FACSIMILE TRANSMISSION

FROM:

The
National Institute of Diabetes and Digestive and Kidney Diseases

National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

FROM:

Name: Lisa Schwartzbach

Office: OHRR, NIDDK

Building: 31 Room: 9A04

Phone: (301) 496-3583 FAX: (301) 496-7422

Date: 7/31/97

Please contact the addressee below for delivery of this communication.

TO:

Name: Sara Hurwitz

Office: Domestic Policy

Institution:

Address:

Phone: FAX: 202-456-5557

Please feel free to contact us if we can be of further assistance

Number of pages in this transmission including this cover sheet: 12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

National Institute of Diabetes and
Digestive and Kidney Diseases
Bethesda, Maryland 20892

July 30, 1997

NOTE TO MS. SARA HURWITZ, WHITE HOUSE DOMESTIC POLICY OFFICE

As you requested on the telephone with Lisa Schwartzbach today, I have attached a brief overview of diabetes research (also sent to Victoria Wachino, OMB, on Friday, 7/25/97). The document describes the National Diabetes Outreach Program (NDOP) and the planning for the National Diabetes Education Program (NDEP) on page 9. The NDOP consists of two campaigns. "Do Your Level Best: Start Controlling Blood Sugar Today" encourages physicians and people with diabetes to adopt a treatment approach that greatly reduces the complications of diabetes. The second campaign, "Feet Can Last A Lifetime," features a cooperation among ten federal and private sector agencies to reduce amputations by informing people with diabetes about daily foot care.

The new NDEP is a collaborative effort led by NIDDK and the Centers for Disease Control with a partnership of private sector diabetes organizations. The program is in the planning phase at present, following a series of meetings with representatives of the diabetes community and other health-oriented organizations.

I hope this information is helpful to you.

Elizabeth H. Singer
Director, Office of Health Research Reports
NIDDK/NIH

Attachment:
Excerpt from NIDDK Program Planning Process:
Diabetes Prevention and Treatment Initiative

cc:
Dr. Varmus

National Institute of Diabetes and Digestive and Kidney Diseases

Diabetes Overview

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), a component of the National Institutes of Health (NIH), leads the national research effort to combat the major public health problem posed by diabetes.

An estimated 16 million Americans have diabetes, a chronic disease that has enormous adverse impact on people who are afflicted, as well as a staggering economic cost to the nation--about $92 billion annually. However, about one-half of these people are unaware that they have diabetes. Serious health complications result from diabetes, including eye, heart, kidney, and nerve damage. Basic research, much of it funded by the NIDDK, underpins many therapies developed for diabetes--insulin pumps, various forms of insulin, and strategies for treating insulin-dependent, or type 1, diabetes; and a host of medications for non-insulin-dependent, or type 2, diabetes. Even with these therapies, however, diabetes remains an exceedingly difficult disease to control. The health complications that result from uncontrolled or poorly controlled diabetes are largely responsible for the toll diabetes takes on human health and on the health care system. Thus, effectively treating and preventing diabetes and its complications are major goals of research.

Type 1 diabetes (also called juvenile-onset diabetes) affects an estimated 500,000 to 750,000 Americans. It is usually diagnosed in childhood or young adulthood. Daily injections of insulin are necessary to sustain life, and compliance with this treatment regimen is often difficult, especially for teenagers. In this form of the disease, the body's immune defense system destroys the insulin-producing cells of the pancreas--an "autoimmune" disease process.

Type 2 diabetes (also called adult-onset diabetes) accounts for about 90 percent of all diabetes. What makes type 2 diabetes so insidious is that it often is diagnosed only after it has wrought years of damage on the heart, blood vessels, kidneys, eyes, and nerves. In addition, as type 2 diabetes develops it becomes increasingly difficult to treat. Therefore, if type 2 diabetes can be prevented, or even significantly delayed, the health and economic implications will be significant. There is growing evidence that type 2 diabetes, which generally appears in middle age, is in fact a preventable disease.

Funding for diabetes research programs within the Public Health Service is estimated to be nearly $340 million in FY 1997. The major portion of this funding is through the National Institutes of Health ($316 million), with the NIDDK contributing the most support ($209 million) to diabetes research. The majority of this funding is used to support basic diabetes research.

Scientific Opportunities in Diabetes Prevention and Treatment

Researchers working in the field of diabetes believe that they are on the threshold of major new discoveries. From this threshold, the prevention and effective treatment of diabetes appear to be not only within their sight but also within their grasp. Sustaining research momentum at this critical point in time is therefore vital to the 16 million Americans with diabetes, and to their families and loved-ones.

Of enormous importance with respect to type 1 diabetes are the impressive results of a major NIDDK multicenter clinical trial that was completed in 1993. The "Diabetes Control and Complications Trial" (DCCT) showed that maintaining blood glucose levels as close to normal as possible throughout the day can prevent and delay the onset of diabetic complications. Intensive therapy reduced the risks of eye disease by 76 percent, of nerve disease by 60 percent, of kidney disease by 50 percent, and of cholesterol elevation by 35 percent. A recent analysis determined that intensive treatment of diabetes is cost effective in improving the quantity and quality of life for persons with type 1 diabetes. In addition, the benefits of carefully controlled blood glucose levels revealed by the DCCT are transferrable to the successful management of type 2 diabetes.

