Such a rehabilitation facility may be established by State rehabilitation agencies, or by the State agency in cooperation with other public or private agencies. These facilities are an especially useful resource in the Program's deinstitutionalization efforts.

Under the Rehabilitation Training program, graduate training is supported in the field of rehabilitation counseling and other professional fields contributing to the vocational rehabilitation of the severely mentally retarded. Curriculum content on mental retardation is included within the course of study of all of these programs, and clinical fieldwork experience is carried out in facilities and agencies serving the mentally retarded. In addition, training is provided to employed rehabilitation agency personnel within State vocational rehabilitation agency in-service training programs and Rehabilitation Continuing Education Programs, in order to improve professional skills in rehabilitating mentally retarded persons.

Rehabilitation Research

Under the public rehabilitation program, grants are made to States and public and non-profit agencies and organizations, including institutions of higher learning, to pay part of the costs of projects for the purpose of planning and conducting research, demonstrations and related activities which aid in the provision of vocational rehabilitation services to handicapped individuals, including the mentally retarded. Research in the office of Rehabilitation Research and Evaluation continues to focus on rehabilitation services for mentally retarded individuals that enhance the development of human qualities and capabilities which bridge the gap between attained competency and what is required for normal social and vocational independence and those which protect a mentally retarded person from exploitation and other threatening conditions beyond his control.

The differences in need for each kind of rehabilitation services between a mentally retarded person and a so-called normal one is not really a difference in kind, but one of degree.

Obviously the more severe the degree of mental retardation the greater the need for rehabilitation services and the greater the gap that is likely to remain between attainable services and those required for independence. The goals of rehabilitation research are the lessen the dependence on special forms of supportive services, yet still maintain a person's social and vocational adjustment to the point that he can meet the demands placed upon him and reduce the likelihood that he needs to be institututionalized.

Research and Training Centers

Grants are made to three Rehabilitation Research and Training Centers in Mental Retardation, which were established by Congress in 1965, to conduct multidisciplinary programs of research on the major psychosocial, vocational, and personal adjustments in the lives of the mentally retarded persons. The training activities in which each Center is involved are geared toward wide dissemination and utilization of new knowledge resulting from research findings.

In response to HEW's increased recognition of the need to develop adequate alternatives to long-term institutional care, research projects conducted by the three Research and Training Centers are directed toward facilitating the integration of the mentally retarded persons into independent or semi-dependent community life with productive employment as the ultimate objective. The three Centers are located at the Universities of Wisconsin, Texas Tech and Oregon.

Research and Training Center Training Activities

A Research and Training Center's primary training responsibility is dissemination of research results through consultations and technical assistance, seminars, workshops, courses of study, conferences and demonstrations which will enhance the skills of students, professionals, paraprofessionals, consumers and all other personnel involved in the rehabilitation process. Inasmuch as solutions to rehabilitation problems, in most instances, require the coordination of bio-medical, psychosocial, engineering, education, and vocational rehabilitation disciplines, the Research and Training Center Training programs encompass training into all those components of rehabilitation that will lead to employment.

Mental Retardation Projects in Special Foreign Currency Countries

There are five Research and Demonstration Projects in the field of mental retardation currently being supported through the Special Foreign Currency Program. These are located in Israel, Poland, Tunisia and Egypt. It is expected that three new projects in mental retardation will be initiated under this Program in 1979.

OFFICE OF HUMAN DEVELOPMENT SERVICES
Rehabilitation Services Administration

MENTAL RETARDATION

Number of People Rehabilitated:

Fiscal Year	All Rehabilitants	Persons Rehabilitated With Mental Retardation
1975	324,039	38,338
1976	303,328	36,000
1977	291,202 1/	34,857 1/
1978	283,000 1/	34,400 1/
1979	277,000 1/	33,900 1/

1/ Estimated

OFFICE OF HUMAN DEVELOPMENT

Developmental Disabilities

MENTAL RETARDATION

The Developmental Disabilities Office is responsible for a broad range of programs designed to meet the problems of the developmentally disabled including the mentally retarded. Under the Developmental Disabilities Services and Facilities Construction Act, as amended, mental retardation is one of the four primary disabilities covered by this Act. Because of the nature of mental retardation, it is often combined with one or more of the other three disabilities--cerebral palsy, epilepsy, or autism--in the individual with mental retardation. This multiple handicapped condition prevents the identification of specific monies which may be expended solely for mental retardation.

Mentally retarded individuals comprise the largest group of developmentally disabled. Calculated national rates of prevalence for mental retardation is 2.8% of the total population or approximately 6,397,348 individuals. The majority of the retarded are mildly retarded and therefore able to benefit from education and training, hold a job, and participate in community affairs. Current focus is on the more severely retarded who may also be multiple handicapped and have been the ones most often found in public institutions.

Under the State Grants Activity, a State submits an annual comprehensive plan on developmental disabilities and after approval of this plan, receives grant funds based on a formula distribution. These funds may be used to support evaluation; diagnosis; personal care; education; treatment; information and referral; follow-along; recreation; counseling; sheltered employment; training; special living arrangements; day care; transportation; socio-legal; and domiciliary care. This basic State formula grant program provides assurances that the developmentally disabled population receives assistance in the form of services in the sixteen areas indicated. Without these services, the major portion of this population would continue to be institutionalized or otherwise not accepted as part of the everyday community living and working environment. The States must utilize not less than 30% of their allotment towards the goal of deinstitutionalization.

The mentally retarded population is now progressing toward a life of independence due to the efforts of Federal/State government and local communities in the goal towards deinstitutionalization. The movement of clients to community-based alternative living arrangements allows them to enjoy a more normalized way of living. Supervised group homes, community residences or apartments are places in many communities across the nation where young and adult mentally retarded persons now reside. They are learning to function independently and are taught household responsibilities, how to shop, and how to socialize in the community. Some individuals are placed in foster homes; others have returned home to their families. Services for their needs are made readily available in or near the community in which they live.

A project in Rhode Island has established an intensive training program for severely and profoundly retarded adults in a group home setting. These adults are taught self-help skills which enable them to be maintained outside of an institutional setting. One of the main objectives of this project is to demonstrate that coordination of day and residential programs can achieve significant positive change in those people who previously had little hope of successful community habilitation.

Also included in the State Grants Activity are formula grants to States to implement a system to protect and advocate the rights of persons with developmental disabilities. .This system provides the authority to pursue legal, administrative, and other appropriate remedies to insure the protection of the rights of the developmentally disabled who are receiving treatment, services, or habilitation within the State.

Under the Special Projects Activity, discretionary grants are awarded for the purposes of providing technical assistance; training; demonstrations of established programs which hold promise of improving services; elimination of attitudinal and environmental barriers through public awareness and public education programs; coordination of available community resources; demonstrations of services to be provided to the developmentally disabled who are economically disadvantaged; improving techniques in the development of services; improvement of the quality of such services; and gathering and disseminating information.

Many of the special project grants awarded in 1977 and some to be continued in 1978 were devoted specifically to mental retardation. There are projects such as 1) Evaluation of the Impact of Deinstitutionalization on the Mentally Retarded, their Families, and the Community; 2) Profound Retardation Education Program; 3) Halfway House for the Deaf Mentally Retarded; 4) Pre-vocational Evaluation and Planning for the Mentally Retarded; 5) Weekend Care for the Mentally Retarded in Rural Communities; 6) Community Living for Institutionalized Adult Mentally

Retarded Persons; 7) Socio-recreational Skill Program for Retarded Persons; 8) Mentally Retarded Juvenile Offender Model Service System.

Specific examples include a grant to the American Association of Community and Junior Colleges which produced a guidebook designed to help community colleges develop programs to train direct care personnel for new community-based residential facilities for developmentally disabled people. It is generally felt that community colleges are best equipped to train many of these direct-care workers. The guide book provides information related to the question, "Shall we institute such a program?" and a guide to structuring the program itself. Such programs will be increasingly needed because the society has recently given a high priority to new forms of care for these people and has granted them new legal status.

Another grant entitled, "Rehabilitation of the Severely Developmentally Disabled" was awarded to increase the number of developmentally disabled people who are vocationally rehabilitated. Over a three-year period, a total of 582 persons were served and 398 were successfully placed in competitive employment. Of the clients placed, 22% were former residents of an institution and 31% were multi-handicapped. Placements were made in over 50 different job classifications for both full-time and part-time employment and compensation as high as $168 a week.

A project of national significance with the American Bar Association, Commission on the Mentally Disabled, assists in the publication of the Mental Disability Law Reporter. The Reporter is a complete, continually updated compendium of legal and legislative developments for the use of not only the mental disability bar, legal service projects, general practitioners and State attorneys but also for service providers and consumer organizations. It includes summaries of recent court decisions, texts of significant cases, a legal and technical bibliography, articles on particular aspects of mental disability law and related technology, and other legal material.

Five projects of national significance are devoted to the problems of the aging and aged developmentally disabled. Data will be collected, organized, evaluated, and disseminated on this generally unserved population. This will provide a base for planning and decision making. The result of this combined effort is to form a network in the area of aging and aged developmentally disabled to which agency personnel and consumers can turn for information, training, and assistance.

The University Affiliated Facilities Activity covers the training of personnel needed to provide the broad spectrum of services to the developmentally disabled and demonstrations of exemplary services and service delivery systems. This includes assisting various service agencies in expanding and improving the quality of service they provide to the mentally retarded. Currently there are 37 university affiliated facilities grantees receiving support under this program.

HEALTH CARE FINANCING ADMINISTRATION

Medicaid Bureau

MENTAL RETARDATION

Title XIX, known as Medicaid, provides Federal matching payments for State expenditures for health care for the poor. In FY 1977, fifty-three States and jurisdictions were participating in Medicaid (Arizona is the only State not participating).

With the federalization of the adult categories on January 1, 1974, under the Supplementary Security Income (SSI) program, States are not in all cases required to provide Medicaid to all adult recipients of cash assistance under Title XVI, as was the case in the past under Titles I, X, XIV, XVI. Limited Medicaid coverage of SSI cash assistance recipients will apply in States which, in determinating Medicaid eligibility, opt to apply any eligibility criteria from the January 1, 1972 medical assistance standard which is more restrictive than the eligibility requirements for the Federal Title XVI program for aged, blind, and disabled individuals. States which retain any eligibility factor(s) from their January 1, 1972, standard which is (are) more restrictive than the Title XVI eligibility factor(s) must deduct a person's medical expenses from his income in determining eligibility. (They are not required to cover Title XVI cash assistance recipients who otherwise do not meet the January 1972, medical assistance standard.) As of January 1, 1977, fifteen States and three jurisdictions have restricted Medicaid eligibility of SSI recipients under this option.

Thirty-five States extend Medicaid coverage to all recipients of cash assistance under the SSI program. States also have the option of providing Medicaid coverage to persons receiving a State Supplemental payment, subject to certain limitations. In addition, thirty-two States and jurisdictions have elected to cover certain medically needy persons who are eligible for help only with their medical bills and who do not receive maintenance payments.

All Medicaid services included under the State plan (mandatory services include inpatient hospital care, outpatient care, physicians' services, skilled nursing facility services for individuals 21 years of age and older, early and periodic screening, diagnosis and treatment services for children under 21, lab and X-ray services, and home health services; in addition, States may cover a range of optional services including dental care, drugs, eyeglasses, intermediate care facility services, etc.) are available to eligible mentally retarded individuals.

Effective January 1, 1972, P.L. 92-223 transferred intermediate care services to Title XIX as an optional State service and authorized the provision of intermediate care facility services in public institutions for the mentally retarded if the institution provides health or rehabilitative services and if the eligible individuals are receiving active care and treatment. To assure that the Federal dollars made available for such institutional care would lead to higher quality care and services in an improved environment, and not simply to a

replacement of State dollars, the legislation contained a provision requiring the States to maintain their own fiscal effort. Forty-four States have responded to the new Title XIX authority by adding to their State plan coverage of ICF services in public institutions for the mentally retarded. Prior to January 1, 1972, some 17 States claimed Federal matching in the costs of care in institutions which qualified as skilled nursing home services. It should be noted that because services in the past were being provided to the mentally retarded as skilled nursing home services, the adoption of the intermediate care facility program resulted in a redesignation of facilities in some States. The result is that these facilities are able to provide services at a more appropriate level of care in instances where skilled nursing care is not medically necessary. States, however, continue to provide care for the mentally retarded in skilled nursing facilities where medically appropriate.

Total Federal expenditures for services for the institutionalized mentally retarded (in ICF's only)were estimated to be $395 million in FY 1977. Estimates are not available on the number of Medicaid dollars expended on all other Medicaid services provided to the mentally retarded. It should be emphasized that the Medicaid eligible mentally retarded person may receive the full range of Medicaid services, and receive them on the same basis as the rest of the Medicaid eligible population.

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
PROGRAMS FOR MIGRANT AND OTHER SEASONAL FARMWORKERS

Opportunities for the economic and social advancement of the population of migrant and other seasonal farmworkers are limited for a variety of reasons including high seasonal unemployment, limited coverage under labor legislation, undereducation, poor health status and unfulfilled housing needs.

The Department of Health, Education and Welfare has the responsibility for funding and administering four programs which are designed to meet some of the needs of this special population. They are as follows:

1. Migrant Education - Office of Education

   Legislative authority:
   Elementary and Secondary Education Act of 1965, as amended; Title I (20 U.S.C. 241b)

   Objective:
   To provide grants to States for programs and projects to meet the special educational needs of children of migratory agricultural workers and fishermen, and to coordinate with similar programs and projects in all of the States.

   Programs: Grants to States

2. Special Vocational Rehabilitation Projects - Rehabilitation Services Administration

   Legislative authority:
   Rehabilitation Act, section 304(c)

   Objective:
   To provide rehabilitation services to handicapped migratory and other seasonal farmworkers.

   Programs:
   Demonstration projects in selected States.

3. Migrant Head Start - Administration for Children, Youth & Families

   Legislative authority:
   Economic Opportunity Act of 1964, as amended; section 222 (42 U.S.C. 2809)

   Objective:
   To expand child-care facilities available to children of migrant families and to develop a network of cooperating grantees to serve these children both while migrating and while they are in their home base areas.

   Programs:
   Child care and Head Start services

4. Migrant Health - Health Services Administration, Bureau of Community Health Services

Legislative authority:

Public Health Service Act, as amended (42 U.S.C. 242h)

Objective:

To provide grants to public and non-profit institutions and organizations to finance part of the cost of (1) establishing and operating family service clinics and (2) special projects to improve health services and health conditions for domestic agricultural migratory and seasonal workers.

Programs:

Full-time comprehensive health service projects
Part-time comprehensive health service projects
Part-time medical service projects
State-coordinated projects offering direct health services in several counties
Other health service projects

U.S. OFFICE OF EDUCATION

REPORT ON MIGRANTS

Title I of the Elementary and Secondary Education Act, Public Law 89-10, as amended, provides for payments to State educational agencies for assistance in educating migratory children of migratory agricultural workers and migratory fishermen.

Funds are used for programs which are designed to meet the special educational needs of migrant children, and to coordinate these programs with similar programs and projects in other States.

A Migrant Student Record Transfer System (MSRTS) data bank facility is headquartered in Little Rock, Arkansas. Teletype terminals are located in 153 strategic areas serving the 48 continental States and Puerto Rico. Provisions are now being made to accomodate and provide the record transfer system services to migrant children in Alaska, Hawaii, Guam, American Samoa, the Virgin Islands, and the Trust Territory of the Pacific Islands. Migratory children in the outlying territories are now eligible for migrant program services as authorized by Public Law 93-380. The record transfer system is funded by an equal percentage of each State's allocation set aside by the U.S. Commissioner of Education. The purpose of the system is to provide to school districts enrolling migrant children with rapid transmittal of pertinent general, health, and academic data for each migrant child.

This system was developed through the cooperative efforts of the participating States working through an interstate committee. The program direction, specifications for the computer, and the manner by which the system was to be operated were the tasks given and completed through this cooperation.

Because of the mobile nature of the target population, traditional educational practices needed to be adapted to meet, in an educational environment, the transitory state of the migrant child. Since the inception of the program, States have undertaken this challenge and have developed unique approaches to meet these specific conditions. These efforts have resulted in the learn and earn vocational programs in Florida, New Jersey, and North Carolina, in which career awareness and salable skills such as supermarket cashiering, assembly line techniques and quality control, automotove tune-up, and paramedic training, just to mention a few, have been introduced. These activities provide a small monetary compensation to the migrant student, which places relevency in instructional services, acknowledging the economic situation in which migrants find themselves.

The California Mini-Corps Program was designed to utilize current and former migrant children as tutors and program assistants. It has had a two-fold impact: 1) providing assistance to former migrant pupils in order for them to pursue further educational opportunities in junior colleges, colleges, and universities; and 2) providing a model or individualizing instruction to further the educational achievement level of underachieving migrant children.

Since the inception of the program, much attention has been focused on the language development of migrant children. These lanuage development efforts have taken the form of bilingual and bicultural instruction, the development of oral language skills, and programs of English as a second language. The migrant program has made a reality of the inservice training of teachers as a basic component of all State activities to facilitate the adequate and efficient delivery of services to migrant children. Because of the mobile nature of the children, cooperation between sending and receiving States as required in order to assure a continuum of educational services. As a result of that challenge, the States have cooperated in workshops and conferences, and exchanges of teachers, mobile educational facilities, and consultant services.

Currently, there are three major interstate program thrusts. The States of Minnesota, Wisconsin, Illinois, Indiana, Ohio, and Michigan have formed a consortium of States to cooperatively plan and implement programs in their respective areas. Thirteen western States have assumed a similar responsibility regarding their migrant population. The States on the east coast have already demonstrated their cooperation and concern in interestate efforts by meeting at least annually to share ideas and to discuss concerns relating to the east coast migrant stream. In May of 1978, Minnesota will host the 11th Annual Migrant Education Conference in Minneapolis, Minnesota. This conference is initiated, organized, and participated in by all the States providing educational services for migrant children.

An estimated 530,000 migrant children were served under this program in calendar year 1977. This figure will rise to approximately 580,000 in 1978 and to 625,000 in 1979. These estimates are based on the expanded eligibility provision of Public Law 93-380.

OFFICE OF EDUCATION

REPORT ON MIGRANTS

Under Title I of the Library Services and Construction Act (LSCA), funds are made available to the States for the provision of library services to disadvantaged persons in rural and urban areas and for the extension of library services to geographical areas and groups of persons without such services.

Migrants are served on location with library programs and resources delivered by either the State library or nearby local libraries. Library resource centers and bookmobile services are the traditional means by which migrant workers are served, but these are often enhanced by special programs that recognize the severe difficulties experienced by migrants in obtaining adequate education. Such programs provide basic literacy and bilingual language instruction with the aim of acquainting migrants with library and other educational resources available to them.

The following projects exemplify the types of services LSCA supports: In New Jersey, the Cumberland County Library serves migrant farmworkers by incorporating a wide variety of library activities into its mobile delivery program. Spanish language films, magazines, books, and other materials are used as the basis for movie nights, consumer education classes, children's storyhours, games, and contests that win the migrants' trust. The library also has developed a Basic English program, planned in cooperation with other community agencies that serve migrants (e.g. Department of Health), and consisting of a manual and a series of video films.

Reaching out to migrants in Alabama, the North Pell City Library takes its services to the top of Chandler Mountain where more than 600 migrants plant, tend, and harvest crops. A library resource center is temporarily established there each season and is reopened whenever the migrants return.

In Washington, a library program, funded jointly by LSCA and Right-To-Read, provides access to basic literacy instruction for Spanish-speaking migrants in the eastern counties of the State. A bookmobile, stocked with materials in both Spanish and English and staffed by Spanish-speaking personnel, visits the migrant camps on a regular basis during the picking seasons. Tutors conduct small classes in basic reading skills, beginning in Spanish and eventually introducing English language skills.

Report on Migrants

(ESEA IV-B)

In FY 1976, one-half appropriation for ESEA Title II was granted under ESEA Title IV, Part B (Libraries and Learning Resources) and was administered categorically as Title II. The other half of the funds was combined with one-half the appropriation of equipment and minor remodeling (NDEA Title III), and the testing, counseling, and guidance portion of ESEA Title III. ESEA Title IV, provides funds for school library resources, textbooks, other instructional materials; instructional equipment and minor remodeling for strengthening instruction in the academic subjects; and testing, counseling, and guidance materials, equipment, and services for elementary and secondary schools. Children, teachers, and other school staff in public and nonpublic private elementary and secondary schools may benefit. ESEA Title IV annual program plans prepared by the States require a formula for the distribution of Part B funds to local educational agencies. The formula must be based on enrollment, high tax effort, and large numbers or percentages of children whose education imposes a higher than average cost. Children identified as high cost receive additional benefits. Two States selected migrant children as high cost, and 41 States also identified children from low-income families as imposing a high cost. Migrant children also qualify as b eing from low-income families. In FY 1977 and FY 1978, no separate funds were appropriated from ESEA Title II. All funds for Title II purposes were consolidated in ESEA Title IV, Part B appropriations.

Vocational Education

Matching grants are made to States on a formula basis to assist States in maintaining, extending, and improving existing vocational education programs and to develop new programs in vocational education. Many States have programs assisting children of migrant workers but the vocational education reporting system does not collect data to identify these children separate from other children. There is also no accounting for dollars by this category.

Adult Education

Formula grants are made to State departments of education under the Adult Education Act, as amended. These grants assist the States in establishing and expanding programs of adult public education so that adults can continue their education through completion of secondary school and secure job training to enable them to be more employable.

Adults sixteen years of age and older (including migrants) with less than a twelfth grade level of education are eligible for participation in this program. However, many State and local education agencies do not keep records of how many migrants paricipate in local programs or the amount of funds expended on such participations.

The Office of Education does not collect this information from the States. However, based on prior telephone surveys to the Regional Offices it was determined that approximately 1.8% of the total appropriation was being utilized for the education of adult migrants.

Obligations for Programs for Migrants

	1976 Actual	1977 Estimate	1978 Estimate	1979 Estimate
Elementary and Secondary Education:				
Educationally deprived children (Title I)	$97,090,478	$130,909,832	$160,000,000	$170,000,000
Library Resources:				
Public library services (LSCA-I)	178,000	185,000 1/	200,000 2/	200,000 2/
School libraries and instructional resources (ESEA IV-B)	3/	3/	3/	3/
Occupational, Vocational, and Adult Education:				
Adult education, grants to states	1,215,000	1,287,000	1,449,000	1,449,000
Vocational education	4/	4/	4/	4/
Total	98,483,478	132,381,832	161,649,000	171,649,000

1/ Reports not yet received, figure based on States' annual programs.

2/ No program figures available -- only budget request used for estimate.

3/ Information not provided under current reporting system.

4/ Vocational Education reporting system does not collect data to identify migrant children.

OFFICE OF THE ASSISTANT SECRETARY FOR EDUCATION

Fund for Programs on Migrants
(In thousands of dollars)

	1977 Actual	1978 Estimate	1979 Estimate
Fund for the Improvement of Postsecondary Education.....	27	1/	1/
Total, Office of the Assistant Secretary for Education.....	27	1/	1/

1/ Estimates are not available at this time. Funds for this program are awarded on the basis of approval of individual projects, the totality of which address many program areas.

Colegio de la Tierra
Goshen, California

For the past year, Colegio de la Tierra has been developing a new approach to teaching Chicanos in the rural areas how to read and write. But the method goes much deeper than guiding students to learn the mechanics of language. It is based on Paulo Freire's theory of learning that education must be both a liberating and humanizing process. To date, this process has been used only with students enrolled full-time at the Colegio. It has become clear to us, though, that this method can be used on a much wider basis, namely--popular education in the community.

The methodology employed establishes a teacher-student relationship that involves the learners and teachers in a learning process as "equal-knowing subjects." Through dialogue centered on themes related to the group's similar experiences, images and words are extracted that have socio-cultural significance to the group. The extracted words with selected images are "decodified" (broken down to discover the essence of their meaning). The eventual result of "decodification" leads to what Freire calls "The shattering of the culture of silence." The information and materials accumulated from the dialogues and writings of students have been compiled and produced into writing exercises.

The emphasis of the second year will be implementation of the method in the community with a much wider base of students. The project will be implemented primarily by those students who participated in the project during the first year. As a result of the project, we anticipate the use of this model in other areas of learning not directly related to language skills.

The expected outcomes of the project are the following: (1) To develop and implement a successful language program for the students of the Colegio and for the participants of a community-based education program, (2) To develop the materials and exercise manuals necessary to implement such a program, (3) To raise the learning capacity of the participants of the project by raising their critical consciousness of their social and cultural reality, and (4) To create a major impact on improving the educational conditions for the rural Chicano.

St. Edward's University
College Assistance Migrant Program
Austin, Texas

The plight of migrant farmworkers has been well documented in recent years. Hard work, intermittent employment, meager wages, poor living conditions, inadequate schooling, alienation from the American mainstream are but some of the problems that beseige them. Together, these problems form a self-perpetuating cycle, for with poor education and lack of skill development, there is little chance for the children of migrant farmworkers to improve their economic status or to move out of the migrant trek.

One of the most effective efforts to eliminate this problem has been CAMP, the College Assistance Migrant Program, estiblished by the Department of Labor. Its goal is to provide young migrant farmworkers with an opportunity to obtain a postsecondary education as a means of acquiring credentials that would enable them to enter a more productive and rewarding economy. The program is designed to provide full financial aid, academic support and personal assistance for the first year of college for the eligible student.

The St. Edward's CAMP program was a participant in the Fund's National Project II, Alternatives to the Revolving Door. St. Edward's evaluated all four CAMP programs: San Diego State University; Pan American University, Edinburg, Texas; Adams State College, Alamosa, Colorado; in addition to St. Edward's. Because the goals of these four programs were similar, St. Edward's was able to do an overview of program implementation; analysis revealed a retention rate of 90%. Virtually none of the graduates have returned to migrant field work.

OFFICE OF HUMAN DEVELOPMENT SERVICES

Rehabilitation Services Administration

MIGRANTS

Appropriations for Special Projects for vocational rehabilitation services to handicapped migratory agricultural workers and seasonal farmworkers were made available for the first time in 1974 under Section 304(c) of the Rehabilitation Act. Eight projects were established in the following States: California, Florida, Idaho, New Jersey, New York, Oregon, Texas and Wisconsin. In 1977, the project in Oregon was successfully concluded and a new project was established in Illinois. Six Regional Offices are involved in the administration of these projects. Recent site visits confirm the fact that they are providing badly needed vocational rehabilitation services to this underserved minority group.

In accordance with Section 304(c), cooperation has been obtained from the Office of Education, the Public Health Service, and the Department of Labor, all of which sponsor projects for migratory workers.

Data provided by other programs substantiate proportionately greater health problems and related disabling conditions, and the necessity for concentrated services, including outreach efforts to familiarize migrants about services and to encourage them to modify their migratory patterns in order to be served. Emphasis which can be most effectively focused through this special program is necessary to deliver services, in cooperation with other programs, to migrants who present such unique and extensive problems.

A meeting was held in Washington in April 1975 which was attended by project directors and officials from State and Regional offices, cooperating agencies and consumer groups where information was exchanged on providing rehabilitation services to handicapped migratory workers. In 1976, San Antonio was the site of a second meeting. A third meeting is planned for March 1978 in San Jose, California. Attending this meeting will be a select number of members of the staff from Central and Regional Offices, Directors and staff from the eight projects, representatives from government, public and private agencies, consumer groups and members of the migrant community. Innovative techniques and methods which can be used to expand and enhance vocational rehabilitation services to migratory workers will be presented, and proceedings of this meeting will be published.

RSA can make a significant contribution toward the solution of the complex problems of the migrants, particularly as they are related to the preparation for and return of migrant workers to more stabilized employment.

The need for extending and improving the delivery of social and rehabilitation services to greater numbers of these people is becoming more urgent in light of USDA projections that there will be a reduction in the migratory work force in the future due to mechanization.

OFFICE OF HUMAN DEVELOPMENT SERVICES
Rehabilitation Services Administration

MIGRATORY AGRICULTURAL AND SEASONAL FARMWORKERS

Number of People Rehabilitated:

Fiscal Year	All Rehabilitants	Migratory Agricultural Workers and Seasonal Farmworkers
1975	324,039	319
1976	303,328	249
1977	291,202 1/	377 1/
1978	283,000 1/	900 1/
1979	277,000 1/	1,000 1/

1/Estimated

Budget Data:

Fiscal Year	1975	1976	1977	1978	1979
Basic State Grants	$ 680,000	$ 720,000	$ 740,000	$ 760,000	$ 785,000
Special Projects	736,000	795,000	530,000	1,500,000	1,600,000
Total, RSA	$1,416,000	$1,515,000	$1,270,000	$2,260,000	$2,385,000

Administration for Children, Youth and Families

The Indian and Migrant Program Division (IMPD) in the Administration for Children, Youth and Families funds grantees to provide comprehensive developmental services to migrant preschool children and their families.

Because of the unique needs of migrant farmworking families, programs had to be designed to provide the family with access to these resources without creating economic or other hardships. Resources alone, without an adequate system of delivery, will not solve the problems of migrant families with preschool children.

IMPD has developed and worked with several different program models during the past few years. Some of these models have proven to be less successful than others. IMPD's findings have shown that in any given area or region, a combination of program models is necessary to meet the existing needs.

All of the models used a basic program design which incorporates Head Start standards and quality child care services. This design calls for some structural modifications to the traditional Head Start program including: (1) extending the hours of operation to coincide with the parents' working hours; (2) allowing all preschool children to participate, including infants, and (3) utilizing bilingual and bicultural staff where needed. These modifications are necessary in order to provide the type of full service program which is tailored to the life style of migrant families.

Basically, there are two categories of program models, the Local Programs and the National Programs. Local Programs are Head Start programs which are funded to serve local communities, and which may also serve migrant children.

There are two National Program models; the Prime Grantee model and the Network model.

The Prime Grantee model approaches the need to extend the period of services by funding programs in user areas which had longer field work seasons and could operate in one location for four or five months. Families remaining in the area for the entire work season had access to a full service program and the children received educational benefits from having been enrolled for a sufficiently long period.

The prime grantee model also attempts to deal with the problem of program continuity. A referral system was devised to refer participants to Head Start programs operating in their home base areas. The child's medical and educational records are also to be transferred. The home base programs, however, are under no obligation to accept referrals and frequently the programs are filled by the time the child returns to the area.

The network model differs from the others in that it operates programs in both the home base areas and user states. The program operations follow the migrant streams during the seasons when field work is available and are located in established centers where large concentrations of migrants are found. As the families move from one area to the next the children can be enrolled at the next site. As the target population increases or decreases in a given area, staff members can be regrouped to accommodate the change.

IMPD will continue to refine these models and to develop other innovative approaches to guarantee that delivery systems of quality services are provided to the target population. In addition, IMPD recognizes the growing need for an increased effort in program development on behalf of migrants who are attempting to settle out and for seasonal farmworker families.

In addition, Head Start funds training and technical assistance projects providing direct assistance to Migrant Head Start programs. Other ACYF funds are used to support child abuse and neglect and experimental and research projects.

	FY 1977 Estimate	FY 1978 Estimate	FY 1979 Estimate
Migrant Programs.....	$18,904,000	$32,000,000	$32,000,000

PUBLIC HEALTH SERVICE

Health Services Administration
Bureau of Community Health Services

Migrant Health

The Migrant Health Program awards grants to plan, develop and operate projects to provide health care services to migrant agricultural laborers and seasonal farmworkers and their families in order to improve and maintain the level of their health relative to that of the general population. Services provided include diagnostic, therapeutic, and follow-up medical services, linkages with other Federal, State and local resources, referral for dental health care, counseling, preventive and outreach services.

The purpose of the Migrant Health program is to assure the availability and foster effective utilization of health care services by migrant agricultural laborers and seasonal farmworkers and their families. The Migrant Health Program is one of the integral parts of the Rural Health Initiative. Through this initiative projects provide access to primary care services that are linked with other community health social service programs. By integrating projects that serve migrants with other BCHS programs, the resources of the Migrant Health program have been expanded to make comprehensive services available to an increased number of migrant and seasonal farmworkers and their families. Through the linkages, migrants are also provided access to cummunity services such as hospitalization, nutrition, Medicaid, mental health, and alcohol and drug abuse programs.

During the current fiscal period (1978) the Migrant Helath Program, administered by the Bureau of Community Health Services, HSA DHEW, supports 138 migrant health projects. These projects provide the main source of health care services for the Nation's 2,700,000 migrants and seasonal farmworkers and their families. By September 30, 1978, these projects will have provided services to nearly 557,000 persons.

A special demonstration program, designed to provide hospital care effectively and economically for a selected migrant population and to gather and evaluate data on hospital utilization and cost of hospital services, was initiated during fiscal year 1974 at a level of $3 million. The Bureau of Health Insurance SSA, serves as the fiscal intermediary for reimbursing hospitals for care provided to eligible migrants in this demonstration. Ten migrant health projects are enrolled in 19 hospitals to provide inpatient care for approximately 3,000 migrants at a fixed daily rate.

MULTIPLE SCLEROSIS

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
National Institutes of Health:					
National Institute of Neurological and Communicative Disorders and Stroke	$ 6,980,000	$ 9,590,000	$11,095,000	$12,620,000	$12,800,000
Office of Human Development Services:					
Rehabilitation Services Administration:					
Innovation and Expansion	44,000	34,000	34,000	34,000	38,000
Basic State Grants	1,360,000	1,441,000	1,481,000	1,521,000	1,571,000
Special Projects	---	---	---	174,000	404,000
Total, RSA	1,404,000	1,475,000	1,515,000	1,729,000	2,013,000
TOTAL	$ 8,384,000	$11,065,000	$12,610,000	$14,349,000	$14,813,000

NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological and Communicative Disorders and Stroke

MULTIPLE SCLEROSIS

Multiple sclerosis (MS) is a devastating neurological disorder of young adults. Its unpredictable episodes attack the brain and spinal cord and destroy the protective nerve covering called myelin. When myelin destruction, or "demyelination" occurs, messages from nerves to muscles and sensory organs are impeded or lost, causing varying degrees of impairment. The extent and location of demyelination determines symptoms and severity. These can include impairment of muscle strength, control, or movement, or they can result in sensory disturbances such as blurred vision or speech problems. When myelin destruction is either widespread or critically located, its effects are crippling.

Because myelin destruction is sporadic and myelin repair is only partial, MS symptoms follow a totally unpredictable course. MS patients may have symptoms which occur once with no additional episodes; or they may have a progressive series of episodes with varying periods of exacerbation (worsening of symptoms) followed by remission (cessation of symptoms); or they may have chronic progressive symptoms. This course differs for each person with MS.

Thus, each young man or woman afflicted with MS must endure the burden not only of coping with the symptoms, but the uncertainty of how to carry out life's activities without knowing how often the symptoms will strike, how long they will last, or how severe or incapacitating they may become.

It is estimated that 250,000 American men and women between the ages of 20 and 40 are victims of MS; another 250,000 suffer from closely related demyelinating disorders.

There is no specific treatment for MS and no prophylactic measures are available. In the past, hopes for the many victims of the disease have been raised by premature publications of new forms of treatment before adequate scientific evaluation was obtained. Unfortunately as the disease progresses many patients develop associated anxiety and depression. In desperation patients and their familites seek out any type of treatment which has even the remotest possibility of being efficacious. As a consequence the social and economic problems related to the disorder are amplified.

The very nature of MS renders it a difficult disease to study. The marked variation from patient to patient, both in clinical presentation and clinical course, as well as the characteristic exacerbating and remitting pattern of the disease are important variables which must be considered in any scientific study of the disease. Finally, because of errors in diagnosis and because spontaneous remissions are characteristic, the evaluation of treatment is exceedingly difficult and time consuming.

The National Advisory Commission on Multiple Sclerosis wrote in its 1974 report, "...the time is now for a concerted, well-managed effort to unravel the mysteries of MS." The Institute has incorporated many recommendations made by the nine-member Multiple Sclerosis Commission, appointed by the Secretary of Health, Education, and Welfare in accordance with Public Law 92-563.

As suggested by the Commission and prompted by important research leads, the NINCDS has greatly intensified MS research both in the Intramural Program in Bethesda and at other institutions, including support of 6 major MS Clinical Research Centers located at: University of California at Los Angeles; University of Pennsylvania, and The Wistar Institute, Philadelphia; Emory University, Atlanta, GA; Albert Einstein College of Medicine of Yeshiva University, Bronx, NY; Scripps Clinic and Research Foundation, La Jolla, CA.

