

**TWENTY-FIRST ANNUAL REPORT OF THE  
DIABETES MELLITUS INTERAGENCY COORDINATING  
COMMITTEE**

**FISCAL YEAR 1994**

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Chairman

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## INTRODUCTION

In accordance with Section 429 of the Public Health Act, the Diabetes Mellitus Interagency Coordinating Committee (DMICC) prepares an annual summary report of its activities as well as other Federal research activities in the field of diabetes. It is submitted to the Secretary, Department of Health and Human Services and the Director of the National Institutes of Health. This is the annual report of the DMICC for Fiscal Year (FY) 1994.

## LEGISLATIVE MANDATE

The DMICC was authorized by Public Law 93-354 and was established in fall 1974. Subsequent legislation modified some of the charges to the Committee. The legislative authority of the Committee is presented in Appendix A. The charge to the DMICC is to coordinate the research activities of the National Institutes of Health and other Federal agencies relating to diabetes mellitus and its complications and to contribute to the adequacy and technical soundness of these activities by providing a forum for communication and exchange of information.

The Committee includes representatives from Federal agencies whose programs are relevant to diabetes mellitus and its complications. The chairman, designated by the Director, National Institutes of Health, is the Director, Division of Diabetes, Endocrinology, and Metabolic Diseases, National Institute of Diabetes and Digestive and Kidney Diseases. In FY 1994, the DMICC membership included representatives of 20 Federal organizations and a liaison representative with the American Diabetes Association (ADA). A roster of Committee members is included as Appendix B.

## ACTIVITIES OF THE DMICC

The DMICC facilitates cooperation, communication, and collaboration among agencies that conduct or support diabetes-related activities. These activities may range from support for biomedical research to direct provision of health care services. The DMICC provides both a forum for initiating interactions and a mechanism for tracking their progress. The DMICC collects fiscal data to document diabetes-related expenditures from each agency. A summary of these expenditures for FY 1994 is presented in Appendix C.

In FY 1994, the DMICC held four meetings and focused its efforts in two specific areas. First, the Committee held several meetings to begin to develop an approach for establishing the National Diabetes Education Program (NDEP) by translating the results of the Diabetes Complications and Control Trial (DCCT) to both the lay public and health professionals. The release of the DCCT results provides a focused message for diabetes patients to control their blood glucose levels. Second, the DMICC cosponsored with the National Diabetes Information Clearinghouse (NDIC) a conference on *Diabetes in Native*

*Americans: The Eastern Tribes*, held in November 1994. The conference addressed issues such as metabolic factors influencing diabetes in Native Americans, the influence of American Indian culture in diabetes, and attitudes and beliefs of Native American patients with diabetes.

The DMICC intends to continue formulating plans for the NDEP as well as pursuing projects that focus on bringing together indepth information from the varied programs represented by the member organizations; being the catalyst for the initiation of projects; and guiding the progress of projects involving several agencies.

## ACTIVITIES OF MEMBER ORGANIZATIONS

In its role as a facilitator in the collection and dissemination of information about Federal activities related to diabetes mellitus, the DMICC is pleased to present the following summary of diabetes-related activities reported by organizations represented on the DMICC.

### **National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)**

The NIDDK is the lead agency of the Federal Government for research efforts to combat diabetes mellitus and its complications. The Institute conducts and supports research and research training related to a broad array of diseases that are characterized by chronicity and long-term disabling effects. The NIDDK's Division of Diabetes, Endocrinology, and Metabolic Diseases has responsibility for extramural programs related to diabetes research. Additional diabetes-related activities are supported by the Institute's divisions of Intramural Research; Digestive Diseases and Nutrition; and Kidney, Urologic, and Hematologic Diseases.

Diabetes is the sixth leading cause of death from disease in the United States. It afflicts an estimated 13 to 14 million people, but approximately one-half of these cases are undiagnosed. It is also the leading cause of new adult blindness, kidney failure, and nontraumatic amputation and is a major risk factor for stroke, heart attack, and premature death. The annual economic cost of diabetes to the Nation is estimated to be \$91-\$105 billion in medical care and lost productivity. In addition, minority populations, including African Americans, Hispanics, Native Americans, Hawaiians, and Alaska Natives, are disproportionately affected by diabetes and by its enormous cost burden.