Building on the results of the DCCT, and as an outgrowth of previous diabetes research programs, the NIDDK in 1994 began a new, comprehensive initiative targeted at preventing diabetes and its complications. This multi-faceted initiative, called the Diabetes Prevention and Treatment Initiative, encompasses opportunities in basic and applied research, clinical studies and trials, national multicenter trials, and a national education program.

Fundamental Research on Diabetes: Basic studies on diabetes, which comprise the single largest component of NIDDK-supported diabetes research, continue to provide the underpinning for clinical methods to diagnose and treat, and for strategies to prevent, diabetes. The support of both intramural and extramural investigator-initiated efforts in all areas of basic diabetes research is of the highest priority. Areas of continued or enhanced scientific opportunity include: the mechanism of insulin action (i.e., insulin receptor, regulation of insulin action, insulin resistance), risk factors for diabetes, immunologic aspects of diabetes, the regulation of glucose metabolism, the cell biology of the insulin producing beta cells of the pancreas, the regulation of insulin synthesis and secretion from the beta cell, the interplay of genetic and environmental factors that results in diabetes, genetic analyses of all aspects of diabetes, and the role of advanced glycosylation end-products and other factors in the development of health complications from diabetes.

Scientific Conference to Identify Opportunities in Diabetes Research: On September 4-5, 1997, the NIH and NIDDK will cosponsor a scientific conference entitled "Diabetes Mellitus: Challenges and Opportunities." Led by invited, internationally-recognized experts in diabetes research, this conference will involve all institutes having a scientific interest in diabetes, and will focus on scientific opportunities and directions that a broad interdisciplinary approach brings to diabetes research.

The Diabetes Prevention Trial-Type 1: In the past few years, investigators have been able to establish immune, metabolic, and genetic screening tests to identify individuals at high risk for developing type 1 diabetes. Researchers also have shown, in animal models and in preliminary human trials, that low-dose insulin therapy may prevent or delay the onset of the clinical manifestation of type 1 diabetes. Thus, scientists have the tools to identify individuals at high risk of type 1 diabetes and to intervene with a safe and, hopefully, effective therapy. These tools are being applied in a major NIDDK-sponsored multi-center clinical trial to prevent or delay the onset of type 1 diabetes, called the Diabetes Prevention Trial-1 (DPT-1). Nondiabetic relatives of persons with type 1 diabetes are being screened for this trial and, of these, 0.6 percent are expected to be found at high risk or intermediate risk for type 1 diabetes. Two protocols are applied to individuals depending on their relative risk for developing type 1 diabetes. Three-hundred forty subjects at high risk will be identified and randomized, either to low-dose daily insulin treatment and yearly courses of intravenous insulin or observation. For four-hundred ninety individuals at intermediate risk for type 1 diabetes, insulin will be administered orally to ascertain if presentation of an islet cell autoantigen, such as insulin, to the immune system via the intestinal mucosa can induce disease-relevant immunological tolerance, thereby delaying the development of type 1 diabetes. Patients will be followed for four years to determine whether either protocol can reduce the risk of developing type 1 diabetes. The trial is expected to run six years and is a collaborative effort between the NIDDK, the National Institute of Allergy and Infectious Diseases, the National Institute of Child Health and Human Development, and the National Center for Research Resources, the Juvenile Diabetes Foundation International and the American Diabetes Association.

The Diabetes Prevention Program Clinical Trial: The Institute's newest clinical trial for diabetes, called the Diabetes Prevention Program, or DPP, is designed to determine whether type 2 diabetes can be prevented or delayed in at-risk populations. Because type 2 diabetes disproportionately affects minority populations, approximately 50 percent of those enrolled in the DPP will be from those populations. Four thousand patients at high risk for developing diabetes (e.g., obesity or history of gestational diabetes) ultimately will be enrolled at 25 sites in the U.S. These patients will have been determined to have impaired

glucose tolerance (IGT), which is a major risk factor for development of type 2 diabetes. IGT is a less severe stage of altered blood glucose control that often precedes type 2 diabetes. Those enrolled in the trial will be randomized into four treatment groups. One of the groups will be given the drug metformin, a second group will be given the drug troglitazone, a third group will receive an intensive diet and exercise intervention, and a fourth will receive healthful lifestyle information about how to prevent diabetes. All of these interventions are aimed at preventing or delaying the progression from the pre-diabetic, IGT state to diabetes, over a period of about four and one-half years. All patients will be counseled on healthful diet and exercise habits, and all will be followed closely for their blood pressure, blood lipids, and diabetes status. We are hopeful that at the conclusion of this trial, in about seven years, we will have definitive evidence on how to prevent type 2 diabetes. Evidence of this kind would have major positive human and economic consequences. The DPP is a collaborative effort between NIDDK, National Institute of Child Health and Human Development, the National Institute on Aging, the NIH Office of Research on Minority Health, the NIH Office of Research on Women's Health, the NIH Office of Behavioral and Social Science Research, the Centers for Disease Control and Prevention, the Indian Health Service. This clinical trial also is receiving major support form the private sector.