Research related to MS continues to be a major concern of the Institute's intramural program. The 3 major NINCDS laboratories currently engaged in viral research have been augmented by a recently established Neuroimmunology Branch, which is conducting both basic and clinical MS research. Basic research directly related to the neurochemistry of myelin is being conducted in two NINCDS laboratories.

Also, as suggested by the Commission, a contract has been awarded to ascertain the overall impact of MS by determining incidence, prevalence, and costs. The country's neurologists and neurosurgeons, and approximately 2,000 primary care physicians (selected at random), have been asked to identify all possible and probable MS patients seen through the years. Similar information is being collected from the Nation's teaching hospitals, as well as participating non-teaching hospitals, in order to assess incidence and prevalence. Patients in the study will keep a 90-day diary of all health-related expenditures from which the direct and indirect cost of the disease will be ascertained.

Although the causes of MS are unknown, remarkable advances in understanding "slow" viruses, coupled with important discoveries concerning the immune (defense) system, as well as an increased understanding of myelin have brought new levels of sophistication to MS research. Perhaps the key to demyelination and MS lies in an integration of these three components.

Viral Involvement in MS

Clinical Studies

Research on the possible viral etiology of MS received a tremendous boost after the brilliant demonstration of the existence of "slow viruses" by Nobel Laureate in Physiology or Medicine, Dr. D. Carleton Gajdusek, working with Dr. Clarence Gibbs and colleagues. These NINCDS scientists showed that at least two disorders affecting the central nervous system (CNS) are caused by atypical viruses which lie dormant in the body for years before some mechanism triggers them into action.

Evidence Supporting a Viral Illness

While MS bears no clinical or pathological resemblance to these other two slow virus disorders, slow viruses may cause several different types of disease. Arguing against the theory of slow viral involvement in MS is the failure to transmit it to laboratory animals. However, several important factors indicate an infectious etiological involvement: first, there is an inflammation around blood vessels, consistent with viral infection. Second, epidemiological studies of the pattern and distribution of MS suggests a latent viral infection. Such studies have shown that persons who migrate from areas of high risk for MS to a low risk area before age 15 (and possibly as early as before age 5) adopt the low risk of their new country while those who migrate after age 15 maintain the high risk of their homeland. This suggests that some factor or combination of events operating early in life leads to the subsequent development of MS. Third, many MS patients have elevated cerebrospinal fluid (CSF) levels of immunoglobulin G (IgG) which is consistent with a viral infection. When separated by electrophoresis the IgG lines up in bands known as an oligoclonal pattern. Using a highly sensitive radioimmunoassay, two other immunoglobulins, IgM and IgA, have recently been shown to be elevated in the majority of MS patients. These immunoglobulin molecules are antibodies. For example, in another neurological disorder, subacute sclerosing panencephalitis (SSPE), caused by measles virus, the CSF immunoglobulins are elevated,

exhibit oligoclonal banding and are antibodies against measles. Therefore, the important unanswered question is what agent(s) are the CSF immunoglobulins directed against in MS? In order to approach this problem, scientists in the Infectious Disease Branch and Neuroimmunology Branch have recently developed sensitive immunological assays to study antibody activity in the CSF.

Possible Relationship to Measles

Since the initial report of Adams and Imagawa in 1962, serological studies have indirectly related measles virus to MS. Direct implication was suggested in a report from Long Island College Hospital and Kings County Hospital in 1976. Measles antigen was reported present in the small bowel of 30 patients with MS but none of the non-MS controls. The scientists postulated that chronic measles infection occurred in the small bowel. Although this was a provocative and intriguing possibility, over the past year scientists in the Infectious Disease Branch of the Intramural Research Program at NINCDS have failed to confirm the above observations. Upon looking into this matter in greater detail it appears that the antisera used in the original report react with components other than the measles virus. This area thus remains controversial, but the findings demonstrate the essentiality of using the best possible basic immunological and virological techniques in investigating the clinical disease.

The Multiple Sclerosis Associated Agent (MSAA)

Another lead that MS was related to a virus came from the reports of researchers at New York State Institute for Basic Research and Mental Retardation. These workers initially found that MS tissue, CSF and serum produced depression of the polymorphonuclear cells (PMN) of mice. Another biological effect of the MS tissue was to suppress the growth of a mouse tissue culture cell line (PAM cells). Other scientists (at NIH, as well as in Belfast, Ireland) could not confirm these observations. However, in December 1975 a group of scientists working in Philadelphia confirmed and extended the initial observations. Although many scientists working in this field continued to doubt the validity of the observations because of the complexity of the assay systems employed, this confirmation was widely publicized in editorials of scientific journals and in the lay press. This undoubtedly raised the hopes of many victims of the disease, physicians caring for these patients, and scientists not actually working in the field. Disappointment now follows. In the October 1977 issue of a major medical journal, the Philadelphia investigators joined with the original group in questioning the validity of their earlier observations; and secondly, in concluding that the assay system employed in their work be discontinued because of its complex nature. Scientists at NINCDS have failed to reproduce the findings of the above investigators, and also discovered that the PAM cell line was infected by PPLO organisms.

These are intracellular parasites slightly larger than viruses which could alter the growth of PAM cells and explain some of the observations. The complexity over this research reinforces the need to establish sound scientific principles before applying them to complex biological problems such as MS.

Basic Research Related to Slow Viral Infections

Defective Interfering Particles and Virus Mutants

Important knowledge on how viral infection may be slowed is emerging from intensive studies by another group of NINCDS scientists of viral fragments which are accidently formed by certain viruses during replication. They are called defective interfering (DI) particles and are not infectious. But importantly, when they enter a cell with the infectious virus, they slow down viral infection by successfully competing with the infectious virus for materials needed for replication. In addition, the course that a virus infection takes can be influenced by many factors. Work at the Institute's laboratories in Bethesda have confirmed that certain genetic mutations of viruses slow the viral development and create a clinical picture that resembles that seen in some slow, chronic degenerative diseases. These observations suggest that mutants of common viruses, as well as exotic slow viruses, should be screened in the search for an MS virus.

Chronic Virus Infections in Animals

There are no perfect animal models of a chronic viral infection identical to MS. However, two natural infections, canine distemper and visna in sheep, do resemble the disease in many aspects. Recent knowledge from the study of visna seems highly relevant. Sheep infected with this virus develop a chronic progressive demyelinating disease associated with inflammation in the brain; elevated CSF gamma globulins, and oligoclonal bands in the CSF. Routine histological immunofluorescent and electronmicroscopic studies rarely reveal the presence of virus. However, the agent has been isolated from brain and lymphoid tissue grown in tissue culture explants. The visna virus has an RNA coded DNA polymerase and through the action of this enzyme can incorporate its genetic material into the nucleus of the host cell, i.e., the infected sheep. Although unrecognized by routine morphological techniques, however, the DNA copy of the virus (provirus) can be identified by sensitive molecular biological techniques. These are difficult to execute and expensive, but show that the visna virus genetic material is present in sheep CNS tissue. Furthermore, an investigator at The Johns Hopkins University has demonstrated that new forms of the virus probably mutants, appear as the disease progresses. With the appearance of each new form of the virus there is an immune response to new antigenic determinants. To reiterate, many investigators believe visna has to have profound implications to MS for the following reasons:

1. Visna is a natural infection which establishes that the observations can occur in nature and are not artificially induced in a laboratory.

2. The pathology of visna is very similar to that seen in MS.

3. The virus cannot be identified by routine morphological studies.

4. Basic research in molecular biology has shown that the virus can be present in a molecular form in the host genetic material.

5. The virus does reappear and evokes a corresponding immunological reaction.

Immune System Alterations in MS

Immunogenetics and HLA Antigens

If a common virus is involved in MS, why are only a few people affected by it? Bearing on this question are important studies concerning the immune (defense) system of MS patients. Evidence now suggests that there may be some association between susceptibility to MS and inherited "histocompatibility antigens." Initial interest derived from studies of tissue rejection in transplant patients where histocompatibility (HLA) antigens were found to evoke tissue rejection.

HLA antigens are strategically located on the cell surface and are glycoproteins (molecular complexes of sugars and proteins). These components of the cell membrane may have important roles in cell-cell interactions such as occurs in myelin formation, discussed below. Secondly, they could serve as receptors for viruses. Thirdly, based on studies in mice these could play a role in regulation of the immune response. Initially, it was demonstrated that 40% of the patients with MS have increased representation of two histocompatibility antigens, HLA A-3 and HLA B-7. Subsequent studies have revealed an even higher incidence (approaching 70%) of another antigen HLA DW-2. Over the past two years, increased representation of other antigens, preferentially expressed on bone marrow-derived lymphocytes and designated as B-cell antigens have been demonstrated in 90-95% of the patients with MS. These have come from scientists at Rockefeller University, and others at UCLA (under contract to NINCDS). In addition, these observations have been confirmed and extended in the Neuroimmunology Branch of the Intramural Research Program in the NINCDS. Other important observations have been reported by a group of neurologists and immunologists from the United Kingdom, who reported that the majority of patients in England share a specific B-cell detected by BT-101 serum. This antigen only occurs in about 35% of normal individuals. It is relevant that all of the patients in this study were white Anglo-Saxon. Studies of an Arab population of patients did not show an increase in the BT-101 antigen;

however, another antigen, BT-102, was found in 88% of the patients with MS as compared to only 35% of controls. Subsequently, these investigators demonstrated that the BT-102 antigen had an increased incidence in Northern Italian patients with MS. Thus, these findings indicate that in given populations there may be tissue antigens which predispose to MS.

In order to analyze this association between HLA types and MS in greater detail, four important studies have been initiated. First, the Neuroimmunology and Infectious Disease Branches in the Institute's Intramural Research Program are conducting studies of families in which more than one member has MS. This investigation, which now includes the study of identical and non-identical twins, consists of extensive evaluation of blood and CSF in relationship to the HLA background and clinical features.

A massive study is being conducted in the Scottish Orkney and Shetland Islands where an astounding 250 persons per every 100,000 have MS (the highest known prevalence of MS in the world). Investigators at Massachusetts General Hospital, Boston, conducting the study under contract to the NINCDS, are exploring the relationship between MS and histocompatibility antigens and other possibly related biological factors. Additionally, an NINCDS contractor at the University of Newcastle, is investigating the genetic lineage--going back 200 years--of MS patients, their families and non-MS controls. This is possible because the Islands have extraordinarily well kept records from parish marriage and death certificates. Information gained from interviews will be verified and will show whether MS incidence can be traced back to a particular family, as was the case in this country with another neurological disorder, Huntington's disease.

Third, 100 patients with MS are being studied at the Institute-sponsored MS Clinical Research Center at the University of Pennsylvania.

Fourth, NINCDS grantees at UCLA are following 150 families with at least two members with MS, including 75 families with MS among primary relatives. Of particular additional interest is a cluster of MS patients in King County, Washington, where 8 students of the same high school graduating class of 1953 now have MS.

Immune Regulation

A second area of increasing clinical importance is regulation of the immune response. All of the studies to date on MS suggest that the immune response is involved in the disease. One important mechanism which regulates the immune response includes suppressor cells. These are a subpopulation of thymus-derived (T) lymphocytes. Scientists at the University of Chicago, Department of Neurology have developed an assay for measuring the activity of this subpopulation of immune cells.

In a study of MS, reduced suppressor T function is being detected in young patients. This would predispose to immunological over-activity. After an attack of MS the suppressor function seemingly returns to normal. Furthermore, in older patients who are not having attacks the number of suppressor cells closely proximate those seen in normal individuals. These investigators believe that this aberration in mechanisms which regulate the immune response may have a direct relationship to the characteristic clinical course of patients with MS.

Autoimmunity

In certain other diseases such as myasthenia gravis and lupus erythematosus, it has been established that an aberrant immune response is directed at certain parts of the human body. This process produces abnormalities responsible for symptoms. For many years it has been postulated that similar mechanisms might be operative in MS. Originally this stemmed from the disease, post-vaccinal encephalomyelitis, a complication of rabies vaccine. Individuals who had been inoculated with rabies vaccine prepared in rabbit spinal cord developed a demyelinating disease which in many respects resembles acute MS, both clinically and pathologically. It is now established that injection of rabbit spinal cord used to grow the virus initiated an immune response that ultimately became directed at human nervous systems. The disease has virtually disappeared because rabies virus vaccine is no longer prepared in nervous tissue. An animal model of post-vaccinal encephalomyelitis is experimental allergic encephalomyelitis (EAE). In this model the injection of myelin and components of myelin, namely the basic protein, is followed by neurological abnormalities. The pathology consists of infiltration of paravascular inflammatory cells and myelin loss. The study of this experimental disease has provided insight into the mechanisms which can regulate and reactivate an autoimmune reaction in the nervous system. These mechanisms include genetic factors, i.e., the capacity to develop EAE is partly under genetic control. Secondly, the chemical nature of the myelin and the basic protein component of myelin can make a difference in the intensity of the disease. For example, within the past year the portion of the basic protein molecule responsible for EAE in rats has been narrowed to a peptide consisting of 19 amino acids. A slight change in only one of these amino acids can markedly decrease or alter the experimental disease. Such studies as this may have profound implications for the immune response to other antigens. Thirdly, the mechanisms mediating EAE have been more accurately delineated. For many years the disease could be transmitted from one animal to a second animal with immune cells, but not with serum. Over the past year the specific population of cells responsible for transfer of disease have been identified as the thymus-derived T lymphocytes and not the bone marrow-derived B lymphocytes.

Because EAE is usually a monophasic illness, it is regarded as an imperfect model for MS which has an exacerbating and remitting course. Recently, three groups of investigators have produced chronic and

relapsing forms of the model disease. More extensive study of these chronic conditions should provide insight into immune regulation and provide clinical investigators with scientific rational for approaching MS. A final important observation in EAE, is the recent demonstration that in animals having recovered from the disease, the responsible cells can be reactivated by exposure to mitogens which stimulate lymphocytes. The reinjection of the activated cells into normal animals is followed by a severe occurrence of the disorder. In MS, as well as other exacerbating and remitting diseases, the explanation for reactivation is unknown. Additional investigation of experimental phenomena may be revealing.

Even though EAE is an important model and has provided considerable new knowledge concerning immune regulation and control, a direct relationship to this model and MS has not been established. Extensive studies seeking an immune reaction to the basic protein of myelin in patients with MS have been marginal at best. New sensitive techniques such as radioimmunoassay are being applied to this important problem. Furthermore, investigators are looking not only at blood cells, but also at the capacity of cells in the CSF to respond to the myelin basic protein. An important finding by workers in the Neuropathology Laboratory at NINCDS is that spinal fluid from patients with MS contains a factor that causes loss of myelin from the optic nerve after injection into tadpoles. The tadpole optic nerve is used because it can be directly visualized and the myelin breakdown studied. This approach initially described several years ago has been extended within the past year. The toxic agent in the spinal fluid appears shortly after an active attack which suggests that it might even produce the attack. Preliminary studies indicate that the toxic factor is an immunoglobulin. Hence, this may represent an autoimmune process. As yet it is not known which component of myelin the immunoglobulin is directed against. Of course one of the materials being investigated is the myelin basic protein as well as other components described in the section below.

What Role Does Myelin Play?

If a virus or immune system defect--or both--are operating in MS, what is their role in demyelination? NINCDS chemists have shown that mammals have three glycoproteins on the myelin surface. These glycoproteins are the first to be destroyed by toxic agents. Furthermore, in other cells, they are known to be receptors for certain viruses. Scientists believe changes in glycoproteins may be involved in the regulation of viral replication.

In addition, one of the most exciting advances in MS research this year concerns the release of myelin basic protein in the CSF. In two separate studies supported by the National Multiple Sclerosis Society, one at The Johns Hopkins University, Baltimore, the other at the University of Tennessee, Memphis, myelin basic protein and fragments were

found in the cerebrospinal fluid of patients with MS but seldom in fluid from patients with other neurological disorders. These observations were made possible by the application of radioimmunoassay to measure the basic protein. Moreover, increased amounts of myelin basic protein correlated with increased MS activity. Patients with inactive MS did not have myelin basic protein in the cerebrospinal fluid; those with slowly progressive MS had low protein levels; while patients with an acute MS attack had very high protein levels. Thus, this technique had application for the evaluation of drugs in the treatment of the disorder. Those which effectively reduce myelin basic protein levels could reasonably be expected to produce an improved clinical picture. Furthermore, drug evaluation would be objective. This would be a tremendous advantage over the current subjective assessment of patients which is wrought with difficulties since MS symptoms can disappear for no apparent reason and may be totally unrelated to drug efficacy.

Treatment

During the past several years, two other experimental approaches to treatment--both involving the immune system--have been under investigation. Conflicting results have been reported concerning immunosuppressive therapy (lowering the immune response) using transfer factor. This consists essentially of transferring white cells from healthy donors to MS patients. A scientist at the Rockefeller University, N.Y., observed negative results, while an investigator in Denmark reported favorable data. Scientists are awaiting further substantiation from other scientists. The other approach, which consists of increasing the immune response of MS patients, still is under investigation in several studies. At the NINCDS-supported MS Clinical Research Center at Emory University, the immunoreactive drug levamisole is being clinically tested in 25 MS patients.

In addition to seeking curative treatment of MS, several studies are pursuing methods of ameliorating MS symptoms. One of the studies being conducted at Georgetown University, Washington, D. C. includes the experimental combined use of chloropromazine and phenytoin (Dilantin) to suppress spasticity in MS patients. Scientists at the UCLA Clinical Research Center are using two drugs, methyl-dopa and dibenzyline for relief of bladder spasticity which causes incontinence. This is not only a difficult and embarrassing physical complication of MS, but can lead to potentially fatal infections. The drugs' action on bladder sphincters produce relief of urinary urgency. In one of the most important clinical advances to date, an investigator at Albert Einstein College of Medicine reported adapting a surgical technique for bladder incontinence to patients with MS.

The technique involves making an incision in the bladder which is kept closed except when the patient inserts a catheter to void, four times daily. In addition, work is continuing on possible development of electrical stimulation to provide bladder control. To date, experimental animal tests at the University of California, San Francisco, under contract to the NINCDS neural prosthesis program, indicate it may be possible simultaneously to stimulate contraction of muscles in the bladder wall while relaxing exit sphincters, similar to the natural urinary process. This procedure, which is still in the animal testing stage, may have potential for helping not only MS patients but those with spinal injury as well.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

MULTIPLE SCLEROSIS

According to the 1975 National Hospital Discharge Survey, in 1975, an estimated 25,000 patients were hospitalized in short-stay hospitals in the United States with a first-listed diagnosis of multiple sclerosis. The average length of stay for these patients was 13.6 days. About three out of every four discharges were females, and more than half (55 percent) of the patients with a first-listed diagnosis of multiple sclerosis were between the ages of 15-44 years. In addition to those patients with a first-listed diagnosis of multiple sclerosis, an estimated 16,000 patients were discharged with a secondary diagnosis of multiple sclerosis. These are patients who had another diagnosis listed as first or principal, but had multiple sclerosis also shown on their medical records.

OFFICE OF HUMAN DEVELOPMENT SERVICES

Rehabilitation Services Administration

MULTIPLE SCLEROSIS

Because of the nature of the disease, sometimes rapidly progressive and sometimes relatively quiescent for a period of years, multiple sclerosis has been a challenging problem for workers in the field of vocational rehabilitation. Estimating ultimate employment potential is extremely difficult, and the State-Federal program of vocational rehabilitation has had limited success in serving this disability group.

In October 1977, RSA completed a Joint Statement of Principles of Cooperation with the National Multiple Sclerosis Society. The Council of State Administrators of Vocational Rehabilitation was also a signatory to the Joint Statement, which has as its basic purpose the fostering of a collaborative effort to extend and improve rehabilitation services for people severely handicapped by multiple sclerosis.

As a step in expanding the scope of Special Projects for the Severely Handicapped authorized by Section 304(b)(1) of the Rehabilitation Act to additional groups of severely disabled people, RSA plans to support a project focused on multiple sclerosis in FY 78.

With further advances in drug therapy, neurosurgical procedures, and rehabilitation techniques, the rehabilitation potential of those suffering with multiple sclerosis should be greater than at present.

Rehabilitation Research

The Research and Training Centers supported by the Rehabilitation Services Administration are conducting research which leads to both the understanding of the mechanisms of the disease and to provide a rational basis for prevention and treatment, and innovative approaches to its management. Specific research projects are directed toward nerve impairments and the medical rehabilitation management of neurological disorders.

RSA and the National Multiple Sclerosis Society, recognizing the impact of Multiple Sclerosis upon the economy and general welfare of the nation, agreed that effective coordinating of resources of the two agencies was necessary. The result is the development of a monograph by the University of Washington R & T Center on the vocational aspects of M.S. which will include "check lists" for both physicians and vocational counselors.

OFFICE OF HUMAN DEVELOPMENT SERVICES
Rehabilitation Services Administration

MULTIPLE SCLEROSIS

Number of People Rehabilitated:

Fiscal Year	All Rehabilitants	Persons Rehabilitated With Multiple Sclerosis
1975	324,039	603
1976	303,328	637
1977	291,202 1/	553 1/
1978	283,000 1/	500 1/
1979	277,000 1/	500 1/

1/ Estimated

MUSCULAR DYSTROPHY

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
National Institutes of Health:					
National Institute of Neurological and Communicative Disorders and Stroke	$ 9,393,000	$ 9,955,000	$ 9,266,000	$10,574,000	$10,864,000
Office of Human Development Services:					
Rehabilitation Services Administration:					
Basic State Grants	680,000	720,000	740,000	760,000	785,000
Innovations and Expansion	22,000	17,000	17,000	17,000	19,000
Total, RSA	702,000	737,000	757,000	777,000	804,000
TOTAL	$10,095,000	$10,692,000	$10,023,000	$11,351,000	$11,668,000

NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological and Communicative Disorders and Stroke

MUSCULAR DYSTROPHY

Definition

The muscular dystrophies are a group of several chronic inherited disorders characterized by progressive weakening and wasting of the voluntary skeletal muscles. All types of muscular dystrophy are inherited, but any may occur spontaneously in a family as the result of a new genetic mutation, or seem to be spontaneous in the case of a recessively inherited trait. They affect children and adults of all ages.

As the disease progresses, a patient may become confined to a wheelchair or have difficulty performing the ordinary daily activities of living. A common cause of death in these patients is respiratory failure resulting from pneumonia. Heart failure also occurs in some patients.

Duchenne muscular dystrophy is the most common of the muscular dystrophies. Being a sex-linked recessive disorder, it affects male children virtually exclusively. It generally appears between 2 - 6 years of age. The first symptoms are a waddling gait and difficulty in climbing stairs or in rising from the floor due to hip girdle muscle weakness. Later, shoulder girdle muscles become affected impairing use of the arms. It progresses, usually to cause wheelchair or bed confinement by age 12 and death by age 20. In a woman, clinically normal but who is the carrier of the defective gene, each of her sons has a 50 percent chance of having the disease and each of her daughters a 50 percent chance of being a carrier of the defective gene like herself. The cause and treatment are not known.

Myotonic muscular dystrophy, sometimes called myotonic atrophy, is also common. It is a dominantly-inherited disease beginning in infancy, childhood or adulthood. Each child of an affected person has a 50 percent chance of having the disease. It is characterized initially by a weakness in the hands and feet which can progress to severe disability from muscle weakness and wasting. There is also an unusual myotonic stiffness of the muscles characteristically expressed as an inability to relax the hand grip. The disease also affects other body tissues including the heart, lens of the eye, testicles and brain.

Facio-scapulo-humeral muscular dystrophy mainly affects the muscles of the face and shoulders, beginning in childhood. It can be transmitted as a dominant genetic trait. Each child born of an affected parent has a 50 percent chance of being affected.

Limb girdle muscular dystrophy mainly affects the muscles of both the hip, thigh, shoulders and arm regions, beginning in childhood or adulthood. It progresses, sometimes rather rapidly, confining the patient to wheelchair or bed, and leads to death after a variable number of years. When both parents are carriers of the autosomal-recessive defective gene, each child has a 25 percent chance of having the disorder and a 50 percent chance to be a carrier of it. Limb-girdle muscular dystrophy strikes between the first and third decade of life and its progress is sometimes rapid.

Some forms of the muscular dystrophies have been found to be caused by specific enzyme or metabolic deficiences. They are inherited as autosomal recessive traits. Acid maltase deficiency of muscle can begin in infancy, childhood or adulthood. In infancy it also affects the heart and is fatal, in childhood it mimics Duchenne dystrophy and in adults it mimics limb-girdle dystrophy. Carnitine deficiency of muscle mimics Duchenne dystrophy of limb-girdle dystrophy in childhood or adulthood. Phosphorylase deficiency, inability-to-utilize-long-chain-fatty-acids, and Carnitine-palmityl-transferase deficiency begin in childhood and cause severe muscle cramps and pains during or after muscle activity, and later sometimes cause a progressive muscle weakness like limb-girdle dystrophy. Infantile-fatal-fasting-rhabdomyolisis can cause death in early childhood.

State Of The Art

In none of the musclar dystrophies is the treatment or prevention known, and in all except the very few instances of known enzymatic defects the cause is unknown. Clinical research studies involve improving diagnostic methods, seeking the basic cause, trying experimental therapy when available, and genetic counseling. Also fuller understanding of the basic biologic and pathogenic responses of muscle are being sought.

Diagnosis

Accurate diagnosis of the exact type of muscular dystrophy is vital for (a) genetic counseling of the patient and his family and (b) evaluation of any new treatment to be tried. Moreover, even though there is no treatment yet available for any of the types of muscular dystrophy, there are patients with different neuromuscular diseases closely simulating a muscular dystrophy that can be treated successfully, such as dermato-myositis/polymyositis.

Special methods developed through clinical research are providing scientists and clinicians with inreasingly more detailed knowledge of the various muscular dystrophies and are leading to improved diagnosis. Diagnosis is usually based on the combination of clinical examination, family history, microscopic examination of muscle biopsy samples, electromyographic recording of the muscle's electrical activity, and determination of levels of creatine phosphokinase (CPK), the enzyme that leaks out of damaged muscle tissue into the blood.

Muscle biopsy studied by histochemical techniques is important in the diagnosis of all muscle disorders, and in certain ones is the primary diagnostic test.

Muscle biopsy histochemistry has also proven valuable as a clinical research method to learn about muscle fibers in their normal and diseased states. It has been shown histochemically that normal human muscle fibers are of two basic types -- Type I and Type II fibers, usually about evenly distributed. Histochemistry shows that they may be affected together or separately depending on the kind of muscle disease. Recently, subtypes of these fibers have been recognized by special histochemical analyses, and they too can be affected together or selectively depending on the disease. Thus typing and subtyping of muscle fibers in diagnostic muscle biopsies may prove valuable in diagnosing and evaluating the pathological processes in certain neuromuscular disorders.

Electromyography (EMG), the study of the electrical activity of the patients' muscles is a well-established technique. However, important new extensions of the technique have been made. One recent one was open-biopsy EMG, the first technique to permit the correlation of electrical activity with chemical analysis (histochemistry) of the muscle fibers and subtypes. In this procedure, developed by NINCDS scientists, the electromyography apparatus is brought into the operating room, the electrical activity of the muscle fiber is recorded, and the muscle tissue sample is excised and prepared for histochemical study. The correlated data obtained provide new information important for the diagnosis and pathogenic analysis of muscle diseases. This technique has now been extended in two ways: (a) to be correlated with muscle-fiber histochemical subtypes and (b) the correlation of the single-fiber EMG technique, developed in Sweden, with histochemistry of muscle fibers, their types and subtypes, to give a new "open-biopsy single-fiber-EMG" technique, also to provide new diagnostic and pathogenic information.

A new, rapid and simple method of measuring active skeletal muscle damage in experimental animals using diphosphonate labelled with the radioactive tracer Technetium^{99}m was developed by NINCDS scientists. The method has been extended to clinical studies. It is now useful for diagnosing muscle damage in several muscle disorders, including Duchenne muscular dystrophy, other dystrophies, and dermatomyositis, and in following the effect of treatment. The investigators were able to show good correlation between the uptake of the tracer and body levels of other chemical indicators conventionally used in diagnosing these disorders. Unlike the conventional techniques which require considerable processing of blood or tissue, the new procedure requires only an intravenous injection of tracer and external scan of the patient.

These various established and new diagnostic tests are applied to patients at numerous neuromuscular disease clinics throughout the country. Most of these clinics were established by the Muscular Dystrophy Association, Inc., and offer differential diagnosis free to anyone suspected by his physician to be suffering from muscular dystrophy or related neuromuscular disorders. In addition to the MDA primary support of the clinics, there are NINCDS-supported clinical and basic investigators in most of the clinics who are an integral part of the clinic function.

Treatment

No medicine is yet known to cure, improve or even slow the progression of muscle weakening in any of the muscular dystropies. All that can be offered are: (a) antibiotics to control infections, which can lengthen the life of many patients; (b) various orthopedic-surgical and physical-medicine measures, including physical therapy. These have increased the mobility of these patients and enabled them to lead more active lives, and include physical therapy to delay contractures tightening the muscles, surgical relief of contractural deformities; braces, walkers, special shoes and corsets to partly compensate for muscle weakness; special schooling arrangements, and special summer camps for afflicted children.

Preventive Measures

There is no medical means of preventing any of the forms of muscular dystrophy if a person has inherited the abnormal genes. Genetic counseling, though, can tell a family member of an individual affected with one of the muscular dystrophies whether he or she or his or her children have a chance of developing the disease and what percent that chance is. Genetic counseling is therefore absolutely dependent on accurate diagnosis (discussed above). However, in Duchenne muscular dystrophy, because it can be inherited as an x-linked recessive trait and because there are dectable blood abnormalities, mothers who are proven carriers of the disease can be prevented from having affected sons but helped to have clinically normal daughters (but each of whom has a 50 percent chance of being a carrier like her mother). This requires: (a) accurate identification of the carrier state, (b) detection of the sex of the fetus in the uterus, and (c) therapeutic abortion of male fetuses. If a reliable means can be developed to detect in the uterus male fetuses affected with the disease, a Duchenne dystrophy carrier mother can be helped to have normal sons.

Carrier detection accuracy is enhanced by performing several tests on the parent seeking evidence of subtle muscle damage. These have included blood creatine phosphokinase measurements and study of muscle biopsy specimens by histochemistry for evidence of degenerating and regenerating muscle fibers.

Sex determination of the very early stage fetus is now easily done by sampling the pregnant woman's amniotic fluid and studying the chromosomes in the harvested cells. If the fetus is male the mother who knows she is a carrier can be alerted and given an opportunity to decide if she wishes to terminate the pregnancy.

A new direction is to try to determine whether the male fetus is actually affected with Duchenne dystrophy. This involves studying the amniotic fluid for various muscle-leakage substances such as CPK, as in carrier-detection, v.s.

Less valuable but of importance is determing that a suspected carrier is a definite carrier by identifying as early as possible that a male infant has the disease, so that genetic counseling and the fetal sex-determination measures can be effected if requested. Thus the mother can be counseled regarding subsequent pregnancies only after she has had one dystrophic son. Preliminary evaluation of a simple test to diagnose Duchenne muscular dystrophy in newborns has been promising. The procedure, developed by NINCDS grantees at the University of Iowa, measures creatine phosphokinase in a drop of dried blood and appears to be significantly more effective than standard CPK measurements. The accuracy of this test is being further evaluated. Other tests of early recognition need to be developed.

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The Search for Underlying Causes of the Various Muscular Dystrophies

The clinical and basic research methods of seeking the cause of the different muscular dystrophies have some approaches common to them all, and to other muscle diseases, and some specially for the particular disease being studied. Because all of the muscular dystrophies are inherited, it is presumed that there is a defect in metabolism which is within, or otherwise affects, the muscle (that an inherited defect might make muscle cells susceptible to environmental toxins or viruses is possible but considered unlikely).

In only a few of the muscular dystrophies is the metabolic defect known, v.s., and even in these, a rational method of treatment is not yet known.

A new approach to muscle disease is the growing of human muscle, obtained from diagnostic biopsies, in tissue culture -- this elaborate technique, developed by NINCDS scientists, provides unique opportunities for evaluation of growing muscle fibers without neural, vascular, and other extraneous influences that are operating in the patient. The observation of whether structural and chemical changes present in the patient's biopsied muscle fibers will or will not be reproducible in a tissue culture environment could help in explaining the nature of a given disease. When the same morphologic and chemical aspects of the disease are "reincarnated", i.e., reproduced, in the cultured fibers, one can then attempt new treatment of the disease in culture without any possible danger to the patient. Indeed, NINCDS scientists have been able to reproduce in cultured tissue enzymatic and structural defects characteristically found in acid maltase deficiency, in biopsies from 8 different patients of various types. This now represents a system of potential use in evaluating methods of preventing muscle fiber damage in this disease.

In muscle phosphofruitokinase deficiency, too, biochemical abnormality has been reproduced in muscle cultured from a patient by NINCDS investigators.

In muscle phosphorylase deficiency, NINCDS investigators, using their tissue-culture system, recently confirmed an earlier NINCDS study by being able to provoke production of the enzyme myophosphorylase in the muscle fibers of patients suffering from myophosphorylase deficiency. The "revival" of this enzyme, which is essential in metabolism of the sugar glucose, occurred when the muscle cells were regenerating in tissue culture or in the patient after injury. This development was a surprise since the enzyme had generally been considered to be genetically absent. They also showed, with colleagues in Paris, France, that the enzyme is the typical type by isozyme analyses. It is now hoped that therapeutic efforts can be directed toward promoting production and retention of myophosphorylase in mature fibers in the patient. Conceivably this approach could apply to other genetic enzyme deficiencies as well.

Carnitine deficiency, a newly found metabolic defect causing a form of muscular dystrophy, has been studied by NINCDS grantees in Minnesota and elsewhere. Carnitine, a component of muscle tissue, was found to be absent in the skeletal muscle of patients with progressive muscle weakness. The scientists have also uncovered a second type of carnitine deficiency disorder which can mimic primary liver disease. The reason for the carnitine deficiency is not known. Prednisone therapy has been shown to improve the patients' weakness, for totally unknown reasons. This has not yet been reproduced in muscle cultured from the patients.

In some cases of muscle disease a specific biochemical defect is not known but a characteristic morphologic involvement of mitochondria is found, associated with loose coupling of oxidation phosphorylation. Only a minority of these cases are inherited and so most cannot be precisely called a form of muscular dystrophy; yet the findings may be relevant in some cases to epilepsy as well as neuromuscular disease. Tissue culture in NINCDS biopsies of three such patients, two of whom also have epileptic seizures and retarded growth, has resulted in reincarnation of the same electromicroscopic mitochondrial defect in the cultured fibers. This result, which takes us a major step forward, is explainable as showing either a metabolic defect in the muscle cell or perpetuation in culture of a subliminal virus infestation. Both possibilities are now being explored.

In Duchenne dystrophy the plasmalemma is known to be leaky, evidenced by elevation of CPK enzyme and other muscle cell constituents in the blood, but the cause of the plasmalemmal leakiness and of the disease is unknown. It could be a primary defect of that membrane or one secondary to defective energy supply from inside or outside (e.g.,vascular defect) of the cell, or the appearance of a membrane toxin from inside or outside the cell. These possibilities are being systematically explored in patients and experimental models.

In individual biochemical studies, NINCDS grantees at various universities have found apparent abnormalities of muscle plasmalemma, red blood-cell plasmalemma, muscle sarcoplasmic reticulum, DMD muscle growing in tissue culture, blood platelets, particles on muscle membranes by SEM and white blood cells. These abnormalities are of potential importance in Duchenne dystrophy, but first each must be tested to determine: (a) confirmation in other laboratories, (b) disease specificity for DMD, and (c) whether such a defect is (i) primary or secondary in the organelle studied and (ii) important or unimportant for the pathogenesis of DMD.

Another approach in DMD has resulted from histochemically based "ischemia hypothesis" of NINCDS investigators that the muscle damage may be produced by abnormalities of the small (arterial) blood vessels with the muscles rather than by a defect solely in the muscle fiber itself; they further postulate that such blood vessel abnormalities may become apparent only when certain blood vessel constricting agents are present

in the circulation. To support the hypothesis, animals with functional ischemia of muscle were shown to have abnormality similar to that of DMD, as were patients with muscle ischemia from peripheral vascular disease. Since preceding studies of DMD patients have not yielded evidence of ischemia, this hypothesis, too, awaits further supportive confirmation.

