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United States General Accounting Office
Washington, DC 20548

RELEASED

Human Resources
Division

B-198957

October 23, 1980

The Honorable H. John Heinz III
United States Senate



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Dear Senator Heinz:

Subject: [Federal Diabetes Activities] (HRD-81-21)

This is in response to your request that we review (Federal efforts to implement the National Diabetes Mellitus Research and Education Act) (Public Law 93-354) and later diabetes legislation. In discussions with you, we agreed to concentrate on reviewing diabetes programs of two organizations of the Department of Health and Human Services (HHS): 1/ the National Institutes of Health (NIH) and the Center for Disease Control (CDC). We also agreed to look at mechanisms to coordinate the various Federal and non-Federal efforts to overcome diabetes and the extent to which health insurance plans cover certain services provided to diabetics.

On June 19, 1980, we briefed your office on the status of Federal diabetes efforts. The information we presented was an elaboration of the items discussed in our June 4, 1979, interim report to you (HRD-79-90). Your office asked that we report to you the results of our work as presented during the briefing.

Accordingly, the enclosures contain information on:

- The objective, scope, and methodology of our review (enc. I).
- Biomedical research involving diabetes, including a description of diabetes and its impact, the Federal response to the need for diabetes research, NIH efforts to solve data collection problems, and recent research advances (enc. II).

1/On May 4, 1980, a separate Department of Education commenced operating. Before that date, activities discussed in this report were the responsibility of the Department of Health, Education, and Welfare.



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- Diabetes control efforts, including a definition of diabetes control and a description of how CDC's efforts in diabetes control began, the progress of CDC's control efforts, CDC's future plans in diabetes control, and efforts to obtain support from health insurers and others for CDC-sponsored patient education courses in diabetes control (enc. III).
- Federal coordination efforts to overcome diabetes, including the efforts of the various Federal and private organizations and the need to coordinate their activities (enc. IV).

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As agreed with your office, we did not obtain written comments from HHS. We did, however, discuss the contents with NIH and CDC officials.

If you or your staff have any questions about the enclosed information, we are available to discuss it with you further. As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report for 30 days. At that time, we will send copies to interested parties and make copies available to others upon request.

Sincerely yours,

Edward A. Mansmore

for Gregory J. Ahart
Director

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ABBREVIATIONS

CDC	Center for Disease Control
HHS	Department of Health and Human Services
HSA	Health Services Administration
NIAMDD	National Institute of Arthritis, Metabolism and Digestive Diseases
NIH	National Institutes of Health

OBJECTIVE, SCOPE, AND METHODOLOGY

The objective of our review was to assess Federal efforts to implement the National Diabetes Mellitus Research and Education Act. We made our review during 1979 and 1980 at National Institutes of Health (NIH) headquarters in Bethesda, Maryland; at Center for Disease Control (CDC) headquarters in Atlanta, Georgia; at 3 of the 8 NIH-supported diabetes research and training centers; and at locations of 6 of the 12 CDC-supported diabetes control demonstration projects.

We performed review work in seven States--Georgia, Illinois, Maine, Massachusetts, Michigan, Nebraska, and New York. These States were selected for the following reasons:

- Michigan and Illinois both have an NIH-supported diabetes research and training center and a CDC-supported diabetes control demonstration project, and we wanted to obtain information on coordination of the two operations.
- According to CDC officials, Nebraska and Maine both offer examples of the most advanced diabetes control demonstration projects.
- The diabetes control demonstration project in New York has reported advances in seeking support from health insurers, and we wanted to obtain more information on these advances.
- The diabetes research and training center in Massachusetts is operated by the Joslin Foundation, a pioneer in researching diabetes, providing diabetes training to medical personnel, and delivering health care services to diabetics.
- The diabetes control demonstration project in Georgia provided geographic balance to our review.

We analyzed the National Diabetes Mellitus Research and Education Act and other diabetes legislation. We reviewed the National Commission on Diabetes' Long-Range Plan to Combat Diabetes and action by the National Diabetes Advisory Board and Federal agencies to assure that recommendations in the plan are properly implemented. We also analyzed annual reports by the Board and reports of diabetes activities by the Veterans Administration, the Departments of Agriculture and

Defense, and various Department of Health and Human Services (HHS) organizations. We discussed diabetes research and control with more than 100 Federal and non-Federal personnel involved in research on diabetes and delivery of health care to diabetics, including representatives of the American Association of Diabetes Educators, the American Diabetes Association, and the Juvenile Diabetes Foundation.

We reviewed policies of major health insurers for covering costs incurred by their subscribers who participate in programs to educate diabetics in the use of diabetes control techniques. The Medicare program was selected because it is a federally funded national plan. The Blue Cross and Blue Shield Service Benefit Plan and the Aetna Life Insurance Company Indemnity Benefit Plan were reviewed because they are national plans that cover more than 6.5 million Government workers and their dependents. In addition, because they are major insurers in the States where we performed our review, we reviewed the extent of coverage provided by Blue Cross and Blue Shield plans in the six States where CDC-supported diabetes control demonstration projects are operating. The State Medicaid plans were reviewed because they are partially funded by the Federal Government.

BIOMEDICAL RESEARCH INVOLVING DIABETES

Congressional recognition of the magnitude and severity of the diabetes problem has led to increased Federal emphasis on research since the mid-1970s. NIH has expanded research efforts since that time to include support of regional diabetes research and training centers. To overcome data collection problems that have hampered some research efforts, NIH is working on a system to improve the usefulness of data collected on diabetes and the medical complications it causes. Although no cure appears imminent, promising research advances are being made.