Approaches To Achieving Normal Blood Glucose Levels (Euglycemia) in Diabetes: The NIDDK has planned a program to encourage new or improved approaches to achieving euglycemia. Research will be focused on gaining new fundamental knowledge about the growth and development of pancreatic beta (insulin-producing) cells; improved immunologic approaches to beta cell or islet survival in transplantation; improved techniques for isolation, encapsulation, and implantation of beta cells and islets; and bioengineering cells with the properties needed for regulated insulin secretion. Mechanical approaches such as glucose sensors and insulin pumps will also be examined.

Inherent in many of the approaches to achieving euglycemia is the need to produce a self-renewing population of beta cells, which allow for potential treatments for diabetes by replacement of beta cells by transplantation, implantation in an immune-protected site, or by encapsulation in an immune-protective membrane. These potential applications have been hampered by our lack of knowledge of the cell and developmental biology of beta cells. The natural growth and differentiation factors for islet cells have not been fully elucidated. In addition, the isolation of a self-renewing stem cell and identification of markers that can follow the movement and development of the beta cell from the duct cell are critical for our understanding. These markers will also be important in charting the development of other islet cells and in establishing the architecture of the islet. Several factors have been isolated that are beta cell specific. In FY 1998, the NIDDK will conduct a scientific workshop to address the developmental biology of

beta cells, as well as other relevant cell types. After the workshop, a Program Announcement will be issued to encourage research in this important area.

Genetics of Diabetes: Genetics appears to be the common denominator underlying the various factors that lead to diabetes. Intensified genetic research offers great promise for understanding, controlling, and preventing diabetes. There has been a recent surge of data on genetic susceptibility to both type 1 and type 2 diabetes. This has resulted in large part because many more genetic markers now have been identified in the human genome that can serve as guideposts for the identification of potential disease-causing genes. Also, molecular genetic techniques have improved dramatically, so that many such markers can be evaluated much more rapidly than was previously possible. Scientific opportunities that would build on these technical advances include: (1) To encourage the collection of informative families from different populations and ethnic groups. It is important that initial results that suggest linkage or association of regions of the genome with diabetes be extended to, and confirmed in, additional informative families from appropriate populations and ethnic groups; and (2) To promote the identification of genes that convey genetic susceptibility to diabetes. Having identified regions of the genome that confer susceptibility to disease, it is essential to localize the specific genes and characterize the corresponding gene products that are functionally abnormal, thus leading to disease. As genetic mutations are identified, it is likely that investigators will employ transgenic and knockout genetic technologies to create animal models for examining the roles of these genes in the development of diabetes. It may further be possible to develop diagnostic tests that can be used to identify prediabetic individuals; such individuals might then take advantage of appropriate interventions to prevent diabetes.

Metabolic Staging of Type 2 Diabetes: Type 2 diabetes is a multifactorial disease with a significant genetic component, although the specific genes that underlie most cases of type 2 diabetes have remained elusive. The Metabolic Staging opportunity, which would start with a scientific workshop, ultimately would develop strategies for the detailed metabolic analysis of inherited and acquired defects in insulin-regulated carbohydrate metabolism among patients who go on to develop type 2 diabetes. The overall goal is to provide a road map of type 2 diabetes on a metabolic and molecular basis. Examination of differences in the predisposing factors--both environmental and genetic--among different racial and ethnic groups would be a necessary component of this initiative. Establishing the stage of metabolic abnormality should lead to: more precise diagnosis; a basis for rational therapy; an improved ability to monitor response to therapy and disease progression; and improved ability to examine the role and timing of environmental factors as precipitating events for the overt diabetic condition. It should also then be possible to select patients for further detailed metabolic and molecular studies

on a rational basis, and lead to a genetic strategy focussing on fewer rather than more candidate genes.

Obesity and Diabetes -- Basic Research: It is well established that obesity is a major risk factor for type 2 diabetes. In the last two years, major progress has been made in understanding the role of the neuroendocrine system in the control of energy metabolism. Investigators, many funded by the NIDDK, in a diverse array of research areas, have contributed to this explosion of discovery. Investigators in neuroendocrinology, diabetes, cell biology, obesity, mouse genetics, and animal behavior all now are being drawn to common problems of significant clinical relevance. Thus, the NIDDK has identified an opportunity to enhance support for research on the relationship of obesity to type 2 diabetes. The Institute has planned a program that would encourage research to: (1) Identify hormonal and metabolic factors that control fat distribution and the metabolic consequences of differing fat distributions; and (2) Determine whether increased physical activity will improve the metabolic fitness of obese individuals with diabetes with or without weight reduction.

As a first step in this program, the NIDDK is convening a workshop on the brain-fat cell regulatory process in 1997. A goal of this workshop will be the identification of research opportunities and collaborations to accelerate the pace of discovery in this field and promote the rapid application of these discoveries to the treatment of obesity. Thus, the NIDDK proposes to support additional research on the molecular basis of energy balance in 1998 through pilot grants to attract investigators, as well as through funding of novel research in this area.