Myotonic muscular dystrophy (myotonic atrophy) is also of unknown cause. Previously, NINCDS investigators had found biochemical abnormalities, the meaning of which is unclear - hypercatabolism of serum IgG, reactive hyperinsulinism without hypoglycemia; they also found histochemically selective atrophy of type II muscle fibers. Most recently they have found in the myotonic muscle cell plasmalemmal resistance to blocking by a-bungarotoxin and atropine, and 50 percent reduction in the enzyme adenylate cyclase. They have postulated a defect of neural influence on muscle causing the observed muscle-cell plasmalemmal abnormalities. This has been supported by the findings of a Scottish scientist who used a computerized method for analyzing the electrical output of muscle fibers to evaluate myotonic muscular atrophy patients and by Greek investigators doing similar studies.

Several NINCDS grantees are seeking biochemical abnormalities of the muscle cell and red-blood-cell plasmalemma, and there are some preliminary findings of abnormality; these must now undergo vigorous examination for reproducability, disease-specificity and significance to the causation of the disease.

Animal models of myotonia, including hereditary myotonia of goats and myotonia induced by chemicals such as the herbecide 2,4-D, the cholesterol-lowering agent atromid, and diazacholesterol, are being studied by NINCDS scientists and grantees to seek a clue relevant to human myotonic disorders.

A new, somewhat empiric treatment of the myotonic phenomenon (but not the basic disease), resulting in considerable relief to the patient has been reported by NINCDS grantees and scientist -- it is acetazolamide.

NIH Program

The center of intramural research activities on muscular dystrophies and other neuromuscular disorders is the Medical Neurology Branch, NINCDS, dedicated entirely to research in the neuromuscular disorders. In addition, the Institute supports four clinical research centers, at Washington University in St. Louis, the University of Pennsylvania, Columbia University, and Duke University, some 83 research grants, and two contracts.

Unsolved Problems

These are legión, since no treatment is known for any of the muscular dystrophies, and in most the presumed metabolic disorder is unknown. However, with the cascade of new and apparently relevant information being gleaned by both clinical and basic research studies, investigators working on at least some of these diseases are optimistic that clinical treatment of the basic diseases will begin to be developed in the near future.

MYASTHENIA GRAVIS

Myasthenia gravis is a chronic neuromuscular disease characterized by progressive weakness and abnormally rapid fatigue of the voluntary muscles, with improvement following rest. Muscles of the eyes, speaking, breathing, chewing, and the limbs are affected. Untreated patients often die from weakness of breathing or from choking because of weakness of swallowing. The disease may occur at any age from 12 to 80; females are more affected below age 40 and males more so above that. NINCDS support of research is in conjunction with research and patient guidance supported by the Myasthenia Gravis Foundation and research and patient care by the Muscular Dystrophy Association.

State of The Art

Over the past two decades research advances have produced significant reductions in the death rate and degree of illness in myasthenia gravis patients, even in the most severe cases. Improvements in support systems, such as intensive hospital care, respirators, and antibiotics, and widespread use of tracheostomy (surgery to open the windpipe) certainly have contributed to the welfare of the myasthenia gravis patient. But the most dramatic advances have centered on: (a) the development of drugs that facilitate the transmission of nerve impulses across the nerve-muscle junction for muscle activation, since in myasthenia gravis, transmission of this nerve-to-muscle impulse is defective in some way, (b) removal of the abnormal thymus gland by thymectomy, and (c) antidysimmune treatment, especially prednisone, ACTH, azathioprine, thoracic duct drainage and plasmaphoresis. Formerly many myasthenia gravis patients died within the first few years of their illness. Today, scientists believe the majority of MG patients will live out a normal lifespan. Many patients cooperating with their physicians can expect to lead virtually normal lives.

The ultimate cause of MG remains unknown, but the immediate cause of weakness is lack of effective transmission at the nerve-muscle junction of acetylcholine from the motor nerve ending to the muscle fiber at their neuromuscular junction. Normally a substance called "acetylcholine"

is released from the nerve ending and crosses a gap or synapse to a muscle region called the end plate. There the acetylcholine attaches to certain protein molecules on the end plate known as receptors and triggers muscle contraction. In myasthenia gravis this mechanism is impaired.

The cause of the impairment was found by NINCDS scientists, and grantees, to be an IgG antibody produced in the patient against his own motor end-plates at the neuromuscular junction; i.e., he has become "allergic" to his own NMJs. This appears to be exactly parallel to an animal model in which weakness and death occur in association with allergy provoked against the nicotinic acetlycholine receptor at the neuromuscular junction endplate (following injection of electric eel or electric fish purified receptor), as shown by NINCDS grantees and scientists. Why it is thymus provoked is not known. The gland is abnormal, hyperplastic or a benign thymomatous tumor, in the majority of MG patients.

Diagnosis

Diagnosis of clear-cut myasthenia gravis usually can be made without difficulty on the basis of history and physical examination alone. Myasthenia gravis may affect any voluntary muscle, but usually involves those of the eyes, face, lips, tongue, throat, and neck and breathing muscles more severely than the limb muscles. However, involvement of limb movement can be severe. Symptoms may vary depending upon which muscles are affected. The disease may begin with a localized weakness, or as a severe generalized weakness. A patient may experience difficulties in breathing, swallowing or talking, or have double vision, or arm or leg weakness. There may be unusually rapid muscle fatigue following repetition of a movement.

Confirmation of the diagnosis is achieved with drug studies as well as electrical, mechanical, and X-ray tests. Injection of an anticholinesterase drug that facilitates nerve-muscle message transmission results in a dramatic increase in strength. Administration of a neuromuscular blocking agent that inhibits the transmission of nerve-muscle messages, such as curare, causes increased weakness. Responses to these agents usually confirm the diagnosis of myasthenia gravis. Repetitive electrical stimulation of the nerve-muscle apparatus provides objective evidence of impaired transmission. X-rays can detect enlargement of the thymus gland in the chest from hyperplasia or thymoma. A new technique is radioisotope scanning with radioactive gallium for thymic abnormality. If there is a diagnosis of tumor of the thymus in myasthenia gravis patients, this will have an important bearing on both the treatment and outcome of the disease. Moreover, the basic role of the thymus in the disease is of increasing research interest.

Another new diagnostic technique developed by NINCDS scientists involves intravenous infusion of lactate. This produces a decrease in voluntary muscle functions, including respiration, voice, grip, and movement of eyelids in a series of patients. This lactate infusion appears to be reliable and specific, and is somewhat safer than the generally used curare test for evoking myasthenic weakness.

The newest diagnostic techniques involve testing for anti-ACh-receptor antibody, by one of several techniques. Those involving radioimmunoassay are considered completely disease-specific and more than 90 percent accurate.

Treatment

This is the neuromuscular disease most successfully treated, as shown by a number of studies by NINCDS grantees.

Several drugs provide relief from symptoms, and others may be effective against one or another cause. Anticholinesterase drugs, especially pyridostigmine and neostigmine, have been mainstays of symptomatic treatment for nearly 40 years.

Prednisone

NINCDS scientists continue efforts to expand on their development of a new treatment -- a high-single dose, alternate-day, oral prednisone regimen--which has proven extremely beneficial over long periods in the majority of patients tested. It appears to be the treatment of choice in the majority of patients. Prednisone is a synthetic drug that acts similarly to the natural hormone, cortisone. Patients of all ages and both sexes respond, but patients over 40, especially males, appear to respond best to this treatment. Physicians throughout the world have confirmed the beneficial results. In fact, NINCDS scientists concurred with by others throughout the world now consider alternate-day prednisone the most effective treatment. It is the yet unproved hope that prednisone may suppress the disease sufficiently long for it to totally disappear.

ACTH

ACTH (adrenocorticotrophic hormone) can benefit severely ill patients. A disadvantage is that many receiving a 10-day course of daily ACTH experience temporary muscle weakness and increased difficulty in breathing for the first several days before improvement begins to appear. Paradoxically, the patients who experience the greater initial weakness usually showed the more striking eventual recovery. Continued maintenance ACTH injections every few days or weekly recently were found to prolong the beneficial effects. Short intensive courses of ACTH are useful in improving temporary weakness.

Thymectomy

Thymectomy (surgical removal of the thymus) is beneficial in nearly 90 percent of patients, including severely affected ones. Some investigators consider that thymectomy should be performed routinely on all myasthenia gravis patients, especially younger females.

Other Immunosuppression

Immunosuppressive drugs, such as azathioprine, cyclophosphamide, and methatrexate, have been reported beneficial in MG. They are, presumably, inhibiting the abnormal immune response in the disease.

Thoracic-duct Drainage

This has been reported beneficial in severely affected patients, probably because of removal of lymphocytes and plasma detrimental to the patient--reinfusion of either caused the weakness to reappear.

Plasmaphoresis

Removal of the plasma containing the weakening IgG antibodies can be beneficial for short periods of time, and for long periods when combined with prednisone and azathioprine immunosuppresors.

Prevention

Since the cause of MG is not known there cannot be prevention. It is usually non-hereditary, suggesting an environmental triggering factor, such as a virus or a toxin. Tissue HLA typing suggests certain persons are more susceptible. But until the cause, presumably environmental, is identified, prevention is impossible.

Outlook

The outlook for MG patients, vastly improved in recent years, is expected to continue to improve. The Federal program, together with the efforts of the voluntary agencies working in the field, is hastening the day when the cause will be known and a cure found.

OFFICE OF HUMAN DEVELOPMENT SERVICES

Rehabilitation Services Administration

MUSCULAR DYSTROPHY

Because of the nature of the disease, victims of muscular dystrophy have limited potential for gainful employment, and therefore only a small number of them have been rehabilitated through the State-Federal program of vocational rehabilitation. It is hoped, however, that the acquisition of new medical knowledge concerning this disabling condition will contribute to positive gains over the next decade in the work capacity of the muscular dystrophy case. State vocational rehabilitation agencies will be serving increased numbers of persons disabled by muscular dystrophy due to the emphasis in the Rehabilitation Act of 1973 on serving the severely disabled.

Rehabilitation Research

Research in the Rehabilitation Research and Training Centers is directed towards studying the changes in the structure, ultra structure and innervation of the muscles to identify causes of muscle weakness, effects of various therapeutic effects, and how to maximize the positive functions and to minimize the secondary disability resulting from impaired muscle control.

Number of People Rehabilitated:

Fiscal Year	All Rehabilitants	Persons Rehabilitated With Muscular Dystrophy
1975	324,039	319
1976	303,328	249
1977	291,202 1/	277 1/
1978	283,000 1/	300 1/
1979	277,000 1/	300 1/

1/ Estimated

ORGAN TRANSPLANTATION

Clinical Immunology: Allergy and Organ Transplantation

Immunology, the study of the immune system--the body's principal defense against invaders such as bacteria, viruses or tumor cells--has grown rapidly since the late 1950's. This discipline is no longer solely a technology of preventive medicine, controlling infectious diseases such as polio, smallpox, and whooping cough through immunization. Today, immunology affects almost every branch of medicine, touching an ever-widening range of practical medical problems in the fields of infectious diseases, autoimmune states where the immune system reacts against the body's own cells or proteins, cancer, maternal-fetal relations, aging, transplantation and allergy.

Recognizing the vast potential that exists for the application of immunologic methods, the National Institute of Allergy and Infectious Diseases (NIAID) has been a major supporter of research in this field. This report deals with 2 areas of immunology --allergy and organ transplantation--in which NIAID-supported scientists have been particularly instrumental in developing many of the basic principles which are now being applied clinically.

Obligations

Obligations for Programs in Clinical Immunology: Allergy and Organ Transplantation

	1975	1976	1977	1978 Estimate	1979 Estimate
National Institutes of Health:					
National Institute of Allergy and Infectious Diseases	12,018,521	10,741,000	11,005,000	13,005,000	14,305,000
National Eye Institute*	312,339	560,840	589,666	594,463	501,661
National Heart, Lung and Blood Institute*	3,000,000	3,000,000	3,000,000	3,000,000	3,066,000
Total	15,330,860	14,301,840	14,594,666	16,599,463	17,872,661

*Figures are for organ transplantation only

NATIONAL INSTITUTES OF HEALTH

ORGAN TRANSPLANTATION

Allergy

When the immune system functions properly, it protects the individual against foreign invaders. However, in some individuals, this system can overreact to otherwise harmless foreign substances--referred to as allergens--and cause allergic disease. Frequently, these allergens are common substances --pollens, molds, dust, foods, drugs, insect venoms. The symptoms of allergy vary from itching, swelling and redness to airway obstruction, and, occasionally, shock and death.

Approximately 35 million Americans suffer from one or more types of allergy, the most common of which is hayfever. These disorders cost the nation an estimated $2.5 billion annually. In addition to medical expenses, this figure includes other costs such as ambulatory care and time lost from work.

In light of this sizable impact of allergy on Americans and the rapidly accumulating knowledge of immunology, NIAID in 1971 began to establish a network of Asthma and Allergic Disease Centers (AADC) across the country. The goal of these centers--currently numbering 14--has been to translate the rapidly expanding knowledge of the immune system into improved diagnosis, prevention and treatment of asthma and allergic disorders.

Last year, NIAID established a Task Force on Asthma and the Other Allergic Diseases to describe the state of knowledge, incidence, and impact of asthma and the other allergic diseases. In addition, the 12 committees--composed of both medical professionals and non-professionals--will identify research objectives which may be expected to advance basic understanding, diagnosis, prevention and therapy of these diseases.

Mechanisms of the Allergic Response. Since the discovery by NIAID grantees in 1967 of Immunoglobulin E as the "allergic" antibody, scientists have made consider-able progress in understanding the causes and mechanisms of allergy. It is now known that allergy-prone individuals produce IgE antibodies in response to allergens. These antibodies attach to the surface of mast cells--tissue cells found in the respiratory tract and skin. When allergens react with the IgE on these cells, a series of events occur within the cells, causing them to release certain chemicals--known as mediators which produce the symptoms of allergy.

Several of these mediators have been identified by NIAID grantees and scientists who are now working to elucidate the processes by which they are generated and released. Such knowledge would enable

scientists to develop specific means of interrupting these harmful processes, providing relief to those allergic persons not helped by present medications.

An NIAID scientist at the AADC in Bethesda has found that, during the allergic reaction, the parasympathetic nervous system is stimulated, releasing a hormone, acetylcholine. This causes an increase in the cyclic GMP--a chemical found in all cells--resulting in increased amounts of mediators being released by the mast cells. These mediators, in turn, amplify the release of more mediators.

His studies also provide an explanation for the effect of cyclic GMP on cell structures. He found that this chemical facilitates the conversion of certain structures in the mast cells into a functional form that is necessary for the release of mediators. Conversely, cyclic AMP--a chemical which blocks mediator release--converts these structures into a nonfunctional form. These studies should help to explain the nature of hives, and asthmatic and nasal reactions to allergen exposure.

The role of another mediator--histamine--is being studied by several inves-tigators. At the AADC at Scripps Clinic in La Jolla, CA, scientists have shown that patients with severe asthma have a higher level of histamine in their blood than do normal individuals. This finding implicates histamine as an important mediator in spontaneous asthma attacks along with mast cells and basophils--the cells which contain histamine. Development of drugs to inhibit the release of histamine from these cells should benefit asthmatic patients.

Histamine also plays a role in another allergic disorder, urticaria--hives. Having previously shown that histamine is an important mediator in patients who develop hives upon exposure to cold, the director of the AADC in Bethesda has now shown that histamine is released into the affected skin of patients with exercise-induced hives, solar urticaria, and immediate pressure urticaria. Patients with chronic urticaria were found to fall into 2 groups--those who had 5 times the normal level of histamine in the hive but not in their normal skin and those who had high levels of histamine both in the hive and the normal skin. This suggests the presence of an abnormality in the skin prior to the development of a hive in these latter patients.

Cellular Abnormalities. NIAID grantees at the University of Cincinnati Medical Center are investigating the role of platelets--blood cells

important in the clotting of blood--in allergic conditions. They have found that these cells do not function normally in patients with asthma and allergic rhinitis. In patients with the latter disorder, these abnormalities--one of which is an increase in the time required for blood to clot--returned to normal after the end of allergy season. During allergy season this prolongation of bleeding time can enhance the susceptibility to and occurrence of nosebleeds in patients with this disorder.

Drug Mechanisms. NIAID grantees at the Washington University AADC in St. Louis are delineating the mechanisms of action of theophylline-- - one of the most effective drugs currently used to treat asthma. They have shown that this drug inhibits the release of mediators by raising cyclic AMP levels in mast cells. In addition, they have now found, in animal cells, that adenosine--a substance present in the fluid surrounding mast cells--can triple the rate of their mediator release. However, theophylline blocks this effect of adenosine, suggesting an entirely new approach to asthma therapy--drugs that specifically block adenosine's effects.

Treatment. Desensitization injections--commonly known as allergy shots--are a form of immunotherapy designed to increase a patient's tolerance for an antigen to which he is allergic. Scientists at the Northwestern University AADC in Chicago have developed a polymerized form--by chemically linking together identical molecules--of ragweed antigen E, the major culprit in hay fever. When used to desensitize ragweed allergy patients, the polymer is safer (fewer side reactions) than the standard extract and appears to produce the same benefits in one-third the time. This material, thus, offers the benefit of immunotherapy to a greater number of ragweed patients with less risk and less expenditure of time and money. The investigators are presently developing polymers of the common grass pollens.

Allergic reactions to the stings of insects such as bees, yellow jackets, wasps, hornets, and fire ants can lead to a serious drop in blood pressure, shock and possibly death. An estimated 50-100 Americans die annually from this problem.

Over the years, such patients have been tested and desensitized with an extract prepared from the whole body of the insect (WBE). However, the usefulness of WBE for both purposes has been repeatedly questioned. NIAID grantees at Johns Hopkins University AADC and at State University of New York, Buffalo have now shown that WBE is not as reliable in identifying allergic individuals as an extract containing only the insect's venom. In addition, the Hopkins group

found that specific venom extracts were extremely effective for desensitization. Approximately 100 patients were successfully desensitized with venom as demonstrated by their almost total lack of reactions to a sting by the insect to which they were allergic. Furthermore, WBE was shown to be of no more value in desensitizing patients than a placebo--a solution without any insect antigens. Institution of this new regimen would be of tremendous value to allergic individuals. NIAID's Research Reagents Branch has prepared pure venoms from several insects which are presently available to clinical investigators for skin testing.

Occupational Asthma. In the past 50 years, the burgeoning of industrial processes has greatly multiplied the number and nature of materials encountered at the work place. Several occupational lung diseases are being investigated by grantees at the Tulane University AADC in New Orleans. They have recently found that an occupational asthma caused by toluene diisocyanate (TDI)--a chemical widely used in the plastics industry--was not due to an immune mechanism. Rather, TDI acted like a drug to cause constriction of the bronchial airways. The scientists have also identified a simple test which can be used to diagnose TDI sensitivity by the presence of irritable airways. These findings may enable physicians in the future to screen prospective employees to determine those susceptible to the development of asthma from TDI exposure.

Current approaches to treating allergic conditions rely on the identification of allergens and treatment with drugs or desensitization. However, as scientists gain increased understanding of the biochemical events leading to the release of chemical mediators, of the interactions of the immune and nervous systems, and of the genetic and developmental factors leading to allergic diseases, much more effective methods of treating allergy patients should result.

Organ Transplantation*

Thousands of people are alive or leading more normal lives today because of a successful transplant of an organ or tissue. Surgeons have solved many of the technical problems involved in transplanting material from one human to another. However, the full potential of organ transplantation has not been realized. The major obstacle to success continues to be the rejection of the graft by the recipient's immune system which recognizes the new tissue as foreign.

Through basic research, tremendous strides have been made in understanding the mechanisms of the immune response and particularly,

its role in rejection. Although these findings have provided scientists with new or improved approaches to manipulating the immune response, the routine use of these concepts in organ transplantation is not yet at hand.

Consequently, two approaches are used today to minimize graft rejection: suppression of the immune response by drugs, and selection of the most compatible donor-recipient combination. NIAID scientists are continuing to make important contributions to both of these areas. In the field of immunosuppression, re-searchers in NIAID's Laboratory of Clinical Investigation have identified the sub-populations of cells involved in the rejection processes--known as the host versus graft (HVG) and also the graft versus host (GVH) reaction. These scientists have also identified the specific cell populations upon which various drugs used to suppress the immune response act. This knowledge should eventually enable physicians to suppress only the rejection process rather than the patient's total immune system since the latter procedure leaves him highly vulnerable to life-threatening infections.

Rejection of a transplanted organ would not be a problem if everyone had an identical twin. Since this is not the case, scientists have identified over the years, a number of genetic factors --antigens on cell surfaces -- which appear to play an important role in the rejection process. There are 51 known HLA -- or human histocompatibility antigens -- which are found on lymphocytes (white cells important in immune responses) and on almost all other body cells. These antigens are controlled by 4 histocompatibility genes known as HLA-A, HLA-B, HLA-C, and HLA-D.

Commonly, cells from recipients and donors are typed for HLA-A and HLA-B antigens by a serologic (blood) test. NIAID's Serum Bank, established in 1965 is the world's chief source of reagents to identify these antigens. The Bank currently contains over 1800 different antisera. NIAID collects, analyzes, and distributes these reagents to approximately 400 laboratories in this country and abroad. This program makes possible both the matching of donors and recipients for transplant, white cell and platelet transfusions and studies on the relation-ship of HLA antigens to disease susceptibility.

These antisera -- which are obtained from various human sources -- present some difficulty as typing reagents because they are usually not specific and each contains a wide array of antibodies against strong as well as weak antigens. In addition, they are often in short supply. NIAID grantees at Scripps Clinic and Research Foundation in La Jolla, California have taken two approaches to improve this situation. They

have successfully produced antisera against a specific antigen, HLA-A9, in animals, (rabbits and goats). They have also been able to isolate the HLS-A9 antigen from human urine. Although the clinical usefulness of these reagents is not yet clear, these sources of antisera and immunologically functional HLA antigens should prove valuable in elucidating the structure and chemical composition of these genetic markers and their relevance to transplant rejection and other disease states.

NIAID's Research Resources Branch distributes standardized typing trays preloaded with 60 of the most reliable HLA antisera. Clinical laboratories in the U.S. can obtain these trays without cost to type donors and recipients for solid organ and bone marrow transplants. However, a report must be made of the results, which are used as part of the regular surveillance of the effectiveness of reagents and of the effect of matching on the success of transplants. During 1976, 124 labs used over 30,000 trays to type for most of the 3500 kidney transplants -- a testimony to their value.

Another commonly used test for donor selection utilizes the interaction of lymphocytes of the recipient with those of prospective donors to determine the presence of HLA-D antigens. These antigens appear to be of great significance in graft rejection. However, scientists have identified another set of antigens -- apparently controlled by the HLA-D genes -- that, unlike the HLA antigens, are found only on one class of lymphocytes, the B-cells. NIAID grantees have led the way in describing these B-cell antigens which seem to play a signficant role in both graft rejection and susceptibility to certain diseases. A grantee at UCLA has defined 22 antigens of this system while other grantees including those at Milwaukee Blood Center, Scripps Clinic and the University of Paris are acquiring reagents that can be used to identify these antigens by serologic tests. It is expected that the next major advances in tissue typing will come from B cell investigations.

Studies on HLA antigens have yielded a valuable bonus -- recognition of an association between these factors and susceptibility to a wide variety of diseases including multiple sclerosis, juvenile

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*Additional information concerning progress in kidney transplanation can be found in the special report of the National Institute of Arthritis, Metabolism, and Digestive Diseases entitled "Kidney and Urinary Tract Diseases and the Artificial Kidney", page

diabetes and ankylosing spondylitis -- an arthritis-like disease of the spine. In addition to aiding physicians in identification of susceptible individuals, results of these studies have also made possible, in several diseases, the recognition of more than one form of a disorder. For example, a NIAID grantee at UCLA first found an increased frequency of HLA-B8 in myasthenia gravis -- a disease characterized by muscle weakness. Through HLA typing, he has now been able to identify 2 forms of this disease with distinct clinical characteristics. This finding should be of great importance, not only in the diagnosis but also in the specific treatment of each form.

Bone Marrow Transplants. Transplantation of bone marrow has become a valid treatment for several disease states. Although many basic problems remain to be solved, a NIAID and National Cancer Institute grantee at the Fred Hutchinson Cancer Research Center in Seattle has achieved remarkable results in 2 types of patients.

In a study of 110 patients with end-stage leukemia who were treated with radiation followed by a bone marrow transplant from a sibling, the Seattle investigator has found that long-term survivors of this therapy have been "cured" of their leukemia. The longest survivors are now more than 7 years post-transplant and are off all medications.

A group of patients with aplastic anemia -- a highly fatal disorder in which the bone marrow fails to produce blood cells --have also benefited from bone marrow transplants. The longest survivors in this study are now more than 6 years post transplant and are leading normal lives without medication and transfusions.

Bone marrow transplantation also offers promise for treatment of genetic diseases such as thalassemia and sickle cell anemia, since it would provide the patient with a new source of cells. An international bone marrow transplant registry enables data collection related to progress in this field.

Thymus Transplants. A NIAID grantee at the University of Wisconsin has found that fragments of thymus -- the organ which controls the development of T lymphocytes -- grown in culture in a nutrient fluid will change its composition so that it can be transplanted without fear of rejection. He has given this cultured thymus to 15 children with fatal forms of immune deficiency disease, seven of whom are still alive 4-15 months after transplantation. Since the transplant is easy

to perform and does not seem to have severe complications, it holds great promise for these patients who usually die before age 2 as well as those with milder forms of the disease.

National Heart, Lung and Blood Institute

Since the first successful heart transplant was performed in 1967, 338 individuals have received transplanted hearts, 77 of whom are still alive with functioning grafts.

One of the most successful heart transplant teams is headed by NHLBI grantee, Dr. Norman Shumway at Stanford University in California. As of August, 1976, these scientists transplanted hearts in 109 patients, 44 of whom were still alive. They have found that the first three months after surgery are the most critical ones for these patients. For the 69 patients who survived beyond this period, prospects for long-term survival improved substantially. After one year, 80% of the recipients were alive, although this percentage decreased annually thereafter, declining to 43% after 5 years. However, 90% of the survivors were restored to normal cardiac functional status by their transplants and 74% resumed their previous occupations or activities.

This encouraging trend is a result of several factors: early and aggressive diagnosis and treatment of infections in the immunosuppressed transplant recipients; better criteria for selecting patients most likely to benefit from this procedure; and careful control of diet and other factors increasing the vulnerability of the transplanted heart to accelerated coronary heart disease. Also, a recently developed technique which permits physicians to safely biopsy -- remove a small piece of tissue -- the heart wall or endomyocarium provides an improved means for the early detection of rejection episodes. Serial biopsies permit the evaluation of the results of immunosuppressive therapy.

National Eye Institute

Each year, approximately 3,000 people in the U.S. undergo corneal transplantation to restore vision in one or both eyes. This procedure has a success rate of 75-85%, making it one of today's most successful types of transplants. The National Eye Institute supports research directed at improving this success rate and extending the range of applicability of corneal transplantation.

During the past year, progress has been made in improving the

quality of donor tissue and thereby reducing the incidence of graft failure. One approach -- corneal tissue culture -- is still in the experimental stages but offers hope of improving the preservation of the cornea's epithelium -- the outer layer of cells -- as well as the endothelium -- the cell layer which helps to maintain the cornea's transparency. Grantees at the University of Minnesota have been able to maintain corneal tissues in culture -- using a special solution with nutrients -- for up to 35 days. They have transplanted a number of corneas that had been incubated for 14 days in culture, with results as good as those ascribed to operations using tissue preserved by currently accepted methods.

Maintenance of corneas in tissue culture may also reduce the antigenicity of tissue. When transplantion of cultured chicken corneas to rabbits was attempted, rejection was delayed or prevented when the corneas were maintained for 3 weeks in tissue culture. This suggests the possibility that the culture of corneas may greatly reduce the rejection rate of human grafts, and also that it may be possible eventually to use animal tissue for human grafts in emergency situations when suitable human material is not available.

These finding provide some indication of clinical research progress in transplantation. However, as basic research unravels the enormous complexity of the immune response, we have a clearer understanding of the extent of the problems that must still be overcome before transplantation achieves its full potential. More research is needed to develop specific methods of manipulating a recipient's immune response so that a graft will not be rejected. In addition, techniques must be improved or developed to identify those antigens which are most important in the rejection process and an adequate supply of reagents must be available to type all prospective organ donors and recipients.

If science can continue its progress in the field of transplantation, it seems likely that the success rate of today's type of transplants will improve, while organs not now considered transplantable -- lungs, intestines, or uteri -- may become possible. In addition, elucidation of the genetic control of the immune response -- through the study of histocompatibility genes -- should provide physicians with valuable tools for diagnosing and treating diseases as well as for genetic counseling.

PARKINSON'S DISEASE

Obligations for Programs in Parkinson's Disease

	1975	1976	1977	1978 Estimate	1979 Estimate
National Institutes of Health: National Institute of Neurological and Communicative Disorders and Stroke	$6,497,000	$5,703,000	$6,757,000	$7,048,000	$7,235,000

NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological and Communicative Disorders and Stroke

First described in 1817 by James Parkinson, a London physician, Parkinson's disease affects brain centers involved in the control and regulation of movement. Due to disordered control of movement, rigidity of the muscles develops, accompanied by uncontrollable tremor of the extremities, stooped posture, loss of facial expression, and difficulty in walking, talking, writing, or any action requiring a high degree of muscular coordination.

Parkinson's disease is one of the most severely crippling chronic disorders of the nervous system. Estimates of prevalence range from one case per 1,000 to one case per 200 population. The disease most frequently attacks people in their 50's and 60's. Parkinson's disease is rarely a primary cause of death, but often weakens the victim so, that he falls prey to other diseases. The National Institutes of Health (NIH) has had a long-standing responsibility for research and research support in parkinsonism, dating from the establishment of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) in 1950.

Treatment

Research Success Story

Advances in the treatment of parkinsonism have been one of the major neurological research success stories of the decade. For the better part of a century, patients were treated with extracts from the belladonna plant, and, after World War II, a variety of synthetic belladonna-like drugs. These drugs were of some help, but none was truly effective. Then a period of real progress occurred in the 1950's, when scientists began experimenting with tranquilizers as a means of controlling high blood pressure. This research produced a large amount of new information on the action of chemical neurotransmitters--substances that transfer information between nerve cells. Contributions came from a number of countries, but some of the most crucial basic research was done at the National Institutes of Health. It was shown that reserpine, a tranquilizing drug, produces symptoms similar to those of parkinsonism when given in large doses. In studying the biochemical effects underlying the symptoms, scientists found that reserpine reduces high concentrations of the neurotransmitter chemical, dopamine, in parts of the brain responsible for motor control. A key finding making these studies relevant to parkinsonism was reported in 1960, when scientists at the University of Vienna found a striking shortage of dopamine in the brains of parkinsonian patients at autopsy. This clearly pointed to the possibility of replacement therapy, and led to immediate efforts to treat Parkinson's disease with dopamine.

The Blood-Brain Barrier

Early attempts to replace dopamine directly (intravenously) were unsuccessful. It would not cross the blood-brain barrier--a protective biochemical mechanism which selectively screens substances passing from the blood into the central nervous system. Then, scientists found that dopamine's metabolic precursor--the preceding link in the chain of chemical reactions leading to its production--would cross the barrier. The precursor, levodopa or L-DOPA, at first was not given in large enough dosage, for a long enough time, or by the best route to build up an effective and stable blood level.

It was subsequently found that by starting on small oral doses and increasing the rate very slowly, the majority of patients could tolerate effective amounts of levodopa. After extensive trials in many medical centers, the drug was approved for prescription sale in June 1970.

Side-Effects

The new therapy was not without problems, however. Chief of these were side-effects caused by the extremely large doses necessary to control parkinsonian symptoms. Levodopa is broken down very rapidly in the body, and large doses are necessary to achieve the saturation required for penetration into the brain. In some cases, side-effects were so severe that the drug had to be discontinued. Later, a way was found to reduce the high dose levels--and certain side-effects--by giving levodopa with a decarboxylase inhibitor, a substance which slows its peripheral metabolic breakdown, permitting a reduction in dosage level of approximately 80 percent. And, since use of a decarboxylase inhibitor tended to decrease levodopa-induced nausea and vomiting, more patients were able to tolerate therapy. After extensive trials, a pill combining levodopa and such an inhibitor, alpha methyldopa hydrazine or carbidopa, was approved for prescription sale, and this stands as the most effective antiparkinsonian treatment currently available. The majority of patients are benefited in some degree: some moderately, some with striking relief from their symptoms.

However, despite this exciting progress in alleviation of symptoms, the disease progresses, and many patients continue to have severe problems even with the best efforts of their physicians. For example, one of the most serious difficulties facing parkinsonian patients today is abrupt fluctuation from near immobility or involuntary movement to states of normal function. These changes, termed "on-off" reactions, appear to correlate with cumulative, high-dose administration of levodopa. Thus, the obvious need is for an increasingly intense research effort, so that the fundamental causes of parkinsonism can be discovered, the disease process revealed in molecular detail, and an optimal means of halting progression found.

The Research Program

A major component of the NINCDS program in parkinsonism are studies conducted by the Institute's Intramural Research Program in laboratories and clinics at the Bethesda, Maryland campus and on the island of Guam. This program has made very large contributions to the progress described above, and continues to be one of the Nation's chief producers of new knowledge in both basic and clinical research relating to parkinsonism and other extrapyramidal disorders. The NINCDS effort in parkinsonism also includes grant support for interdisciplinary research groups at Mt. Sinai School of Medicine and Cornell University Medical College in New York, and the University of Colorado School of Medicine in Denver, as well as 24 smaller, more circumscribed research projects. In general, researchers are determining which nerve cells and areas of the brain use specific transmitter molecules. Increasingly, there is interest in the study of the peptide transmitters which may be involved in the derangement seen in Parkinson's disease. Work is actively proceeding in several laboratories on the separate categories and distribution of dopamine receptors and on the chemistry of neurotransmitters.

Dopamine Agonists

At NINCDS, scientists are exploring new therapeutic approaches to Parkinson's disease using substances called dopamine receptor agonists. These substances mimic dopamine in that they have a direct effect on receptors for this neurotransmitter. Unlike levodopa, however, they do not depend on enzymatic conversion of a precursor. Thus, dopamine agonists may induce more consistent therapeutic effects, and could continue to operate even if the enzymatic machinery needed to convert levodopa to dopamine is destroyed. And, if an agonist were relatively specific--that is, acting primarily on those receptors defective in parkinsonism--then side effects linked to the more generalized actions of dopamine might possibly be avoided.

NINCDS scientists have reported a statistically significant response in double-blind studies with the agonist bromocriptine. Adverse reactions were dose dependent, reversible, and qualitatively similar to those encountered with levodopa. In one series of patients, many were able to stop levodopa while taking bromocriptine. In another, the drug was added to otherwise optimum therapy, including levodopa. The improvement was measured at about 10 percent in patients with minor disabilities, and at about 20 percent in those with more severe disease. During the past four years, NINCDS scientists have administered bromocriptine (with or without levodopa) to over 100 research patients. The agonist appears to have a therapeutic profile similar to levodopa, but with evidence of more prolonged action. Although completely successful management of "on-off" reactions has yet to be realized, concomitant administration of bromocriptine with lower doses of levodopa has helped to ameliorate the condition in many patients. A major issue yet to be resolved, however, is whether the efficacy of bromocriptine can be sustained during long-term therapy without inducing "on-off" or other late adverse reactions. To help answer this question, Intramural scientists are doing careful follow-ups of patients with no previous history of levodopa therapy, who are now taking bromocriptine alone.

Blocking Agents

Paralleling work with bromocriptine and other dopamine agonists are related studies of enzymes which block substances known to destroy dopamine in the brain. Preliminary studies involving use of one such drug, deprenyl, have prolonged the therapeutic effects of levodopa, alleviating mild "on-off" symptoms. Thus, NINCDS scientists are approaching the problem of dopamine depletion from both ends--by finding ways to mimic dopamine or by blocking substances that destroy it.

A rare form of parkinsonism, parkinsonism-dementia, or PD, occurs among the Chamorro people of Guam and the other Mariana Islands at a far greater rate than that of parkinsonism elsewhere in the world. It accounts for 10 percent of adult Chamorro deaths, and is rapidly progressive, leading to death in four to five years.