DIABETES AND ITS IMPACT

Diabetes mellitus, commonly called diabetes, is a chronic condition characterized by impairment of the body's production or use of insulin. Normally, the body's digestive juices process sugars and starches (carbohydrates) into a form of sugar called glucose, which circulates in the blood to be burned as needed for energy. Insulin is one of the major regulators of the body's use of glucose. In cases of insulin impairment, excessive glucose accumulates in the blood and tissues and may result in the diabetic experiencing a coma or various other health problems.

There are two main forms of diabetes. Insulin-dependent diabetes often occurs from infancy through young adulthood, although it may occur later. Because the islet cells of the pancreas fail to produce enough insulin, these diabetics usually must take insulin injections once or twice a day for life.

Noninsulin-dependent diabetes often occurs after age 40. The islet cells produce insulin, but it is blocked from affecting appropriate tissues. Noninsulin-dependent diabetes accounts for more than 85 percent of all cases of diabetes, according to estimates by the National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD), an institute of NIH. This type of diabetes is usually associated with obesity, and most of these diabetics can maintain their glucose at relatively normal levels by controlling their weight and adhering to a prescribed diet.

HHS' National Center for Health Statistics estimates that 5 million people in the United States have diabetes, that its incidence is rising, and that it killed more than 30,000 people in 1978, making it one of the country's five

leading causes of death by disease. NIH officials say diabetes is the main reason why U.S. adults go blind (5,000 diabetics become blind each year) and is a major contributor to heart and kidney disease and to problems resulting in amputations of toes, feet, and legs. Officials within HHS gave us an estimate which indicates that the direct cost of medical care for diabetics exceeded \$3.4 billion in 1977 and that there were also substantial indirect costs, such as lost wages due to incapacity caused by diabetes. Because diabetes contributes indirectly to so many medical problems and is sometimes difficult to diagnose, these estimates may be low, according to NIAMDD's Associate Director for Diabetes. For instance, he said that there may be 5 million undiagnosed diabetics in the United States, in addition to the estimated 5 million diagnosed diabetics.

FEDERAL RESPONSE TO THE NEED
FOR DIABETES RESEARCH

In 1921 the discovery of insulin's function made it possible to significantly reduce such readily identifiable complications as diabetic coma. Some doctors believed that all diabetes complications could be eliminated. Insulin injections have helped diabetics live longer, but with their longer life expectancy, it has become increasingly apparent that the rate of medical problems among diabetics is abnormally high.

In 1974, after diabetics and their representatives made the Congress aware of the significant diabetes-associated medical problems occurring nationwide, the National Diabetes Mellitus Research and Education Act was passed. The act provided that the Director of NIH establish a National Commission on Diabetes--composed of Government and non-Government scientists and physicians and members from the public--to prepare a long-range plan to combat the disease. The Commission surveyed the diabetes problem and, in 1975, submitted its plan to the Congress and the Secretary of HHS. The Commission, recognizing that by law it was slated to go out of existence, recommended that the Congress set up an advisory board to implement the plan. The Congress responded in 1976 by adding section 440 to the Public Health Service Act, which requires that the Secretary of HHS establish a National Diabetes Advisory Board.

Under the long-range plan, most Federal diabetes research was to be supported by NIH, with leadership by NIAMDD. Now, after later legislation, all 11 NIH institutes and several

other NIH entities, such as its Division of Research Resources, are involved to some degree in diabetes-related research. NIAMDD, however, spending more than half of every dollar spent by NIH on diabetes, remains the largest source of Federal funds for diabetes research.

The 1974 act requires that the Secretary of HHS establish regional diabetes research and training centers to help develop scientific information and therapies to deal with diabetes. During fiscal years 1977 and 1978, NIAMDD established four centers and expanded the role of four of its six existing research centers to include dissemination of information on diabetes and training of health professionals in the delivery of health care services to diabetics. The eight centers are operated by university hospitals, except for the Joslin Center, which is operated by a private nonprofit foundation.

The 1974 act requires, consistent with applicable recommendations of the National Commission on Diabetes and insofar as practical, that the centers be located on the basis of population density throughout the United States and in environments with proven research capabilities. At present no centers are located south of Nashville or west of St. Louis ^{1/} because, according to NIAMDD's Associate Director for Diabetes, authorities who review grant applications to NIH have not yet identified any center applications from these areas with sufficient scientific merit to warrant funding. In establishing additional centers (a total of 15 are planned), he said NIAMDD will attempt to achieve greater geographic balance. An August 1979 NIH announcement said that funds were available for exploratory grants to establish centers. Although NIH had not received any exploratory grant applications as of September 1980, the chief of the centers program at NIAMDD told us several institutions in the Western United States have expressed interest in developing centers. One of these institutions has submitted an application to become a research center which is pending. The centers program chief said that this institution would be in a good position to become a diabetes research and training center if it first establishes itself as a diabetes research center. She explained that NIAMDD requires an institution to have an established diabetes research program before it can qualify as a diabetes research and training center.

^{1/}Centers are located in Ann Arbor, Boston, Charlottesville, Chicago, Indianapolis, Nashville, New York City, and St. Louis.

The 1974 act also requires the Secretary of HHS to evaluate and annually report to the Congress on the centers' activities. In the first and second annual reports to the Congress, HHS said previous evaluations of center activities were limited because the centers were still relatively new. NIAMDD's Associate Director for Diabetes recognized that the evaluations have not been meaningful because they have been so limited in scope. In visits to the Chicago, Boston, and Ann Arbor centers in April and October 1979, we found all three had established a variety of activities that could be comprehensively evaluated in the near future.