Obesity and Diabetes -- Health Effects of Intentional Weight Loss Clinical Trial (Preliminary Concept)*:* While short-term weight loss clearly reduces obesity-related risk factors, there are few data available to show that sustained weight loss actually results in reductions in morbidity and mortality. In fact, some observational studies show an increase in morbidity and mortality with weight loss. However, these studies are likely confounded by several factors, including inability to control for illnesses that may cause weight loss and difficulties assessing the intentional nature of such weight loss. Because of the magnitude of obesity as a public health problem, and the need to provide recommendations based on sound scientific data, the NIDDK, National Heart, Lung, and Blood Institute, National Institute on Aging, and the Centers for Disease Control and Prevention convened a workshop in April 1997 to assess the desirability and feasibility of a randomized clinical trial of the health effects of long-term intentional weight loss in obese individuals. The consensus of the participants was that such a clinical trial is crucial to assess the risks and benefits of weight loss in obesity. The study should be conducted in individuals of moderate to severe obesity, who have one or more risk factors for disease, and outcome measures should include one or more "hard

endpoints" to document improved health, rather than solely measuring change in risk factors, such as blood lipid levels.

To address this need, the NIDDK proposes, as a preliminary concept, to assess the health effects of intentional weight loss in a high-risk obese population by studying approximately 3,000 women who have been newly discovered to have type 2 diabetes during the screening for the Institute's Diabetes Prevention Program clinical trial. These women would be randomized to usual care, medication alone, or medication plus an intensive behavioral treatment program for three to five years. The hypothesis is that, among those women with non-fasting hyperglycemia (high blood sugar), progression to fasting hyperglycemia will be significantly reduced in the treatment groups, with the most robust benefit in the combined treatment group. Of those who initially present with fasting hyperglycemia, we hypothesize that those in the treatment groups will be more likely to revert to impaired glucose tolerance or to the level of normal blood glucose than those in usual care, and of those on medication, the treatment groups will be significantly more likely to reduce their usage of hypoglycemic medications (medications to bring down high blood glucose levels). Global measures, such as quality of life, would also be assessed. This is a unique opportunity to achieve significant cost savings in the planning and conduct of a trial on the health consequences of intentional weight loss by enrolling a population already screened for the DPP and making use of existing sites and mechanisms. This is a preliminary concept for a major clinical trial requiring substantial resources that would have to be conducted concomitantly with the ongoing DPP.

Comparison of Intensive and Standard Control of Glycemia in Type 2 Diabetes: Over the past decade, a clinical trial comparing intensive and standard control of glycemia in type 2 diabetes has been proceeding in the United Kingdom. At its conclusion, this trial will provide important information on the risks and benefits of intensive management of type 2 diabetes using a variety of approaches to achieve near normal glucose levels. The DCCT clearly demonstrated the benefits of improved glycemic control in reducing microvascular complications in people with type 1 diabetes. Since there are common mechanisms of development of microvascular (eye, nerve, and kidney) complications in type 2 diabetes and type 1 diabetes, reduced microvascular complications would be anticipated with improved glycemic control in type 2 diabetes as well. Thus the NIDDK has no plans to undertake a complementary study in the type 2 diabetes population. However, there may be significant differences in the pathogenesis of the macrovascular complications (cardiovascular disease and stroke) of type 2 diabetes and type 1 diabetes, due in part to the contribution of the insulin resistance characteristic of type 2 diabetes, making extrapolations regarding macrovascular disease more controversial. Moreover, at the conclusion of the DCCT, subjects had not yet reached the age at which macrovascular complications occur with sufficient

frequency to allow assessment of the effectiveness of intensive blood glucose control in reducing macrovascular complications. Coronary artery disease, stroke, and other macrovascular complications are substantially increased in type 2 diabetes and are a major source of morbidity and mortality. Thus the ongoing United Kingdom trial has important public health implications for the 16 million people in the U.S. with type 2 diabetes. Fiscal constraints in the U.K. have threatened the continuation of this study and a modest contribution from the U.S. would allow its successful completion over the next two years.

Therapy of Coronary Artery Disease in Type 2 Diabetes: The NIDDK proposes to cofund, at a modest level, a clinical trial in people with type 2 diabetes and coronary artery disease (CAD), which is being initiated by the National Heart, Lung, and Blood Institute (NHLBI). This trial would compare early and late angioplasty and standard and intensive blood glucose control in subjects with both type 2 diabetes and coronary artery disease. This study is highly relevant to the mission of both the NIDDK and NHLBI and the study could benefit from the involvement of Institute staff with complementary expertise. The NIDDK believes that cofunding by NIH institutes and offices of ongoing multi center trials initiated by NIDDK to be important not only because of the increased resources they provide, but also because of the involvement of staff who contribute expertise to the study group. A similar model would be beneficial for the NHLBI trial the NIDDK proposes to cofund.