In an attempt to learn why PD is so devastating within this small isolated population, the NINCDS Intramural Research Program operates a permanent clinical research center on Guam. The search has focused on discovering possible genetic or familial factors, and also on uncovering any possible viral or toxic metal causes. Treatment of these patients with levodopa-carbidopa has been highly successful in alleviating parkinsonian symptoms, although the dementia of PD has not been alleviated. The scientists expect in the near future to have enough experience to determine whether the drugs alter the natural history of this form of parkinsonism, or produce any changes in morbidity and mortality patterns. Research patients on Guam form an important resource population for basic studies by NIH scientists. The Guam Research Center also serves as the setting for cooperative studies involving researchers from universities and other institutions.

In studies both in Bethesda and on Guam, new techniques for measuring the uptake and activity of neurotransmitters are now being developed. Recently, for example, Oxygen^{18} has been used instead of radioactive labeling to profile the activity of dopamine and other substances in the human central nervous system. At the same time, computerized techniques are helping to define with greater specificity the degree of movement disorders in parkinsonian patients. These and other technological advances are greatly helping Intramural scientists in their search for improved therapies, as well as for a better understanding of the pathology of Parkinson's disease.

Mt. Sinai

Mount Sinai School of Medicine in New York City, is the site of the largest interdisciplinary research team supported by a grant from the Institute. This group, now in its 14th year, has made major contributions to drug therapy in parkinsonism, and also has served as a leading training center for young scientists interested in this field. During this time, it has operated a clinical center for Parkinson patients, and has conducted hundreds of basic studies in virtually all areas relevant to parkinsonism, including neurochemistry and pharmacology, neurophysiology, ultrastructure and histochemistry, nerve regeneration, and neurovirology.

At present, clinical studies include a long-term effort to determine the effect of levodopa on life expectancy, studies of several untried drugs on disorders different from but similar to parkinsonism, and studies of the "on-off" effect. The investigators in this group have reported an improvement in control of parkinsonian symptoms by combining levodopa with bromocriptine. Studies aimed at alleviating the "on-off" effect have shown that pilocarpine may prevent L-DOPA induced dyskinesia. Also in progress are studies aimed at measuring intellectual deterioration in parkinsonism, and at determining whether levodopa affects the process. In a report published last year, the Center noted a reduced ability in patients to form concepts, and no apparent benefit from the drug in concept formation. However, the scientists did find an improvement in "vigilance" with levodopa.

Other clinical studies at the Center relate to eye movements in parkinsonism as a possible diagnostic aid and means of evaluating the disease state and therapy; the question of whether the dopamine deficiency of parkinsonism also exists in the retina; and studies of the effect of levodopa on carbohydrate metabolism.

The Center has a registry with over 1500 parkinsonian patients who are followed on a regular basis. The data collected is extensively used for evaluation of the progress of the disease, prognosis, treatment regimens, and education of scientists and clinicians.

The Center has a bank of brains removed at autopsy, and is continuously adding to it. The brains received are from patients who have been thoroughly studied clinically, and samples of tissue are made available to researchers. This is an unusually valuable research resource.

Several examples of the basic research projects at the Center are studies of two newly discovered proteins in nerve cells which may be part of the mechanism of transmitter release; and a long-range study of the exact neuronal morphology, synaptology, and anatomy of the basal ganglia--the brain area most affected in Parkinson's disease.

Cornell

A group at Cornell University Medical College is credited with the original development of levodopa therapy, and is continuing an extensive biochemical and genetic exploration of parkinsonism. First interested in manganese poisoning, whose symptoms are similar to those of parkinsonism, the Cornell scientists are continuing studies of the role of manganese in neurotransmission. By feeding manganese to newborn mice, they have found that cerebral dopamine levels correspond with cerebral manganese. They feel that this provides strong evidence that trace quantities of the metal participate in the development and normal functioning of the dopamine neurochemical system.

Also being conducted by this group are studies of a number of novel antiparkinsonian drugs. One of particular interest is N-propyl norapomorphine, or NPA. An analogue, or close relative of the drug, tried earlier had caused azotemia (urea in the blood) and had to be abandoned; NPA, however, completely circumvents this problem, and appears to have other advantages over prolonged levodopa administration, particularly in that it reduces involuntary movements and the "on-off" phenomenon mentioned earlier. Combined with small doses of levodopa in the form of Sinemet, NPA has been found to be superior to other treatments in that it offers maximum antiparkinsonian effects, maximal diurnal stability of symptoms, and minimal dyskinesia (involuntary movements).

An interesting drug development reported by the Cornell workers during the year concerns diphenylhydantoin (DPH), an anticonvulsant drug widely used in medical practice, and of considerable current interest in clinical research. Whereas it has reportedly improved the symptoms of

otherwise untreated Parkinson patients, in was found to block the therapeutic effects of levodopa, both in Parkinson patients and in patients with manganese poisoning. Thinking its use might throw light on the puzzling fact that symptoms of Parkinson's disease and Huntington's chorea are affected in opposite directions by some tranquilizers and levodopa, the scientists tried DPH in Huntington's chorea, and found that the patients were made worse.

In a study of long-term experience with levodopa, the Cornell scientists have followed one group of 67 patients very closely for up to 8 years. They have found that 10 percent of the patients continue to improve after the first year of treatment; that 60 percent retain initial improvement for 2 to 7 years, and that in 30 percent, some loss of therapeutic effect or emergence of limiting side effects becomes evident after the first year.

University of Colorado School of Medicine

At the University of Colorado School of Medicine, a broad clinical and laboratory investigation of levodopa and catecholamine metabolism is in progress. A large group of patients is being studied over a three-year period. In these studies the pharmacodynamics of therapeutic agents and their effects on motor functions, as well as psychological and behavioral manifestations are evaluated. Levels of metabolites are being monitored in sequential urine samples, and correlated with therapeutic and side-effects, including psychiatric status. Clinical studies in human patients are supplemented with research in primates. The biochemical, enzymatic and electrophysiological events in response to administration of various anti-parkinsonian drugs are monitored. From these and the human studies it appears that the extrapyramidal side-effects associated with L-DOPA therapy may in some way be related to the metabolism of the drug. This center has a strong psychiatric interest and the role of neurotransmitters in schizophrenia is being studied along with their role in organic brain disease. In untreated Parkinson patients, for example, low urinary dopamine excretion correlates with schizophrenic symptoms as well as with Parkinson symptoms. Just as studies in blood pressure lowering agents led to the most effective antiparkinsonism drug yet found, studies of neurotransmitters in parkinsonism could lead to new ways of treating one of the most baffling of the mental disorders.

Other Research Efforts

A group at New York University has used a monkey model of Parkinson's disease to screen potential therapeutic agents and provide for biochemical and histochemical analyses of the nervous system. Therapeutic trials of dopamine agonists in patients with Parkinson's Disease are continuing and expanding. They have been particularly fruitful in advancing our understanding of drug induced involuntary movements. Knowledge gained from these animal studies is applied in the study of parkinsonian patients where the therapeutic effect of drugs and the side effects of these treatments can be evaluated.

Unsolved Problems

"On-Off" Reactions

Management of "on-off" reactions continues to be an overriding problem in parkinsonian therapy. As noted previously, use of bromocriptine in combination with levodopa had often resulted in some improvement of these phenomena. Other alternatives include temporary withdrawal from levodopa or maintenance of total daily intake through administration of smaller, more frequent doses. In an attempt to delay "on-off" reactions, many scientists are now advocating that patients use less potent antiparkinsonian drugs to alleviate early symptoms, while reserving levodopa for later, more severe stages. Of course, therapeutic regimens should be determined on an individual basis to fit each patient's unique needs.

Problems with Animal Models

Another recurring difficulty is that limited correlation may exist between animal and human toxicity. In one study encouraging results were obtained using the dopamine agonist lergotrile. Unfortunately subsequent Intramural trials produced evidence of liver dysfunction in patients, in spite of negative liver toxicity tests in animals. Because of this research, it is doubtful that lergotrile will ever be marketed.

In all pharmacological approaches to Parkinson's disease, human toxicity will continue to be a primary concern. Thus, ways must be found to improve the therapeutic index of drugs; that is, the ratio of wanted to unwanted effects.

Outlook

Although great advances have been made in treatment of symptoms, the causes and methods of prevention and cure of Parkinson's disease remain essentially unknown. However, research is steadily progressing, and should produce answers to these most critical questions. The gains made in the past ten years have justified an optimistic belief among scientists, physicians, and patients that control of this disabling disease can be achieved.

QUALITY OF CARE

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
Alcohol, Drug Abuse, and Mental Health Administration:					
National Institute on Drug Abuse	$11,439,736	$12,256,733	$14,797,017	$12,923,000	$12,930,000
National Institute of Mental Health	92,000	347,000	426,000	474,000	514,000
National Institute on Alcohol Abuse and Alcoholism	147,315	104,858	168,800	306,800	206,000
Total, ADAMHA	11,679,051	12,708,591	15,391,817	13,703,800	13,650,000
TOTAL, PHS	11,679,051	12,708,591	15,391,817	13,703,800	13,650,000
Health Care Financing Administration:					
Professional Standards Review Organizations	31,157,000	53,841,000	54,091,000	64,866,000	82,720,000
TOTAL	$42,836,051	$66,549,591	$69,482,817	$78,569,800	$96,370,000

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute on Drug Abuse

QUALITY OF CARE

The National Institute on Drug Abuse (NIDA) sees quality of care as the fundamental objective for all of its efforts to deliver appropriate treatment and rehabilitation services to drug abusers. It is generally well known that just a few years ago the major Federal response to drug abuse was precipitated by a crisis stage. Emphasis at that time was clearly on the rapid development of treatment capacity where the need for services was found to exist. With such proliferation of programs, and the entry of thousands of workers into the field, additional needs surfaced in the areas of staff training and the development of criteria and standards for program operations.

Concern with quality of care issues transcends all components of the Institute. However, for purposes of this report, focus will be placed on the activities of the Division of Community Assistance and the Division of Resource Development (Services Research Branch, Manpower and Training Branch).

Division of Community Assistance (DCA)

The predominant mechanisms for ensuring quality of care for programs funded by DCA are monitoring conducted by DCA staff and assistance provided through the Program Management Review contract. Where the need to improve program operations is identified via the monitoring process, technical assistance is provided.

In order to establish minimum standards for quality treatment services, NIDA developed the Federal Funding Criteria (FFC) for Drug Treatment Services and Central Intake Units. All the states are actively being encouraged to develop their own standards for program approval or licensure. State standards which are substantially consistent with the FFC may be accepted by NIDA in lieu of the FFC. In addition, NIDA has supported the development of optimal standards for drug abuse treatment and rehabilitation programs by the Joint Commission on Accreditation of Hospitals (JCAH).

Related activities in DCA include the development and distribution of program manuals and a clinical self-evaluation methodology. The latter is designed to assess a program's effectiveness by furnishing measures that relate to normative data based on extensive retrospective studies.

Services Research Branch, Division of Resource Development

This Branch supports a variety of demonstration projects aimed at discerning special treatment needs of women, youth and minority group members. Studies are further oriented toward evaluation of the effectiveness of different treatment models designed to meet client needs of these groups. Similarly, in the area of vocational rehabilitation, studies focus on the service needs of drug abuse clients, on assessment

of differing techniques for meeting those needs, and on the ability of vocational rehabilitation efforts to enable clients to achieve vocational adjustment as well as control over illicit drug use and criminal activity.

Manpower and Training Branch, Division of Resource Development

The Manpower and Training Branch is directly involved in a number of program activities relating to the quality of care. These programs can be divided into two specific categories:

1. Development and delivery of training programs that provide job related skills for workers providing direct treatment services.

2. Identification and measurement of job skills and competence standards related to service delivery.

The following summaries describe the main program components within each category:

Skill Training - The majority of Branch programs are directed to this area either through the development of training programs or direct delivery of training. The National Drug Abuse Training Center provides validated training packages most of which involve skill development for direct treatment service deliverers. These packages are utilized by Regional Support Centers and the State Training Support Program (STSP) to meet skills related needs of drug workers. Additional demonstration programs funded through grants to academic and community programs provide both long and short term skill development for workers in all treatment service areas.

Job Skills - Two contracts have been funded for the purpose of specifying and measuring job related skills. The first is with the Medical College of Pennsylvania and represents the conclusion of three years of activity by both special contractors and state agencies in the identification of functions and skills actually involved in the delivery of treatment as well as the administration of drug programs. The result will be a skill matrix which will be provided to states for use in the development of their own credentialing programs. The second contract, with the Board of Medical Examiners, is developing competency related questions in Substance Abuse for inclusion in Medical license examinations.

The Branch has also established an extensive program working directly with states to develop their capabilities to utilize a systems approach to the delivery of training services. This program - the State Training Support Program (STSP) involves identification of job related skill needs, development and utilization of resources to meet these needs and implementation of a credentialing process more directly related to job skills performance than to abstract academic requirements.

Other Training - As described above, the development of increased skills relating to quality of care is the primary objective of the Branch. However, other job and professional skill development activities which are not directly related to primary care must be maintained to ensure successful program operation and professional growth. These programs mainly involve the further development of trainers at the state and program level, administrative and fiscal training, and the development of evaluation efforts to further improve the relationship between effective skill development and the "Quality of Care".

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health

QUALITY OF CARE

In the last four years the National Institute of Mental Health (NIMH) has become increasingly concerned about the quality of care in mental health settings. This concern has been reflected by increased staff activity and commitment of resources in the quality assurance area and plans for an even larger investment in the future. These activities can be broadly classified into three major areas: the development and implementation of standards; treatment assessment; and the development of quality assurance systems.

Development and Implementation of Standards

One of the most important activities in this area in the last three years has been the development of standards for Community Mental Health Centers (CMHCs). Since 1974 the NIMH has supported the development of CMHC standards by the Joint Commission on Accreditation of Hospitals (JCAH), which entered the field testing stage in August, 1976. In addition the NIMH has developed a set of National Standards for CMHCs, fulfilling the requirement in the Community Mental Health Centers Amendments of 1975 (P.L. 94-63) that such standards be submitted to the House and Senate within 18 months of enactment of this legislation.

Many of the regulations developed in the past year and a half for the new CMHC amendments in P.L. 94-63 will relate directly to quality of care. The most important of these are requirements that centers develop their own internal quality assurance programs and an integrated medical records system.

In addition to standards for CMHCs, the NIMH has been concerned with standard development and implementation by other agencies for other mental health service settings. Activities include staff consultation to the Bureau of Health Insurance (BHI) and Bureau of Quality Assurance (BQA) in their development of standards for psychiatric hospitals and psychiatric units in general hospitals; technical assistance under a BHI/NIMH contract to provide NIMH consultant teams for Medicare survey of psychiatric hospitals; a contract with the Southern Regional Education Board to develop a report on the development of standards by State mental health agencies; and the sponsorship of a symposium for mental health professionals on standard setting and the law.

Treatment Assessment

In the last two years NIMH under contract to the Department of Defense (DOD) has been largely responsible for the initiation of a variety of Civilian Health and Medical Program of the Uniformed Service (CHAMPUS) treatment assessment activities including review of children and adolescents in residential treatment facilities and review in selected areas of patients with a diagnosis of schizophrenia. Plans are now underway for

review in selected areas of all inpatient psychiatric care. Working closely with the Civil Service Commission, Blue Cross/Blue Shield, and Washington area mental health providers, the NIMH has supported the development and implementation of provider peer review systems for assessing the quality of care in the Federal Employees Health Benefit Program (FEHBP) and the collection of utilization data for mental health services under this program.

In the coming year the NIMH will sponsor two studies, one evaluating the quality of mental health services in an organized general medical care setting and the other a two-state collaborative study of mental health treatment outcome. For 1978 the NIMH now plans to initiate a major $2 million targeted research effort to address efficacy of mental health treatments.

Development of Quality Assurance Systems

Activities in this area include all those technical assistance and resource development efforts aimed at increasing the capabilities of CMHCs, State mental health agencies, and others involved in and relating to the mental health field to develop functional quality assurance systems. The NIMH staff college is currently sponsoring a series of workshops on assuring the quality of mental health services and last year the NIMH co-sponsored, with NIDA, NIAAA and ADAMHA, a series of workshops on PSROs and the mental health, alcohol and drug abuse service systems. A manual has been developed and distributed to CMHCs on assessing and assuring quality in CMHCs which will assist them in meeting the new P.L. 94-63 quality assurance requirements. A large three-year grant has been awarded to the State of North Carolina for the development of a model State-wide patient care analysis and quality review system.

In addition to these activities the NIMH has been actively involved in consultation to the BQA regarding those aspects of the PSRO program which relate to mental health. More extensive liaison activities are planned with BQA in the future in this regard.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute on Alcohol Abuse and Alcoholism

QUALITY OF CARE

In FY 1977 much of the work related to quality assurance activities was performed in-house by Institute staff. These activities included work with ADAMHA and the other two Institutes on development of criteria for a set of Alcohol, Drug, and Mental Health core standards that will be useful to each of the Institutes for provider participation under Medicare and Medicaid for PHS funded facilities, work with the ADAMHA/NIAAA Planning Panel on Alcoholism Counselor Credentialing, and development of minimum Federal funding criteria for alcohol treatment programs.

Program Standards

In FY 1977, the Institute along with ADAMHA, NIMH, and NIDA set about the task of developing a contract with the Joint Commission on Accreditation of Hospitals (JCAH) that would develop a set of universal core standards with the capability of being used to measure the quality of services, regardless of auspices, facility type, geographic location and target population. In the development of these core standards, those elements of existing standards which serve to address the unique needs of each of the fields (e.g., alcohol, drugs, and mental health) and which maintain essential program integrity will be retained. As a result of this work, a Request for Contract (RFC) has been developed and a contract should be awarded in early 1978.

Practitioner Standards

In an attempt to assure the quality of health care provided the alcoholic patient by treatment personnel a planning panel was formed by NIAAA/ADAMHA. This Panel was composed of outside experts; NIAAA provided technical assistance, staff support and some financial assistance. The Panel recommended that a National Credentialing Organization for alcoholism counselors be established whose functions would be to:

1. Establish standards for certifying bodies;
2. Conduct research;
3. Collect and disseminate information;
4. Provide for mediating, cooperative and joint activities;
5. Perform a public information role;
6. Encourage the development of education and training programs for alcoholism counselors; and
7. Foster constructive relationships with credentialing efforts of related occupational groups.

Core Standards for Provider Participation

NIAAA along with ADAMHA, NIMH and NIDA developed areas in which core standards can be generated that will allow for provider participation under Medicare/Medicaid for Public Health Service funded facilities offering alcohol, drug, and mental health services. These standards will combine those elements that are common to each of the Institutes, while at the same time, respect and maintain essential program integrity.

Federal Funding Criteria

NIAAA is planning to launch a greater cooperative effort with the State Alcoholism Authorities and members of the alcoholism constituency aimed at developing minimum Federal funding criteria for alcoholism treatment programs. It is expected these criteria will be field tested and published for comment. Ultimately, these criteria will be applied to all NIAAA funded service projects.

HEALTH CARE FINANCING ADMINISTRATION

Professional Standards Review Organizations

QUALITY OF CARE

The PSRO program was authorized by the 1972 amendments to the Social Security Act. This provision of Public Law 92-603 (Section 249F) requires the Secretary to establish and support a nationwide network of voluntary, nonprofit groups of local physicians (PSROs) to assure the quality and appropriate utilization of health care services financed by and provided to beneficiaries and recipients of Medicare, Medicaid, and Maternal and Child Health programs. The purpose of the statute is twofold: (a) to improve the quality of health care services; and (b) to make more cost effective the expenditures for health care services financed by Titles XVIII, XIX, and V of the Social Security Act. PSROs accomplish these objectives through the application of sophisticated concepts of peer review, including concurrent review, medical care evaluation studies, and profile analysis. PSROs serve as a major vehicle for establishing a partnership between government and the medical community. Concurrently, over 140,000 physicians are members of PSROs. There are 195 designated PSRO areas nationwide. PSROs are responsible for the review of the estimated 15 million Medicare, Medicaid and Maternal and Child Health annual hospital admissions. The Statute also requires PSRO review of long term care and ambulatory care. The PSRO legislation intends that the existing Utilization Review programs of Medicare and Medicaid be replaced by PSRO review.

Impact of 1979 Budget Request

The FY 1979 Budget Request is designed to provide the support necessary to insure full implementation of PSRO hospital review by 1980 and to provide limited support for PSROs to review ambulatory care services and services provided in long term care institutions.

By the end of FY 1978, operating PSROs will have been established in all 195 PSRO areas. A majority of these PSROs will have fully implemented their hospital review systems. It is estimated that 6.3 million Medicare and Medicaid hospital admissions will be under PSRO review. In addition, 71 PSROs will be performing long term care review and 10 PSROs will be performing ambulatory care review on a demonstration basis.

In FY 1979, PSROs will continue to expand and improve their hospital review activities. An estimated 10.5 million Medicare and Medicaid hospital admissions will be reviewed. Specific efforts will be devoted to expansion

of PSRO review to hospital ancillary services, outpatient departments, and emergency rooms. Review of these services offer significant opportunity for PSROs to have an impact on improving the quality and appropriate utilization of hospital services. PSROs will be encouraged to focus their concurrent review activities (reviews of admissions and continued stays within the hospital) only on those patients where experience indicates the need for concurrent review. Patients not subject to concurrent review will be reviewed through the other parts of the existing PSRO review systems, such as profiling, medical care evaluation studies, etc. This focusing will reduce the average unit cost of performing hospital review, since concurrent review is the most expensive component of the hospital review system. PSROs also will be encouraged to develop objectives which will directly benefit patients, such as reduction in unnecessary surgery and the inappropriate use of drugs. Many PSROs already have experience in these areas and can assist all PSROs in developing objectives which improve the quality of care in an immediate and measurable manner.

PSROs will continue activity in the areas of long term care review and ambulatory care review during FY 1979. The 71 PSROs supported in FY 1978 for long term care review will be continued. The average funding of these projects will increase to allow these PSROs to extend their review to additional long term care facilities in their areas. Long term care review is an integral part of the PSRO review system. Recent legislation (P.L. 95-142) reaffirms the requirement that PSROs review services provided in long term care institutions (all skilled nursing facilities and intermediate care facilities where the State is not performing effective review). PSRO long term care review will replace the existing Utilization Review activities of the Medicare and Medicaid programs, which have not proven effective. In addition, it will relieve States of the possibility of being financially penalized pursuant to Section 1903(g) of the Medicaid law for failure to have a utilization control program for Medicaid patients. The PSRO review approach will apply the same type of objective peer review techniques as in hospital review and will address both the quality of care and appropriate placement of patients.

The 10 PSROs supported in FY 1978 for ambulatory care review will be continued during FY 1979. Recent changes in the PSRO statute as a result of P.L. 95-142 now require PSROs to conduct review of ambulatory care services within two years after being fully designated. PSRO ambulatory care review provides HEW and the States with their first significant review mechanism to deal with utilization and quality for Medicare and Medicaid ambulatory care. Ambulatory care review offers potential for achieving considerable impact on utilization and quality of care by effecting the use of drugs, X-rays, and other office practices.

RESPIRATORY DISEASE

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
National Institutes of Health:					
National Heart, Lung, and Blood Institute	$24,805,000	$29,286,000	$31,227,000	$34,813,000	$35,579,000
Center for Disease Control:					
National Institute for Occupational Safety and Health	3,500,000	4,600,000	4,100,000	3,700,000	3,700,000
Health Services Administration:					
Bureau of Community Health Services	2,000,000	2,200,000	2,534,000	2,600,000	2,600,000
TOTAL, PHS	30,305,000	36,086,000	37,861,000	41,113,000	41,879,000
Office of Human Development Services:					
Rehabilitation Services Administration:					
Basic State Grants	6,800,000	7,203,000	7,403,000	6,844,000	6,284,000
Research and Training Centers	75,000	250,000	250,000	300,000	300,000
Research and Demonstrations	75,000	400,000	475,000	304,000	180,000
Total, RSA	6,950,000	7,853,000	8,128,000	7,448,000	6,764,000
TOTAL	$37,255,000	$43,939,000	$45,989,000	$48,561,000	$48,643,000

RESPIRATORY DISEASE

The chronic respiratory diseases—including such insidious and largely irreversible lung disorders as emphysema, chronic bronchitis, cystic fibrosis, various dust inhalation diseases, and pulmonary fibrosis, among others—constitute a national health problem of increasing dimensions. In the U.S., chronic lung diseases account for an estimated 150,000 deaths each year, cause 45 million days lost from work, 40 million days of bed-restricted activity, and cost the economy $6 billion a year in lost productivity, wages, and medical care costs.

The National Heart, Lung, and Blood Institute (NHLBI) bears primary responsibility for basic and clinical research to increase knowledge of lung structure and function, and to develop improved methods for the prevention, diagnosis, and relief of chronic lung diseases. The National Institute of Allergy and Infectious Diseases; National Cancer Institute; National Institute of Environmental Health Sciences; National Institute of Arthritis, Metabolism, and Digestive Diseases; and the Division of Research Resources also support some research projects bearing on chronic respiratory diseases.

The chronic respiratory diseases constitute an exceedingly complex problem demanding a broadly based, diversified approach to insure that each of the many aspects of the problem will be adequately explored.

NATIONAL INSTITUTES OF HEALTH

National Heart, Lung, and Blood Institute

During Fiscal Year 1977, National Heart, Lung, and Blood Institute support of research and training activities in the field of chronic respiratory disease amounted to $31,227,000. The money funded research in Institute laboratories in Bethesda, Maryland, grants and contracts for R & D projects in medical institutions and industrial laboratories throughout the country, and related administrative costs. Most of this research is administered by the Institute's Division of Lung Diseases (DLD), and involved approximately 50 percent of the DLD budget.

This report focuses on the magnitude of health problems posed by these disorders; the current status of their diagnosis, prevention and treatment; and recent research advances, current research thrusts and future prospects concerning the following disease entities:

- chronic obstructive lung disease (COLD), primarily emphysema and chronic bronchitis.
- fibrotic and immunologic lung diseases, characterized by uncontrolled scar tissue growth and often preceded by the inhalation of noxious dusts, gases, or infectious agents.
- cystic fibrosis, a leading cause of chronic progressive lung disease in children.

Chronic Obstructive Lung Disease (COLD), a term largely synonymous with emphysema and chronic bronchitis, is a progressively debilitating, generally irreversible condition and a major cause of death and disability in the U. S. Currently, it accounts for more than 40,000 deaths annually. National Health Interview Survey data indicate that 6 1/2 million Americans have chronic bronchitis, and 1 1/4 million have emphysema. Nearly 1/2 million Americans suffer somewhat restricted activity because of COLD and another 20,000 are confined to bed. Emphysema now ranks third, after coronary heart disease and schizophrenic disorders, in terms of disability payments by the Social Security Administration.

Chronic bronchitis is characterized by a persistent inflammation and swelling of the linings of the bronchial airways, excessive production of mucus and other fluids that tend to block the airways and that lead to coughing and shortness of breath. The principal known factors contributing to the bronchial irritation of chronic bronchitis are smoking, air pollution, and recurrent respiratory infections. And these same irritants can promote the development of the companion disorder, emphysema. (Emphysema and chronic bronchitis quite frequently occur together, and it is often impossible to determine which of the two is the more important contributor to disability in a patient.)

The exact cause of emphysema is not known, but the initial event appears to be a breakdown in the thin coating of mucus and the many hair-like cilia that line all air passageways throughout the respiratory system. This lining normally protects lung tissues against inhaled dust, bacteria and other harmful materials, and the waving cilia propel these particles toward the throat where they can be eliminated from the body. With the breakdown of this protective lining, the noxious materials may begin to destroy normal lung architecture, producing large, inefficient air spaces. As a result, resistance to air flow increases and breathing becomes progressively more difficult.

COLD develops so insidiously that many victims are unaware of their condition until 50 percent or more of their lung function has been destroyed. For this reason, great emphasis has been placed on early detection of structural, physiological and biochemical abnormalities which

precede the development of more symptomatic, relatively irreversible disease. Pulmonary function tests can now identify asymptomatic COLD patients as well as identify the site of airway impairment. These tests not only provide the capability for early detection but also allow for a more complete investigation of the natural history of the disease and the influence of treatment and environment.

Cigarette smoking is recognized as the primary risk factor predisposing to the development of COLD, and as a major factor in aggravating and accelerating its clinical course. But other risk factors --environmental, occupational, and genetic--and their interrelationships are also under close scrutiny in efforts to develop prevention, education and control programs against COLD. The latter include:

- a hereditary deficiency of an enzyme called alpha-1-antitrypsin predisposes to the development of an accelerated, severe form of emphysema that attacks young adults, making them more susceptible to the harmful effects of air pollution and smoking than normal subjects. Studies currently underway to clarify this abnormality include efforts to provide synthetic substitutes for the deficient enzyme.

- a population study of smokers has shown that, once pulmonary function abnormalities occur, they are progressive, and that age as well as smoking contributes to the downhill course. However, a 25% or greater reduction in cigarette consumption improved pulmonary function in all age groups studied.

Therapy is aimed at arresting or slowing the progress of COLD, relieving symptoms, improving the patient's physical condition, and helping him make the best use of whatever lung function he has. In addition to avoidance of smoking, air pollution and other irritants, therapy may include:

- bronchodilating agents to dilate constricted air passages.

- mucolytic drugs to liquify viscid mucus clogging air passages.

- respiratory stimulants to increase respiratory drive.

- steroids, to reduce inflammation and allergic reactions.

- antibiotics to protect against respiratory infections.

- physical therapy and breathing exercises to increase capacity for physical activity.

- oxygen therapy in selected patients to meet special oxygen needs resulting from exertion or mild-to-severe episodes of breathlessness.

The scientists speculate that a viral insult together with a genetic predisposition to the disease triggers an antigenic or "rejection" response by the body, complete with mobilization of phagocytes and other wandering inflammatory cells, directed against the now "foreign" collagen.

Tending to substantiate this theory are: the flu-like symptoms that commonly precede the onset of idiopathic pulmonary fibrosis; the tendency of the disorder to be familial, i.e., to occur in several members of the same family; and results of immunological comparisons of susceptible families with persons having no family history of the disorder.

Four Specialized Centers of Research (SCOR) in Fibrotic and Immunologic Pulmonary Diseases were established in FY 1977. In these centers, investigators of diverse scientific backgrounds will focus their expertise on:

- disease mechanisms leading to fibrosis, and improved characterization of fibrotic material.
- the physical and chemical nature of mineral and metallic agents that induce fibrosis and their effects on cellular biochemistry, metabolism, proliferation and other aspects of cell function.
- connective tissue metabolism in fibrotic lung disease.
- studies correlating structure and function in the lungs' immunological defense system, and the role played by lung macrophage cells in this system.
- health effects of occupational inhalants including silica, asbestos, cotton, coffee, abrasive substances used in air-blasting operations, and industrial solvents.
- purification and characterization of lung antigens for the development of animal models and clinical studies of immunologic lung disorders.

Hopefully, this multidisciplinary approach to idiopathic pulmonary fibrosis will continue to produce new and useful knowledge concerning the causation, diagnosis, pathophysiology and therapy of this disorder.

Cystic Fibrosis (CF), with an estimated frequency of one in 2,000 live births in white populations, is the most common lethal genetic disease of Caucasians. It causes much of the chronic progressive lung disease encountered in children. Indeed, obstructive lung disease accounts for 90 to 95 percent of deaths among those afflicted with cystic fibrosis.

When first recognized, cystic fibrosis seemed invariably and rapidly fatal. However, improved diagnosis and therapy has resulted in a U.S. population of 15,000-20,000 surviving CF patients, 2,000 of whom are adults. An additional 800-2,000 patients are diagnosed annually.

Clinically, cystic fibrosis is characterized by chronic pulmonary disease, pancreatic insufficiency, and elevated sweat electrolytes (sodium, chloride and potassium). Sweat electrolyte elevations are a cardinal diagnostic feature of CF, but are not related to the severity of the disease. (However, increased electrolyte excretion can result in massive salt depletion and even cardiovascular collapse.) Most CF morbidity and mortality stems from a mucus secretion abnormality: excessive amounts of unusually thick, viscous mucus obstruct organ passages, thus giving rise to chronic pulmonary disease. Detailed information on early pathological events occuring in the lung, however, is very sparse and the underlying cause of the defect is unknown.

Thus, areas of NHLBI research interest in cystic fibrosis include:

- secretion of mucus in the respiratory tract.
- the clearance of mucus and entrapped foreign particles and toxic substances by mucociliary transport.
- biochemical studies of mucus.

Recently, improved techniques for collecting tracheal mucus for physicochemical analysis, measuring the rate of mucus clearance, and measuring ion and water movement in airway tissues have been developed in laboratory animals to the point where some of these may be clinically applicable in man. They may help provide new insights into the role of airway secretions in CF and other lung diseases and on the effects of environmental factors and lung disease processes on mucus secretion and transport.

The search also continues for a biochemical or genetic marker that might identify individuals who are heterozygous carriers of the gene for CF, and that may also make possible the prenatal diagnosis of CF by amniocentesis when the risk is great that the unborn infant may be afflicted.

Such a marker may have been found with the discovery, in CF patients and in cultures of cells from parents of CF patients, of a factor that inhibits ciliary motion. Since ciliary movement is an important part of mucociliary clearance, there may be a direct connection between the presence of such a factor in CF patients and their mucus obstructions. Some progress is being made toward isolating and further characterizing this substance, called ciliary inhibitory factor.

These investigations may elucidate the basic defect of cystic fibrosis, open new possibilities for genetic counseling and prenatal diagnosis, and provide insights for more effective therapy of CF and its complications.

Conclusion

Chronic respiratory diseases constitute a major health problem that place great social and economic burdens upon our national resources.

Research studies in recent years have confirmed that predisposing factors for these diseases are smoking and "polluted" environments. Further, these studies have shown that improvement can be achieved by reducing smoking and/or altering the environment. A recent task force has recommended major programs in education and prevention that could significantly influence the impact of these diseases in future years. Adequate control of these disorders, however, can only come through continuing basic and clinical research to reveal where and how to halt the progression of these diseases and appropriately treat the millions of persons already diseased.

CENTER FOR DISEASE CONTROL

National Institute for Occupational Safety and Health

RESPIRATORY DISEASE

It is estimated that approximately half of occupational disease is respiratory in nature. Under the Occupational Safety and Health Act of 1970, NIOSH has transmitted to the Department of Labor a substantial proportion of criteria documents that deal primarily with respiratory effects of various substances.

The focal point for occupational respiratory disease research within NIOSH is the Appalachian Laboratory for Occupational Safety and Health (ALOSH) located in Morgantown, West Virginia. This unit has long been responsible for coal research and service programs mandated by the Federal Coal Mine Health and Safety Act of 1969. Until FY 1977, the Institute had no single coordinated program in occupational respiratory disease.

FY 1977 Program

NIOSH laboratory and clinical investigations during FY 1977 included both biological and microbiological studies of the effects of inhaled particulates on the lung. The NIOSH recommended standard for asbestos exposures was made noting the lack of health data for exposures to low fiber levels and definitive information of the biological response to different size fibers.

It was shown through industrial hygiene surveys that exposure to talc containing fibrous asbestiform material increases the risk of mortality due to lung cancer and non-malignant respiratory disease. The study showed an excess of deaths from non-malignant respiratory disease due to exposure to non-fibrous talc.

During 1977, a longitudinal investigation to establish the environmental determinants and biologic response of workers continued. Environmental and biologic data are correlated with the aim of determining dose-response relationships and host factors which may influence respiratory health effects.

Field environmental evaluations were completed on a group of pesticide formulators and applicators chronically exposed to pesticides to determine if behavioral, neurological or biochemical dose/effect relationships could serve as early warning indicators of adverse effects on worker safety and health.

Previous research studies have demonstrated an excessive prevalence of chronic non-specific lung diseases and related health problems in the grain handling industry. However, owing to the great diversity and lack of standardization in scientific design and approach which has been reported by various investigators in studying the respiratory symptoms of grain handlers, much of this work is not directly comparable.

The objective of a NIOSH study begun in FY 76 is to determine the presence and extent of health hazards associated with occupational exposure to grain dust and other potential etiological agents of repiratory diseases to which workers in the grain elevator industry are exposed. Personal and general area air samples will be collected at selected country and terminal grain elevators located in various geographical regions of the continental United States to more precisely quantify worker exposure to the above agents in the grain handling industry as a whole. These data collected will be correlated with medical findings when possible to establish cause-effect relationships.

NIOSH research in FY 77 also included investigation into the physiology of cells in lung tissue. These studies included research in the mechanisms by which foreign substances are removed from alveolar macrophages by photosytosis. This process is known to be a major defense mechanism of the lung.