NIAMDD's Associate Director for Diabetes agreed that all the centers have now been in existence long enough to begin meaningful evaluations of their programs. He said that NIAMDD hired a consultant in April 1980 who is to work on developing a comprehensive evaluation plan. Even with this addition, the official said NIAMDD lacks sufficient staff to totally develop and implement such a plan. In October 1980, the centers program chief said that a request for proposals had been issued for a contract to develop a more comprehensive evaluation plan and that proposals are due by December 1, 1980. This plan will be used to determine how well individual centers, and NIAMDD's overall centers program, are meeting legislative and other objectives. The NIAMDD official in charge of the centers program estimated that the plan will take at least 2 years to develop and another year to implement. In the meantime, the official said, NIAMDD will make annual evaluations as comprehensive as staffing levels will allow.

The experience of the National Cancer Institute in evaluating its comprehensive cancer centers could be of value to NIAMDD. This institute used a subcommittee of its National Cancer Advisory Board to review and evaluate 16 centers. In a May 1978 report to the Board, the subcommittee identified 10 evaluation characteristics, including:

- Purpose of the center.
- Management and administration.
- Basic science.
- Training and education.

If some of this methodology could be transferred, and if NIAMDD could make similar use of the National Diabetes Advisory Board, time and money could be saved in developing an evaluation plan. Also, the problem of NIAMDD staff shortages could be reduced. NIAMDD's Associate Director for Diabetes told us that maximum use would be made of the National Cancer Institute's experience.

NIH EFFORTS TO SOLVE
DATA COLLECTION PROBLEMS

The lack of uniformity in defining, classifying, and diagnosing diabetes has led to collecting data that are not comparable and therefore of limited use. Without a recognized standard classification system, it is difficult to measure the impact of diabetes and its complications and to identify those who are at the greatest risk of incurring medical problems from the disease.

To illustrate, the National Center for Health Statistics reports that, in 1977, diabetes death rates per 100,000 population ranged from under 10 in three States (Alaska, Colorado, and Hawaii) to over 18 in five States (Delaware, Indiana, Louisiana, Ohio, and Pennsylvania). In February 1979, NIAMDD's Director told the Senate Committee on Appropriations during hearings that the reason for different State rates could be discrepancies in reporting and classifying individuals as diabetic, or real differences, such as various nutritional factors and environmental and socioeconomic causes. Interpreting statistics on deaths due to diabetes is difficult because physicians often do not list diabetes as an underlying cause of death when such diabetes-associated complications as heart disease or kidney failure are involved.

NIAMDD set up the National Diabetes Data Group in September 1977. Through the Group's effort, NIAMDD sponsored an international workshop in 1978 that developed a standard classification system that seeks to (1) provide a uniform basis for planning and conducting clinical research in diabetes, (2) serve as a framework for collection of epidemiologic data on diabetes and its complications, and (3) help clinicians identify diabetics and those who may develop diabetes. NIH completed its development of a standard classification system in 1979 and is making medical personnel aware of it through publications in professional journals, such as the Journal of the American Medical Association.

RECENT RESEARCH ADVANCES

Reports by the National Diabetes Advisory Board and others indicate that research advances have been made in seven areas since 1975. NIH has supported research in all of these areas, which are listed below.

1. Physicians have long suspected that viruses might cause some types of insulin-dependent diabetes. In 1979, NIH and the National Naval Medical Center reported that a virus isolated from the pancreas of a child with insulin-dependent diabetes, when injected into mice, caused symptoms of diabetes. NIH scientists say that, if a relationship between diabetes and viruses can be established, a preventive vaccine might be developed.
2. Two devices being tested on humans have the potential for eliminating the need to inject insulin into the body one or more times a day, a practice that can cause abnormal fluctuations in the body's insulin supply and may contribute to diabetes-associated complications. The devices can be used to control the flow of insulin into the body so that blood glucose levels are kept within normal ranges. Use of the devices in research may allow scientists to determine whether diabetes-associated medical complications can be reduced by keeping blood glucose levels within these ranges. However, one of the devices, due to its bulk, limits patient mobility, and both devices must be tested further to learn whether they can be used safely on a long-term basis.
3. According to a 1978 report by scientists at the University of Miami and Howard University, strict control of blood glucose levels in pregnant diabetic women significantly decreases infant deaths near the time of birth. This finding has helped reduce the number of infant deaths associated with pregnancies of diabetic women by encouraging them to keep their blood glucose levels within normal ranges.
4. Making synthetic human insulin is expected to be one of the first commercial applications of recombinant deoxyribonucleic acid (DNA) research, according to NIH. Commercial plants were under construction in July 1980, but estimates as to when production would begin were not available. This industry is a spinoff of

research reported in 1978 by scientists at Harvard University and the Joslin Diabetes Foundation. Commercial availability of synthetic human insulin may virtually eliminate allergic reactions sometimes caused by currently available insulin and assure unlimited quantities of insulin at a lower cost, according to NIAMDD's Associate Director for Diabetes.