Role of Glycemic Control in Preventing Cardiovascular Disease: Observational studies have shown a strong association between blood glucose control and cardiovascular disease morbidity and mortality. Clinical trials have shown a trend towards reduced cardiovascular disease (CVD) in those under intensive treatment, but these effects were not statistically significant. Thus, the role of intensive blood glucose control for prevention of macrovascular disease remains to be defined; a clinical trial is needed to address this issue. A trial of intensive blood glucose control in those with high grade proteinuria (too much protein in the urine), who account for most if not all of the increase in cardiovascular disease risk, would answer this important question. In addition, such a trial would define the role of intensive treatment in the prevention of kidney failure in those with kidney disease. The results of the trial would have the greatest impact on women's health, since CVD risk in women with diabetes is equal to or higher than men; women bear the brunt of the increased CVD risk from diabetes. In addition, this trial would have special significance for certain populations, such as Native Americans, where diabetes with proteinuria is the predominant risk factor for CVD. The trial would be the basis of ancillary studies of disease mechanisms, including the genetics. This major effort is proposed to be undertaken during the first decade of the next century.

Epidemiology of Diabetes Intervention and Complications: The Institute is conducting a long-term follow-up study to ascertain clinical microvascular and macrovascular disease endpoints in the DCCT cohort. This cohort of over 1,400 subjects who participated in the DCCT provides a unique population in which to study the development of and risk factors for long-term complications of type 1 diabetes, especially heart disease and clinical kidney disease. The DCCT recruited subjects of relatively young age with short duration of diabetes and focussed on development of early damage to small blood vessels that could be expected to occur within the planned follow-up period of 10 years. This population has now reached an attained age and duration of diabetes at which disease of main blood vessels and overt kidney disease will begin to appear. Further, comprehensive and detailed data collected during the DCCT on microvascular diseases, metabolic control, and risk factors for heart and kidney disease will be available for combination with data collected during the follow-up study.

Diabetes Prevention Studies in Minority Populations: Research has shown that the most prominent risk factors for type 2 diabetes are a family history of diabetes, obesity, insulin resistance, increased insulin production, a history of diabetes in pregnancy, and impaired glucose tolerance. The NIDDK continues to encourage increased research efforts on the disproportionate impact of diabetes in minority populations, including African Americans, Hispanic Americans, Asian and Pacific Islanders, Alaska Natives, and Native Americans and Hawaiians. Addressing the problem of diabetes in minority populations will require deeper knowledge of the causes of the disease in these high risk populations. This program builds on the NIDDKs initiatives for "Diabetes Prevention Studies in Alaska Natives and Native Americans" and "Interventions in Diabetes Among Minority Populations," and will target prevention of diabetes and its complications in other minority populations, including African Americans, Hispanics, and Asian and Pacific Islanders.

National Diabetes Education Program: To facilitate implementation of the DCCT recommendations, the NIDDK initiated a National Diabetes Outreach Program and a media campaign, "Do Your Level Best: Start Controlling Blood Sugar Today." The campaign encourages physicians and people with diabetes to adopt a treatment approach that greatly reduces the complications of diabetes. Most recently, the NIDDK, the Centers for Disease Control and Prevention, and private sector diabetes organizations are collaborating to design a National Diabetes Education Program (NDEP). The program will incorporate research results, specifically those of the DCCT, in public messages about diabetes care. Opportunities exist to expand implementation of the NDEP.

Kidney Disease of Diabetes Mellitus (KDDM): KDDM is the single most frequent cause of end-stage renal disease. The NIDDK is continuing its long-term effort to encourage research in this area. Through Institute- and investigator-initiated studies, several avenues of research are approaching the problem of how KDDM develops and how it might be arrested before serious kidney damage occurs. Scientific needs and opportunities in KDDM research include:

- Basic Research Studies. The NIDDK has developed a plan to encourage and enhance research efforts that would lead to further understanding of the basic mechanisms and/or factors that result in KDDM, the kidney's response to metabolic and hemodynamic injury, and ultimately, the identification and testing of optimal prevention and treatment strategies for KDDM in diabetes.

Clinical Trials:

- *KDDM in Caucasians and Other U.S. Populations.* This program, which represents one of the three arms of the overall KDDM Clinical Trials Initiative, is intended to identify and test possible treatment interventions to prevent progression of KDDM in type 2 diabetes. The other two arms of the program (below), will address the same issue. They will, however, focus only in African Americans and Hispanics with KDDM caused by type 2 diabetes.
- *Kidney Disease in Native Americans: The Zuni Indians Program.* The objective of this program is to characterize the underlying mechanisms and resulting primary renal disease which so commonly affects the Zuni Indians, with the ultimate goal to influence the occurrence as well as the progressive nature of kidney disease in this population.
- *Kidney Disease of Diabetes Mellitus in African Americans and Hispanics.* This program will encourage the study of kidney disease in African and Hispanic Americans. A workshop will help define the spectrum of kidney diseases before end-stage. Subsequent to the workshop, the initiative will focus on investigations in KDDM caused by type 2 diabetes in African and Hispanic Americans. The areas of investigation will include basic and clinical science, epidemiologic, and clinical trials.