### Research Accomplishments

The NIDDK supports a wide range of fundamental and clinical studies related to the etiology, pathogenesis, prevention, diagnosis, treatment, and cure of diabetes and its complications. Recent research advances include the following:

Research has uncovered evidence that an environmental factor, coxsackie virus, may be involved in the initiation of insulin-dependent diabetes mellitus (IDDM).

The drug troglitazone has been found to reduce elevated blood glucose and insulin concentrations in diabetic animals and humans and to improve the two conditions that give rise to noninsulin-dependent diabetes mellitus (NIDDM)—impaired glucose tolerance and insulin resistance—and hypertension in obese, but not yet diabetic, individuals.

Research has identified the molecular defect that causes insulin resistance in animals.

A gene was discovered whose overexpression is unique to the skeletal muscle tissue of individuals with NIDDM. Skeletal muscle is the major site of insulin resistance in the diabetic and prediabetic patient. Overexpression of this gene may be responsible for the aberrant regulation of glucose processing that gives rise to NIDDM.

Antibody tests have been developed that can identify individuals at high risk for developing IDDM.

An antihypertensive medication has been found to slow the progression of diabetic kidney disease.

### Program Initiatives

Diabetes Prevention and Treatment Initiative (DPTI): To investigate methods of preventing and treating diabetes, the NIDDK has begun a new, comprehensive initiative targeted at preventing diabetes and its complications. The DPTI encompasses basic and applied research, clinical trials, and national multicenter clinical trials. New strategies for the prevention of diabetes will encompass ethnically diverse and multiracial patient populations. An important element of the DPTI is a national multicenter clinical trial for the prevention of IDDM. The trial will investigate whether intervention prior to clinical onset of IDDM can delay the disease in first-degree relatives of individuals with established IDDM. At-risk individuals will be treated either with low-dose insulin injections or with oral insulin administration. Because IDDM is considered an autoimmune disease, these approaches are anticipated to “immunize” the at-risk individuals against self-destruction of their insulin-secreting pancreas cells. This trial is expected to run 5 years.

A second important element of the DPTI is a clinical trial of intervention strategies to prevent the onset of NIDDM in people with impaired glucose tolerance or gestational diabetes mellitus who are at high risk for developing the disease. NIDDM disproportionately impacts minority populations, who accordingly will make up 50 percent of the study population in order to ensure applicability of the results to these groups. Pharmacologic and lifestyle interventions, such as those targeting diet and exercise, are being evaluated for inclusion in this study. The trial is a collaborative effort

between the NIDDK, the National Institute of Child Health and Human Development, and the NIH Office of Research on Minority Health and is scheduled to last 7 years.

National Diabetes Outreach Program (NDOP): Results announced in 1993 of the NIDDK's landmark DCCT showed that very careful management of blood glucose levels dramatically reduces the risk of life-threatening microvascular complications—eye, kidney, and nerve damage—due to diabetes. Following release of the DCCT results, it was apparent that these findings could have profound implications for the life-long health, and quality of life, for insulin-dependent diabetics. Thus, the NIDDK has initiated efforts designed to disseminate, evaluate, and investigate these results. Early in FY 1995, the Institute launched the NDOP to help disseminate the results of the DCCT to patients, health care professionals, and the general public regarding the importance of controlling blood sugar levels. The Institute's Division of Diabetes, Endocrinology, and Metabolic Diseases and National Diabetes Information Clearinghouse are collaborating with voluntary health organizations, the private sector, and other Federal agencies to address the issues surrounding dissemination of the DCCT results to the diabetes community and to people at risk for developing IDDM.

Search for Diabetes Genes: Genetics appears to be the common denominator underlying the various factors that lead to diabetes. Intensified genetics research offers great promise for understanding, controlling, and preventing diabetes. The NIDDK continues to enhance support for both the basic understanding of diabetes and the direct application of this knowledge to the clinic.