5. In 1980, a researcher at the Washington University Diabetes Research and Training Center reported that he had developed a way to transplant pancreatic islet cells from rats to diabetic mice without rejection--a problem that has foiled islet cell transplant attempts in humans. NIAMDD's Associate Director for Diabetes said this significant advance provides hope for a cure for insulin-dependent diabetes, but considerably more research will be required before the development can be perfected for use on humans.
6. An NIH scientist recently confirmed in the laboratory a growing belief among diabetes experts that many diabetics' chief problem is not insulin deficiency, but obesity and possibly other factors that impair efficient use of insulin. The scientist said that obese diabetic mice he observed produced enough insulin and their symptoms of diabetes disappeared after they were placed on a diet.
7. Other research has aimed at improving methods of detecting and monitoring blood glucose levels. Current methods often do not conclusively show whether one is diabetic and do not totally assure that the diabetic's blood glucose levels are being controlled. In 1978, a scientist at the Rockefeller University in New York City reported on his studies which suggest that levels of hemoglobin A_{1c}, a component of the red blood cells, are higher in diabetics with greatly elevated blood glucose levels than in nondiabetics, or in diabetics whose blood glucose is maintained at acceptable levels.

DIABETES CONTROL EFFORTS

As part of a planned nationwide effort, CDC operates a diabetes control program which funds demonstration projects in 12 States to determine whether diabetes-related medical complications can be reduced through increased emphasis on education in diabetes control. The program encourages the demonstration project officials to set goals and priorities in the effort to clarify the problems of diabetes, to improve the coordination of public and private resources, and to improve the quality of data collected on deaths and illnesses caused by diabetes. The State projects have developed their own demonstration plans, and some are attempting to demonstrate the effectiveness of diabetes control classes. CDC funds have not been sufficient to cover class costs, and efforts are underway to secure agreements with Federal and private health insurers to cover costs to subscribers who attend the classes.

DEFINITIONS OF DIABETES CONTROL

In the management of public health programs, diabetes control refers to reducing diabetes-associated deaths and illnesses to minimum levels, using existing technology. But on an individual level, diabetes control refers to diabetics maintaining blood glucose levels within a normal range. Effective maintenance requires proper diet, exercise, monitoring of blood and urine glucose levels, and, when necessary, medication. Because no two cases of diabetes are exactly alike, physicians usually prescribe specific control actions. Responsibility for carrying out these actions rests with diabetics and their families. Therefore, the National Commission on Diabetes and other experts in diabetes have said that well-educated patients and families are keys to effective diabetes control.

HOW CDC'S CONTROL EFFORTS BEGAN

The National Commission on Diabetes, in its first report to the Congress in 1975, recommended that HHS implement a diabetes control program under the direction of CDC. Besides improving access to quality education in current control measures, the Commission believed such a program would encourage more rapid dissemination of new research findings and improved methods of health care delivery to diabetics.

The recommended program provided for starting with demonstration projects in diabetes control and expanding to a nationwide effort within 5 years. Ten demonstration projects were to be started the first year, and another 10 were to be added the second year. Contingent upon their effectiveness, projects were to be put in all 50 States during the remaining 3 years.

Demonstration projects were to be implemented in two phases. Phase I, to be completed during the first year, required each project to (1) collect and assess illness, death, and health care resource data, (2) identify populations with major problems in terms of illnesses and deaths associated with diabetes, (3) establish a framework for improving coordination of community resources and communications among those with interests in diabetes, and (4) develop a plan for responding to identified needs of diabetics. Phase II required each project to implement its plans to monitor, coordinate, improve, and--a key element according to CDC officials--evaluate the delivery and outcome of care for diabetics.

As goals, CDC has wanted the demonstration projects to reduce:

- Excess days of hospitalization among diabetics by 50 percent. (Diabetics average 4 more days a year in the hospital than nondiabetics.)
- Lower extremity amputations among diabetics by 10 percent.
- Deaths associated with diabetic coma in juvenile diabetics by 50 percent.
- Infant deaths near the time of birth (which occur 10 times more frequently in diabetic women than in nondiabetic women).

The program began in fiscal year 1977, when CDC announced the availability of funds for diabetes control projects and 29 States responded. In September 1977, after technical and financial reviews of State responses, CDC awarded contracts to 10 State health departments (Colorado, Georgia, Illinois, Maine, Michigan, Mississippi, Nebraska, New York, Rhode Island, and South Carolina). CDC continued to fund existing projects in fiscal year 1978 and awarded contracts to health departments in two more States (Ohio and Washington). Funding of the 12 projects continued during fiscal years 1979 and 1980.

In September 1980, in compliance with recommendations for expansion to eight more States by the National Diabetes Advisory Board and the Congress, CDC expanded its program to State health departments in California, Kentucky, Louisiana, Minnesota, Missouri, New Jersey, Pennsylvania, and Utah.

PROGRESS OF CDC'S EFFORTS

All the initially funded projects have completed Phase I and begun Phase II. As of July 1980, the Ohio and Washington projects were still in Phase I.

We reviewed six of the initially funded projects. All had established advisory boards of in-State diabetes experts, collected historical information on diabetes-associated deaths and illnesses in the project areas, identified possible sources for obtaining similar data in the future, identified existing diabetes education programs, and obtained information on the availability of health care services for diabetics.

Project officials were usually unable to determine (1) the extent of patient education covered in physicians' offices, (2) the quality of services offered by existing diabetic education programs, or (3) the extent to which existing services were being used by diabetics. CDC and project officials said that, because obtaining this kind of information would be too difficult, costly, and time consuming, they decided to use the information they were able to collect, coupled with the informed judgments of their State advisory boards, to develop Phase II plans.