July 1997

American Diabetes Association

D.C. Office: 1211 Connecticut Avenue, N.W.; Suite 501
Washington, D.C. 20036

MD Office: 407 Central Avenue
Reisterstown, MD 21136

FAX

Until There's A Cure,

There's The American Diabetes Association

Date: 7/30/97

Number of pages including cover sheet: 8

To: Sarah Hurwitz

Fax phone:

Phone:

CC:

From: Debra

Fax phone: D.C. (202) 331-1402
MD (410) 526-4995

Phone: D.C. (202) 331-8303, ext.____
MD (410) 526-2900, ext.____

REMARKS: ☐ Urgent ☐ For your review ☐ Reply ASAP ☐ Please comment

Per your request.

United Way

NYHA

DIABETES FACTS

PROFILE OF THE DIAGNOSED

There are nearly 14 million people in America who have diabetes. Diabetes is actually a general term for a number of separate but related disorders. These disorders fall into two main categories: type I, which usually occurs during childhood or adolescence, and type II, the most common form of the disease, usually occurring after age 30.

What is type I (insulin-dependent) diabetes?

Type I (insulin-dependent) diabetes is a disease which results from the body's failure to produce insulin -- the hormone that "unlocks" the cells of the body, allowing glucose to enter and fuel them. This is most often the result of an autoimmune process in which the body's immune system attacks and destroys the insulin producing cells of the pancreas. Since glucose cannot enter the cells, it builds up in the blood and the body's cells literally starve to death. People with type I diabetes must take daily insulin injections and regularly monitor blood sugar levels.

- There are an estimated **700,000** people with type I diabetes in the United States today.
- The risk of developing type I diabetes is **higher** than virtually all other severe chronic diseases of childhood.
- **Peak incidence occurs during puberty**, around 10 to 12 years old in girls and 12 to 14 years old in boys.
- The symptoms for type I diabetes can **mimic the flu** in children.
- Type I diabetes tends to run in families. Brothers and sisters of children with insulin-dependent diabetes have about a **10%** chance, or a **20-fold increased risk**, of developing the disease.
- The identical twin of a person with insulin-dependent (type I) diabetes has **at least 50 times** the risk of developing type I diabetes than a child in an unaffected family.
- In type I diabetes, incidence is highest among whites. Scandinavian countries have the highest incidence in the world, approximately 30 cases per 100,000 children.

What is type II (non-insulin-dependent) diabetes?

Type II (non-insulin-dependent) diabetes results from the body's inability to make enough or properly use insulin. Often type II diabetes can be controlled through dieting and exercise alone, but sometimes these are not enough and either oral medications or insulin must be used. The fact that few people with type II diabetes require insulin has led to the myth that this is a "mild" form of the disease.

- Of the nearly 14 million Americans with diabetes, **more than 95%** have type II diabetes.
- People with type II diabetes **often develop the disease after age 30**, but are not aware they have diabetes until treated for one of its serious complications.
- The risk for type II diabetes increases with age. By ages 65 to 74, nearly **17%** of the United States white population, **25%** of African Americans, and more than **33%** of Hispanics have type II diabetes.
- Studies indicate that diabetes is generally under reported on death certificates, particularly in the cases of older persons with multiple chronic conditions such as heart disease and hypertension. Because of this, the toll of diabetes is believed to be **much higher** than officially reported.

What are the complications of diabetes?

With its complications, diabetes is the fourth leading cause of death by disease in the United States. Each year, more than 160,000 people die as a result of diabetes and its complications.

- **Blindness** due to diabetic retinopathy. Each year 15,000 to 39,000 people lose their sight because of diabetes. Diabetes is the leading cause of new blindness in people ages 25-74.
- **Kidney Disease** due to diabetic nephropathy. Ten percent of all people with diabetes develop kidney disease. Diabetic nephropathy is the most common cause of end-stage renal disease, a condition where the patient requires dialysis or a kidney transplant in order to live.
- **Heart Disease and Stroke**. People with diabetes are two to four times more likely to have heart disease (more than 77,000 deaths due to heart disease annually). And, they are five times more likely to suffer a stroke, with more than 1,000 deaths each year.
- **Nerve Damage** due to diabetic neuropathy. Approximately 50% of all those who have diabetes for over 25 years have evidence of nerve damage. This can lead to loss of feeling, muscular weakness, amputation and impotence.
- **Amputations**. Diabetes is the most frequent cause of non-traumatic lower limb amputations. The risk of a leg amputation is 27.7 times greater for a person with diabetes.
- **Impotence** due to diabetic neuropathy or artery blockage. Impotence afflicts more than one third of all men who have diabetes.

DIABETES FACTS

DSH hospital project Elizabeth Cong. Andrews

Diabetes Among African Americans

Today, African Americans compose 12% of the United States population or more than 30 million people.

- It is estimated that more than **2 million** African Americans have diabetes.
- African Americans are **1.6 times more likely to have diabetes.**
- Nearly **6%** of African American men and nearly **8%** of African American women have diabetes.
- African Americans experience **higher rates of at least three of the serious complications of diabetes:** blindness, amputation and end stage renal disease (kidney failure).