Diabetes in Minority Populations: Research has shown that the most prominent risk factors for NIDDM are a family history of diabetes, obesity, insulin resistance, hyperinsulinemia, history of gestational diabetes, and impaired glucose tolerance. African Americans, Hispanics, and Native Americans are disproportionately affected. The U.S. Congress and the Department of Health and Human Services have highlighted the growing problem of diabetes in minority populations as important public health issues deserving increased research effort.

In addition to the DPTI, another component of the NIDDK's diabetes prevention effort in minority populations is the Institute's program initiative entitled "Intervention Studies in Diabetes Among Minority Populations," which will broaden understanding of the cause, course, diagnosis, treatment, cure, and prevention of NIDDM and its complications among African Americans, Asian Americans, Hispanics, and Native Americans as well as Alaska Natives, Pacific Islanders, and Native Hawaiians.

The NIDDK and the NIH Office of Research on Minority Health are collaborating on a clinical study of the development of NIDDM in Mexican-American women. The aim of the study is to identify early metabolic defects in Mexican-American women who are at high risk for NIDDM because of prior NIDDM associated with pregnancy. In future

studies, these early defects may be targeted for interventions aimed at delaying or preventing the onset of NIDDM.

Kidney Disease of Diabetes Mellitus (KDDM): KDDM is the single most frequent cause of end-stage renal disease. Several avenues of research are therefore approaching the problem of how KDDM develops and how it might be arrested before serious kidney damage occurs.

Urologic Complications of Diabetes Mellitus (UDDM): Although the prevalence of UDDM is undetermined, physicians have long recognized that diabetics have a high incidence of urinary incontinence, urinary tract infection, and erectile impotence. Just as diabetes affects the development of these disorders, the disorders can have a significant impact on the metabolic regulation of diabetes and patient compliance with diabetes treatment.

### Future Plans

The NIDDK has developed program initiatives in diabetes where significant scientific opportunities exist. These initiatives include expansion of clinical trials to prevent diabetes, research on the genetics of diabetes, methods for achieving euglycemia in diabetics, expansion of fundamental diabetes research, research on the prevention and treatment of complications from diabetes, and research on the relationship of obesity to diabetes.

### **National Institute on Aging (NIA)**

Recent diabetes-related research support includes the following:

Mechanisms by which glucose intolerance and insulin resistance develop with advancing age, including studies on insulin-responsive glucose transport systems, the role of exercise and diet in reversing aging, and the role of dietary restriction on glucoregulation.

Role of advanced glycosylation endproducts (AGEs) in the pathogenesis of vascular disease in the elderly, including cloning, sequencing, and regulation of expression of AGE-receptor binding unit genes, and the importance of AGE-endothelial cell interactions in promoting development of age and diabetes-related vascular pathologies.

Role of chemical pathways of the Maillard reaction under physiologic conditions as a basis for hyperglycemic-induced aging.

Investigation of reasons for lack of compliance with medical regimens in a rural Native American population with a high incidence of NIDDM.

Importance of glucose abnormalities on memory performance and glucoregulatory hormone levels in the elderly.

Conduct of a retrospective study of NIDDM in the elderly and hospitalization rates as a basis for support that greater demands for health care services will accompany increased longevity as a result of higher levels of age-specific morbidity.

Importance of interplay among aging, sympathetic nervous system function, insulin resistance, and salt sensitivity in contributing to hypertension in the elderly.

Role of insulin as a physiologic regulator of human androgen (adrenal dehydroepiandrosterone) metabolism as a possible mechanism for the atherogenicity of hyperinsulinemia in humans.

### **National Institute of Allergy and Infectious Diseases (NIAID)**

Recent diabetes-related activities include the following:

An RFA issued for research into the basic mechanisms of human immunotherapy trials, including the Diabetes Prevention Trial-1 (DPT-1). This initiative, which is also supported by the NIDDK, the NIAMS, and the ORWH, will use patients already enrolled in clinical trials to investigate the basic mechanisms of autoimmune diseases.