The specific direction of each project varied, but they all sought, through education in control methods, to reduce medical problems caused by diabetes. The projects either promoted establishment of classes in diabetes control or implemented plans involving existing patient education programs in the target areas. All the projects have proposed means by which they hope to measure the effect of their efforts. Some have estimated the dates by which they hope to begin to demonstrate project effectiveness in reducing diabetes-associated medical complications.

CDC and project officials recognize that demonstrating a cause-effect relationship between reported changes in medical problems from diabetes and project efforts will be difficult. For instance, better reporting due to increased awareness of problems caused by diabetes might affect reported changes.

The following summary of demonstration efforts in the States we reviewed shows (1) the kinds of projects implemented, (2) the number of diabetics receiving training through demonstration efforts, and (3) the plans for measuring project effectiveness in reducing medical complications in diabetics.

Georgia

The Georgia project, in September 1979, established a diabetes control education course at one county hospital. By July 1980, 100 diabetics, plus an undetermined number of family members, had attended the course. In September 1980, work was underway with the health department in another county to establish a second course. By fiscal year 1983, project officials plan to begin comparing changes in reported complication rates in the two counties with those of similar counties.

Illinois

The Illinois project, in March 1979, began sponsoring training programs at the Washington University Diabetes Research and Training Center in St. Louis, Missouri, for medical personnel who operate diabetic education programs. By July 1979, 46 medical personnel from 24 hospitals had received this training. By January 1981, project officials plan to begin comparing changes in reported complication rates in these hospitals with those of 26 other hospitals that also operate education programs for diabetics.

Maine

The Maine project began in January 1980 to help establish what now amounts to 39 diabetes control education courses in 23 of the State's 42 hospital service areas. By July 1980, 375 diabetics and 245 family members of diabetics had attended the courses. Project officials plan to monitor reports of hospital admissions of diabetics in all 42 areas and compare admissions trends between areas with and without the courses. They also hope to compare diabetic readmissions and selected diabetes-associated complications. By 1985, project officials hope to begin to demonstrate project effectiveness.

Michigan

To assure that diabetics develop and maintain adequate knowledge about use of diabetes control techniques, the Michigan project in July 1980 began to follow up on diabetics recently discharged from hospitals in the project area after receiving instruction in diabetes control. The project administrator expects that, by January 1981, 130 participants will have been enrolled in the demonstration effort. Project officials plan to compare (1) patients' prior records of complications with complications encountered after becoming participants and (2) medical complications experienced by a group of nonparticipant diabetics with those experienced by the participant group. The project administrator hopes to begin to demonstrate project effectiveness by fiscal year 1983.

Nebraska

Through training courses for medical personnel and expanded use of home health care nurses, the Nebraska project has placed increased emphasis on educating diabetics in the use of available control techniques. One demonstration project in central Nebraska began operating in April 1979; another in southeast Nebraska, in October 1979. By July 1980, training had been provided to 96 diabetics and an undetermined number of family members. Project officials plan to compare data on diabetes-associated complications experienced by diabetic attendees with similar data on diabetics not attending the courses. By fiscal year 1982, officials hope to be able to begin to demonstrate project effectiveness.

New York

The New York project in November 1979 began to help establish diabetes control education courses in four hospitals. By July 1980, 443 diabetics and an undetermined number of family members had attended the courses. Project officials plan to compare data being collected on diabetes-associated complications experienced by diabetic attendees with similar data on diabetics not attending the courses. CDC's public health adviser for diabetes in New York said he cannot yet predict when demonstration of project effectiveness will begin.

CDC'S FUTURE PLANS IN DIABETES CONTROL

CDC plans to analyze the experiences of the 20 State demonstration projects before expanding the program to additional States. Beginning in fiscal year 1982, the National Diabetes Advisory Board has recommended that phased expansions resume at a pace that will permit all 50 States to have received support by fiscal year 1985. CDC officials say the current proposals--which call for an expansion rate slower than was initially planned--are appropriate because resources have been limited and because experience has shown the originally proposed rate was too rapid.

The chief of CDC's diabetes control program says that the effect of past limitations on staffing must be considered in making future plans. The Commission's 1975 plan called for 50 positions for fiscal year 1977, but only 10 were authorized and filled. The authorization was increased to 34 for fiscal year 1979, but, because of an HHS-imposed hiring ceiling, only 20 were filled. The hiring ceiling was lifted in fiscal year 1980. Because the program has not expanded as fast as initially expected, CDC officials believe the additional hiring authority will eliminate the staffing shortages. However, the shortages have caused them to fall behind in compiling and analyzing data on the existing projects, and otherwise consolidating their experience.

The program's chief says the effect of past funding limitations also must be considered in making future plans. He said that, because these limitations have resulted in slower than anticipated program development, the pace of future development needs to be adjusted accordingly. As the following table shows, funding for the program generally has been less than the amounts requested in both the Commission's 1975 plan and CDC annual proposals, but more than amounts requested in the President's Budget.

<u>Source</u>	Funding figures (fiscal year)				
	<u>1977</u>	<u>1978</u>	<u>1979</u>	<u>1980</u>	<u>1981</u>
	----- (millions) -----				
Commission's 1975 plan	\$3.6	\$5.1	\$8.4	\$10.6	\$10.6
CDC's annual proposed budget	0	3.6	5.1	10.8	8.0
President's Budget	0	0	1.5	2.6	5.0
Congressional appropriation	1.5	1.5	2.6	4.6	(a)

a/Pending.