Kevin Murin 690-6633

9/93

DIABETES FACTS

479-9590

Diabetes Among Native Americans

Today, there are more than 2 million Native Americans in the United States, a 37% increase from 1980.

- It is estimated that in excess of **47,000 Native Americans** in the United States have diabetes.
- One tribe, the Pimas of Arizona, have the **highest rate of diabetes in the world.** About 50% of Pimas ages 35 years or older have diabetes.
- Today, diabetes has reached **epidemic proportions** among Native Americans. Complications from diabetes are major causes of death and health problems in most Native American populations.
- Early reports by physicians working with Native Americans indicated that diabetes was rare. By the mid-1980's Native Americans were more than **10** times more likely than the general population to develop diabetes.
- The serious complications of diabetes are **increasing** in frequency among Native Americans. Of major concern are increasing rates of kidney failures, amputations, and blindness. More than **60%** of the Arizona Pimas develop diabetes-related kidney disease.

10/93

DIABETES FACTS

Diabetes Among Hispanics

There are more than 22 million Hispanics in the United States, an increase from close to 15 million in 1980. Hispanics are the fastest growing population in the country.

- It is estimated that in excess of **1 million Hispanics** in the United States have diabetes.
- Approximately **one in every 10** Hispanic adults has diabetes.
- Nearly **10%** of both the Cuban American and Mexican American populations have diabetes.
- Approximately **one quarter** of Mexican Americans and Puerto Ricans between the ages of 45-74 have diabetes.
- Nearly **16%** of Cuban Americans between the ages of 45-74 have diabetes.
- Population studies among Hispanic women with diabetes show **significantly higher death and complication rates** during pregnancy.
- Cuban Americans are **one and a half times more likely** than the general population to have diabetes.
- Both Mexican Americans and Puerto Rican Americans are **twice as likely** as the general population to have diabetes.

2/94

DIABETES FACTS

Diabetes in Youth

Children usually develop insulin-dependent (type I) diabetes which requires daily insulin injections and regular monitoring of blood sugar levels.

- There are about **1.7** cases of insulin-dependent (type I) diabetes **per 1,000 people under age 20** in the United States.
- There are more than **123,000 children and teenagers** with diabetes in the United States today.
- The risk of developing insulin-dependent (type I) diabetes is **higher** than virtually all other severe chronic diseases of childhood.
- **About 18 out of every 100,000 people under 20 years of age** will develop diabetes. Peak incidence is around 10 to 12 years old in girls and 12 to 14 years old in boys.
- The symptoms for diabetes can **mimic the flu** in children.
- Insulin-dependent (type I) diabetes tends to run in families. Brothers and sisters of children with insulin-dependent (type I) diabetes have about a **10%** chance, or a **20-fold increased risk**, of developing the disease.
- The identical twin of a person with insulin-dependent (type I) diabetes has **at least 50 times** the risk of developing type I diabetes as a child in an unaffected family.

9/93

DIABETES FACTS

Diabetes in Seniors

Diabetes prevalence appears to increase with age. There are more than 31 million people, aged 65 years or older, in America.

- Of the nearly 14 million Americans with diabetes, **more than 95%** have non-insulin-dependent (type II) diabetes.
- People with non-insulin-dependent (type II) diabetes often develop the disease **after age 30**, but are not aware they have diabetes until treated for one of its serious complications such as heart disease, stroke, blindness, amputation or kidney disease.
- By ages 65 to 74, nearly **17%** of the United States white population, **25%** of African Americans, and more than **33%** of Hispanics have diabetes.
- Studies indicate that diabetes is generally under reported on death certificates, particularly in the cases of older persons with multiple chronic conditions such as heart disease and hypertension. Because of this, the toll of diabetes is believed to be **much higher** than officially reported.

9/93

DIABETES

In 1995, about 16 million people in the United States had diabetes, but only 8 million had been diagnosed with the condition. The number of persons with diagnosed diabetes has increased from 1.6 million in 1958 to 8 million in 1995, representing a fivefold increase. Diabetes is the seventh leading cause of death in the United States, resulting in 400,000 deaths. Each year, 650,000 Americans develop diabetes; each decade 6 million people develop diabetes.

Health Problems caused by diabetes:

In any 24 hour period, 1,800 persons will be diagnosed with diabetes, 150 diabetes–related amputations will occur, 30–65 people will go blind because of diabetes, 55 people with diabetes will experience kidney failure, and more than 1,000 people will die from diabetes or its complications.

* **Blindness**: Diabetes is the main cause for blindness among working aged adults (adults over age 30). Diabetic retinopathy causes between 12,000 to 24,000 new cases of blindness each year.

* **Heart Disease**: Cardiovascular disease is 2 to 4 times more common in people with diabetes and is present in 75% of diabetes–related deaths. Middle–aged people with diabetes have death rates twice as high and heart disease death rates about 2 to 4 times as high as middle–aged people without diabetes.

* **Stroke**: The risk of stroke is 2 to 4 time higher among persons with diabetes.