A recently announced RFA, cosponsored with the Juvenile Diabetes Foundation International (JDFI) and the NIDDK, for Interdisciplinary Programs in Autoimmunity to support basic, molecular, immunologic, and genetic research into the pathogenesis of autoimmune disease.

Collaboration with NIDDK and NICHD on the DPT-1.

Funding of four program project grants to study the pathogenesis of autoimmune disease by the combined effort of basic and clinical researchers. Several of these programs have components studying IDDM.

An RFA released in collaboration with NIDDK and JDFI for additional Diabetes Interdisciplinary Research Programs. This request for program project applications is intended to foster an interdisciplinary approach to diabetes research with the application of the most recent advances in basic molecular biology, genetics, cell biology, immunology, and biophysics.

### **National Institute of Child Health and Human Development (NICHD)**

The NICHD funds research on prevention of both IDDM and NIDDM in addition to funding research on behavioral aspects of diabetes mellitus, particularly studies of compliance in adolescents with IDDM. Much of the NICHD research program on diabetes is concerned with research on gestational and neonatal aspects of diabetes mellitus. The Institute supports more than half a dozen diabetes-related research efforts: Insulin-Dependent Diabetes Mellitus (IDDM); In Vitro Expression of the Insulin Gene; Prediction of IDDM (the preeminent accomplishment of this programmatic activity has been to establish that IDDM is an autoimmune disorder with a strong genetic component); Diabetes Prevention Trial (DPT-1); Noninsulin-Dependent Diabetes Primary Prevention Trial; Diabetes in Pregnancy; Studies in Offspring of Diabetic Pregnancy; and Perinatal Studies of Disorders of Fetal Metabolism. In addition, the NICHD currently supports one program project grant and two Perinatal Emphasis Research Centers that are devoted to the study of diabetes mellitus in pregnancy.

### **National Institute of Dental Research (NIDR)**

Recent diabetes-related accomplishments include the following:

The establishment of the National Oral Health Information Clearinghouse to disseminate information to special populations with high risk for oral disease. One such group is diabetics, who have increased incidence and severity of periodontal diseases, mucosal infections, salivary dysfunction, and oral neuropathies including burning mouth syndrome.

The release of an RFA in July 1994, in collaboration with the NIDDK, entitled "Research on Periodontal Complications of Diabetes." One purpose of this initiative is to encourage collaborative research by clinicians and basic scientists to better define the pathogenesis of periodontal diseases associated with both type 1 and type 2 diabetes. Another purpose is to further our understanding of the effects of periodontitis on glucose metabolism in diabetics. The applications are to be reviewed in March 1995.

### **National Eye Institute (NEI)**

In 1994, NEI involvement in diabetes-related activities has been in the areas of basement membrane biochemistry and biology, advances in aldose reductase research, and epidemiology of diabetic retinopathy. NEI's National Eye Health Education Program (NEHEP) has expanded its efforts to reach people at risk for diabetic eye disease. These efforts include the distribution of NEHEP education kits that are directed to individuals who are responsible for educating people at risk for diabetic eye disease. The NEHEP staff also is monitoring the progress of three applied research projects on diabetic eye disease education and providing technical assistance in the development of health education materials.

The ADA and the NEI are jointly conducting an awareness campaign on diabetic eye disease for National Diabetes Month. Nine other NEHEP partnership organizations have

offered their support to increase the public's awareness about the importance of annual dilated eye examinations for diabetics and will coordinate local activities. An extensive media campaign that included a video news release, press release, print advertisements, and a radio program targeted to radio stations with a predominantly African American audience was conducted to augment local efforts.

### **National Institute of General Medical Sciences (NIGMS)**

In addition to other activities, the NIGMS supports a significant genetic resource, the Human Genetic Mutant Cell Repository. The repository contains cell lines from normal controls as well as from patients with a wide variety of genetic disorders such as those from individuals with various types of diabetes, including IDDM and diabetes mellitus and insipidus with optic atrophy. In 1994, the repository provided researchers at universities throughout the United States with cell cultures from patients with IDMM, maturity onset diabetes in the young, diabetes mellitus and insipidus with optic atrophy, and diabetes mellitus of the Pima Indians.