ATTEMPTS TO DEVELOP ALTERNATIVE
SOURCES OF SUPPORT

CDC's diabetes control operation usually has not provided projects with enough support to cover the total costs of operating diabetes control education classes. CDC and project officials see Federal and private health insurers as the most logical sources of this support and are soliciting their cooperation. Insurers usually do not cover the cost of diabetes control education classes, but some have agreed to provide limited coverage for certain projects.

CDC support does not
cover all project costs

The funds CDC provides to some State projects are spent for day-to-day operations, data collection and evaluation efforts, training of health care personnel, and other efforts to start diabetes control education courses. Little is left for operating the courses. Of the six States we reviewed, Nebraska, Maine, and New York have established diabetes control education courses. The Nebraska project's course costs were being covered by CDC, but a project official said the project plans to try, after collecting data on effectiveness of the courses, to get health insurance companies to cover these costs. The Maine and New York course costs were not being covered by CDC. Discussions were continuing among health insurers, project officials, and course officials on who will pay for course costs.

The Maine project provides training to course instructors but no funds for operating the courses. Project officials say funds from CDC are used to pay for project staff salaries, project coordination, and diabetes data collection. Nearly all of the hospitals that operate project-sponsored courses are small--50 beds or fewer. They have little funding of their own for the projects, and a project official said they agreed to begin the courses only after they were assured that the project would promote negotiations for coverage by health insurers. Agreements with some of the hospitals were for three week-long classes only. Although individual communities might want the classes, the project official who encouraged the hospitals to start the classes doubted if the classes would continue very long without outside support, such as health insurance reimbursement.

The New York project provides seed money to participating hospitals to develop and implement patient education courses. Like those in Maine, New York project officials say funds from CDC are used for paying staff salaries and other project operating costs. We visited course officials in Utica, who credit the project with providing \$25,000 in startup costs. Because this money was not enough, the Utica officials obtained additional funding through garage sales and contributions of money, supplies, and equipment. Although they raised enough to begin the project, Utica officials believe that their course will not survive without an outside source of continuous funding.

Health insurance:
A possible funding source

CDC and project officials we contacted believe health insurance plans are the most logical funding source for costs to teach diabetics how to control their blood glucose levels. Health insurance traditionally has been an important source of funds for treatment services provided in the United States, and the National Commission on Diabetes, in its Long-Range Plan to Combat Diabetes, said education of diabetics should be considered treatment.

Health insurance plans usually do not cover services provided by CDC-sponsored diabetes education courses given to outpatients. The plans we reviewed permit hospitals to include the cost of patient education courses in the overall hospital costs used to establish hospital room rates. They also cover charges for certain visits to physicians and permit education in diabetes control during otherwise covered visits. However, they will not provide direct coverage for patient education courses in diabetes control unless health insurance officials specifically approve the courses for reimbursement.

Efforts to obtain health insurance support

Project officials in all of the States we visited said they plan to seek health insurance support for patient education in diabetes control. However, at the time of our review, all of the projects were still in the early stages of their operations, and except for Maine and New York, efforts to obtain health insurance support had been limited to informal preliminary contacts with hospitals and health insurance officials.

Maine project officials have been working with private and Government-funded plans to secure coverage for project-sponsored diabetic patient education classes.

- In 1979, project officials drafted proposed reimbursement guidelines for review by Blue Cross and Blue Shield. The insurers revised the guidelines but, as of September 1980, had not approved coverage to subscribers who attend the classes.
- Project officials proposed to HHS' Health Care Financing Administration regional office for Maine that Medicare, a federally funded health insurance plan, cover costs to teach their diabetic subscribers how to control blood glucose levels. In an August 5, 1980, memorandum, the regional office said coverage would be provided only if classes are incident to physician services.
- Although certain matters still needed to be clarified, Maine's diabetes public health adviser from CDC told us that, during preliminary contacts with Medicaid authorities there, he was told reimbursement agreements could be reached for project-sponsored classes.

The New York project has been notified that several health insurance plans have agreed to cover the diabetes patient education course that it sponsors in Utica.

- Private plans, including some offered by Blue Cross and Blue Shield and Equitable Life, have agreed to cover certain costs to their subscribers for attending the classes.
- In a December 6, 1979, memorandum, the Health Care Financing Administration's New York regional office wrote that Medicare coverage for the Utica course had been approved, and in October 1980, course officials said Medicare had begun to cover the cost of the course.
- In November 1979, the project applied to the State's Medicaid program for coverage of the courses, but a project official said the application was still pending as of September 1980. Also pending were requests for health insurance coverage of the three other project-sponsored courses.

In September 1980, CDC officials told us they were monitoring the extent of Medicare coverage being provided for project-sponsored diabetes education classes. Coverage has been approved under legislation that allows coverage for the cost of services considered medically necessary and incident to physicians' services. If the approved coverage is determined to be inadequate, CDC officials plan to explore the possibility of securing more liberal coverage under legislation, such as section 222 of Public Law 92-603, which allows the Administrator of the Health Care Financing Administration to approve Medicare coverage for demonstration programs not proven to be medically necessary.

The National Diabetes Advisory Board has recently increased its activities to convince health insurers to cover education services provided to diabetics. These activities might help efforts of State project officials and others who are attempting to secure health insurance coverage of patient education courses in diabetes control. In June 1980, the Board sponsored a health care delivery conference in which health insurers were asked to determine what it would take to convince them to cover diabetes control education courses for diabetics. It was concluded that the health insurers needed more information on the efficacy of such education and on costs in relation to benefits, and that standards needed to be developed for trainers and for a patient education curriculum. The Board's executive secretary said that, in developing the information, the Board plans to use CDC-sponsored project data, expected to be available in the spring of 1982 at the earliest.