Continuing in FY 77 were clinical studies investigating the physiology of the gas/liquid boundary of the lung. It is known that surfactant, the liquid material lining the alveoli and airways, has a profound effect on the pressure volume characteristics of the lung. This is because of its effects on the surface tension at the gas/liquid boundary. The liquid material lining the airways and alveoli is directly exposed to any inhaled particles. Therefore, it is possible that one mechanism for alteration in lung function by occupational exposure is a change in character of the surfactant system.

Recent NIOSH clinical investigations have concentrated on determining the effect on lung function. The researchers used spirometry, submaximal exercise testing, lung fibroblasts, the function of airway smooth muscle and various tests to measure disease in the lungs, and small airways where conventional spirometry does not reveal dysfunction.

A computerized system for interpretation of chest x-rays has been developed under NIOSH contract in an effort to reduce the amount of time required in this procedure. Stability checks have been performed on the system. A set of 500 films are currently being interpreted by three radiologists and they will be used to test the system. Approximately 23,500 chest x-rays were interpreted for pneumoconiosis and other diseases in FY 77.

The National Coal Study entered its third round of examinations in FY 77. Past results from the first two rounds of the study are published in no less than 40 major articles in medical journals. The project is basically a continuation effort and involves the examination of over 10,000 coal miners throughout the nation.

A study of the effects of diesel emmissions in non-coal underground miners was continued in FY 77 as well as a new study of diesel emmissions on coal miners. The latter study was started as an adjustment to the National Coal Study. To date, 832 individuals have been studied in five coal mines where diesel haulage equipment is used for transporting coal from the face. Mortality studies of coal miners and metal miners continued in FY 77. A study to determine whether those miners who have already left the coal mining industry are different from those who remain in the industry, was begun in FY 77.

The National Coal Workers' Autopsy Study continued in 1977. The NCWAS disaster plan was administered in mine disasters in Kentucky, Pennsylvania, and Virginia.

FY 78 Program

Much of the work begun in FY 77 and in prior years will continue in FY 78. There is a continuing need to carry out review of criteria documents and documents related to standards development. A study to develop and test a series of standards for a more precise pathological diagnosis of coal workers' pneumoconiosis began in FY 77 will continue into 1978.

A number of laboratory studies will be undertaken in FY 78. These include sampling methodology for environmental mutagens, the effects of various metals on the physiological integrity of cell membranes, and a study of the toxicity as well as a study of beryllium disease in humans. In cooperation with the Mining Enforcement and Safety Administration, NIOSH will conduct a study of cement workers. A medical study of divers will also be done with the Enviromental Protection Agency.

The decrease in cost for this program in 1978 and 1979 is related to the coal workers' pneumoconiosis program. The third round examinations for this program were initiated in 1977 and the costs were much greater. The third round examinations will be completed in 1979.

With the passage of the Metal and Non-metallic Mining Act of 1977, NIOSH's responsibility in the area of metal and non-metal mining research will increase.

HEALTH SERVICES ADMINISTRATION

Bureau of Community Health Services

RESPIRATORY DISEASE

Title V of the Social Security Act authorizes award of grants to public or non-profit private institutions of higher learning for training personnel in providing health care and related services for mothers and children. Under this authority, the Maternal and Child Health program supports training and education of professional and para-professional personnel in eleven Pediatric Pulmonary Centers which treat children suffering from illnesses such as asthma, chronic bronchitis and cystic fibrosis.

In 1976, approximately 15 percent (10.8 million) of U.S. children under 18 suffered from chronic respiratory disease which is the largest chronic illness in children and which accounts for more lost school days than any other chronic illness.

A 1977 study entitled Children and Their Lungs: A Report on Pediatric Pulmonary Disease and Crippled Children's Services was conducted by the Association of Pediatric Pulmonary Centers for the Maternal and Child Health program. The study was conducted of the Maternal and Child Health and Crippled Children's services program in 44 States and the eleven Federally-assisted Pediatric Pulmonary Centers. The following data come from information provided by the 44 States and eleven Pediatric Pulmonary Centers studied. In most cases, data were not reported for all States and centers.

Of the 44 States, 41 included cystic fibrosis in their MCH/Crippled Children's services: 16 included other respiratory problems, e.g., asthma and allergies; 13 bronchiectasis; and 22 chronic pulmonary disease, respiratory disease syndrome, allergies, bronchitis, etc. In 1975, 13,997 persons were provided services in these programs at a cost of $6,172,360.

In 1977, the eleven Pediatric Pulmonary Centers provided services to 31,563 patients, 21,766 outpatient and 9,797 hospital admissions. In the outpatient clinics, 31 percent of the patients were seen for asthma and allergy problems, 24 percent for chest problems and 8.8 percent for cystic fibrosis. Of the hospital admissions, 23.5 percent were for asthma and allergy, 42 percent for acute respiratory distress, and 4.2 percent for cystic fibrosis. Of the outpatient visits, 60 percent of diagnoses were for asthma and allergy, 7 percent for chronic pulmonary disease, 16 percent for cystic fibrosis, 3 percent for immune deficiencies and abnormalities and 9 percent for acute respiratory distress. The most frequent laboratory procedures were pulmonary function study and sweat tests. A slight majority of the patients were males; 69 percent were under 2 years of age, 14 percent preschool, and 16 percent school age.

In 1976-1977, the centers provided some training to 750 physicians, residents, interns, and medical students in chronic pulmonary disease. An additional 2,800 para-medical personnel, including nurses (70 percent), physical and respiratory therapists (15 percent), health educators, and other para-medical personnel, received some training. Of the 2,800, 339 were involved in multi-disciplinary training. The training periods ranged from several hours to one year.

The eleven centers were participating in 107 research projects supported by public, private and Federal resources, other than the Maternal and Child Health program. Twenty-one percent of the research projects were conducted on neonatology and 74 percent on childhood pulmonary disease. And all eleven centers were involved in developing new programs, including data collection, increased and improved patient identification and referral, and upgrading of personnel skills and training programs.

The primary goal for MCH funding of these centers is to provide training for health professionals in the treatment of respiratory disease and to support the development of regionalized pediatric pulmonary services. In 1978 and 1979, 159 health professionals will be provided short or long-term training and at the same time will provide services to 38,000 persons. Training activities will include in-service training for physicians, registered nurses, and allied health personnel, and seminars on respiratory disease treatment, etiology, pulmonary function and longitudinal progress of patients.

HEALTH SERVICES ADMINISTRATION

Bureau of Medical Services

RESPIRATORY DISEASE

The Department of Health, Education, and Welfare has a legislative mandate to provide direct health care services to specified beneficiaries under provisions of the Public Health Service Act and the Dependents' Medical Care Act. This responsibility is discharged, in part, through the Bureau of Medical Services (BMS) of the Health Services Administration and, within the Bureau, through its Division of Hospitals and Clinics and Division of Federal Employee Health. The program authority of the Bureau's Division of Emergency Medical Services does not encompass the direct delivery of health care services.

The Division of Hospitals and Clinics provides comprehensive health care services to American Seamen, active duty members of the U.S. Coast Guard, members of the National Oceanic and Atmospheric Administration, and to active duty Commissioned Officers of the U.S. Public Health Service. Services may also be provided to retired members of the uniformed services and to dependents of active duty and retired members of the uniformed services under the authority of the Dependents Medical Care Act.

In addition, the Public Health Service Act permits the providing of limited health services to Federal employees by the Bureau's Division of Federal Employee Health.

Health care services within the Division of Hospitals and Clinics (DHC) are provided by eight general medical-surgical hospitals, one specialized treatment center (Hansen's Disease), 26 free-standing outpatient clinics, and more than 300 contract physicians and hospitals located throughout the United States. This major system constitutes a nationwide network within the Department for the delivery of comprehensive health care services, for training, and for research. In addition, the Division of Federal Employee Health operates 143 clinics in Federal installations across the country.

As compared to Fiscal Year 1976, total workload increased throughout the system, particularly with respect to ambulatory care visits which registered a 3.3% increase during Fiscal Year 1977.

Funds for clinical research studies are distributed through the Central Clinical Investigations Committee of the Division of Hospitals and Clinics, a formally-constituted body, that is also responsible for monitoring and evaluating research programs. During the year,

approximately $250,000 of Fiscal Year 1977 funds of the Division of Hospitals and Clinics were expended for clinical research, of which $7,440.00 was allocated to research in respiratory diseases. Other studies in PHS hospitals received $279,000 from the National Institutes of Health and $600,000 from the National Center for Health Services Research during Fiscal Year 1977 for research projects not related to respiratory diseases.

All of the general hospitals and outpatient clinics within DHC diagnose and treat respiratory diseases. Unfortunately, at this time, data are available for only the first half of FY 1977 (October, 1976 through March, 1977) and precise data on an outpatient basis cannot be obtained yet. Between October 1, 1976 and March 31, 1977 there were 11 discharges in which the primary diagnosis was emphysema. This diagnostic group used 263 patient days with an estimated cost of services of $34,453 based on an average daily rate of $131. There was only one discharge for Black Lung disease. This hospitalization was for eight days at an estimated cost of $1,048 based on the same average daily rate.

Twenty-five inhalation therapists are employed in the USPHS hospital system and each hospital has at least one inhalation therapist on staff to provide these services. Six USPHS hospitals have administratively identifiable inhalation therapy services and are, therefore, able to provide more extensive clinical services and training opportunities. These hospitals are located in Baltimore, Boston, New Orleans, San Francisco and Staten Island. The hospitals with only one inhalation therapist on staff are located in Carville, Galveston, and Norfolk.

OFFICE OF HUMAN DEVELOPMENT SERVICES

Rehabilitation Services Administration

Pulmonary-Respiratory Diseases

Chronic obstructive pulmonary diseases (COPD) are a major health problem in the United States today. The mortality rate from COPD has doubled in the past five years and this rate is accelerating. COPD is rising four times as fast as the mortality from bronchogenic carcinoma, even though this tremor has the fastest rising incidence among all malignant neoplasms. In addition, more social security disability funds are expended on COPD than any other disease or condition, except coronary heart disease.

The Rehabilitation Services Administration has initiated a clinical research presently in COPD to attack this seriously disabling condition. RSA research in the chronic pulmonary diseases has potential for significant cost benefits in addition to the improved quality of life for these persons. Hopefully, this new research effort will encourage the VR agencies to expand physical restoration and vocational preparation services more readily to this large population, once rehabilitation success can be proven. The concept of maintaining employment and productive living will be emphasized. This is a significant step to keep persons in employment rather than to become so handicapped as to lose self-sufficiency.

Recently completed research at the University of Nebraska Medical Center reports a high death rate, continued complications, and minimal return to employment for many COPD patients. It is therefore indicated that a re-evaluation of clinical techniques and methods be initiated so that definitive benefits can be identified. These techniques are all widely accepted and the evaluation of them should significantly affect the field. New techniques have also been forthcoming for the prediction and evaluation of those COPD patients who have rehabilitation potential. These techniques require further analysis and refinement before application to clinical practice. Thus, both RSA staff and outside consultants have agreed in formulating appropriate new directions of research, that immediate goals should be based upon the research knowledge and clinical knowledge gaps identified previously. This will assist rehabilitation facilities and hospitals to develop and utilize those methods and techniques which are most effective in maintaining work and functional capacity. The development of meaningful predictive criteria will enable rehabilitation counselors and State VR administrative and supervisory personnel to evaluate, plan and service COPD patients with the knowledge that cost effective results can be achieved. In FY 1978, two collaborative studies are being conducted to evaluate predictive physiological criteria for rehabilitation potential.

OFFICE OF HUMAN DEVELOPMENT SERVICES

Rehabilitation Services Administration

Number of People Rehabilitated:

Fiscal Year	All Rehabilitants	Persons Rehabilitated with Pulmonary-Respiratory Diseases
1975	324,039	3,179
1976	303,328	2,876
1977	291,202 1/	2,766 1/
1978	283,000 1/	2,400 1/
1979	277,000 1/	2,100 1/

1/ Estimated

RURAL HEALTH

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
Health Services Administration:					
Bureau of Community Health Services	---	---	$174,503,000	$191,935,206	$208,376,000
Alcohol, Drug Abuse and Mental Health Administration:					
National Institutes of Mental Health	52,069,000	59,825,000	64,404,000	74,727,000	74,967,000
Health Resources Administration:					
Bureau of Health Manpower	12,178,006	11,861,750	14,016,544	16,522,966	15,897,957
TOTAL, PHS	$64,247,006	$71,686,750	$252,923,544	$283,185,172	$299,240,957

ACUTE RESPIRATORY INFECTIONS

Respiratory infections are the major cause of acute illness in the U.S. Each year these infections take a heavy toll particularly in young children and infants, who often require hospitalization for serious lower respiratory tract involvement. In addition, statistics show that two major respiratory infections -- influenza and pneumonia -- rank fourth among all diseases causing death.

Prevention and control of these diseases rely on a thorough understanding of their causative agents. With advanced laboratory techniques, 50 percent of acute respiratory illnesses can be linked with a microbial agent, ususally a virus. Presently, more than 100 viruses -- many of which were identified by scientists at the National Institute of Allergy and Infectious Diseases -- are known to cause acute respiratory diseases.

Despite this information, progress in the control of respiratory infections has been slow. As with other viral diseases, there are virtually no effective drugs to treat the vast majority of these illnesses and commercial vaccines offer less than optimal protection.

Thus, the development of effective methods of preventing and treating acute respiratory infections is an important goal of research supported by the NIAID. Scientists are focusing on identifying the unknown respiratory viruses as well as developing antiviral compounds and live attenuated vaccines -- two of the more promising approaches to control. Closely linked with these efforts are studies aimed at elucidating the respiratory disease process and the role of the body's immune system in enhancing and inhibiting these poorly understood mechanisms.

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
National Institutes of Health.....	$7,001,857	$7,461,000	$8,415,000	$9,088,000	$9,825,000

NATIONAL INSTITUTES OF HEALTH

ACUTE RESPIRATORY INFECTIONS

This research is carried out by intramural scientists in Bethesda, Maryland as well as by extramural scientists located at medical schools, universities, and research institutions throughout the country and around the world. To mount a co-ordinated effort against respiratory infections, the Institute encourages and supports collaborative studies with other interested governmental and non-governmentalinstitutions.

Influenza

Influenza is the most important of all the viral respiratory diseases affecting man. For the 1976-77 flu season, the Center for Disease Control reported 72,603,000 cases of influenza-like illnesses serious enough to restrict activity or require medical attention. This figure is lower than the one from the previous year, but epidemiologists are predicting a pandemic or worldwide outbreak sometime in the late 70's.

The reason for this gloomy forecast is the nature of the human influenza virus of which there are three distinct immunological types; A, B, and C. The A virus which causes most disease is notoriously fickle, changing or "shifting" its antigenic make-up every 10-12 years. As a result, the population is generally without immunity to the "new" virus and thus a pandemic (world-wide epidemic) occurs. Lesser variants of the A virus also appear almost every flu season.

Epidemiology

Predicting and preventing epidemic influenza outbreaks constitute a major public health goal. One research approach to the problem is the surveillance of both human and animal influenza viruses to learn more about their transmission and to detect new variants that pose pandemic threats.

Last year, through its Development and Applications Branch, the NIAID initiated an Influenza Surveillance Network, which, to date, has been the most effective advance warning system within the country. Scientists at twelve centers throughout the continental U.S. collect specimens for virus isolates from individuals with upper respiratory symptoms who present themselves for treatment at selected hospital emergency and out-patient clinics. The Center for Disease Control is then notified of the nature of all viral isolates by NIAID's coordinating laboratory at the University of Colorado Medical Center in Denver. Through such efforts the network was the first to identify the widespread epidemic of influenza B which occurred last winter.

Now in its fourth year of operation, the NIAID-sponsored Influenza Research Center at Baylor College of Medicine continues its surveillance of the Houston population for influenza activity. Collaborating with community hospitals, neighborhood health centers and private physicians, the Center's staff has demonstrated that a prospective virus isolation program is the most effective way to detect early isolates of strains that may herald the occurrence of a serious outbreak. To date, the Baylor influenza researchers have followed three epidemics in Houston and were instrumental in identifying the newest variant of influenza A, A/Texas/77.

In related studies, Baylor epidemiologists -- tracking influenza infection in families -- have revealed some interesting information on transmission of flu and have demonstrated the severity of the disease in children. In the 38 families studied during an epidemic, those with school-aged children -- 5 to 19 years old -- had the highest rates of infection. Thus, this age group was found to be the single most important factor in the introduction and early spread of the disease. In addition, surveillance of children hospitalized with respiratory viral infections indicated that influenza A is a serious pediatric problem deserving more widespread recognition.

Flu researchers believe that surveillance of animal influenza viruses may provide some clues to the mysterious origins of new human pandemic strains. One theory is that frequent recombination of the two principal influenza antigens -- neuraminadase and hemagglutinin -- might account for both animal and human virus shifts. Headquartered at the St. Jude's Children's Research Center in Memphis, Tennessee, the network for animal influenza surveillance samples the commercial swine population in the U.S. by screening slaughter houses and hog farms throughout the Midwest. This network was responsible for detecting cases of swine influenza in humans. In collaboration with the U.S. Department of Agriculture, St. Jude's Children's Research Hospital plans to collect additional animal samples for viral isolation and antibody determination.

In addition to swine, migratory birds are thought to play an important role in the ecology of influenza viruses. At the University of Hong Kong NIAID-supported investigators reported isolating influenza A viruses from ducks, chickens and geese at a local poultry plant. Of the 13 different influenza viruses identified, seven possessed combinations of hemagglutinin and neuraminidase not previously reported. This finding -- combined with discovery of the presence of two different influenza A viruses in one duck--suggest that recombination may be occurring in nature. As yet, the significance of these viruses and the new combinations remain to be determined.

Vaccine Research and Evaluation

Currently available influenza vaccines are inactivated preparations that offer protection only against the strain or strains prevalent in the community at the time or during the previous flu season. Research scientists, therefore, have focused their efforts on developing vaccines made from live attenuated viruses in the hope that they will adequately protect against newly emerging variants of the influenza A virus.

One approach to live vaccines -- vigorously pursued by Dr. Robert Chanock and his co-workers at the NIAID -- has been to obtain temperature-sensitive (ts) mutants of the influenza A virus. These vaccines are made by chemically treating influenza viruses and selecting out the mutants with ts lesions that restrict their growth in the warmer temperatures of the lungs, where they can cause illness, rather than in the cooler regions of the upper respiratory passages. Temperature sensitive mutants with shutoff temperatures between 37-38° appear to be the most attenuated.

In their quest for safer and more stable ts mutants, the NIAID scientists have found that "double mutants" -- viruses with two genetic defects -- are more attenuated than viruses with only one ts lesion. The goal of this research is to create suitably attenuated, stable, double mutant donor viruses that can be mated with wild type viruses to produce double mutant recombinants or hybrids that have "inherited" the two ts lesions from the donor virus. In collaborative efforts with Drs. M. Ritchey and P. Palese at the Mt. Sinai School of Medicine in New York City the NIAID investigators have studied and located the two ts lesions found in recombinants of the double mutant ts-1 [E] virus. Investigations such as this are aimed at elucidating and manipulating the genetic basis for the ts lesions.

In additional studies, the NIAID scientists produced prototype vaccines by combining the ts-1 [E] virus with a well-known wild type virus -- A/Victoria/75. However, when administered to adult volunteers, these recombinant vaccines produced illness in those individuals with no preexisting immunity to one of the influenza surface antigens -- neuraminadase. Among seronegative children both illness and reversion to the wild type were observed. Thus, attenuation of these vaccines depends, in part, on some preexisting immunity to influenza. The NIAID scientists plan to examine further the effect of neuraminadase immunity on the reactogenicity of the ts-1 [E] recombinants by testing them on volunteers with different levels of immunity.

These same scientists have found that when immunity to both influenza surface antigens is lacking, which occurs at the time of pandemics, a better approach to immunization may be to develop double mutant recombinants whose attenuation depends solely on the

degree of defectiveness of the ts lesions rather than on preexisting immunity. A recombinant with this greater degree of attenuation can be produced by mating two separate mutant viruses -- each with one highly defective ts lesion.

Using this method, the ts-1A2 recombinants were developed at NIAID and tested in hamsters who received a vaccine preparation produced by mating the ts-1A2 with the A/Victoria/75 wild type virus. The A/Victoria/75-ts1A2 recombinants-- with growth restrictions at 37°C -- protected hamsters against challenge with the wild type virus, although the recombinants failed to grow or revert to more virulent forms in the lungs -- unlike the ts-1E recombinants. Similar encouraging results were obtained in trials with human volunteers indicating that the ts-1A2 recombinants appear to be the most predictably attenuated, genetically stable live influenza vaccine candidates developed to date.

In future studies, the intramural scientists plan to construct a series of double mutant donor viruses -- based on the principle of the ts-1A2 recombinants -- for eventual evaluation in animals and humans.

In addition to the ts mutants, the NIAID is also supporting studies on other attenuated vaccines referred to as cold adapted recombinants. Researchers at the University of Michigan are working with a master strain of influenza virus that grows at 25°C, but not at temperatures above 37°C. This virus -- A/Ann Arbor/6/60 -- has been used to donate genetic markers to influenza viruses isolated from nature. The resulting progeny viruses are attenuated and are under investigation as vaccine candidates.

An integral part of the influenza program includes extensive evaluation of both presently used inactivated and experimental live influenza vaccines. Much of this work is carried out by five Vaccine Evaluation Centers under contract to the NIAID.

During the past year, important information has been forthcoming from studies performed at the Vanderbilt University (Nashville, Tennessee) and collaborating institutions carrying out influenza immunization in children. For the first time, inactivated influenza vaccines (A/NJ, A/Victoria, B/Hong Kong) were evaluated prospectively for safety and ability to produce a protective antibody response in a large number of children. The results of this trial demonstrated the feasibility of immunizing young children with inactivated influenza vaccines.

Children are more susceptible to adverse reactions from influenza vaccines than adults and are less likely to develop effective levels of immunity at tolerable doses. To alleviate these problems, influenza researchers at Baylor College of Medicine and elsewhere are testing the usefulness of HANAflu vaccines -- purified versions of influenza vaccines containing only the antigens necessary to induce immunity. Results obtained from this work indicate the need for further evaluation of both commercial and investigational vaccines in high risk and normal children.

At the University of California at Los Angeles, NIAID-contractor, Dr. James Cherry is planning to conduct a large scale study of young children -- six to 36 months of age --who have been immunized with currently licensed inactivated vaccines. These children will be followed for at leastthree years to determine the safety, effectiveness and longterm side effects, if any, associated with vaccines.

Three Vaccine Evaluation Centers -- Baylor, Vanderbilt and Rochester -- continue to evaluate live attenuated vaccine candidates -- the temperature sensitive mutants and cold-adapted recombinants. Results obtained from clinical trials in adult volunteers indicate that the level of attenuation cannot be reliably predicted as yet. In related work planned for next year, the Center for Disease Control in Atlanta, Georgia, will undertake a study, through an interagency agreement, to analyze the physiochemical properties of the cold-adapted recombinants. It is hoped that these analyses will provide insights into attenuation of these promising live vaccine candidates.

Immunology

Understanding the body's natural defense mechanisms against influenza as well as the immunologic response to inactivated and attenuated influenza vaccines is essential to the development of effective methods of control. Since commercial vaccines do not always offer adequate protection, the use of adjuvants to enhance protection will be explored in the coming year.

At one contract institution -- St. Jude's Children's Research Hospital -- investigators provide purified influenza viral proteins to other contractors for studying the response of immunologically inexperienced individuals to influenza antigens. Using these proteins, other NIAID-supported scientists are looking at the role of the cellular immune system in the cytopathology associated with influenzal disease. These investigations suggest that the viral membrane protein may be a key element in the disease process observed in influenza infections.

Baylor immunologist -- Dr. Thomas Cate -- has recently developed a mouse model system for studying the cell-mediated response to influenza. Dr. Cate and his co-workers have discovered that these responses may be a "double-edged" sword, important in resistance, but also important in the development of influenza complications, such as pneumonia. Further projects with the mouse model will attempt to discover why infection with one influenza virus may lead to more severe disease during a second infection with a different influenza virus.

Respiratory Synctial Viruses (RS Virus), Parainfluenza Viruses and Adenoviruses

Seventeen per cent of all respiratory illnesses in infants and young children are estimated to be caused by the RS virus and parainfluenza viruses, resulting in approximately 42,000 hospitalizations for croup, bronchiolitis, and pneumonia annually. The adenoviruses follow closely behind as important agents of respiratory infections in the very young.

RS Virus Infections

RS virus epidemics occur each year, causing bronchitis and pneumonia in many susceptible infants. Approximately 12,000 of these young children require hospitalization. Still others develop RS virus infections while hospitalized for another illness.

During a community outbreak of RS virus disease, NIAID-supported investigators at the University of Rochester (New York) recorded the frequency and significance of hospital-acquired RS virus infections in infant wards. The researchers found that among the 14 hospitalized infants who developed RS virus infection, the risk of acquiring the RS virus was related to length of hospitalization, rather than to age or underlying disease. In the same study, 42 percent of the staff also acquired RS virus. These adults appear thus to play a major role in transmitting RS virus to hospitalized infants.

Alerted to this possibility, the Rochester group evaluated methods for preventing and controlling hospital-acquired RS virus during the next seasonal outbreak. Strictly enforced isolation procedures were found to reduce RS virus infections significantly among the hospitalized children. However, the staff continued to be infected, perhaps in caring for the children.

In other epidemiologic studies, these same Rochester scientists --led by Dr. Caroline Breese Hall -- have found that older siblings

appear most likely to introduce the RS virus into the family. Although a suitable vaccine might protect infants from RS virus, control should also include immunizing other children in the family.

During the past year, researchers at NIAID's Laboratory of Infectious Diseases have reported success in establishing several primate and non-primate species as animal models for the RS virus.

The most practical and readily available animal model was found to be the cebus monkey -- the first animal known to develop extensive pulmonary disease that closely mimics RS virus pneumonia in human infants. The NIAID researchers hope that investigations with this animal model will provide valuable information on the pathogenesis of RS virus infections.

In related studies at the NIAID, Dr. Gregory Prince has reported success with smaller, less expensive animals -- the ferret and the cotton rat. RS virus infection in ferrets -- weasel-like animals -- approximates age-dependent RS virus infections in humans. Viral replication in the lungs of these animals takes place when the animal is inoculated a few days after birth. After that time, infection is limited to the nasal area -- as in adult human RS virus infections. Unlike the ferret, the cotton rat is susceptible to RS virus pulmonary infections at any age, allowing researchers to manipulate the disease process in this animal model. Both of these animals have been proposed as suitable models for studying immunity to RS virus infections.

Protection from RS virus infections, especially in infants less than six months of age, is currently under investigation by several NIAID-supported scientists. In a cross-sectional study of children admitted to D.C. Children's Hospital, Washington, D.C. the RS virus was found to be most frequently isolated in 2-3 month old infants -- the age group when most infants have high levels of passively acquired maternal RS virus antibodies. One explanation for this paradox may be that maternal antibodies actually suppress the infant's own immune response during an RS virus infection. Dr. Kenneth McIntosh, an NIAID contractor at the University of Colorado, has been studying the role of local antibody in secretions from young infants with RS virus infections. Although this antibody is present during and after an RS virus infection, its role in protection needs to be elucidated.

At the University of California at Los Angeles, NIAID-contractor Dr. Stephen Suffin has shown that transfer of maternal antibody in infant ferrets occurs via the colostrum and milk rather than across the placenta. Infant ferrets -- nursed by mothers that have antibody

to RS virus -- resist infection when challenged with the virus; whereas infants born of immune mothers, but nursed by non-immune mothers, do not. Thus, acquired resistance to RS virus has been demonstrated, but the factors responsible for this resistance need to be determined.

Because of the importance of RS virus infections during childhood, scientists have been attempting for more than 10 years to develop effective vaccines. The current approach is to develop ts mutants --similar to their influenza counterparts -- that can be administered locally to the respiratory tract of infants and young children.

Scientists at NIAID's Laboratory of Infectious Diseases have prepared and tested several ts mutants to the RS virus. Vaccine trials with the ts-2 mutant seem promising. In studies with chimpanzees, the inoculated animals developed a serum antibody response -- indicative of infection -- without signs of illness. However, these same animals shed virus for several days, the significance of which is still undetermined. In human adults, similar encouraging results were observed with the ts-2 mutant. None of the 14 inoculated volunteers became ill, nor did any of them shed virus. In future work, the NIAID scientists will attempt to clarify the significance of virus shedding from inoculated animals to determine if the shed virus is, in fact, the wild type or an impostor.

Parainfluenza Viruses

The parainfluenza viruses are exceeded only by the respiratory syncytial virus as important causes of lower respiratory tract disease in young children. In a recent NIAID-supported study of 619 children -- carried out by Dr. R.H. Parrott at D.C. Children's Hospital -- 81% of croup cases were found to be primarily associated either with a parainfluenza or influenza virus.

Last July, speaking at a workshop on RSV and parainfluenza viruses, Dr. Parrott suggested that 40-50% of severe croup could be prevented if an effective vaccine were developed against parainfluenza virus types 1,2, and 3. Focusing on this effort, the NIAID is supporting research at Rutgers University,(New Brunswick, New Jersey) to develop ts-mutants as potential parainfluenza vaccine candidates. Several mutants have been isolated and are undergoing tests for safety, genetic stability and effectiveness in hamsters.

In related work at Vanderbilt University, NIAID-supported investigators -- led by Dr. Peter R. Wright -- recently tested an attenuated vaccine for parainfluenza type 3 in seropositive and seronegative children, two years of age or older. This "mid-passage"

vaccine -- derived by 75 laboratory passages in monkey kidney and egg -- was previously shown to be attenuated in adults and in older children. Seven of the eight seronegative children shed virus and most developed upper respiratory symptoms. This study emphasizes the importance of evaluating vaccine candidates in the target population (seronegative children) under carefully controlled conditions.

Although the significance of parainfluenza in early childhood has been established, the frequency of reinfection and the degree of resulting illness remain open to question. In addition, an understanding of natural immunity and how it can be enhanced and manipulated will contribute to successful immunization.

Adenoviruses

Recent studies suggest that the average child experiences at least 2-3 respiratory illnesses caused by an adenovirus usually types 1,2,3,5, or 7. In one large cross-sectional study involving 18,000 infants and young children, adenovirus infection was found to be associated with approximately 10% of lower respiratory tract illnesses serious enough to require hospitalization. From the same study, it was estimated that 5 percent of serious pharyngitis and bronchitis is also caused by the adenoviruses.

At the Baylor College of Medicine -- one of NIAID's Vaccine Evaluation Centers -- scientists are testing new subunit vaccines in adults. To date, these vaccines appear to be safe and effective in producing a protective antibody response. Future testing in children is planned.

STREPTOCOCCAL DISEASES

The Streptococcal pneumoniae--also known as the pneumococcus --is the most common cause of bacterial pneumonia in the United States. Despite the wide use of antibiotics, this disease claims the lives of an estimated 25,000 people annually. An important factor in the mortality rate is the increase in the number of pneumococcal strains resistant to antibiotics.

Epidemiologic studies have determined that fourteen to sixteen types of pneumococci account for 80-90% of all such infections. Since the 60's, the NIAID has actively supported research on the development and testing of vaccines effective against the types of pneumococci responsible for most cases of pneumonia. These vaccines are made from the complex sugars (polysaccharides) found in the gelatinous capsules surrounding virulent forms of the bacteria.

Currently, two field trials evaluating the effectiveness of prototype vaccines are nearing completion in the U.S. In San Francisco, an NIAID contractor at the Kaiser Permanente Medical Center has been testing the effect of a vaccine containing 12 types of pneumococcal polysaccharides in preventing pneumonia in adults over 45. Another NIAID-supported efficacy trial -- at Dorothea Dix Hospital in Raleigh, North Carolina -- involves administering two vaccines simultaneously -- each containing 6 different pneumococci types --to thirteen hundred volunteers. Although the data from these studies are not yet completely analyzed, the results to date indicate that the vaccines provided protection against pneumococcal infection. Much of this work has been conducted and coordinated by Dr. Robert Austrian -- a NIAID contractor at the University of Pennsylvania,(Philadelphia) --who continues to act as a consultant to all NIAID pneumococcal vaccine studies.

Results from studies in South Africa, where pneumococcal pneumonia is endemic among gold miners, clearly demonstrate that the vaccines were more than 80% effective in preventing type-specific pneumococcal bacteremia. More importantly, elimination of disease by these types did not lead to its replacement by illness caused by other pneumococcal types.

Some of the most encouraging results have been obtained from studies of pneumococcal vaccines in populations with a high risk of overwhelming and often fatal pneumococcal infections. Investigators in San Francisco have recently reported that one of the experimental vaccines seems to protect children with sickle cell disease and other people without functioning spleens. Dr. Arthur T. Ammann and fellow physicans at three hospitals in the San Francisco area found that during a 2-year period no cases of pneumococcal infection occurred in a group of 77 immunized sickle cell patients. In contrast, 8 of 106 sickle cell patients who had not been immunized developed a serious pneumococcal infection during the two-year period.

Based on the results of these and other studies, the FDA recently licensed a pneumococcal pneumonia vaccine prepared from 14 pneumococcal types. The Merck, Sharp, and Dohme vaccine -- effective in at least 80% of the people who receive it -- is expected to be particularly useful for the elderly and for people over the age of 2 with serious chronic diseases.

In addition to pneumonia, S. pneumoniae is responsible for 40 to 50 percent of serious ear infections in children. Almost every child has otitis media -- inflammation of the middle ear --at least once and 20 to 30 percent have six or more occurrences.

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Of special concern to scientists engaged in attempts to prevent otitis media is the response of children under 2 -- those most prone to this disease -- to the pneumococcal vaccines. To find out whether this group will respond, NIAID is supporting 2 trials -- one at the Boston City Hospital and the other in Huntsville, Alabama -- on the efficacy of an octavalent (8) polysaccharide vaccine in infants and young children who have had previous middle ear infections. In addition, scientists at Vanderbilt University are seeking to determine the optimum vaccine dose and booster schedule for maximum antibody response in infants and young children.

At the University of Minnesota, a contractor is developing an animal model -- the chinchilla -- which will enable scientists to study the disease mechanisms and immunology of pneumococcal otitis media. Preliminary work has proven successful in establishing middle ear infections in these animals.

Outlook

Research on improved and new vaccines has furthered progress in the prevention of acute respiratory diseases. However, treatment and eventual control of many of these illnesses may rest on the development of effective antiviral substances -- too few of which exist at the present time.

In 1969, the NIAID established its Antiviral Substances Program to support research on the development of agents effective in preventing and treating viral diseases. Many of these research efforts are directed toward interferon -- a naturally occurring substance long recognized for its antiviral properties. Its effectiveness in controlling the common cold has been demonstrated, but the present cost of exogenous interferon production limits its usefulness.

Another promising antiviral -- amantadine hydrochloride --is now being recommended to prevent as well as to relieve symptoms caused by influenza A virus strains. Rimantadine -- a chemical derivative of amantadine believed to produce fewer side effects --is also being tested for use against influenza A. These two drugs -- used alone or in combination with vaccines -- may be the physician's first line of defense when a serious influenza outbreak strikes an unprotected population. Similar drug-vaccine combinations may prove beneficial in other respiratory infections as well.

The search for new antiviral substances continues, as scientists bring closer the day that acute respiratory infections will be brought under better control.

HEALTH SERVICES ADMINISTRATION

Bureau of Community Health Services

RURAL HEALTH

The Rural Health Program has as its objective the improvement of the health of the population residing in rural areas of the United States. This segment of the population makes up about 31 percent of the total population.

Becuase of the remoteness of many of the areas in which the rural population resides, there is often very poor access to health services and facilities. Certain health indicators reflect the results of inadequate care for this large segment of the population.

In view of the conditions which characterize many rural areas such as low population density, high proportion of elderly and poor population, and remoteness from hospitals, it is not surprising that there is a critical shortage of physicians. It is the purpose of the Rural Health Program to reduce barriers of access to care by bringing health personnel into these areas and establishing health care delivery systems. To induce personnel to remain in the area and to improve the access to secondary and tertiary care, the Program is focused, also, on developing linkages with existing health services and hospitals in the surrounding areas. Such linkages make more comprehensive care available to the target population and provide the health service personnel with professional contacts and educational opportunities that hopefully will induce many to settle permanently in the areas they are serving.