Among the diabetes-related research projects supported by the NIGMS are studies of the regulation of insulin gene expression; the transport of proteins, including insulin, within the cell; protein secretion by the cell; the structure and function of receptors for insulin and other proteins; basic metabolic processes at the cellular and molecular levels; and the effect of severe trauma and disease on glucose metabolism and insulin resistance.

### **National Heart, Lung, and Blood Institute (NHLBI)**

In 1994, the NHLBI funded numerous studies that investigate issues relevant to diabetes: "Insulin, Androgen and Risk in African-American Women"; "Mechanism of Reduced Endothelium-Dependent Relaxation Diabetic Blood Vessels"; "High Blood Sugar Potentiates the Constrictor Effects of Protein Kinase C in Arteries"; "Adhesion Molecules and Atheroma in Rabbits"; "Genetics of Diabetes"; "Effect of Diabetes on Short- and Long-Term Mortality of Acute Myocardial Infarction"; "High Glucose Reduces Basic Fibroblast Growth Factor-Induced In Vitro Angiogenesis: Implications for Vascular Impairment in Diabetes Mellitus"; "Acculturation and Diabetes"; "Abdominal Fat Is a Strong Risk Factor for Abdominal Diabetes"; and "Distribution of Insulin Sensitivity in Three Ethnic Groups."

### **National Institute of Neurological Disorders and Stroke (NINDS)**

The NINDS is responsible for the conduct and support of diabetes-related research that investigates the complications of diabetes in the peripheral and central nervous systems. NINDS-supported diabetes-related research conducted in 1994 included the following studies: "Epidemiology of Diabetic Neuropathy"; "Diagnosis of Diabetic Neuropathy"; "Pathogenesis of Diabetic Neuropathy"; "Diabetes as a Stroke Risk Factor"; "Neural Mechanisms of Peripheral Pain in Diabetes"; and "Treatment of Diabetic Neuropathy."

## **National Institute of Nursing Research (NINR)**

NINR's research interests in diabetes concern factors related to prevention and control. The following studies reflect grants in their 1994 portfolio:

Attention to the link between biological and behavioral factors is critical in order to deal with clinical problems experienced by diabetic patients having kidney transplants. NINR investigators are determining these biobehavioral factors responsible for improved quality of life following pancreas-kidney and kidney-only transplant.

A two-phased longitudinal study is examining parent and family system adaptation to the care of a chronically ill child, using a family stress and coping framework. In the second phase, comparisons will be made between 90 families who have a child with diabetes mellitus and 90 families who have a child with congenital heart disease.

A pilot study of a low-impact exercise intervention for women with NIDDM is being supported within an exploratory center's grant targeted to studies of fatigue management. This study examines the effect of exercise on fatigue, activity levels, and metabolic control in these women.

A longitudinal, randomized study is comparing a patient-centered education/support intervention among community-residing elderly black diabetics with a family-centered intervention.

## **National Center for Research Resources (NCRR)**

NCRR diabetes-related investigations conducted in 1994 included the following: "Decreased Polymorphonuclear Leukocyte (PMN) Deformability in Noninsulin-Dependent Diabetes Mellitus (NIDDM)"; "Improvement in Glucose Tolerance and Insulin Resistance in Obese Subjects Treated with Troglitazone"; "Assessment of Insulin Action and Glucose Effectiveness in Diabetic and Nondiabetic Humans"; "<sup>13</sup>C-Nuclear Magnetic Resonance Spectroscopy of Hepatic Glucose Metabolism in Normal Subjects and Subjects with Insulin-Dependent Diabetes Mellitus (IDDM)"; "Control of Cerebral Vasculature in Diabetic Dogs"; "Caloric Restriction and Aging in Nonhuman Primates"; "Evidence for Superantigen Involvement in the Onset of IDDM"; "D-Chiro-Inositol and Diabetes Mellitus"; and "Role of Sorbitol Dehydrogenase in Mediating Sorbitol Pathway-Linked Vascular Dysfunction Induced by Diabetes."