FEDERAL COORDINATION EFFORTS

The national effort to overcome diabetes involves various Federal and private organizations. The number and complexity of activities carried out by these organizations require concerted coordination to encourage the best resource allocation.

FEDERAL DIABETES CONTROL ACTIVITIES

Organizations both within and outside HHS are involved in diabetes-related activities. Besides NIH and CDC, the following HHS organizations engage in diabetes-focused activities as part of their overall missions:

- The Health Services Administration (HSA) emphasizes integration of service delivery between public and private financing systems. HSA has awarded a grant to the University of Kentucky to support a diabetes education program and, through interagency agreement with NIAMDD and collaboration with CDC, sponsors model diabetes care programs at five health service units operated by its Indian Health Service.
- The National Institute of Mental Health, according to a report to the Director of NIH, conducts several research projects relevant to psychological problems of diabetics.
- The National Center for Health Statistics conducts national surveys that include estimates of the incidence rate of diabetes and the death rate due to diabetes.

Outside HHS, we identified the following Federal agencies that carry on diabetes-related work:

- The Department of Agriculture has reported to the Director of NIH that it supports research with particular relevance to diabetes. For instance, some of the Department's projects involve the effects of various dietary sugars, fibers, and patterns of food intake on glucose tolerance.

- The Department of Defense has reported to the Director of NIH that it sponsors a small number of clinical research projects in diabetes-related areas. These projects relate primarily to patient care and teaching in military medical centers.
- The National Science Foundation supports basic research projects relating to diabetes, including projects to learn more about mechanisms involved in the body's production and use of insulin.
- The Veterans Administration supports research and staff training in diabetes, provides health care to diabetic patients, and operates 1,200 specialized medical units which--as part of dealing with veterans' health care needs--have relevance to the research, education, and treatment of diabetes. The Veterans Administration reported to NIH in fiscal year 1978 that it had 24 studies in progress, some of which included patients with diabetes or conditions affecting diabetes control.

The following table shows fiscal year 1979 funding estimates for diabetes activities provided by various Federal organizations. Of an estimated \$144 million in funding for Federal diabetes activities, more than 90 percent came from NIH.

Estimated Funding During Fiscal Year 1979
of Diabetes Activities by
Federal Organizations (note a)

	<u>Funding</u> (millions)
NIH organizations:	
NIAMDD	\$ 75.1
National Eye Institute	16.5
National Heart, Lung, and Blood Institute	14.5
Division of Research Resources	8.4
National Institute of Child Health and Human Development	7.7
National Institute of Neurological and Communicative Diseases and Stroke	4.3
National Institute of Allergy and Infectious Diseases	2.7
National Institute on Aging	1.8
National Institute of General Medical Sciences	1.3
National Institute of Dental Research	1.1
National Cancer Institute	.3
National Institute of Environmental Health Sciences	<u>.1</u>
	<u>133.8</u>
Other Federal organizations:	
Veterans Administration	4.0
CDC	2.6
National Science Foundation	1.6
HSA	1.0
Department of Agriculture	.9
National Institute of Mental Health	<u>.5</u>
	<u>10.6</u>
Total	<u><u>\$144.4</u></u>

a/The Department of Defense and HHS' Health Resources Admin-
 istration said they support diabetes activities but are
 unable to estimate the amount because their accounting
 systems do not provide a basis for such an estimate.

Although it is apparent that more Federal diabetes funds are spent on biomedical research than on health education and control, we could not identify specific amounts because many of the diabetes-related budgets were not broken down that way. For example, such NIH-supported biomedical research programs as the Diabetes Research and Training Center Program have both research and health education components, but NIH officials could not separate the amount for health education and control from that for biomedical research. Diabetes funding provided by the Department of Agriculture, the Veterans Administration, and the National Science Foundation appeared to be primarily for biomedical research. Officials of such organizations as HHS' Health Resources Administration and HSA told us they probably support education in diabetes control as part of their general health care programs, but said they could not identify these activities. The \$2.6 million provided by CDC was the only amount reported by a Federal organization that we could specifically identify as being primarily for health education and control.

PRIVATE ORGANIZATIONS INVOLVED
IN DIABETES-RELATED ACTIVITIES

Private efforts to overcome diabetes include research and health care delivery personnel in laboratories, private practices, clinics, and hospitals across the country. We could not determine the total extent of the non-Federal efforts, but the National Diabetes Advisory Board's March 26, 1979, report to the Congress lists organizations involved in diabetes-related work. That report indicated that the largest national voluntary organizations devoted entirely to diabetes are the American Diabetes Association and the Juvenile Diabetes Foundation. Also, many other national organizations and their local chapters and affiliates support research programs and provide services to diabetic patients and their families. The report indicated that private organizations that submitted information on their diabetes activities reported spending about \$14 million in 1977 on diabetes research and services to diabetics. Following is the Board's list of major non-Federal organizations involved in diabetes research and services to diabetics:

- American Diabetes Association.
- Juvenile Diabetes Foundation.
- American Association of Diabetes Educators.
- Howard Hughes Medical Institute.
- Joslin Diabetes Foundation, Inc.
- Kroc Foundation.
- National Foundation--March of Dimes.
- American Heart Association.
- National Society to Prevent Blindness.
- Research to Prevent Blindness, Inc.
- Fight for Sight, Inc.