In accordance with the basic purpose of the Rural Health Program, to develop new and innovative health care delivery systems for the rural population, the Bureau during fiscal year 1975 initiated an effort to develop rural health care systems in communities having the greatest need. Through a Rural Health Initiative, resources of the Community Health Centers Program, Migrant Health Program, National Health Service Corps and the Appalachian Regional Commission were integrated to better utilize existing programs in addressing obstacles encountered in serving various population groups and underserved areas. A total of 47 projects were developed the first year. This more effective distribution of financial, medical and personnel resources to programs having effective linkages with secondary and tertiary levels of care was expanded to include referral and consultation activities with other PHS programs (such as: Community Mental Health Centers, alcoholism programs, etc.).

Included in this program is the Health Underserved Rural Areas (HURA) program. This program was transferred to the Bureau, effective January 1976, from Medical Services Administration of the Social and Rehabilitation Services (SRS) In order to consolidate major rural health activities under one administration. Presently the HURA program is administered by and included in the Health Services Administration budget request.

Through the Rural Health Initiative (RHI) and the Health Underserved Rural Areas (HURA) programs a total of 350 projects were funded through 1977. It is expected that an additional 112 will be funded in 1978 for a total 462 projects funded serving approximately 2,386,000 persons in rural areas.

The following table indicates the total rural health activities supported by the Bureau in fiscal year 1978.

Program level of funding	Purpose	Rural Activities
Community Health Centers		
$262,000,000 ($247,000,000-CHC) ($15,000,000-HURA)	Development of health services delivery capacity in medically underserved areas, with access to family-oriented comprehensive high quality health care in a community based setting. Build health service capacity in areas of extreme need of medical underservice through the integration of the resource of the Community Health Centers, Migrant Health, Appalachian Health and National Health Service Corps Programs to serve populations of all of these programs. Also to provide linkages with other PHS programs (such as: Community Mental Health Centers, Alcoholism programs, etc) to include referral and consultation activities.	401 of the 574 Community Health Centers are serving rural areas at a level of $75,594,206. All of the 106 HURA Projects are located in rural areas.
Home Health $6,000,000	Providing support of the establishment and initial operation of public and nonprofit private agencies which will provide home health services to areas in which such services are not otherwise available.	Of the total 202 projects supported since the beginning of the program, 128 were located in rural areas at a level of $6,593,000. The 1978 rural level is approximately $4 million.

Program level of funding	Purpose	Rural Activities
Comprehensive Public Health Grants to States $90,000,000	Formula grants to assist States in establishing adequate public health services.	States use part of the funds to support activities which serve rural areas, but there is no way to estimate rural versus urban.
Hypertension Program $11,000,000	Formula grants to States to assist in meeting the cost of establishing and maintaining programs for the screening, detection, diagnosis, prevention, and referral for treatment of hypertension.	States use part of the funds to support activities which help rural areas, but there is no way to estimate rural versus urban.
Maternal and Child Health (It is not possible to estimate this amount for formula grants. However, legislation requires emphasis on rural areas and this is taken care of in the maternal and child health formula by weighing rural live births by a factor of 2 to 1 urban live births). $364,656,000	Comprehensive health care and services, with emphasis on preventive services, provided to mothers and children; diagnostic, treatment, and follow-up care provided to children with crippling conditions or handicapping illnesses have been placed in rural areas by the jurisdiction.	The 56 jurisdictions are required by P.L. 93-53 to operate programs of projects in health areas. The 56 health jurisdictions have 342 projects serving rural populations.
Family Planning $128,885,000	Provide a full range of high quality family planning services to people who want such services but for financial or other reasons do not have access to them.	Of the 235 grants supported, 174 will provide services in rural areas at a level of $23,650,000.
Migrant Health $34,500,000	Provides access to health care services to migratory and seasonal agricultural workers and members of their families	All 138 projects serve rural areas. However, 78 of the 138 projects are supported under the Rural Health Initiative.

Program level of funding	Purpose	Rural Activities
National Health Service Corps $42,565,000	To help alleviate the geographic maldistribution of health manpower by providing health professionals to communities where shortages exist.	592 of the 643 NHSC site are providing services in rural areas at a level of $39,191,000.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health

RURAL HEALTH

The goals of this program are the development, extension and improvement of mental health service delivery in rural areas, especially those which are underserved. Major problems include: (1) individual poverty and lack of public funds to support health and social services; (2) lack of transportation; (3) recruitment and retention of professional personnel; and (4) continuing education for mental health staff.

The basic thrust of the rural mental health program at this time is to maximize limited resources through seeking and promoting coordination of health and welfare services on Federal, regional, State and local levels. In addition, research and training appropriate to improvement of service delivery, and tailored to rural needs, are of concern.

An NIMH Work Group on Rural Mental Health meets regularly, and includes most NIMH components, represenatives of the National Institute on Alcohol Abuse and Alcoholism, National Institute on Drug Abuse, Bureau of Community Health Services, and United States Department of Agriculture. An intermittent participant has been the Office of Human Development. Minutes of each meeting are sent to all regional offices. The Work Group serves as a means of communication, information exchange and joint planning as appropriate in addition to serving as an advisory body to the chairman of the group who is responsible for the rural mental health program.

Major activities have included ongoing contacts with the Bureau of Community Health Services, Rural Health Initiative/Health Underserved Rural Areas programs. The RHI/HURA grantees have been matched with federally funded mental health centers and these lists have been distributed to all regional offices. Of the approximately 344 RHI/HURA awards, about 65 percent have overlapping catchment areas in whole or in part with federally funded CMHCs. The 191 RHI/HURA grants awarded in FY 1976 were individually reviewed and mental health material was abstracted. About 75 percent of the RHI/HURA grantees recognized needs for mental health services in their catchment areas, 37 percent were planning linkages with mental health facilities, 31 percent were currently sharing or using mental health services, 15 percent were budgeting mental health-related positions in their grants, 6 percent were contracting for mental health services and 14 percent of the applications contained letters of support from mental health agencies. The material was presented in a paper at the annual meeting of the American Psychiatric Association in May 1977 in Toronto with the Director of the RHI/HURA program as co-author. This paper will be published in Public Health Reports. A second report on this information was presented at the annual meeting of the U.S. Public Health Service Clinical Society in April, in San Francisco.

The Aroostook Mental Health Services, Inc., Fort Fairfield, Maine illustrates the relationship between the federally funded rural health and mental health programs. The RHI program has made a contract with the CMHC, paying $250 a month for consultation, inservice training and evaluation of speech and hearing problems among their clients. Patients in need of mental health services are readily accepted for treatment in the CMHC.

In May 1977, a meeting was convened by the Chairman of the Work Group, bringing together a group of 16 consultants representing CMHCs, academia, a State mental health agency, and four regional offices along with the Work Group. The purposes of the meeting included identifying key issues and contraints in developing and providing mental health services in rural areas, to prioritize these issues, to identify training approaches essential in providing services and important areas for research. A detailed report of the meeting has been prepared and will be disseminated widely. The results of the meeting will furnish directions for program development in rural mental health. The Conference was summarized in a report published in the September 1977 issue of Hospital and Community Psychiatry. The Conference highlighted the following issues that should influence program planning and allocation of resources. Among the problems were:

1. The cost of operating a rural CMHC is increased because of the distances (Northern Arizona Comprehensive Guidance Center, Inc. covers a catchment area of 65,000 square miles; East Montana CMHC covers 50,000 square miles). Numerous satellites are required (East Montana provides services from nine fixed sites and four itinerant sites). Travel time for staff decreases patient contact hours, telephone costs are increased (one rural center director reported spending $35,000 a year for telephone).

2. The lack of human services resources requires CMHC staff to devote time to social and welfare problems which lessens staff time spent in dealing with mental health problems per se.

3. Transportation is a major problem both for clients and staff, especially since a large proportion of clients are indigent. Partial hospitalization programs are limited in rural areas because of lack of transportation. Inpatient length of stay may be increased for this reason.

4. Recruitment of professional personnel is difficult. Professionals are usually trained in urban settings and prefer to remain there. Costs are increased in obtaining specialist consultants (child psychiatrists).

5. Continuing education for professionals, now mandatory for relicensure in some States, is virtually impossible to obtain without travel to distant sites which deprives the facility of staff hours.

Bringing educators to the CMHC raises costs.

In August 1977, utilizing funds left over from the May Conference, a second Conference was convened, bringing in nine outside consultants from CMHCs and academia plus two regional office staff together with the Work Group to consider some questions raised at the May Conference. The group concluded that a research and development approach might be feasible but special consideration is necessary to prevent a narrow approach since rural areas vary greatly. Any research effort should involve research grantees, CMHCs and the local community.

Advocacy and dissemination of information remain important program objectives. A new publication has been prepared by the NIMH which discusses recent research findings pertinent to rural mental health. This publication is part of the new Dimensions in NIMH Services, Report of the Director of NIMH.

Continual review and compiling of informational materials is necessary. Extensive contacts are maintained with the staff person for the the Rural Mental Health Work Panel and Migrant Sub-panel of the President's Commission on Mental Health for provision of information. In August, $5,000 was obtained to let two professional services contracts to prepare overview articles and annotated bibliographies. Dr. Robert Weiss, Columbia University, is covering the literature in medicine, nursing and psychiatry/mental health. Dr. Morton Wagenfeld, State University of Michigan at Kalamazoo, is surveying the literature in sociology, social work and psychology.

Invitations from regional offices to join in CMHC site visits permitted visits to be made also to four RHI/HURA sites in Bangor, Maine; Aroostook County, Maine; Glendive, Montana; and Orange Cove, California to stimulate relationships between CMHC-RHI programs and identify constraints. Reports were provided to the RHI program.

A new program is under way in cooperation with the Bureau of Community Health Services which has proposed to provide 1.5 million to their Community Health Center and RHI/HURA grantees to contract with local CMHCs for mental health personnel to be stationed in the health facilities. This proposal will strengthen relationships between the two programs and help to coordinate services and maximize local resources. Announcements of the program have been sent to regional offices. Successful applicants will be selected jointly by BCHS and NIMH.

Preliminary discussions concerning mental health services for migrants were initiated with the Migrant Health Service. Data on the nature and extent of migrant mental health problems are not available except for a few limited reports. Further discussion will continue to approach the problems in this area. There is very limited data available as to how to provide health services to a mobile population.

Currently, approximately 654 CMHCs are funded. Eighty three are in all rural areas and 161 in mixed, part-rural areas, for a total 244 centers serving 46.8 million people, of whom 20 percent are designated as poverty groups. At present, covered catchment areas include 1,172 counties. There are 2,252 such areas in covered rural counties.

In 1978, current activities will continue in advocacy and dissemination of information through invited speeches and publications. The overview articles/bibliographies in preparation will be monitored and the completed documents disseminated. The Work Group meetings will continue and efforts made to add representation from appropriate agencies to foster program coordination. The new program to place mental health staff in RHI/HURA programs will be a major activity with advocacy exerted to secure a maximum number of placements in rural areas. Following up the meeting of May 1977, NIMH will begin to explore how its training programs can encourage mental health trainees to work in rural areas and also how rural mental health workers can secure appropriate continuing education which now is required by various disciplinary organizations.

Following up the August 1977 research meeting, we will explore the establishment of a R&D center for rural mental health.

A new effort in conjunction with BCHS will begin in relation to improving transportation in rural areas for clients who are unable to reach services for this reason. This effort is seen as long range over a period of years with the goal of legislation to amend the Transportation Act which now primarily is concerned with urban transportation.

Contact with the Extension Leader at the University of Wyoming has led to the possibility of jointly exploring mental health needs in an energy development area occasioned by a rapid influx of new workers and families, many of whom live in trailer camps. This situation is replicated in a number of States.

HEALTH RESOURCES ADMINISTRATION

Bureau of Health Manpower

RURAL HEALTH

The AHEC program provides funds to medical schools and university health science centers for the purpose of decentralizing medical and other health professions programs in rural areas. This program links the resources and training programs of health science centers to community hospitals and other local education institutions. These projects operate from 31 remote site locations covering approximately 250 rural counties in 14 states.

The Nurse Practitioner program has two grant projects which aid in meeting the health delivery needs in rural settings. One project is to develop and implement an on-going educational program for nurse practitioners to meet the demands for family patient care in rural areas, and the other implements and evaluates clinical placement resources in a rural area to be utilized by registered nurses to familiarize them with the social and professional aspects of rural practice.

SPINAL CORD INJURY

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
National Institutes of Health:					
National Institute of Neurological and Communicative Disorders and Stroke	$ 8,819,000	$10,304,000	$13,687,000	$16,630,000	$16,880,000
Office of Human Development:					
Rehabilitation Services Administration:					
Basic State Grants	5,440,000	7,203,000	8,884,000	10,647,000	12,567,000
Innovation and Expansion	176,000	170,000	204,000	238,000	301,000
Special Projects	---	1,000,000	2,481,000	4,500,000	4,500,000
Research and Demonstrations	2,100,000	2,100,000	1,600,000	2,068,000	2,143,000
R&T Center	1,200,000	1,200,000	1,500,000	1,500,000	1,500,000
Special Foreign Currency Program	110,000	150,000	103,500	---	400,000
Total, RSA	$9,026,000	$11,823,000	$14,772,500	$18,953,000	$21,411,000
TOTAL	$17,845,000	$22,127,000	$28,459,500	$35,583,000	$38,291,000

NATIONAL INSTITUTES OF HEALTH

National Institute of Neurological and Communicative Disorders and Stroke

SPINAL CORD INJURY

Almost all functions of the body depend upon the integrity of the spinal cord. When this soft, fluted column of nerve tissue within the bony spine is severely injured, paralysis below the level of the injury almost always occurs. The unfortunate victim suddenly may have no motion, control, or function in the unfeeling body, and be forced to depend on others for help in performing bodily functions and everyday tasks. Although recent advances in treatment and rehabilitation permit the spinal cord injured to participate more fully than before in society's mainstream, most will experience overwhelming medical and surgical problems all of their lives.

The National Paraplegia Foundation, a voluntary health agency, estimates that currently there are 100,000 persons in this country with spinal cord injury. Statistics on new injuries vary. The Foundation indicates that there are approximately 7,500 new injuries each year; data compiled by the Insurance Institute of Highway Safety (IIHS) estimates injuries in excess of 10,000 for 1974, the last year for which statistics are available. According to the IIHS, 50% of these injuries occurred in motor vehicle accidents. Other leading causes of spinal cord injury are falls, sporting and industrial accidents, and gunshot wounds.

IIHS places the cost of immediate and lifetime care of a paraplegic at $92,400. With societal costs (loss of tax revenue, administrative costs of agencies serving the spinal cord injured, etc.) figured in, the estimate rises to $181,320. Total societal costs for new cases from motor vehicle injuries is estimated at $828 million; and total societal costs of all new cases at $1.656 billion. The above estimates are for 1974; in today's dollars they would be even higher.

Contributing to the astronomical cost of spinal cord injury is the fact that two-thirds of the injured are less than 36 years old, and more than two-thirds are male. Ordinarily these people would be at or approaching the height of their earning power.

The Institute's own probability survey of incidence, prevalence, and cost estimates for spinal cord injury is nearing completion and will provide additional data from which more effective planning and setting of priorities can be developed.

In terms of personal tragedy, the cost of spinal cord injury cannot be computed. It is not possible to measure or to set a price on the pain and emotional suffering that is experienced by the patient and the patient's family when they learn he or she will be paralyzed for a lifetime.

The Department of Health, Education, and Welfare's responsibility for clinical, basic, and community research programs in spinal cord injury is centered in the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) of the National Institutes of Health; for rehabilitation, the Office of Human Development Services; and for clinical service, the Health Service Administration.

Structure of the Spinal Cord

The spinal cord is a slightly flattened cylinder of nerve fibers and cells continuous with the lower part of the brain. It is about three-fourths of an inch thick and approximately 17 inches long. A cross section of the spinal cord reveals white tissue on the outside and a gray H-shaped mass in the center. The cord is enclosed in 33 blocklike bones, called vertebrae which allow a remarkable range of motion and normally protect the cord from injury. Nevertheless, injury can and does occur.

Causes of Injury

Spinal injury can result directly from falls, blows to the neck or back, stab wounds, gunshot, shrapnel, and other penetrating missles, and fractures or dislocations of the spine which affect the spinal cord or

its nerve roots. However, the vast majority of cord trauma occurs indirectly as a result of excessive flexion or extension of the spine in falls, diving, and especially motor vehicle accidents.

Severity of Spinal Cord Injury

The lower the injury on the spinal cord, the lower the level of paralysis because more of the cord remains functional. Another key factor in predicting the degree of paralysis is the extent of cord injury. A cord that has been completely severed by a bullet or a penetrating missle fragment cannot be repaired, and such an injury always results in permanent motor paralysis and sensory loss below the level of transection.

In all but the latter cases, some degree of improvement may be possible. The outlook is most optimistic when the symptoms result mainly from contusion (bruising) or hemorrhage (bleeding) into the cord. As long as some of the nerve fibers in the spinal cord are uninjured, improvement may occur, usually during the first six months, but sometimes even longer after injury.

Acute Spinal Cord Injury Research Program

It has been recognized for many years that there are two basic reactions of the spinal cord to mechanical or physical injury. There is the immediate anatomical disruption which is irreversible, and there is a secondary reaction involving swelling and hemorrhage beginning in the central gray matter. This latter reaction may account for much of the final spinal cord dysfunction; however, in its acute stages the process may be reversible.

Prevention, Diagnosis, and Treatment

The NINCDS research efforts on prevention of acute spinal cord injury are aimed at either preventing or stopping the progress of the neurophysiological, neurochemical, and neuroanatomical events that cause progressive damage after the initial injury.

Accordingly, scientists at Institute-supported Acute Spinal Cord Injury Research Centers at Ohio State University, Yale University, St. Joseph's Hospital and Medical Center, Phoenix, Arizona, the Medical University of South Carolina, and New York University, as well as within the Institute's Intramural Research Program, have designed a number of approaches to this problem which are being tested in both experimental and clinical studies.

At the New York University Center clinical researchers have observed increasing evidence of free radical damage to the neuronal membrane of the contused spinal cord. They theorize that when the spinal cord is

contused a complicated series of chemical reactions take place, which lead to progressive damage of the cord's myelin (or insulation). Validation of this theory would make it possible for researchers to turn their attention to finding an agent to inhibit this destructive process.

Clinically useful developments are continuing to emerge from electrophysiological studies conducted at the Medical University of South Carolina Center. This work has established useful correlation of evoked potential measurement with the clinical state of the patient. By repeatedly stimulating a peripheral sensory nerve with a mild electrical shock, it is possible to record from the scalp a response which provides valuable information about the functional integrity of anatomical pathways in the spinal cord. This technique is ideally applicable to the patient with spinal cord injury where the first and most important question to be answered is whether the cord has been transected, or whether some neural activity can still be conducted through the damaged area.

Another new development of great potential value in the diagnosis and assessment of acute spinal cord injury is computerized axial tomography. This modified x-ray technique permits scanning of soft tissues everywhere in the body, including the cervical (neck) cord. At the NIH Clinical Center, NINCDS neuroradiologists, who have played a central role in the utilization of this non-invasive technique, anticipate that it may be helpful in the assessment of certain aspects of acute spinal cord injury, associated bleeding, and delayed spinal cord cavity formation.

Attempts to develop a rational treatment for progressive secondary damage in acute spinal cord injury sometimes end in disappointment. Investigators at the New York University Acute Spinal Cord Injury Research Center discontinued a randomized study of the use of epsilon-aminocaproic acid when an analysis of 100 cases revealed no benefit. However, the use of high dosage of steroids to maintain the vascular integrity of the cord following acute injury is viewed as promising by researchers and soon will be tested in controlled clinical trials at all Centers.

In addition to pathophysiological investigations, these Centers also have a responsibility for community research on problems such as roadside diagnosis and emergency therapy, rapid transportation to the Centers, emergency room differential diagnosis, and patient handling. The nature of the treatment during these phases of the injury may be key factors in preventing lasting damage to the spinal cord. This research program is being conducted in coordination with the Emergency Medical Services Program of the Public Health Service.

In addition to its Centers' programs, the NINCDS is supporting a number of separate individual research projects on the pathogenic process responsible for the progressive damage of acute spinal cord injury. Such a study is being conducted at the University of Maryland

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School of Medicine, where the investigator hypothesizes that primary injury to the spinal cord vasculature (veins, arteries, and capillaries) is responsible for setting off a chain of events that produces the characteristic central hemorrhagic lesion which, in turn results in myelin (nerve insulation sheath) and axon (core of the nerve fiber) destruction.

If this hypothesis is correct, the investigator reasons that at least two rational pharmacological approaches are indicated. One would be to decrease the platelet aggregability in the acutely injured patient, utilizing any of a number of platelet antiaggregating agents to prevent thrombus (clot) formation at the site of damage to the layer of cells lining the blood vessels. Another would be the local application of chlorpromazine, a drug which has been shown to prevent and resolve experimentally induced cerebral vasospasm.

Program Developments

With research efforts on acute spinal cord injury now well established at Centers in five geographic areas, the NINCDS is moving to round out its program on this important national health problem. Controlled clinical studies involving all of the Centers will attempt to evaluate optimal treatment of patients with acute spinal cord injury. A common protocol is being developed for these studies. Within approximately the same period, the NINCDS expects to award from three to six research contracts to determine the feasibility of establishing Comprehensive Central Nervous System Trauma Centers for defined geographic areas, with spinal cord injury as a major focus. Finally, a "Central Nervous System Trauma Research Status Report" is being prepared. This, too, will emphasize the problem of spinal cord injury. A brief description of each of these knowledge transfer activities follows.

Establishment of a Spinal Cord Injury Registry

As part of its clinical research program, each Acute Spinal Cord Injury Research Center has recorded the number of patients admitted, level of injury, the neurologic deficit, the treatment and outcome.

However, it has become apparent that no one center will treat sufficient numbers of patients to answer in a reasonable time the questions regarding optimal treatment. Therefore, last year the Institute awarded a contract to the Yale University Neurosurgery Department and the Yale University School of Public Health to develop a format for a spinal cord injury national registry to be used by all centers, allowing pooling of data and more rapid evaluation of therapy.

Under the direction of the coordinator at the Acute Spinal Cord Injury Research Center at Yale, a treatment protocol is being designed with the help of all the groups involved. Controlled clinical trials of patients at all Centers will follow.

Feasibility Study for a Program of Comprehensive Central Nervous System Trauma Centers

Through this study, the NINCDS will attempt to evaluate the feasibility of applying at the community level research developments from its Acute Spinal Cord Injury Research Centers. Emphasis will be on transmitting information and methods now available at university centers to all segments of the health care community. and evaluating their applicability within that setting. The feasibility study also will take into account the incidence, nature, and distribution of central nervous system trauma, regional consideration (e.g., industrial, rural); availability of treatment (e.g., length of time from accident until definitive treatment began); and evaluation of results with regard to activities of daily living.

Central Nervous System Trauma Research Status Report

A report summarizing and evaluating the status of basic and clinical research on spinal cord injury and other trauma of the central nervous system, is being prepared by the nation's leading experts. It is expected to be available in late 1978 for distribution nationally with particular emphasis to young investigators in this area and to researchers in related fields.

Experimental Neural Prostheses

The development and evaluation of safe, stimulating techniques for use in neural prostheses are major goals of the NINCDS spinal cord injury research program. The Institute is directing both animal studies and muscle implant studies in humans toward the development of voluntary proportional control of the upper extremities in paralyzed individuals. The current approach to the problem is to attempt to "by-pass" the injured portion of the spinal cord. This is to be accomplished through the utilization of electrical signals derived from muscles of the unparalyzed part of the body which control electrical stimulation of the paralyzed muscles through implanted electrodes.

With the support of an NINCDS research contract, investigators at Case Western Reserve University, have succeeded over the past few years in activating both paralyzed flexor and extensor muscles in the hand of a quadriplegic patient. Gradually, the investigators have been able to reduce the amount of "hardware" in the prosthetic device, making it considerably less cumbersome for the patient to use in grasping small articles such as pencils and chessmen or in raising and tipping a paper cup of water to his lips. The most recent advance in the long-range development of a totally self-contained stimulation system to allow quadriplegic patients to regain control of their paralyzed muscles is the restoration of "key grasp" by electrical stimulation of the thumb adductor (opposing) muscles.

Another important goal of the Neural Prosthesis Program is the development of a technique to restore normal bladder control to spinal cord injured persons. (In addition to being a psychologically discomforting affliction, bladder malfunction often results in life-threatening complications to paraplegics.) At the University of California, San Francisco, studies are being carried out in animals with upper motor neuron lesions to determine the feasibility of urinary bladder evacuation by electrical stimulation of the sacral spinal roots. Results to date have been encouraging, but further animal testing is being conducted to improve the design before human application is attempted.

Neural control investigations also are being carried out by NINCDS scientists at NIH. Work here is concentrated primarily on analyses of the central and peripheral nervous system mechanisms that are involved in the control of movement. Many of the newer techniques for recording neural activity in intact animals have derived from the long standing interest of these scientists in the problem of developing workable neural prostheses to aid the neurologically handicapped patient. A brisk interchange of ideas and information in this area exists between Institute scientists with backgrounds in clinical science, neurology and biomedical engineering as well as with other groups in this country and abroad who share an interest in motor-system research.

Nerve Growth and Regeneration

If the problem of functional regeneration within the central nervous system (CNS) could be solved, it would put an end not only to the horror of spinal cord injury, but also would improve the outlook for stroke, multiple sclerosis, head injury, and other neurological disorders. Recognizing the importance of the problem, an international group of scientists met in Palm Beach in 1970 to discuss the state-of-the art of regeneration within the CNS. Their formal declaration that regeneration no longer can be considered insoluble, rekindled interest in this most challenging of all research areas.

Since then, intensified research by NINCDS scientists at NIH and at grantee institutions has produced interesting leads, but as yet no convincing proof that the CNS can recover full function following serious injury. These basic studies are aimed at an improved understanding of the biological events involved in the process of recovery from injury to the central and peripheral nervous systems, or adaptive modifications by the nervous system to compensate for such injuries. Studies by NINCDS grantees are supported by approximately 40 research project grants, two research program project grants for multidisciplinary team investigations of CNS regeneration, and a research contract to test the validity of a Soviet report claiming the regeneration of the transected rat spinal cord.

The attempt to duplicate the Soviet experiment is being made at the University of Maryland Medical Center. Working with the female white rat, whose spinal cord is surgically transected, the United States scientists are applying the several enzymes used by the Soviet scientist, separately and in combination, to see whether any of these chemicals might block the formation of scar tissue, allow the severed nerves to grow, and promote functional regeneration. Until these and other investigators who also are attempting to validate the Soviet scientist's findings and have an opportunity to analyze their results, it would be premature to extrapolate their work to humans or to associate it with clinical care.

It should be emphasized that any of the proposed experimental remedies described above, even if proven effective, would be applicable only to new acute spinal cord injuries. For the paraplegic patient whose condition is stabilized, reconstruction of the spinal cord with microneurosurgery techniques is viewed by some researchers as the best long-range possibility for restoring limited function to the lower extremities.

Early this year, an NINCDS grantee at the Veteran's Administration Hospital and University of Wisconsin Health Sciences Center reported a microneurosurgical technique in which a spinal cord gap in the dog, caused by transection one week previously, was grafted with autogenous sciatic nerve segments. Electron microscopic studies disclosed that some axons had successfully bridged the gap between transected spinal cord stumps via the grafted nerve. Although limited return of function was shown, the investigator was not convinced that it had been permanently reestablished. This work is still inconclusive but provocative, and observation that regeneration of spinal cord axons is a graded phenomenon is likely to stimulate work on methods which will further explore the quality of axonal regeneration.

This line of research also is being pursued at NIH. An NINCDS neurochemist, a guest worker from the Paralyzed Veteran's of America, and a research associate from the University of Pennsylvania, are studying the possible use of peripheral nerve allograft to provide a neurilemma system (i.e. Schwann sheath cells and their basement membranes) which might promote the regeneration of host nerve fibers at sites of injury to the peripheral or central nervous system. These workers cite the need to explore the use of a graft from a genetically different animal of the same species because an autograft of sufficient size, quantity, or anatomical structure may not be available and because removal of an autograft in itself causes some neurological deficit. For this reason, they suggest that allografts as well as autografts should be tested in attempts to duplicate the work at the University of Wisconsin which was described above.

An NINCDS neurosurgeon, is conducting experiments in the subhuman primate to discover if the report of functional and histological spinal cord regeneration in dogs can be reproduced in monkeys. The clinical arm of this study which is being carried out in collaboration with neurosurgeons at George Washington University Medical Center, Washington, D.C., consists of a preliminary investigation on the extent of blood supply and vascular damage present in cases of established paraplegia in patients. A small group of patients will undergo selective spinal cord angiography and detailed muscle evaluation. The purposes are: to establish the extent of vascular damage as compared to the neural damage in such cases, and to provide candidates for any nerve grafting procedures that may be done if the experiments in the subhuman primates provide positive and conclusive evidence for spinal cord regeneration.

Outlook for the Future

The implications of the above experimental medical and surgical approaches to solving the complex problem of regeneration in the CNS are of great potential importance. These will be developed and expanded as rapidly as basic data on the biochemical, physiological, enzymatic, and anatomical events involved in the healing process of CNS nerve cells are established. In the meantime, Institute efforts will continue to include fundamental studies of the degeneration and regeneration of neurons in lower vertebrates, and mammals, reestablishment of synapses (neuron to neuron connections) in cell culture and in peripheral nerves, studies of growth of nerve processes (axons) in development and regeneration, and studies of the chemical structure of the nerve growth factor in promoting regrowth of injured nerves.

The NINCDS will continue to encourage research symposia on CNS regeneration, plasticity, and related subjects. When feasible, these will be held as part of the regular scientific sessions of the many relevant scientific societies and groups with an interest in the problem of paraplegia. Furthermore, the NINCDS will continue to support research on scientifically meritorious promising new research leads from neuroscience laboratories throughout the country, and through its research manpower programs stimulate the interest and ability of young researchers to make regeneration of the injured CNS their life's work.

OFFICE OF HUMAN DEVELOPMENT

Rehabilitation Services Administration

SPINAL CORD INJURY

It is estimated that there are more than 125,000 persons in the U.S. paralyzed as a result of spinal cord injury. In addition, approximately 8,000 to 10,000 new cases result each year. Most spinal cord injuries are the result of automobile, water, and contact sports accidents; industrial falls; and incidents of violence, such as gunshot wounds.

Because of the catastrophic and astronomically expensive results of spinal cord injury, the Rehabilitation Services Administration has initiated a program of research to determine the rehabilitation benefits and cost effectiveness of a service delivery system dealing exclusively with spinal cord injury. It is planned that these projects will result in the development of a nationwide network of service systems for all SCI patiients.

Eleven Model SCI Systems have been initiated throughout the U.S. utilizing Rehabilitation Research and Demonstration Grant funds. The system concept includes emergency care and proper handling at the accident scene, sophisticated intensive care, a comprehensive program of rehabilitation services, vocational and educational preparation, and community placement with long-term follow-up services.

The total RSA spinal cord injury rehabilitation effort is developing into a coordinated and effective program through the utilization of both R&D and other Special Projects resources. The results of these projects are being developed into meaningful and effective programs by which State vocational rehabilitation agencies, private rehabilitation facilities or medical institutions can significantly improve and expand comprehensive rehabilitation services to the spinal cord injured. A national coordinating center for the retrieval and analysis of standardized data has been established, as part of a model system.

Due to the interests of other governmental agencies in the prevention, care, and treatment of SCI, the RSA has initiated collaborative activities with the VA, National Institutes of Health, and the Department of Defense in the interest of improved spinal cord injury rehabilitation.

The major emphasis of spinal cord injury research in the RT Centers has been toward the prevention and treatment of costly medical complications, the development of new rehabilitation techniques, and the identification of psychological, social, and community charactersitics that mitigate against successful rehabilitation and independent living. Approximately 60 projects are being conducted in these important areas.

In the research utilization and training areas, the RT Centers have developed specific short-term clinical training programs for medical specialists and in-service training for rehabilitation counselors, social workers, physical and occupational therapists, and hospital administrators.

OFFICE OF HUMAN DEVELOPMENT SERVICES
Rehabilitation Services Administration

SPINAL CORD INJURY

Number of People Rehabilitated:

Fiscal Year	All Rehabilitants	Person Rehabilitated With Spinal Cord Injury
1975	324,039	2,393
1976	303,328	2,904
1977	291,202 1/	3,720 1/
1978	283,000 1/	4,390 1/
1979	277,000 1/	4,900 1/

1/ Estimated

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

SPINAL CORD INJURY

There were an estimated 16,000 patients hospitalized in short-stay hospitals in 1975 who had a first-listed diagnosis of spinal cord injury. More than one-half (63 percent) of these patients were in the 15-44 year age group. An additional 15,000 patients were discharged with a spinal cord injury listed as a secondary diagnosis. The average length of stay for both sexes was 27.3 days, with the males having a longer average length of stay (32.5 days) than did the females (19.1 days).

STROKE

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
National Institutes of Health:					
National Institute of Neurological and Communicative Disorders and Stroke	$11,134,000	$ 9,965,000	$12,949,000	$15,410,000	$15,630,000
National Heart, Lung, and Blood Institute	3,733,000	4,167,000	4,700,000	4,700,000	4,700,000
Total, NIH	$14,867,000	$14,132,000	$17,649,000	$20,110,000	$20,330,000

NATIONAL INSTITUTES OF HEALTH

National Institutes of Neurological and Communicative Disorders and Stroke

Stroke (cerebrovascular disease) ranks third among causes of death in the United States, exceeded only by heart disease and cancer. Each year about 500,000 Americans are stricken, and about 200,000 die. Strokes incapacitate far more people than they kill, and are among the leading causes of long-term disability in the United States. There are about 2.5 million stroke survivors in the country, 30 percent of whom have gone back to work or to their normal activity, with 55 percent disabled, but capable of carrying on the activities of daily living, often with help. Fifteen percent are so incapacitated that total nursing care is required for the rest of their lives.

There are many types of strokes, but in a large number of cases, it may not be possible for the physician, in preparing the death certificate, to identify the specific cause of the stroke. The following table based on figures collected by the National Center for Health Statistics shows the principal categories used by physicians in certifying stroke deaths.

United States Stroke Mortality - 1975

Cerebral hemorrhage	26,862
Cerebral thrombosis	48,457
Cerebral embolism	811
All Other	117,908
TOTAL	194,038

The total of 194,038 for 1975, compared with totals of 207,424 for 1974 and 214,313 for 1973 indicates that a decline in death rate is occurring. A provisional total for 1976 of 188,530, based on a 10 percent sample of death records, continues the good news. The decline is generally attributed to better treatment for transient ischemic attacks, (so-called "little strokes"), improved control of high blood pressure (a presumptive cause of many strokes) and the steadily rising quality of stroke treatment, rather than to new knowledge of the fundamental causes of stroke. Furthermore, although the mortality statistics show a decline, we do not know that the incidence (or rate of occurrence) of cerebrovascular disease is declining. It is indeed possible that the declining death rate is accompanied by an increase in the number of disabled survivors, thus creating an even greater challenge in the field of community services.

What Is A Stroke?

A stroke is a sudden loss of brain function resulting from interference with the blood supply to a part of the brain. It is often the culmination of progressive cerebrovascular disease, which may extend over many years, and which is not easily detectable in the course of the usual physical examination. Some strokes are "minor" episodes, while others may cause death in a few minutes. Usually they are brought on by one of four events: (1) thrombosis--a clot within a blood vessel of the brain or neck; (2) cerebral embolism--the blocking of a blood vessel in the brain by a piece of clot or other material carried through the circulation from some other part of the body; (3) narrowing (stenosis) of an artery supplying blood to the brain, usually as a result of atherosclerosis; or (4) cerebral hemorrhage--the rupture of a cerebral blood vessel with bleeding into the brain tissue.

Whatever the specific process involved, interference with the blood supply to the brain for more than about five minutes invariably leads to death of brain cells and impairment of function. Temporary or permanent loss of movement, thought, memory, speech or sensation is the result.

The NINCDS Program

In the past 10 years there has been a substantial increase in medical and scientific interest in cerebrovascular disease. This has been brought about in large part by the growth of Federal support of research and training. Responsibility for the Federal program resides chiefly in the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), a component of the National Institutes of Health, and located in Bethesda, Maryland.