## **National Center for Human Genome Research (NCHGR)**

The Laboratory of Gene Transfer in the Intramural Research Program of the NCHGR is seeking to locate the genes for a number of different human genetic disorders and to study their function once they have been successfully identified. A new and ambitious effort is

to identify the major loci predisposing an individual to adult-onset diabetes. For this purpose, in 1994, the Intramural Research Program entered into a collaborative project with researchers in Finland to explore the complex genetics of NIDDM. Because NIDDM appears to result from the interaction of one or more genes with environmental factors, the NCHGR is interested in studying it as a model for analyzing the genetics of common diseases. This project includes the participation of patients and researchers in Finland as well as three research centers in the United States, the NCHGR, the University of Southern California, and the University of Michigan.

### **Division of Research Grants (DRG)**

The Metabolism Study Section (MET), a study section within NIH's DRG, reviews most of the applications in the diabetes area. These applications address both type 1 and type 2 diabetes. The contribution of DRG to DMICC activity lies in the pivotal role entrusted to the study section, which is the control of the quality of diabetes research in the areas of

metabolism and endocrinology. The types of applications reviewed are the investigator-initiated grant applications (R01) and the First Awards (R29).

Applications are reviewed by highly qualified scientists from academia and the pharmaceutical industry. After a meeting where experts review the application, a Summary Statement is prepared that includes the scientific comments of the various reviewers and the highlights of the meeting discussion regarding the application as well as addresses the proposed research with regard to potential risk and impact. This information serves to assist the NIDDK in making appropriate research funding decisions and ensures that taxpayer dollars are adequately diverted to the support of diabetes research.

### **Agency for Health Care Policy and Research (AHCPR)**

AHCPR's Medical Treatment Effectiveness Program (MEDTEP) funded the following diabetes-related activities in 1994: a Diabetes Patient Outcomes Research Team; several R01 grants in which diabetes prevention, screening, treatment, or management are addressed; and four AHCPR MEDTEP Research Centers on Minority Populations engaged in diabetes research.

### **Centers for Disease Control and Prevention (CDC)**

In 1994, CDC's Division of Diabetes Translation addressed its congressionally assigned responsibilities as follows:

The Division continued to develop and refine diabetes surveillance at the national and State levels, encouraging the States to utilize the diabetes module of the Behavioral Risk Factor Survey as a primary surveillance tool.

CDC completed qualitative evaluation of *Take Charge of Your Diabetes: A Guide for Care* and *Encarguese de su Diabetes: Una Guia Para su Cuidado*, the English and Spanish versions of a manual designed to assist persons with diabetes to become active members of their own care teams. Also, CDC expanded efforts to implement *Diabetes Today*, a program designed to train health care providers and others in the mobilization of community resources for diabetes prevention and control programs.

CDC completed the pilot phase of project DIRECT (Diabetes Intervention: Reaching and Educating Communities Together), a community intervention demonstration in which important diabetes research findings ready for translation will be put into practice.

CDC's state-based program to reduce the burden of diabetes focuses attention on the changing opportunities and responsibilities of public health agencies in

improving the capacity of the health system to reduce the burden of diabetes. In  
FY 94, CDC

supported diabetes control programs in 42 states and 5 territories through direct headquarters operations, onsite technical assistance, and financial assistance.

In addition to its activities with the DMICC, CDC continued working closely with its Technical Advisory Committee for Diabetes Translation and Control Programs and others to coordinate diabetes translation activities at the national level.

### **National Center for Health Statistics (NCHS)**

The following information reflects recent accomplishments and activities of the NCHS:

Continuous collection of data for diabetes mellitus and other causes of death for both underlying and multiple causes of death and release of these data in various forms, including data tapes and the annual publication *Vital Statistics of the United States*, as well as publication of provisional diabetes mellitus mortality data in the *Monthly Vital Statistics Report*.

Ongoing collection of data in the National Health Care Survey on hospitalizations, ambulatory visits to physicians' offices, ambulatory surgery and visits to emergency and outpatient departments of short stay hospitals for diabetes and its complications, and lengths of stay in nursing homes for persons with diabetes and related conditions.