HOW COORDINATION TAKES PLACE

To coordinate Federal efforts to combat diabetes, three groups--the National Diabetes Advisory Board, the Diabetes Mellitus Coordinating Committee, and the Intra-NIH Coordinating Committee--have been established. Coordination also takes place in the system used by NIH to review grant applications and in the operations of CDC's diabetes control demonstration projects.

National Diabetes Advisory Board

The National Diabetes Advisory Board performs coordination activities as part of its legislated responsibility to assure that the National Commission on Diabetes' Long-Range Plan to Combat Diabetes is properly implemented. Title II of the Arthritis, Diabetes, and Digestive Disease Amendments of 1976 (42 U.S.C. 289c) requires the Board to review and evaluate implementation of the plan.

In compliance with title II, the Board is composed of 23 members: 7 with backgrounds in specialties and disciplines involved with diabetes and related endocrine and metabolic diseases, 5 from the public (including 1 person with diabetes and 2 parents of diabetic children), and 11 from Federal organizations. Non-Federal specialists include the president

of the Joslin Diabetes Foundation and six officials of various universities. Members from the public include the founder and former president of the Juvenile Diabetes Foundation, and the former chairman of the board of the American Diabetes Association. Federal members include NIAMDD's Associate Director for Diabetes, the chief of CDC's Diabetes Control Activity, and other officials from organizations within and outside of HHS.

As of April 1980, the Board had issued three annual reports on the efforts of organizations involved in diabetes activities. The first two included sections on diabetes efforts in the Federal and private sectors. The third did not include a section on the private sector because, according to the Board's executive director, most private sector organizations did not submit their material in time to be included. Besides submitting the reports to the Congress and the Secretary of HHS as required by title II, the Board circulates reports to State and local health professionals and to such organizations as the American Diabetes Association and the Juvenile Diabetes Foundation.

Diabetes Mellitus Coordinating Committee

The Diabetes Mellitus Coordinating Committee is responsible for assuring the adequacy and technical soundness of NIH and other Federal diabetes-related health programs. The Diabetes Mellitus Research and Education Act (42 U.S.C. 289c) created the Committee, which first met in February 1975. Committee members include experts in diabetes and representatives of all Federal agencies with diabetes-related activities. It meets four times a year to discuss issues relating to Federal diabetes programs and solicits reports from the agencies on their diabetes activities. The Committee publishes an annual report describing Federal diabetes programs, which is used by the National Diabetes Advisory Board in fulfilling its responsibilities.

The chairman of this Committee--NIAMDD's Associate Director for Diabetes--said that, like the other groups with coordination functions, the Committee has no authority to require Federal agencies to cooperate, but it has nonetheless gained such cooperation. He said the Committee is most effective as a means of getting together those involved to exchange information on the Federal effort to overcome diabetes.

The Intra-NIH Diabetes
Coordinating Committee

Officials at NIH have recognized that the typical NIH approach--in which institutes are divided by organs or disease entities--does not fully meet the need in diabetes research. They have reported that diabetes research requires a unique approach because the disease affects virtually every tissue and organ in the body, thus falling within the scope of many of the institutes. In 1977, the Director of NIH established the Intra-NIH Diabetes Coordinating Committee to augment the activities of the Diabetes Mellitus Coordinating Committee by focusing primarily on items of internal interest to NIH. He made NIAMDD's Associate Director for Diabetes the chairman of the NIH Committee.

The NIH Committee is composed of representatives from nine institutes, two divisions, and the Office of the Director. It meets four or more times a year. Besides coordinating NIH diabetes-related functions, it gives the institutes information for developing the total NIH diabetes budget. It also submits annual reports on progress made in diabetes research during the year to the Director of NIH and to directors of institutes with programs in diabetes-related research.

NIH review of grant applications

Coordination is built into the system at NIH for reviewing grant applications. Application review begins when scientists in the Division of Research Grants assign an incoming application to one of about 55 study sections to be reviewed for originality and scientific merit. Most study sections have 12 to 16 members--authorities in their selected scientific fields. Members serve 4 years, a period officials at NIH say is long enough to assure that grant applications do not unnecessarily duplicate ongoing research projects. The applications are then forwarded to the national advisory council of the appropriate institute. The council consists of about 12 to 18 members. Leaders in fundamental and medical sciences, education, and public affairs, council members are to ensure that the applications have been adequately reviewed for originality and scientific merit and to evaluate the proposed research's relevance to the institute's needs.

Coordination role of the CDC-supported
diabetes control demonstration projects

CDC-supported diabetes control demonstration projects are to seek the coordination and consensus of interested and expert parties throughout the geographic areas covered by the projects. We reviewed project coordination activities in the two States we visited, which had both CDC-supported projects and NIAMDD-supported diabetes research and training centers.

The CDC-supported project in Illinois coordinates with the Washington University center in St. Louis and the University of Chicago center in Chicago. The Washington center helped plan and implement the Illinois project's demonstration effort. During 1980, project officials plan to have the Chicago center conduct and evaluate diabetes education programs for physicians in the project's northern Illinois demonstration target areas. Also, Illinois has a diabetes advisory council, which meets several times a year and has included as representatives officials from the CDC project and the Washington and Chicago centers.

The Michigan project coordinates with the center at the University of Michigan in Ann Arbor. In October 1977, project and center officials decided to collaborate on the project's demonstration plans and agreed that the project would focus on patient education while the center focused on professional education. Between February 1978 and February 1979, center and project officials met eight times to discuss such matters as selection of target areas for conducting CDC-sponsored demonstration projects. Project and center officials are members of the State's Policy Advisory Council for Diabetes Control, which meets four times a year to coordinate interests in diabetes control.