In Fiscal Year 1977, Institute support for the research in stroke amounted to approximately 12.9 million, representing 36 research project grants, 15 clinical research centers, 9 research contracts, and approximately 30 intramural research projects. Additional support was provided for research training in neurology and related disciplines and for relevant research in fundamental neurosciences, as well as for scientific conferences and publications. These NINCDS programs are coordinated, as appropriate, with relevant programs of the National Heart, Lung and Blood Institute.

Clinical Research Centers

Cerebrovascular clinical research centers in medical complexes across the country make up the largest segment of the stroke program. These units, nearly all of which are multidisciplinary, typically are staffed by as many as 15 to 20 scientists and physicians, plus technicians and other assistants. The centers serve as national focal points for clinical research on prevention, diagnosis and therapy. The research programs vary in approach, some concentrating on single areas, as at The Johns Hopkins University, where the epidemiological aspects of stroke are being studied. These include studies of factors influencing incidence (new cases) and prevalence (total number of cases), methods for early detection of "high risk" segments of the population, familial aggregation of stroke cases, and similar questions. A center at Boston University devotes its efforts primarily to research on aphasia, speech disorders which often follow a stroke.

Other centers are broader in focus, often using several approaches, such as the physical dynamics of blood flow, brain cell metabolism, pharmacology, surgery, the development of better methods of diagnosis and treatment, and many others. Each center has an interrelated clinical and basic research program, and has accommodations for up to 30 research patients. All the centers also conduct training programs for young physicians, scientists, and other workers.

Project Grants

In addition to the team efforts of the clinical research centers, smaller individual research projects are being conducted with Institute support. These range from basic laboratory studies in such fields as neurophysiology and biochemistry to clinical investigations of drug effectiveness, improvement of diagnostic devices and techniques, and development of improved surgical and medical treatments. These smaller projects often produce basic information which is later applied by the larger teams in the stroke research centers.

Cooperative Studies

One type of study which the NINCDS is uniquely able to sponsor by reason of its resources and central role is the cooperative study-- the large scale gathering and analysis of data from groups of institutions, using uniform definitions and methods. In this way, valid statistics can be produced and used as the basis for choices in research planning, and for evaluating improvements in treatment or diagnosis.

NINCDS has sponsored a number of cooperative studies in cerebrovascular disease. One study of current interest is being planned in Egypt, and will focus on strokes in younger age groups (30 to 45). In contrast to the United States, some African and Asian countries appear to be experiencing an increase in stroke incidence among these younger people, and even children. Also, persons in these countries are said to have lower blood cholesterol levels and less hypertension. It would be of great value to know why this is happening, not only to the health officials in the countries concerned, but also to American scientists concerned with strokes in young people here.

Another cooperative study just launched is an evaluation of a scalp artery grafting (extracranial/intracranial by-pass) procedure for the prevention of an impending stroke, described below (see Surgery).

Comprehensive Stroke Centers

A new development in the Institute's stroke program has been the concept of comprehensive stroke centers. As conceived, these regional centers will have the objective of increasing utilization of community resources for applied clinical research and speeding the evaluation and application of new research developments and information at the community level. They also serve as regional models for the best of stroke care. Authorities are convinced that much more can be done for stroke patients through evaluation and coordination of available resources locally, and through improved dissemination of new findings on treatment and prevention. The idea is not new; regional networks for the coordination of health resources and facilities already exist in some health areas, but it is new in the stroke field. The Institute has completed a series of feasibility studies with favorable results, and expects to fund four comprehensive stroke centers in Fiscal Year 1978.

Program Management

In 1976, a Stroke and Nervous System Trauma Program was established within the Institute as a part of an overall reorganization. This unit oversees the Institute's Stroke and Trauma Grant and Contract Programs, advises the Director, and serves as coordinator for the national effort in cerebrovascular disease.

Knowledge Transfer/Information Dissemination

Since its establishment in 1950, the Institute has devoted substantial funds and effort to the dissemination of new knowledge gleaned from its programs. In stroke, the Institute sponsors: biennial "Princeton Conferences," focusing on specific major areas of research interest; annual cerebrovascular clinical research center workshops, primarily for the exchange of information among scientists working in the Institute-supported stroke centers; and a stroke literature abstract service. The abstracts, produced at the Mayo Clinic and published bimonthly in the Journal Stroke, cover virtually all of the journal literature in the field. Additionally, the Institute itself publishes regularly a summary and evaluation of the status of cerebrovascular research and the reports of ad hoc committees, reviews, and other scientific and technical materials, and assists in the distribution of stroke literature, both to the scientific and general publics.

This year, the Institute cooperated with the Health Resources Administration in the production and distribution of Guidelines for Stroke Care, a 280-page guide for health professionals concerned with stroke patients. This has gone into a second printing, and promises to become a "classic" in the field.

Diagnosis

There are many types of cerebrovascular disease, many locations in the brain in which it may occur, and many other conditions which have a bearing on treatment. It is thus of utmost importance to improve diagnosis, both in precision and availability. The effort is characterized both by finding better methods, and by the refinement and improvement of existing ones. The best of the established methods, x-ray angiography, involves injection of radiopaque dye into the neck arteries and subsequent x-ray examination of the brain. However, the procedure carries some risk of reaction to the dye, and the films require great skill for interpretation because of the complexity of the brain's circulation and the problem of obtaining depth or three dimensional perception. Solution of the latter problem has been attempted through the technique of x-ray tomography, in which a picture is focused on a specific section or plane within the head. There is still the problem of shadows from the skull and other tissues above and beneath the target area which obscure precise interpretation.

Many other methods have been tried or are in limited use, including injection or inhalation of radioisotopes and subsequent scanning with a radiation counting camera, ultrasound projection and translation of the echoes into a picture, recording and analysis of bruits (abnormal sounds) in neck and head arteries, examination of retinal arteries, minute measurements of heat patterns radiating from the face or scalp, and various others. Except for the isotope scan, however, all of these methods are still too imprecise to be extensively useful in clinical practice.

A new diagnostic technique, computerized axial tomography (CAT scanning) has been hailed by an NINCDS grantee as "probably the most important advance in radiology in 50 years." The technique employs a narrow beam of x-rays to rapidly scan the patient's head in a series of thin "slices". The beams pass through the head and hit radiation detectors which feed signals into a high speed computer. At each of tens of thousands of points in the plane of the scan, the computer calculates the difference between the x-rays originally emitted and those received on the crystal detectors--the absorption coefficient--of the intervening tissues, blood, and bone. The computer also produces an oscilloscope (TV screen) picture for immediate viewing or photographic recording. The equipment is considered to be approximately 100 times more sensitive than conventional x-ray, and is being used to find cysts, tumors, abscesses, cerebral infarcts, and intracerebral hemorrhages. Several hundred of the devices are now in use in the U.S., and a major effort is under way to refine and improve the method and its application. Whole body scanners also are coming into use, and the equipment is being designed to work at higher speeds, both to enhance population screening possibilities, and also to surmount problems caused by body movements, i.e., breathing and heartbeat. Most of the institutions housing NINCDS stroke research centers have the equipment and are leaders in its further development.

Scanning with ultrasound is also being explored at several Institute-supported stroke centers, including the Massachusetts Institute of Technology, Cambridge, Massachusetts and Bowman-Gray School of Medicine, Winston-Salem, North Carolina. The MIT group will soon have in place a scanner which will produce high resolution transverse, longitudinal and cross-sectional images of the cervical carotid (neck) arteries and a 20-point velocity profile across the arteries. At Bowman-Gray, both extra-cranial and intracranial blood vessels are being studied with ultrasound diagnostic equipment. Ultrasound techniques have reached a level of refinement where they could come into widespread use as mass screening devices in cerebrovascular disease. This is important because of their relatively low cost, and the fact that they are non-invasive, posing no hazard or discomfort to the patient.

Another scanning method, considered to have even greater potential than CAT scanning, is positron emission transaxial tomography (PETT), now undergoing development at the NINCDS-supported stroke research center at Washington University in St. Louis. The principle is similar to CAT scanning, but the equipment employs radiation emitted by injected or inhaled radioisotopes rather than transmitted radiation. An instrument (PETT IV) in operation at the Center produces three-plane images simultaneously in about one minute, and has a resolution of 0.75 cm. and a diameter of reconstruction of 25 cm. Experience with the PETT IV scanner has led to the design of a new instrument to be called NEUROPETT, and intended more specifically for cerebral metabolic studies. The new instrument, to be completed in 1978, will picture seven "slices" simultaneously.

PETT scanning represents a major research advance over other types because it opens up the field of metabolic scanning rather than the anatomic scanning provided by CAT and angiography. CAT scanning and angiography have proven of tremendous value in locating lesions, but for research and eventual clinical purposes it is more important to study the physiologic processes in cerebrovascular disease. With 3 dimensional metabolic scanning, the flow of oxygen and glucose, for example, can be monitored in all parts of the brain, with no danger or discomfort to the patient. Many other aspects of cerebral metabolism can also be studied, with a view toward control of or limiting the destructive cellular processes in cerebrovascular disease.

Treatment

Progress in treatment of cerebrovascular disease is based on many small but significant improvements rather than any striking advances. Treatment must vary according to the stage of the illness and the type of problem encountered. No one new procedure or development is expected to affect the prospects for all patients but mention of a few provides a measure of progress and the generally optimistic outlook.

Surgery

In the past, surgery for cerebrovascular disease has been limited almost entirely to correction of flaws or blockages (aneurysms, clots, malformations, etc.) in the larger arteries such as the carotid arteries in the neck or at the base of the brain, which are relatively accessible. In recent years, intracranial arteries have come within reach of the surgeon. With the operating microscope, it is possible to remove clots from very small vessels (down to one millimeter in diameter) in order to bypass occlusions and provide collateral circulation.

During the year, Institute grantees reported on several projects in this area, including work on the development of better animal models for experimental stroke surgery, and the development of better tissue adhesives for grafting and repair of small and medium sized arteries.

A major event was launching of the cooperative study of the effectiveness of a new surgical procedure for the prevention of an impending stroke. The procedure involves joining blood vessels so that blood travels from a scalp artery through an opening in the skull to supplement the blood supply within the brain. The procedure, known as the extracranial/intracranial bypass has now been carried out in hundreds of patients, both in Europe and in the United States, but it is highly controversial; the only data on long-term effectiveness are in the form of scattered reports from individual institutions.

The new study, being funded by NINCDS and conducted under the leadership of Dr. Henry Barnett at the University of Western Ontario, will collect uniform data on the procedure from 20 major United States medical centers and 3 from outside the United States. More than 600 patients will be studied for five years. The specific objective is to determine whether extracranial bypass grafting will reduce by 50 percent or more the incidence of first or recurrent strokes in patients with certain forms of cerebrovascular disease. Patients will be principally those who have had transient ischemic attacks (little strokes), but a few other categories will be included. It has become more and more widely recognized that transient ischemic attacks (TIA's) represent a medical emergency, and definitive data on the bypass procedure is urgently needed.

Drugs

A broad-scale search continues for better drugs for treating cerebrovascular disease. Anticoagulants are commonly used in non-hemorrhagic strokes, as are blood pressure lowering agents. Efforts are being made to evaluate thrombolytic (clot dissolving) agents, and drugs that relax the brain blood vessels and allow them to open to their fullest diameter (vasodilators). Several drugs now are being evaluated including steroids to control the edema (swelling) following strokes, and anesthetics to control the arterial spasms following subarachnoid hemorrhage.

An exciting new possibility for preventing many strokes is offered by a group of anti-platelet aggregation drugs, most notable of which is aspirin. In clot formation, blood platelets tend to adhere to a foreign surface, such as exposed collagen tissue in the vessel lining or endothelium. This is followed by a "release reaction," resulting in the secretion of several compounds that augment clotting. Aspirin, sulfinpyrazone, and

several other drugs appear to have the ability to interfere with this process. An NIH-supported three-year double blind study in 11 institutions, led by scientists at the University of Texas, has provided strong evidence that aspirin definitely does exert a preventive effect in selected patients. A similar Canadian study, assessing aspirin as well as sulfinpyrazone, has just been completed. Preliminary analyses indicate concurrence with the American study that aspirin is useful in decreasing the occurrence of cerebral infarction in patients having multiple transient ischemic attacks (TIA's or little strokes). The final judgement has yet to be made, and the exact mechanisms of drug action remain to be worked out, but the importance of establishing a way of preventing thromboembolic strokes, a large proportion of which are preceded by warning signs (TIA's), can hardly be overstated. Interesting sidelights have come out of these studies; one is that the effect of aspirin appears to be diminished in the presence of high blood pressure; another is that women do not seem to be as well protected by aspirin as men. Further studies will be needed to refine the data, and also to find out which antiplatelet aggregation drug is most effective, and whether several might work synergistically.

Epidemiology

Another important area of investigation is that of the epidemiology of stroke. During the last three years two large population studies have been conducted to determine the prevalence of transient ischemic attacks (little strokes) in elderly people. In the first study, a questionnaire was distributed to approximately 10,000 elderly persons living in some 40 retirement facilities in 8 cities in the country. This questionnaire was designed to detect the presence of TIA during the previous 12 months and to obtain data as to prior hypertension, cardiac disease, diabetes and other stroke risk factors. Appropriate demographic data were also obtained. A response rate of 74 percent was achieved in this questionnaire survey and a TIA prevalence of 8.3/1000 was found on analysis of the questionnaire response and subsequent neurologic interviews.

The second survey now being completed consisted of a mailed distribution of the TIA questionnaire to some 17,000 persons living in the Leisure World retirement community in Laguna Hills, California. A satisfactory response rate to this survey has been obtained with almost 11,000 persons, i.e., 63 percent of the population, completing the questionnaire forms. In addition, 1,500 of the respondents, have been asked to undergo an interview and examination by a neurologist and thus far more than 90 percent of them have kept their appointments for this evaluation. The administration of the TIA questionnaire and neurologic examination were found to be feasible. In general the residents of the community and the administrative personnel have shown considerable interest in this stroke prevention program. These studies are important

for two reasons: estimating the incidence of transient ischemic attack in the elderly, and for developing a valid and reliable questionnaire that can be used by physicians generally.

Outlook

There continue to be many urgent needs in the field of cerebrovascular disease. With additional numbers of Americans moving into the age groups most menaced by stroke, and with increased recognition of strokes in children and young adults, it becomes increasingly important that the Institute's research and training programs continue to gain momentum. The Federal efforts promise to more than repay their supporters in terms of better health.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

National Center for Health Statistics

STROKE

Based on the 1975 data from the National Hospital Discharge Survey, there were an estimated 608,000 discharges from short-stay hospitals in the United States with a first-listed, or principal, diagnosis of cerebrovascular disease (stroke) and an additional 728,000 discharges with a secondary diagnosis of stroke. These 728,000 discharges had some other diagnosis listed as first or principal, but had stroke also shown as a final diagnosis on the medical record face sheet. Patients with a first-listed diagnosis of stroke remained in the hospital for an average of 13.3 days.

This means that over eight million days of patient care were required for those patients having a first-listed diagnosis of stroke. The average length of stay can only be computed for first-listed diagnosis. Approximately seven out of every ten patients (71 percent) with a first-listed diagnosis of stroke were at least 65 years of age.

SUDDEN INFANT DEATH SYNDROME

Obligations

	1975	1976	1977	1978 Estimated	1979 Estimated
National Institutes of Health:					
National Institute of Child Health and Human Development...	$6,322,000	$ 8,906,000*	$9,704,000	$ 9,900,000	$10,400,000
National Institute of Neurological & Communicative Disorders and Stroke.....	35,000	---	17,000	11,000	11,000
National Heart, Lung, and Blood Institute.	25,000	---	---	---	---
Health Services Administration:					
Bureau of Community Health Services, Office for Maternal and Child Health....	2,000,000	2,556,000*	2,000,000	2,802,000	2,802,000
Office of the Deputy Assistant Secretary for Health, Research, and Statistics					
National Center for Health Statistics...	2,000	3,000*	2,000	2,000	2,000
Alcohol, Drug Abuse and Mental Health Administration:					
National Institute of Mental Health....	163,000	21,486*	---	---	---
Total	$8,547,000	$11,486,486*	$11,723,000	$12,715,000	$13,215,000

*Includes Transitional Quarter

SUDDEN INFANT DEATH SYNDROME

The sudden infant death syndrome (SIDS), also referred to as crib death, sudden unexplained death, and sudden death in infancy, is the leading cause of death between the ages of one and 1 months, with an incidence rate in the United States of about 2 per 1,000 live births. A SIDS death is defined as the sudden death of any infant or young child which is unexpected by history and in which a thorough postmortem examination fails to demonstrate an adequate cause of death. Each year in this country an estimated 7,000 infants, predominantly between the ages of one and six months, die suddenly, quietly, and unexpectedly in their cribs during what is considered a normal sleep period. If no significant cause for death is found at autopsy, these babies will be considered SIDS victims.

The National Institute of Child Health and Human Development of the National Institutes of Health has primary Federal responsibility for research on the sudden infant death syndrome. Other Federal programs supporting projects directly related to SIDS involve the National Institute of Neurological and Communicative Disorders and Stroke, National Institutes of Health; Office for Maternal and Child Health, Bureau of Community Health Services, Health Services Administration; the National Center for Health Statistics, Office of the Deputy Assistant Secretary for Health Policy, Research, and Statistics; and the National Institute of Mental Health, Alcohol, Drug Abuse, and Mental Health Administration.

Prepared December 1977

NATIONAL INSTITUTES OF HEALTH

National Institute of Child Health and Human Development

Crib death is a world-wide public health problem; it strikes without warning. Many reasons have been offered to explain these deaths including neurophysiologic, cardiorespiratory, metabolic, endocrine, immunologic disturbances, and infections. However, to date no single cause has been shown to be responsible for these deaths. Why these infants die so suddenly, quietly, and unexpectedly is still unknown, but it is becoming evident that SIDS victims are not totally healthy infants before death as previously believed, and further that the cause of death is not through a single mechanism.

Although the cause of death for these babies remains a mystery, the characteristics of the SIDS baby, the mother of the SIDS victim, and their environments are well documented. In the majority of cases the SIDS baby is well-nourished and well-developed, and is reported to have been in good health. There is no history of serious upper respiratory infection, although there may be evidence of a slight cold or stuffy nose which is usually of such a minor degree that medical advice is not sought. The peak incidence of SIDS is consistently found the world over to be between the 2nd and 4th months of life. The risk is higher in males than in females, in black babies than in white babies, in one of twins as compared to single born babies, in low birth weight infants and particularly in infants whose gestational ages at time of birth were between 34 and 35 weeks, and in babies who have had recent upper respiratory infections.

It is also known that the highest rate of SIDS is among mothers less than 20 years old; the older tne mother the lower the risk of sudden death for her baby. Moreover, the risk for crib death is more than 4 times as great for those infants whose mothers received no prenatal care in comparison to mothers beginning their prenatal care early in pregnancy. In addition, a higher rate of SIDS occurrence has been observed among infants of mothers who smoke than among infants of mothers who do not smoke.

The frequency of SIDS deaths in the United States is greatest during the cold weather months, and between 12 midnight and 8:00 a.m. than during other periods of the 24 hours. Most infants die at home in their cribs or carriages, and the incidence of SIDS is highest in families of low socio-economic status.

The Sudden Infant Death Syndrome Act of 1974

The Sudden Infant Death Syndrome Act of 1974 (P.L. 93-270 April 22, 1974), fixed by statute the responsibility of the National Institute of Child Health and Human Development for the conduct of SIDS research. It required the Secretary to implement a program to develop and disseminate public and professional informational and educational materials relating to SIDS, and authorized the Secretary to make grants and contracts for projects which

include both the collection, analysis, and furnishing of information (derived from postmortem examinations and other means) as to the causes of SIDS, and to provide information and counseling services to families affected by SIDS. The Act authorized $2 million, $3 million, and $4 million for fiscal years 1975, 1976, and 1977, respectively, for the informational, educational, statistical, and counseling programs and delegated responsibility for these aspects of the legislation to the Office for Maternal and Child Health, Bureau of Community Health Services, Health Services Administration. P.L. 93-270 expired on June 30, 1977. This program was granted a one-year extension under the authority of the Health Assistance Program Extension Act of 1977 (P.L. 95-83, August 1, 1977).

On April 7, 1977, a Special Hearing on the Sudden Infant Death Syndrome was held by a Subcommittee of the Senate Committee on Appropriations. The hearing was chaired by Senator Edward W. Brooke (R), of Massachusetts. Witnesses included officials from the Department of Health, Education, and Welfare, medical research experts, and SIDS parents.

The National Institute of Child Health and Human Development (NICHD) was designated as the lead agency for P.L. 93-270 in 1974 and given responsibility for coordination and implementation of the law. An interdepartmental panel to coordinate Federal efforts in SIDS was established by the Department of Health, Education, and Welfare in 1974. It is chaired by an official of the NICHD and has representation from all Departmental programs with responsibility for SIDS activities. The functions of the Committee are to enhance communication, to coordinate Federal SIDS activities, to keep involved groups informed of ongoing Federal activities in SIDS, and to identify new approaches for SIDS Federal efforts.

NIH Research Programs

During 1977, the NICHD continued to expand its research efforts in line with the objectives and emphasis areas of the Institute's SIDS research program. NICHD SIDS program objectives are to increase understanding of the causes and underlying mechanisms of the syndrome; to identify infants at risk of becoming victims; to explore preventive approaches; to elucidate the psychological impact of a sudden and unexpected infant death on the parents, siblings, and the extended family; to stimulate scientists to direct investigative efforts toward the solution of this complex problem; and to inform the scientific and general communities about SIDS through workshops, conferences, and publications. The Institute's research emphasis areas include developmental neurophysiology, autonomic disturbances, and sleep state; respiratory, laryngeal, cardiac functions and responses to stimuli; metabolic, endocrine, and genetic factors; immunology and infection; epidemiology; anatomic pathology; and the behavioral facets of the problem.

The NICHD obligated $9,704,229 in fiscal year 1977, to support 112 research projects pertaining to SIDS. Of this total, $4,672,452 supported

41 research projects specifically concerned with SIDS in accordance with the provisions of Section 2(c) of P.L. 93-270. The remaining $5,031,777 provided support for 71 projects generally related to the problem of SIDS.

As a result of intensive investigations of SIDS between 1972 and 1977 by NICHD supported investigators, the pathogenesis of the syndrome appears to be related to a number of developmental, environmental, and pathophysiologic factors which under a complex set of circumstances interact in such a way as to set up a sequence of events, which at some point becomes irreversible and leads to death. Evidence that these infants have preexisting difficulties includes anatomic pathologic findings suggestive of chronic stress and hypoxia; abnormalities in sleep state, cardiorespiratory function, and tissue oxygen utilization; postnatal growth retardation; and the infant's temperament and behavioral patterns between birth and death.

Etiologic mechanisms currently proposed by NICHD scientists to explain SIDS revolve around interrelated infectious disease processes and developmental, pathophysiologic, metabolic, and environmental phenomena. A number of them are closely tied to chronic stress and hypoxic states, while other mechanisms are concerned with cardiac, respiratory, and metabolic abnormalities.

Research currently underway has documented that some SIDS victims have suffered from a chronic oxygen deficiency as reflected in changes found in body tissues on autopsy. Some SIDS infants have been observed to have cessation of breathing for very short periods of time (apnea) before death. It also has been documented that these periods of apnea increase and are more frequent when the infant has a cold or slight upper respiratory infection. Some investigators are observing increased amounts of apnea when the baby is in a rapid eye movement (REM) state of sleep, as well as when the infant has experienced a near-miss episode.

Of particular importance to our understanding of SIDS are current studies concerned with the young infant's ventilatory response to carbon dioxide (CO_2) and data showing an apparent increase in CO_2 responsiveness with gestational age. The more immature the infant, the more difficulty he may have in getting rid of CO_2. This is important because SIDS is seen in a large number of premature and otherwise immature infants.

Cardiac arrhythmias may also contribute to sudden death in infants. The mechanism of action is not clear but bradycardia and arrhythmia with apneic episodes have been reported during sleep, mainly non-REM sleep. A high output of catecholamines in response to stress may potentiate fatal arrhythmias. This reaction is more significant in males and may be related to the higher incidence of SIDS among them.

NICHD investigators are also studying the role of many abnormal events to SIDS, such as hypoglycemia; sleep deprivation; laryngospasm; anemia in potentiating apnea; effects of acute metabolic conditions on central nervous system (CNS) development, organization, and function;

CNS dysfunction above the brain stem; abnormalities of the carotid body; inability to metabolize free fatty acids; deficiencies in vitamin E or selenium; lack of secretory component of bronchopulmonary mucosa; nasal obstruction; cardio-vascular instability; and biogenic amine metabolism.

In 1977, based upon advances in knowledge made by its investigators, the Institute contracted with six data collection centers and one data coordinating center, located in New York City, Upstate New York, Chicago, St. Louis, San Francisco, and Seattle, to undertake a cooperative case-control study of SIDS. About 600 cases of SIDS, as defined by a common necropsy protocol developed for this study, will be investigated. Controls, matched for age and race, will be selected from the same hospital of birth as the case. Case-control comparisons for each factor under study will determine the extent of SIDS risk associated with the factor. It is anticipated that as a result of this project it will be possible to identify high risk infants on the basis of information available at birth and in the period shortly after birth.

The Institute has also contracted for the development of an inexpensive prototype respiratory-cardiac electronic monitor for use in the home on high risk and near-miss infants.

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) has continued to support contract research on the 125 sudden infant death syndrome victims from a population of 53,721 live births in the NINCDS Collaborative Perinatal Project. A risk index is being developed based on information easily gathered from hospital charts and observations in the newborn nursery to help put the prediction of SIDS on a quantitative basis. Many of the risk factors which the study identified as primary point to noxious influences in fetal life as the origins of SIDS. These risk factors include maternal cigarette smoking and anemia during pregnancy, few prenatal medical care visits, preterm delivery, abnormal insertion of the umbilical cord, and abnormalities in the neonates' brain functions. The increased frequency of SIDS within crowded housing was almost entirely in victims who had mild respiratory tract infections at the time of death.

NICHD Workshop, Lecture Series, and Information Program

During 1977, the NICHD continued to support an active research workshop, lecture series, and information program as an integral part of its total SIDS effort. The purposes of the NICHD SIDS research planning workshops are to consider the scope of the SIDS problem and to identify specific areas in need of in-depth study. These workshops have played a significant role in strengthening the NICHD SIDS research efforts, and have attracted a number of scientists to work on the problem of SIDS. To date, 13 workshops have been held. A summary report for each workshop is available.

In September 1977 the Institute sponsored its second SIDS Research Reporting Workshop for NICHD Grantees and Contractors. The workshop was attended by more than 100 conferees, included pediatricians, pathologists,

microbiologists, psychologists, biochemists, and parents of SIDS victims. The purposes of the workshop were to provide an opportunity to increase interaction among scientists investigating the problem of SIDS; to review, discuss, and evaluate SIDS related information, theories, and data emerging since the 1975 NICHD SIDS Research Reporting Workshop; to consider the need to reorder NICHD SIDS research priorities in the context of present concepts; to familiarize SIDS researchers with the DHEW effort in SIDS, including the Bureau of Community Health Services' Office for Maternal and Child Health supported SIDS Information and Counseling Centers; and to promote communication between SIDS investigators, SIDS service providers, and the public with a view to enhance the NICHD's research effort and to facilitate the early application of research findings.

In February 1974, the NICHD initiated a lecture series on NEW RESEARCH PROSPECTIVES IN THE SUDDEN INFANT DEATH SYNDROME. The purpose of these lectures is to highlight recent findings by sharing them with the scientific community and the public. The subject of the 1977 lecture, 8th in the series, was "Preventive Studies of Sudden Infant Death in England," presented by Drs. John L. Emery, Consultant Pediatric Pathologist, Children's Hospital, Sheffield, and Robert G. Carpenter, London School of Hygiene and Tropical Medicine, United Kingdom.

During 1977 NICHD staff presented scientific papers on SIDS at 10 professional meetings. The Institute has a large number of SIDS publications available for distribution to the scientific community and general public. These include the SIDS research planning workshops (13); bibliographies (6); scientific articles and books (11); and informational brochures and reports of meetings (3). Approximately 40,000 pieces of SIDS literature were distributed in 1977.

HEALTH SERVICES ADMINISTRATION

Bureau of Community Health Services, Office for Maternal and Child Health

The Sudden Infant Death Syndrome Act of 1974 established a national program to develop public information and professional educational materials; to disseminate such informational and educational materials to persons providing health care, to public safety officials and to the public generally; to award grants for projects which include both the collection, analysis and furnishing of information relating to the causes of SIDS. Priority is given in the awarding of project grants to applicants proposing to provide Statewide services in areas with populations of one million or more people, in areas where the infant mortality rate is higher than the national average, and those areas where community resources can enable the project to provide needed services.

Annually, there are an estimated 6,500-8,000 cases of Sudden Infant Death Syndrome (SIDS) in the United States. SIDS is the major cuase of death in infants after the first month of life. Little is known about SIDS; it cannot be predicted or prevented and has no specific symptoms. A typical case is the sudden unexpected death of a seemingly healthy infant between four and seven months of age, while asleep. SIDS is not confined to geographic areas, ethnic backgrounds, racial groups or socioeconomic classes although studies indicate that males and infants in lower-income, black families are at slightly greater risk. Reactions to the unexpected death of an infant may include accusations by law enforcement officials as well as grief and guilt in surviving family members.

In 1977, the Bureau of Community Health Services supported 29 SIDS projects located in 25 States of all 10 DHEW regions. These projects provided information and counseling services to approximately 3,500 families. In 1978, the number of these projects will increase up to 44 providing services to approximately 4,500 families.

In 1977, the following activities were conduction as part of the development and dissemination of informational and educational materials:

- Approximately 1,800 informational and educational programs were conducted.

- Three educational films continue to be distributed. Copies of these films have been supplied to all Federally funded SIDS projects, to selected community mental health centers, and to voluntary organizations concerned with SIDS. These films have been shown at least 5,000 times to more than 110,000 reviewers including groups such as the American Academy of Pediatrics, American College of Obstetrics and Gynecology, American Nurses Association, American Medical Association, American Association of Physician Associates, National Sudden Infant Death Syndrome, Inc., Guild for Infant Survival, Inc., as well as to schools of medicine, schools of nursing, police academies, and for in-service and continuing education programs.

  The film "After Our Baby Died," which was produced to sensitize health professionals to the problem of SIDS, has been extremely well received. "You Are Not Alone" was designed for use with families recently affected by SIDS. "A Call for Help" instructs police officers and emergency workers to respond to SIDS families with empathy and understanding. The 29 SIDS projects have utilized these films extensively in their educational programs.

- 2 public service announcements for television were completed and distribured; 200 stations reported that these tapes were telecast 2,275 times in 42 States with 122,202,500 viewers; contributed network time value was $61,604.

- More than 500,000 copies of 15 SIDS publications were distributed.

OFFICE OF THE DEPUTY ASSISTANT SECRETARY FOR HEALTH POLICY, RESEARCH, AND STATISTICS

National Center for Health Statistics

The National Center for Health Statistics instituted a special code for SIDS beginning in 1973. Data are available for the years 1973-75. The 1976 data are expected about the end of 1977. New cause lists have been prepared for use beginning in 1979. The SIDS category has been added to the new list of causes of infant death. This will enable more detailed information to be obtained about SIDS deaths than is presently available.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

National Institute of Mental Health

In 1974, the National Institute of Mental Health contracted with the National Sudden Infant Death Syndrome Foundation to assist with the development of organized mental health back-up services to five designated SIDS projects funded by the Office for Maternal and Child Health, BCHS, HSA. The major focus of the work was to carry out an educational campaign about SIDS and its mental health aspects directed to mental health professionals. The goals of the contract were to identify a SIDS mental health consultant within each community to provide support, backup, and assistance to those health professionals and representatives of parent groups working directly with SIDS families; to inform mental health workers of existing support systems for SIDS families within the community, and to encourage affiliation of community mental health centers with existing health service networks concerned with the management of SIDS; and to educate mental health workers about SIDS as a disease entity, and to further their understanding of the mental health aspects unique to SIDS families. The contract ended March 1977; all goals were accomplished satisfactorily.

VENEREAL DISEASES

Obligations

	1975	1976	1977	1978 Estimate	1979 Estimate
Public Health Service:					
Center for Disease Control:					
Grants	$28,000,000	$19,840,000	$25,000,000	$32,000,000	$32,000,000
Direct Operations	8,230,000	8,524,000	9,246,000	10,800,000	10,800,000
Total, CDC	36,230,000	28,364,000	34,246,000	42,800,000	42,800,000
National Institutes of Health:					
National Institute of Allergy and Infectious Diseases	3,069,000	4,324,000	4,091,000	6,000,000	6,075,000
National Institute of Child Health and Human Development	146,000	345,000	656,000	750,000	900,000
Total, NIH	3,215,000	4,669,000	4,747,000	6,750,000	6,975,000
TOTAL, PHS	$39,445,000	$33,033,000	$38,993,000	$49,550,000	$49,775,000

VENEREAL DISEASES

During 1977, the spread of penicillinase-producing Neisseria gonorrhoeae (PPNG) has been contained largely as a result of rapid transfer and implementation of control technologies by Federal, State, and military health authorities. The incidence of syphilis and gonorrhea, although still unacceptably high, decreased; for gonorrhea this was the first decrease in incidence since the Federally financed control programs began. Other sexually transmitted diseases (STD), such as genital herpes virus, nonspecific urethritis, and trichomoniasis, continue to be increasingly recognized as major public health problems.

Through project grants and technical assistance, the Federal Government is helping States to meet the health threats of syphilis and gonorrhea by mounting more effective control programs. In addition, basic and applied research efforts are being directed toward other sexually transmitted diseases with the major objective of characterizing the patho-physiology and epidemiology sufficiently to permit development of control methodologies.

The major Federal foci for State assistance are the Center for Disease Control (CDC) and the HEW Regional Offices; and for research, they are the CDC and the National Institute of Allergy and Infectious Diseases (NIAID). In addition to major research investments in syphilis and gonorrhea, the CDC and NIAID are sponsoring research studies in the other sexually transmitted diseases.

The CDC and NIAID programs are more fully described in the following sections.

CENTER FOR DISEASE CONTROL

VENEREAL DISEASES

Since the early 1930's, the responsibility for venereal disease control has been shared by the Federal, State and local governments, private medicine and voluntary organizations. As a result of this partnership, the prevalence and the severe complications of syphilis have been greatly reduced. Today, most of the newly discovered cases of congenital syphilis are in adults who were born in the previous era of high disease incidence -- only 142 (30.1%) of the 472 cases of congenital syphilis reported in fiscal year 1977 were infants under 1 year of age.

The reported incidence of infectious syphilis, usually interpreted as paralleling the actual syphilis incidence, began to decline in fiscal year 1976 and continued to decline throughout fiscal year 1977. During November 1977, reported primary and secondary syphilis cases declined 5.1 percent over the number reported for November 1976 -- the twentieth successive monthly decline. In fiscal year 1977, reported infectious syphilis cases numbered 22,006, a decrease of 12.5 percent from fiscal year 1976. This favorable trend is continuing in fiscal year 1978, with early syphilis showing a decline of more than 10 percent over the same period of fiscal year 1977. Among men, the decrease in cases was 11.0 percent; for women, 16.8 percent. Men accounted for 74.1 percent of reported infectious syphilis cases; women, only 25.9 percent, the difference reflecting the relatively high incidence in homosexual men.

The trend of syphilis in all stages has declined to 68,148 reported cases in 1977, down 10.9 percent from the 76,518 cases reported in fiscal year 1976. Since successful inroads have been made in reducing the reservoir of untreated syphilis of long duration, control efforts are concentrated on preventing cases.

The focus of syphilis control efforts will continue to be disease-intervention activities, including case detection, surveillance, and prevention. Of about 43 million serologic tests for syphilis performed during fiscal year 1977, 1.5 million were reactive; 54,200 persons were identified as infected with syphilis. The epidemiologic process is applied to cases of early syphilis, to prevent spread of the disease by treating sexual contacts while they are incubating the disease. During fiscal year 1977, these services were provided to 36,725 persons with early syphilis; 106,879 named suspects were examined and 10,300 new cases of syphilis were detected and treated -- resulting in the prevention of an estimated 6,200 additional new cases of syphilis.