Ongoing analytic and statistical support to the lead agencies for the Healthy People 2000 objectives in priority area 22—Diabetes and Other Chronic Disabling Conditions.

Continuing data collection in the third National Health and Nutrition Examination Survey (NHANES III), including questions on diabetes, an oral glucose tolerance test, measurements of glycated hemoglobin, insulin and C-peptide, and retinal photography.

Data collection on levels of ability and disability in the National Health Interview Survey for 1994 that includes information on diabetes among both the disabled and the nondisabled population.

Manuscripts published, submitted for publication, or in press include “An Analysis of Increased Diabetes Mortality Rates 1980-1989”; “The Frequency and Determinants of Screening for Diabetes in the U.S., Based on NHIS Data”; and “Sociodemographic Characteristics of Persons with Diabetes” (for *Diabetes in America*).

### **Food and Drug Administration (FDA)**

In March 1994, an FDA advisory committee voted unanimously to recommend that FDA approve metformin for patients with type 2 diabetes who cannot achieve adequate blood sugar control with diet alone. At this meeting, the president of the ADA urged approval of metformin as a safe and effective drug that controls blood glucose by mechanisms different from mechanisms of currently available drugs. Currently approved and marketed antidiabetic drugs work by stimulating the pancreas to secrete more insulin. Metformin increases the body's response to its own insulin. Unlike the other drugs, metformin rarely causes hypoglycemia and generally does not cause weight gain. It may cause temporary anorexia (loss of appetite), abdominal discomfort, or nausea. It can be used together with currently available oral antidiabetic drugs.

Metformin, to be sold under the trade name Glucophage, has been approved in about 80 countries and has never been withdrawn for safety reasons. The manufacturer, Lipo Pharmaceuticals Company, will conduct an educational campaign to inform health professionals and patients about the drug's risks and benefits and appropriate precautions. The company will also conduct a postmarketing study in 10,000 patients to increase knowledge about potential safety problems.

### **Health Resources and Services Administration (HRSA)**

HRSA's Bureau of Primary Health Care's (BPHC) Division of Community and Migrant Health has developed plans to determine the extent of diabetes mellitus in the populations served by Community/Migrant Health Centers. The following are two recent activities involving diabetes mellitus:

The implementation of clinical outcome measures, which include specific assessment of cardiovascular risk factors in relation to diabetes mellitus in the adult life cycle, functional assessment of mobility and cause of impairment, immunization status, and medication assessment in the geriatric life cycle. These measures are important for the identification and treatment of diabetes mellitus.

The use of the Primary Care Effectiveness Review, a site visit tool containing specific questions related to diabetes mellitus. These include protocols and quality assurance items.

Some Community/Migrant Health Centers continue to work with the CDC or Diabetes Training Centers to upgrade their ability to treat diabetes mellitus. Several are currently assessing how to deliver enhanced services and better care to people with diabetes. Programs include the Comprehensive Perinatal Care Program; the Health Care for the Homeless Programs; and the National Hansen's Disease Program (NHDP), which began national distribution of its Lower Extremity Amputation Prevention (LEAP) Program Information Kit to health care providers in December 1993. (LEAP is a simple and effective program designed to identify patients with diabetes who are at risk for developing plantar ulcers, which can lead to foot amputation.) In addition, in collaboration with the NHDP, BPHC has developed a Diabetic Foot Care Program Five-

Year Strategy in prevention, treatment, training, and evaluation to reduce lower extremity amputations associated with diabetes.

HRSA's Division of Organ Transplantation maintains the national Organ Procurement and Transplantation Network and Scientific Registry under contract with the United Network for Organ Sharing. The most common indication for a pancreas transplant is diabetes mellitus. As of December 1, 1994, 222 patients were waiting for a pancreas transplant, and 1,066 patients were waiting for a combined pancreas-kidney transplant.