The exchange of venereal disease information among State and autonomous local health departments has increased in importance as the population has become more mobile, and program efforts are directed to ensuring the rapid exchange of contact information between program areas. Almost 12 percent of all reported sexual contacts to known infectious syphilis cases during fiscal year 1977 resided in States or countries other than those in which the original patients received treatment. Because of exchange of information in fiscal year 1977, 7,681 persons were examined, and of these, 613 (8%) were treated for previously undetected syphilis infection.

Although gonorrhea ranks first among all reportable diseases, the reported incidence in fiscal year 1977 declined by 9,449 cases from 1976, the first such decline since Federally assisted State and local gonorrhea control programs were implemented. The number of reported cases by sex continues to differ: 600,001 cases in men in fiscal year 1977, compared with 402,805 cases in women. The decrease in reported cases in men was 0.4 percent in 1977 over 1976, whereas in women the decrease was 1.7 percent. Control screening efforts are being focused on screening high-risk populations, and encouraging patients to bring or refer their sexual partners to medical care.

The 64 large urban areas with populations of 200,000 continue to report most of the gonorrhea cases; although these cities contain only 27 percent of the nation's population, they reported 53 percent of gonorrhea cases in fiscal year 1977. The total cases reported by these areas decreased by 2.1 percent over fiscal year 1976, compared with a decrease of 0.9 percent for the nation as a whole; 31 (48%) of these areas, however, reported an increase in gonorrhea during fiscal year 1977. The variations in reported gonorrhea case rates from state to state reflect differences in casefinding activity, availability of public clinics, and reporting practices, as well as variations in attack rates. In fiscal year 1977, the highest gonorrhea rates per 100,000 population were reported by Alaska (1402.0), Georgia (968.7), Nevada (845.8), South Carolina (830.8), and Tennessee (824.6). The lowest gonorrhea rates were reported by Puerto Rico (96.8), New Hampshire (127.1), and Vermont (141.4).

For both syphilis and gonorrhea, young adults (aged 20-24 years) continue to be at greatest risk of infection. Teenagers (aged 15-19 years) make up the second highest risk group for gonorrhea, while the 25-29 year age group is the second highest risk group for syphilis.

Emphasis is being placed on the development and implementation of control programs designed to reduce the incidence of these diseases by focusing on disease intervention activities. The primary objectives of these programs are: (1) Screening high-risk populations for gonorrhea; (2) controlling the spread of penicillinase-producing Neisseria gonorrhoeae (PPNG); (3) surveillance of syphilis through serologic screening of specific population segments; (4) providing contact-referral services to patients with infectious syphilis and gonorrhea; (5) providing venereal disease facts to persons at risk to prevent exposure and to influence infected individuals to seek early medical care for themselves and their sex partners; (6) increasing the involvement of the private medical community in venereal disease control; (7) improving diagnosis and treatment of syphilis, gonorrhea, and other sexually transmitted diseases through consultation and technical assistance to State and local health departments.

The gonorrhea screening program and other outreach efforts are bringing infected women to treatment earlier in their infection. With these women removed from the infectious reservior earlier, further disease spread and serious complications are prevented. In fiscal year 1977, 8,639,429 culture specimens were obtained, of which 394,000 (4.6%) were positive for gonorrhea. Treatment was documented for 93 percent of these infected women.

Outreach medical coverage in addition to gonorrhea screening included applying the contact referral process to 322,919 patients during fiscal year 1977. As a result of the procedure, 199,036 contacts to gonorrhea patients have been examined and 164,733 persons have received therapeutic or preventive treatment. Because of gonorrhea screening, followup and other outreach efforts, an estimated 199,200 cases of gonorrhea were prevented.

Education efforts are directed primarily toward persons considered at greatest risk of acquiring an infection. Particularly important in the epidemiologic model of health education are persons with an infection, because of their importance to other infected individuals, their likelihood of reinfection, and their heightened readiness to learn preventive measures.

In addition to supporting educational and patient counseling efforts as integral parts of a central program, various methodologies for improving patient involvement and enhancing outreach efforts among high-risk individuals were developed and evaluated. Efforts to increase voluntary organization involvement in outreach and support activities were also heightened.

Since previous studies have indicated that the majority of venereal disease patients are diagnosed and treated within the private medical community, program efforts continue to be directed toward improving the clinical competencies and program support levels of private physicians. These activities provide appropriate specialists with up-to-date diagnostic and treatment criteria, encourage physician responsiveness to epidemiologic considerations, and encourage general cooperation among the private and public sectors of health care delivery.

Realizing that expanded research in the clinical area is essential to answer the multitude of outstanding diagnostic and therapeutic questions relating to gonorrhea, the CDC coordinates a wide variety of clinical investigations. These ongoing studies are designed to complement efforts in basic research by providing a field laboratory for new techniques as well as a source of clinical materials for research laboratories. The Center continues its involvement in the serological screening of selected populations, serological test evaluations, therapeutic trials, investigations of the long-term effects of illness and therapy, definition of particular risk factors in host-parasite interactions, evaluation of major control efforts, the study and improvement in clinical services and other related areas of clinical research.

Pelvic inflammatory disease (PID) is the most important and serious sequel of gonococcal infections in women. Morbidity costs (diagnostic and treatment costs as well as costs of time lost from work and school) for this disease have been conservatively estimated at $255 million per year. Present research is focused on the diagnosis, treatment, epidemiology and etiology of PID. In women hospitalized with this disease in a major city hospital, the gonococcus has been the infecting organism in 80 percent of acute PID cases. Women with PID who present as outpatients are also being studied in a larger, six-center therapy trial; two antibiotic regimens are being evaluated. Ultimately, more than 1000 women with PID will be randomly assigned to one of the

current U.S. Public Health Service recommended schedules for PID. At this time 480 women have entered the study; 48 percent of these women have gonorrhea and require long-term therapy and careful followup to ensure cure. Recurrence of the disease is frequent, probably due in part to asymptomatic infections among their male sex partners. Control program efforts are focused on careful contact tracing and treatment of sex partners as an integral part of the treatment of this disease.

In 1976, cases of gonorrhea caused by penicillin-resistant gonococci suddenly emerged in the United States and England. The pathogens produce an enzyme (beta-lactamase) that rapidly inactivates penicillin and renders the standard treatment ineffective. Resistant cases also have been reported in 16 additional countries. Penicillin-resistant gonococci account for 30-40 percent of gonococcal infections in certain populations in the Phillipines and to a lesser extent, in the U.S. military personnel stationed in the Far East.

Monitoring of the prevalence of penicillinase-producing Neisseria gonorrhoeae (PPNG) in the United States and abroad continues. As of November 1977, 249 cases have been documented in the United States. Prompt identification of these organisms by State Laboratories, using tests developed in part at the CDC, coupled with a high level of surveillance and intensive contact tracing around defined cases, may be responsible for the low spread level of this organism. Some basic biological characteristics of the organism may also be partly responsible, and this possibility is also being studied. Work has already shown that there are plasmid, antibiotic sensitivity and auxotypic differences between isolates from Africa and the Far East, which imply different simultaneous foci of the gonococcus' acquiring the penicillinase-producing plasmid. Furthermore, certain of these organisms have genetic material which may increase the ease of transmissibility of resistance to other gonococci. This resistance might be passed to other organisms, unrelated to gonococci, causing serious resistance to occur in these hertofore easily treated organisms. Plans are being considered to establish surveillance of PPNG in other countries in collaboration with the W.H.O.

Studies continue to determine potential alternatives to spectinomycin, the only drug firmly established as an effective treatment for PPNG, since it is possible that resistance to this drug may emerge. Clinical trials of cefoxitin, an experimental cephalosporin resistant to the action of penicillinase, and sulfamethoxizole/trimethoprim are being conducted in three clinics. Preliminary data suggest that cefoxitin is equal in efficacy to aqueous procaine penicillin G in treating gonococcal urethritis in men, and is also free of adverse side effects.

Established to evaluate CDC recommendations for the treatment of uncomplicated gonorrhea, to test new treatment schedules and antibiotics, and to monitor organism antibiotic resistance and adverse drug reactions, the Gonorrhea Therapy Monitoring Network continues in five geographic areas. The penicillin-probenecid regimen was effective in 97 percent of patients

reexamined 3-7 days after therapy; the cure rates for ampicillin-probenecid, tetracycline, and spectinomycin regimens were 94, 98, and 95 percent, respectively. Of new drug regimens tested, amoxicillin was 96 percent effective, and penicillin given in two doses for a total of 4.8 million units was 94 percent effective. The Therapy Monitoring Network and other special studies will continue to study the safety and efficacy of new therapy alternatives.

Organism antibiotic resistance and adverse drug reactions have also been monitored. Of the patients receiving the aqueous procaine penicillin G-probenecid regimen, 2 percent had a least one adverse reaction and 0.18 percent experienced procaine reactions. No life-threatening reactions occurred. The overall reaction rates for the ampicillin-probenecid, tetracycline and spectinomycin regimens were 0.62 percent, 5.9 percent, and 0.61 percent, respectively. Patients were most likely to have relatively resistant isolates if they were not black, had used antimicrobial agents within 2 weeks of treatment, or were men with symptomatic urethritis. Testing all penicillin-resistant isolates over the past 4 years has been shown that no cases were caused by PPNG: Thus the impression is confirmed that their emergence is a recent phenomenon.

Mathematical modeling for gonorrhea control and the development of methods of forecasting disease trends continue. Because data indicated the presence of a core group who were responsible for a large number of the gonorrhea infections, a variety of models for gonorrhea was undertaken. Results indicate that: (1) Prevalence changes are caused by movements of equilibrium resulting from changes in sociosexual behavior, economic conditions or health care. (2) Increasing casefinding activity will find more cases but will reduce the duration of disease and the cases to be found, until a new equilibrium is reached. Then additional program intensity will be needed to reduce incidence. (3) Disease saturation limits gonorrhea in the core group; changes in prevalence outside the core group are in direct proportion to changes in prevalence in the core group. (4) Screening women for gonorrhea has resulted in greater percentage reduction of gonorrhea in men than in women. (5) Screening for gonorrhea kept total gonorrhea incidence down 22 percent below where it would have been without screening. (6) A high-risk group of infected individuals tend to have a high prevalence of disease.

Nonlinear differential equations will be used to quantitatively forecast the results of specific control measures. A model will be used to determine probable costs and benefits of diagnostic and treatment policy changes for control of penicillinase-producing Neisseria gonorrhea.

Sexually transmitted diseases (STD) other than the five traditional "venereal" diseases continue to be increasingly recognized as major public health problems because they cause patients to lose time from work (or school), impose demands on medical care facilities, can be confused with both syphilis and gonorrhea, and produce morbidity -- of those neonates infected with genital herpes, more than half die, and of the survivors, more than half suffer severe complications; chlamydia causes an estimated one fourth of the cases of ophthalmia neonatorum.

Venereal disease clinics in the United States have historically diagnosed and treated only five venereal diseases, of which only syphilis and gonorrhea are of major public health concern. There are a number of other sexually transmissible diseases (STD), but these other diseases are not now reportable under State laws. The Sexually Transmissible Disease Study initiated in 1976 is a reporting system consisting of six geographically dispersed VD clinics which screen all of their patients for each of 15 diseases. A major purpose of the study is to determine the prevalence of each of these diseases among persons attending VD clinics.

To date these six STD clinics have reported 23,740 patient visits and 15,443 diagnoses of sexually transmissible diseases. Among 16,079 male visits, the most prevalent diagnosis was nongonococcal urethritis (4,004 cases) followed by gonorrhea (3,907 cases), venereal warts (669), genital herpes (550), crabs (483), and syphilis (298). Among 7,645 female visits the most prevalent diagnosis was gonorrhea (1,867 cases) followed by nonspecific vaginitis (974), trichomoniasis (901), candida (514), venereal warts (279), genital herpes (165), crabs (161), and syphilis (99).

The CDC has supported studies for the control and investigation of venereal diseases which are designed to: (1) Establish adequate disease sureveillance in the public and private sectors to assess the magnitude of the disease problem; (2) assess various disease control techniques designed to reduce disease incidence and prevalence; (3) increase the efficiency of collecting patient data, expedite patient care, and improve the gathering of epidemologic information; and (4) perform selected studies on biologic and epidemologic aspects of sexually transmitted diseases. These areas continue to form the nucleus for innovative program initiatives.

Emphasis in syphilis continues to be focused on (1) methodology and evaluation of existing serologic tests to make them more reliable and easier to perform, (2) development and evaluation of newer procedures based on recent immunologic technology, and (3) major emphasis on more precise definition of immunochemical characteristics of the reagents and componenets of the FTA-ABS test.

The FTA-ABS is the principal treponemal antigen test for serologic confirmation of syphilis infection and is the standard procedure with which newly developed treponemal tests are compared. Emphasis is focused on developing a better defined alternative to the "sorbent," which is inadequately defined but nonetheless is a vital component of the FTA-ABS test. Newer solid-phase radioisotope and enzyme-linked immunoassays with treponemal antigens are being refined and evaluated. Preliminary findings suggest that these tests may prove to be useful and practical procedures with wider applicability in diagnostic laboratories. Of special interest is the observation that a radioimmunoassay (RIA) procedure may be helpful in differentiating syphilis from the cross-reacting endemic treponematoses (pinta and yaws). This has not been possible with any previous serologic test and would be of great value in those developing countries where these nonvenereal treponematoses are still endemic and cause significant morbidity. This effort is being pursued because of its potential in the diagnosis and control of yaws and pinta.

Other investigative efforts in syphilis have been directed toward the *in vitro* cultivation of *Treponema pallidum*. The development of an *in vitro* cultivation method was reported in the scientific literature, and a major effort was made at CDC to reproduce this finding. Data indicate that the initial report was incorrect. A selective membrane chamber is being investigated to determine its value in supporting the growth of virulent *T. pallidum* both *in vivo* and *in vitro*.

A demonstration project has just begun in a moderately sized, relatively isolated midwestern city to assess the impact of gonorrhea control activities upon disease incidence. The first phase of this project will be to develop sensitive surveillance systems to assess the prevalence of disease and monitor changes in incidence. Also, a thorough epidemiologic analysis of newly occurring cases will provide information to define new control strategies to be used during the intervention phase of the project.

Because of the problem of increasing gonococcal resistance to antibiotics, and the emergence of PPNG, new interest has been kindled in gonococcal immunology and the production of gonorrhea vaccine. Preliminary studies of the relationships of antigenicity to virulence, and the serologic diversity of gonococcal strains from different areas of the country may help to clarify the issues in developing a vaccine. A byproduct of this search will be the possible identification and evaluation of serologic tests for the detection of gonococcal antibody or antigen in clinical specimens which allow diagnosis of gonococcal infections without the need for a culture.

The Center has developed and standardized infection models for gonococci in small laboratory animals. Such models are essential for elucidating immunity to gonococcal infection without the use of human experimentation or the very costly and time-consuming chimpanzee model. A high level of immunity against further infection with gonococci has been demonstrated in some of these small animal models. However, the immunity is dependent on matching the immune type of gonococcus responsible for the infection to the type needed to produce immunity. Gonococci isolated from different sites of infection and from patients in different geographical areas have been classified into different protective groups. Specific protective antigens have been isolated and purified from penicillin-susceptible and penicillin-resistant strains of gonococci. These antigens, free from toxicity, are effective in protecting animals against gonococcal infection. These data form the basis for continued investigation in the development of a vaccine for prophylactic immunization in man. At the same time, the research on the immunochemistry of gonococcal antigens has yielded new information and techniques which are being investigated as a means of fingerprinting gonococci for epidemiological investigations, surveillance, and vaccine production.

One descriptive study was undertaken to determine the reasons male patients became reinfected within 6 weeks. About one-third of male patients acquire their second infection from new sexual partners, and about two-thirds acquire their reinfections from the same sexual partners to whom they were exposed before the first infection. Further analysis of this second group will indicate what specific intervention strategies may be used to prevent reinfection.

The estimated incidence of nongonococcal urethritis (NGU) exceeds that of gonorrhea, which is the most common reportable infectious disease in the USA. Efforts have centered on isolation and identification of the several potential etiological agents of NGU, including chlamydia, mycoplasma, and trichomonas, Haemophilus vaginalis, and Candida species. An antibiotic susceptibility assay has been developed for testing chlamydia grown in tissue cultures. Development of a system to cultivate chlamydia en masse is being developed. This system will be used for immunological study of the antigenic complexes of the organisms and for development of a practical serological test for clinical and epidemiological use.

Ongoing clinical trials should establish improved diagnostic techniques and treatment regimens for herpes infections: A two-center double-blind study of diethyl ether in the treatment of genital herpes is now nearing completion. Other studies focusing on a single-dose therapy of trichomoniasis in women is also ongoing. A study to define the agents responsible for urethritis in women and vaginitis is also being conducted.

Hepatitis B has emerged as a significant sexually transmitted disease among subsections of the population, especially homosexual men. Preliminary data indicate that in selected populations of homosexuals, the conversion rate to antigen positivity may reach 10 percent per year; and prevalence data indicate up to 50 percent of male homosexuals may have antibody, which indicates past infection. A large-scale study is just beginning to determine the epidemiology of this disease, and to identify risk factors for acquisition of hepatitis (which may lead to better counseling of patients); in a five-center nationwide trial, a study is beginning to identify a population suitable for field trial of a hepatitis B vaccine. Such a vaccine is being developed and is undergoing testing for toxicity. This vaccine may be available for clinical trial within a year.

During 1979 syphilis control efforts will focus on disease-intervention activities, including case detection, surveillance, and prevention. Case management efforts will be strengthened, to increase the impact of contact referral and epidemiologic procedures. Consultations and technical assistance to State and local health departments will be increased, to improve techniques in diagnosis and clinical care. Health department policies and control program activities will be geared to specific high-risk groups, such as homosexual men, for which specially tailored programs have proved effective. Because the incidence of syphilis in homosexual men has increased, more cost-effective VD casefinding approaches among this population will be sought and efforts to improve contact with the gay community will continue to be emphasized. Screening and educational methodologies will be sought

for this subgroup of the population, and efforts will be extended to improve the relationships with the private medical community that provides venereal disease services to homosexuals.

Gonorrhea screening programs in high-risk populations will focus on post-treatment and periodic rescreening of both men and women; counseling will continue, to encourage patients to refer sexual partners for diagnosis and treatment -- both producures are geared to discover infections and reinfections quicker and thereby more effectively interrupt disease transmission.

The surveillance system established for penicillinase-producing Neisseria gonorrhoeae, which has been successful in containing the spread of this new strain, will be strengthened by intensifying screening efforts, case followup and referral services.

Efforts will continue to be directed towards (1) intensive laboratory monitoring of gonococcal resistance to penicillin, (2) testing strains of gonococci from all possible population sources against a large number of newer antibiotics in an effort to identify other effective therapeutic agents, (3) finding epidemiological information on penicillin-resistant gonococci for more effective control by use of the latest technology in genetical, biochemical, serological, and immunological research on the gonococcus. Some unique nutritional, biochemical, genetical, and immunological properties have been found in penicillin-resistant gonococci isolated from patients in different parts of the world. These findings indicate that there are two or more auxotypes of gonococci associated with penicillin-resistance. These auxotypes differ in their nutritional requirements and serve as potential models in epidemological studies. This surveillance activity not only will continue, but will be expanded to be even more international in scope than before. The genetics of the various beta-lactamase producing strains of N. gonorrhoeae will be investigated to follow up evidence that more than one plasmid (inheritance transfer factor) is involved.

Because persons with a history of repeated infections are considered the core, high-risk population, educational efforts will focus on reducing further reinfection and disease transmission among this population segment. Other educational efforts will be directed toward providers of medical care services at all levels and at the general public, specifically youths.

Program surveillance and evaluation will focus on private physicians' diagnostic, treatment and followup procedures, on education/counseling and on the other sexually transmitted diseases, on determining the impact of existing VD data sets on policy decisions and on developing alternative strategies for data collection, use and analysis.

Emphasis during fiscal year 1979 will focus on establishing, in all project areas, monitoring and contact-referral services for gonococcal pelvic inflammatory disease. Reasearch efforts will emphasize defining additional risk factors, diagnostic techniques, and therapeutic modalities; direct control

efforts will stress preventing transmission of the primary disease, reinfection and relapse.

Training efforts will concentrate on the development of a unified strategy and evaluation schema for education activities directed toward professional and paraprofessional health care providers in the field of sexually transmitted diseases. Efforts will focus on the development and coordination of curricula for undergraduate and postgraduate medical and paramedical practitioners and the implementation of this facet of the overall educational strategy.

Two special training programs will be established, one for physicians and one for nurse-clinicians and other paramedical personnel in venereal disease clinics.

Recognized since the early part of the 20th century, the social aspects of venereal diseases probably have contributed to the spread of these diseases. Therefore, efforts will be pursued to measure the impact of these factors on disease spread, and to develop intervention strategies based on these behavioral aspects of disease control.

Because of their increasing national significance, sexually transmitted diseases will be the focus of expanded efforts, comprising a balanced program to develop control methodologies, educational plans, and operational research studies. These not only include continued surveillance to assess the magnitude of the disease problem in both the public and private sectors, but will also include (1) assessing various disease control techniques designed to reduce incidence and prevalence of these diseases; (2) increasing the efficiency of collecting patient data, expediting patient care, and improving the collection of epidemiologic information, and (3) performing selected studies on the biologic and epidemiologic aspects of these diseases.

NATIONAL INSTITUTES OF HEALTH

National Institute of Allergy and Infectious Diseases

VENEREAL DISEASES

The public health problem posed by sexually transmitted diseases (STD) has increased enormously in the last 15 to 20 years. Although the magnitude of the problem is well known, the fundamental information needed to solve it is still deficient. Since 1971, the National Institute of Allergy and Infectious Diseases (NIAID) has been expanding its basic and applied research program to try to supply this information and to help bring these diseases under control.

Currently, NIAID supports 52 established venereal disease investigators as well as a number of post-doctoral Fellows in training. Four contractors and a small group of intramural scientists are also working on specialized problems in sexually transmitted diseases.

Three program project grants are encouraging a broad range of multidisciplinary studies at the University of Washington in Seattle, Baylor College of Medicine in Houston, and Cornell University in New York.

Gonorrhea

Gonorrhea continues to be the most common sexually transmitted disease -- in fact, the most commonly reported bacterial infection. It is caused by a bacterium, Neisseria gonorrhoeae or gonococcus. This organism typically infects the mucous lining of the genital and urinary tracts. In men, this results in a purulent (pus-producing) infection of the urethra, the canal carrying urine to the outside of the body from the bladder. In women, the organism usually infects the urethra and the cervix (the opening of the womb). Physicians are also finding evidence of gonococcal infections in other areas of the body, such as the rectum and throat.

Newborn infants may acquire a purulent infection of the eyes in passage through the infected birth canal of the mother. To prevent this and other eye infections, physicians place silver nitrate solution in the eyes of all infants immediately after birth.

Complications of gonococcal infections include sterility and arthritis. About one percent of all patients develop blood-borne infection that can involve the brain and other organs in the body. Dr. David Drutz of the University of Texas has recently developed a method for producing systemic gonococcal infection in rabbits, thus providing an animal model for studying this rare but serious form of gonorrhea.

Early symptoms of gonorrhea usually appear within two to eight days after exposure by sexual contact. However, many persons may have no apparent symptoms of the disease until much later. These symptom-free infections may be a factor in the current uncontrolled spread of this disease.

The gonococcus has been recognized for almost 100 years, but it is still a puzzle in many respects. NIAID-supported scientists are trying to answer the many questions that remain about how the organism grows, affects its hosts, and develops resistance to antibiotics. This latter problem is particularly crucial in the light of the new highly resistant strains currently being seen.

Treatment

Although penicillin has been used for many years as a relatively inexpensive and effective treatment, significantly higher doses have been required because of increasing drug resistance. In March 1976 a strain of gonococcus totally resistant to penicillin was identified in this country. Since then, more than 275 cases have been reported.

This new strain produces the enzyme beta-lactamase (penicillinase), which destroys penicillin and related antibiotics. Several NIAID-supported scientists have reported that these gonococci have plasmids (units of DNA that exist outside the cell's chromosomes) that carry the genetic information for penicillinase formation. Dr. Arthur K. Saz of Georgetown University observed that although these plasmids, called R plasmids, are readily transferable to other gonococci, the recipient cells apparently lose these plasmids extremely rapidly and thus revert to their original sensitivity. This could explain the relatively slow spread of this new type of gonorrhea.

Dr. P.F. Sparling and his colleagues at the University of North Carolina and Drs. Marilyn Roberts and Stanley Falkow of the University of Washington conducted separate studies on how the R plasmid transfer takes place. Both groups of investigators showed that the transfer of the R plasmid occurred through the process of conjugation -- the transfer of genetic material as a result of cellular contact between sexually differentiated bacteria. Conjugation does not ordinarily occur in gonococci. However, both groups of investigators noted the presence of a second plasmid in the donor gonococci that presumably had "sex factor" activity and permitted conjugation to occur.

The presence of sex factor activity in the gonococcus has serious clinical and epidemiological implications. It increases the probability that more strains of gonococci will acquire genes for resistance to penicillin and other drugs, and it also increases the likelihood of

transfer of the R plasmid to close relatives of the gonococcus, such as the meningococcus.

Rapid diagnosis and treatment would help prevent the spread of these resistant gonococci. Drs. Robert P. Williams and Alice Weissfeld, Baylor University, have recently devised a technique whereby even single colonies of penicillinase-producing gonococci can be detected within 24 hours, instead of the two or three days now required by tests presently in use. The procedure is simple and can be done routinely by hospitals and clinics.

In a study of alternative treatments for gonorrhea, Dr. King K. Holmes of the USPHS Hosiptal in Seattle evaluated the use of spectinomycin and tetracycline as alternatives to penicillin. He concluded that both drugs are equally acceptable alternatives although each has distinct advantages and disadvantages. Gonococci are capable of developing resistance to both antibiotics as well as to penicillin. Spectinomycin is indicated for penicillin resistant and penicillinase-producing strains of gonococci. However, it is not effective against other organisms (such as Chlamydia trachomatis) that are sometimes present.

Vaccine Development

Emergence of the penicillinase-producing gonococcus underscores the necessity for continuing basic research in order to develop preventive measures, such as a vaccine. Indications are that one reason infected persons are not immune to a second infection is that there are many antigenically different strains (serotypes) of gonococci.

In exploring this phenomenon Dr. Holmes and his colleagues have developed a reproducible immunologic classification of gonococcal strains using a technique called micro-immunofluorescence. The Seattle scientists were able to group 175 of 180 gonococcal strains into 3 immunotypes and numerous subtypes. They also discovered that gonococcal strains associated with disseminated infections belong to a single immunotype.

Although a great deal remains to be learned about the different serotypes before a vaccine is possible, progress is being made. One very important step necessary for vaccine development was accomplished recently by Dr. Thomas Buchanan of the USPHS Hospital in Seattle. He isolated certain proteins of the gonococcus from the toxic lipopolysaccharide parts of the organism. When used as a vaccine in animals, the isolated pure protein produces antibodies that can kill the organism. He is now ready to test the safety and immunogenicity (ability to stimulate antibodies) in humans. This is perhaps the most promising candidate for a vaccine yet reported.

Syphilis

Syphilis is caused by Treponema pallidum, a spiral-shaped, very mobile bacterium known as a spirochete. Like gonorrhea, syphilis is acquired through sexual intercourse with a person who is in the infectious stage. Syphilis may also be acquired by an unborn child from an infected mother.

Syphilis occurs in several stages. In the primary stage, a small sore (or chancre) may appear 10 to 90 days after exposure. The chancre will disappear without treatment, but a rash may develop three to six weeks later during the secondary stage. Like the chancre, the rash will disappear without treatment, but meanwhile the spirochetes will have begun to invade any of several organs in the body.

If untreated, syphilis remains infectious through a stage known as early latent syphilis, for about two years from the time of initial infection. In this early latent stage, the organisms begin their destructive attack on the heart, brain, spinal cord, or other organs. Untreated syphilis can cause mental illness, blindness, heart disease, and death.

Biology of Spirochetes. A principal hindrance to research on T. pallidum is the inability of scientists to grow this bacterium outside of man -- the only animal that naturally acquires syphilis. Although discovered more than 70 years ago, the organism cannot yet be grown successfully in the laboratory.

For many years, T. pallidum was considered anaerobic, that is, living and growing only in the absence of oxygen. However, Dr. C.D. Cox of the University of Massachusettes has now verified his earlier studies showing that virulent T. pallidum is capable of using oxygen for respiration. These findings provide a new basis and approach for current experiments designed to cultivate the organism in vitro.

Dr. Joel Baseman, at the University of North Carolina, has developed techniques that enable him to characterize the protein-synthesizing capability of T. pallidum for several days after it has been freshly extracted from rabbit tissue. His results on the growth potential of the organism may provide ways to monitor improved environmental conditions for growth and subsequent in vitro cultivation.

Immunity and Vaccine Development. An understanding of the mechanisms of immunity -- the ways in which the host protects itself against invading microorganisms -- is a necessary base for the development of preventive measures such as a vaccine. However, the role of

immunity in syphilis is still unclear. Several investigators are using the rabbit as an experimental model in the investigation of these mechanisms.

Dr. Baseman has studied how virulent treponemes attach to host cell surfaces -- the mechanism does not seem to operate with nonvirulent treponemes. Convalescent rabbit sera significantly reduced the attachment to the host cells, suggesting that surface structures in the T. pallidum could be masked or inactivated by host blood components.

Dr. Daniel Musher of Baylor University has demonstrated, in the rabbit, that infection with T. pallidum suppresses the ability of the host to make immunoglobulin G antibody. A striking degree of immunosuppression persisted for 6 to 8 weeks. This may be a key to the failure of humans to control syphilitic infection.

Herpes Simplex Virus Infections

Herpes simplex virus (HSV) type 2 infection is a sexually transmitted disease of increasing prevalence and great concern. Two types of HSV are known -- types 1 and 2. Type 1 infections are commonly found above the waist, as in "fever blisters," and type 2 below the waist, as in genital infections. Although not as serious as gonorrhea or syphilis, genital herpes infections may produce acute, severe pain and temporary disability. Like fever blisters, these genital infections tend to recur.

Some evidence exists that links genital herpes infections to cervical cancer, but this evidence is by no means conclusive. However, it does emphasize the importance of continued research on this viral infection.

In addition, HSV infection of the female genital region may cause disseminated HSV infection of the newborn -- frequently a fatal or crippling disease. Obstetricians, when they diagnose genital herpes in an expectant mother, often make plans for delivering the baby by caesarean section to avoid its exposure to the virus.

Improved methods of diagnosis are being developed. Dr. Raphael Dolin, working at NIAID, has established immune adherence hemagglutination (IAHA) techniques to measure antibodies to HSV. These techniques seem to be more efficient than other methods for distinguishing type 1 from type 2 infections.

Unfortunately, no treatment is yet available for HSV infections. Dr. Charles an NIAID contractor at the University of Alabama, recently reported that the antiviral drug ara-A (adenine arabinoside) is effec-

tive in patients with other types of herpes infections. Preliminary studies by Dr. Dolin using ara-A to treat HSV infections in experimental animals have been promising, and the studies are continuing.

Dr. Michael T. Jarrett of Baylor University has been working on a herpes virus vaccine. Recent studies with animal models have shown that crude vaccines and circulating anti-herpes antibody of a certain class may interact with the cell-mediated system to enhance resistance against herpes simplex virus infection. These vaccines need to be refined and purified before their effectiveness in humans can be evaluated.

Nongonococcal Urethritis (NGU)

In men, NGU is the second most common STD syndrome in the U.S. The symptoms mimic those of early gonorrhea, and differentiation is important since NGU does not usually respond to penicillin.

Chlamydia trachomatis causes about 30 to 50 percent of the cases of NGU, according to NIAID grantees. Dr. Holmes in Seattle reports that another organism, Ureaplasma urealyticum, is also an important cause of NGU. This organism is a mycoplasma, a particular type of bacteria without cell walls.

Dr. Holmes has also reported that the same organisms responsible for urethritis -- N.gonorrhoeae, C. trachomatis, and U. urealyticum -- also cause acute epididymitis in young men. This inflammation of the elongated cordlike structure along the posterior border of the testis is more commonly caused by coliform bacteria in men older than 35 years.

Chlamydial Infections

C. trachomatis agents are now recognized as leading causes of STDs. One type of C. trachomatis causes lymphogranuloma venereum, an uncommon STD in the U.S. Other types cause, in addition to a serious eye infection, urethritis, epididymitis, and prostatitis in men, and cervicitis and salpingitis in women.

Dr. Cho-chou Kuo of the University of Washington has been working on the development of a simple and specific serologic diagnostic test for C. trachomatis. Using a series of immunochemical methods, he has succeeded in purifying a specific antigen from the organism. This antigen has been used for the serologic diagnosis of lymphogranuloma venereum by counterimmunoelectrophoresis. Work is in progress to use this specific antigen in a more sensitive test for the diagnosis of trachoma genital infections. More importantly, the methods he and his colleagues have developed for the purification of the specific antigen can be usefully applied to other bacteria and viruses.

Dr. Almen L. Barron, University of Arkansas, has been identifying the target tissues associated with chlamydial genital infection using the guinea pig model system. Although C. trachomatis is highly specific for human tissue, the chlamydial agent of guinea pig inclusion conjunctivitis (called Gp-ic) produces infection that correlates with human infection. Dr. Barron's studies indicate that particular cells of the cervix, mainly the squamous epithelial cells of the exocervix, seem to be the main target for the chlamydial infection.

Trichomoniasis and Nonspecific Vaginitis (NSV)

Trichomoniasis is a parasitic infection caused by a protozoan, Trichomonas vaginalis. An estimated 2.5 to 3 million Americans each year have this infection, which is most commonly transmitted by direct sexual contact. In humans, this organism infects only the genitourinary tract. In women, T. vaginalis causes vaginal lesions and a discharge. The infection usually produces no symptoms in men. At birth, the newborn may acquire a genitourinary tract infection from an infected mother.

Although trichomoniasis does not, as far as is known, lead to serious complications, it is personally annoying and can confuse the evaluation of a Pap smear, the test for cervical cancer. This parasite can make test cells appear atypical, often resulting in a false-positive test reading.

Dr. Miklos Muller, of the Rockefeller University, is exploring the metabolism and physiology of T. vaginalis. He is also examining the mode of action of the antitrichomonad drugs, metronidazole (Flagyl) and its analogs. Dr. Muller's studies indicate that the selectivity of these drugs against T. vaginalis and other anaerobic protozoa and bacteria depends on certain metabolic processes that occur in the sensitive organisms but not in the aerobic cells of their hosts.

Dr. Holmes and his colleagues at the USPHS Hospital and the University of Washington, Seattle, have found that metronidazole is also effective against nonspecific vaginitis (NSV). This common but mild infection was studied in 18 women. The causative organism was identified in 17 women as Hemophilus vaginalis, a rod-shaped bacteria. Metronidazole eradicated the organism and eliminated symptoms in all cases.

Group B Streptococcal Infections

The study of Group B streptococcal infections of the genital tract is particularly important because this disease is now one of the most common infections affecting newborns in this country.

In an effort to determine the prevalence of genital tract carriage of Group B streptococci (GBS) in pregnant women and the acquisition by their infants, Dr. Lewis Wannamaker of the University of Wisconsin examined women during pregnancy and labor. He found that 8.3 percent of women in labor carried GBS in their genital tracts. Nearly 50 percent of the babies born to these women acquired GBS at birth.

Dr. Carol J. Baker of Baylor College of Medicine has developed an assay that can be used to study purified polysaccharide from particular strains of GBS as part of an effort to develop a vaccine. A vaccine that could be given to mothers would perhaps prevent these serious infections in newborns.

Despite antibiotic treatment, sexually transmitted diseases continue to be important causes of illness and disability in men and women and to affect unborn children. The widespread occurrence of gonorrhea and syphilis underlines the need for a better basic understanding of the organisms causing these diseases. Research such as that supported by NIAID is providing new hope for controlling all these diseases.

National Institute of Child Health and Human Development

The NICHD supports virological, immunological, epidemiological and clinical studies on sexually transmitted infections, with major concern on the effects of these agents on subsequent development. The objective of this research is to determine the public health significance of these infections in pregnant women, with special emphasis on sexually active adolescents, and in their offspring. There is concern not only for chronic infections, but also for subclinical infections that may ultimately result in significant physiological and/or psychological impairment.

Most of the research is focused on cytomegalovirus, which is being investigated in animal models as well as in human subjects. Research is also concerned with genital mycoplasmas and other microorganisms to determine their roles in the pathogenesis of prematurity, perinatal morbidity, and disorders of reproductive function.

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