The Maternal and Child Health Bureau of HRSA is committed to full, appropriate care for diabetes in its maternal and child populations within existing primary care systems. Special emphasis is on developing systems of care at the community level. Diabetes-related activities include the Healthy Start Initiative and ongoing collaborative efforts with States to disseminate, review, and implement programs for diabetes care as stated in the *Public Health Guidelines for Enhancing Diabetes Control Through Maternal and Child Health Programs*.

### **Indian Health Service (IHS)**

Recent IHS diabetes-related activities include the following highlights:

A nursing orientation package for diabetes in American Indians was developed and distributed.

Diabetes prevention posters that address particular complications, which were developed by an Indian artist and extensively field tested, were printed and distributed.

The Diabetes Program worked with NIDDK to develop a Southwest Indian Center to participate in the NIDDK multicenter trial to prevent type 2 Diabetes.

The Assessment of Diabetes Care measured levels of glycemia on the charts of 8,000 people representing 49,000 diabetic patients receiving care in IHS or tribal facilities. Twenty-seven percent of patients experienced glyceemic control approximately comparable to the intensive group of the Diabetes Control and Complications Trial.

### **Veterans Health Administration (VHA)**

Recent diabetes-related accomplishments and activities include the following efforts:

Encouraging formal patient education programs and formal hospital diabetes committees at all VHA Medical Centers, such as the 1-week national training program held for multidisciplinary teams from all 59 unaffiliated Department of

Veterans Affairs Medical Centers and the Continuous Quality Improvement Program for Diabetes Patient Education and Treatment. This program involved 46 medical centers and outpatient clinics in the Northeast and was sponsored in collaboration with the Regional Medical Education Center's 2-day conference/workshop, to provide training for Diabetes Program Coordinators in developing programs that meet NDAB national standards for patient education. Preventing lower extremity complications. These efforts are exemplified by the designation of diabetes-related lower extremity amputation as a key clinical indicator; the establishment of a national policy (based on a directive from the Undersecretary of Health, issued in July 1993) for the formation of multidisciplinary foot care teams under the direction of the Director of the Deputy Chief Medical Director for Rehabilitation and Prosthetics; and an increase in the number of funded podiatry residencies from 79 to 142, as a result of increased congressional appropriations that were earmarked for current podiatric residency programs.

Monitoring quality of care. These efforts include the establishment of quality assurance monitors for the diabetic ketoacidosis; establishment of ancillary laboratory committees to monitor compliance with quality assurance guidelines for glucose monitoring; and analysis of patient-specific ambulatory care use of glycosylated hemoglobin levels.

## **Appendix A**

### **DMICC Legislative Authority**

## **Appendix B**

### **Roster of DMICC Members**

***Diabetes Mellitus Interagency Coordinating Committee***

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**Appendix C**

**Fiscal Year 1994 Expenditures for Diabetes**

Appendix C

**DIABETES-RELATED EXPENDITURES BY AGENCY**

**FISCAL YEAR 1994**

**National Institutes of Health (dollars in thousands)**

National Institute of Diabetes  
and Digestive and Kidney Diseases 191,409  
National Cancer Institute 1,279  
National Heart, Lung, and Blood Institute 19,779  
National Institute of Dental Research 2,505  
National Institute of Neurological Disorders  
and Stroke 5,717  
National Institute of Allergy  
and Infectious Diseases 4,898  
National Institute of General Medical Sciences 1,704  
National Institute of Child Health and  
Human Development 12,329  
National Eye Institute 22,605  
National Institute of Environmental Health Sciences 415  
National Institute on Aging 6,666  
National Institute of Mental Health 2,036  
National Institute on Alcohol Abuse  
and Alcoholism 329  
National Center for Research Resources 18,577  
National Institute for Nursing Research 1,130  
National Center for Human Genome Research 2,181  
Fogarty International Center 56

Total, NIH 293,615

**Other Federal Agencies**

Centers for Disease Control and Prevention 18,410  
Agency for Health Care Policy and Research 1,210  
Indian Health Service 6,883

Total, PHS 26,503

**Total for NIH and PHS 320,118**

*PLEASE NOTE: This table excludes AREA awards.*