* **High Blood Pressure**: An estimated 60% to 65% of persons with diabetes have high blood pressure.

* **Kidney Disease**: Diabetes is the leading cause of kidney failure requiring dialysis or transplantations, accounting for 36% of new cases. In 1992, 19,790 new cases occurred, and 56,059 people with diabetes were undergoing dialysis or transplantation treatment. Nearly 20,000 Americans develop end stage renal disease from diabetes each year.

* **Nerve Disease**: About 60% to 70% of people with diabetes have mild to severe forms of diabetic nerve damage (resulting in such symptoms of impaired sensation in the feet or hands, delayed stomach emptying, carpal tunnel syndrome and peripheral neuropathy). Severe forms of diabetic nerve disease are a major contributing cause of lower extremity amputations.

* **Amputations:** More than half of lower limb amputations in the United States occur among persons with diabetes; from 1989 to 1992, the average number of amputations performed each year among persons with diabetes was 54,000.

* **Dental Disease:** Periodontal disease, which can lead to tooth loss, occurs with greater

frequency and severity among persons with diabetes. In one study, 30 percent of IDDM patients age 19 and older had periodontal disease. The rate of tooth loss is 15 times higher, and the incidence of periodontal disease is 2.6 times higher among Pima indians with NIDDM.

* **Pregnancy:** The rate of major congenital malformations in babies born to women with preexisting diabetes varies from 0 to 5 percent among women who receive preconception care to 10 percent among women who do not receive preconception care. Three to five percent of pregnancies among women with diabetes result in death of the newborn; this compares to a rate of 1.5 percent for women who do not have diabetes.

The economic costs of diabetes

* The costs of diabetes are estimated to be as high as $140 billion, comprising approximately 15% of the total US health expenditures. Contributing substantially to these costs are the complications of diabetes. For example, in 1992, the cost of treating kidney failure for 56,000 Americans with diabetes exceeded $2.1 billion. This figure did not include the costs associated with disabilities and premature death.

* In this same year, Medicare expenditures per person with diabetes on kidney dialysis averaged $38,700. Because kidney failure is increasing at an alarming rate, these costs are expected to rise.

* More than 60% of lower extremity amputations that are not related to injury occur among persons with diabetes. Approximately 57,000 diabetes–related amputations were performed in 1993. The direct costs of diabetes related amputations are about $600 million annually.

* Many hidden costs are associated with diabetes. These costs include a failure to recognize the role of diabetes in premature deaths and the unknown costs related to undiagnosed diabetes.

* If only 10% of diabetes could be prevented or cured with gene therapy, then it would produce a savings of $10 billion a year.

The benefits of prevention

* Screening and treatment for eye disease among persons with diabetes is saving the federal government about $248 million annually. If all persons with diabetes received recommended screening and treatment, the annual savings to the federal budget could exceed $470 million.

* Women with preexisting diabetes deliver more than 18,000 babies each year. For every

$1.00 invested in preconception care for these mothers, $1.86 can be saved by preventing birth defects.

* The Diabetes Control and Complications Trial, a national 10–year study that involved 1,441 volunteers with insulin–dependent diabetes, confirmed that good control of blood sugar prevented the onset of delayed the progression of eye, kidney, and nerve damage by at least 50%.

* The ADA has asserted that we could save $6.5 billion if we established diabetes prevention and control programs.

Budget Appropriations

1992: 7 million, 1993 10 million, 1994 18 million, 1995 twenty million, 1996 23 million, 1997 26 million.

Opportunities for Prevention

- Diabetes-related blindness could be prevented in 16,250 people a year – **a 65% reduction**
- 32,400 diabetes-related amputations could be prevented each year – **a 60% reduction**
- Diabetes-related kidney failure could be **reduced by 50%**

Public Health Response to Diabetes

As part of its national strategy, CDC provides resources and technical assistance to state health departments, national organizations, and communities

- to determine the size and nature of diabetes-related problems and why they exist
- to develop and evaluate new strategies for diabetes prevention
- to establish partnerships to prevent diabetes problems
- to increase awareness of diabetes prevention and control opportunities among the public, the health care and business communities, and people with diabetes
- to improve access to quality diabetes care in order to prevent, detect, and treat diabetes complications

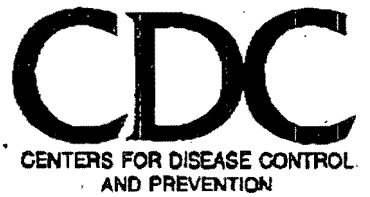
CDC's National Diabetes Control Program

Core capacity-building diabetes control programs	Comprehensive diabetes control programs
Develop initial expertise in diabetes control	Build on expertise in program, science, and policy areas to control and prevent diabetes
Provide a focal point for diabetes control	Coordinate statewide diabetes control and prevention
Establish systems to define the scope of the diabetes problem	Expand systems to define and analyze the scope of the diabetes problem
Identify gaps in diabetes care, for both patient access and quality-of-care issues	Improve access to diabetes care for all people and raise the quality of that care
Develop and evaluate limited intervention projects	Use statewide public health projects to reduce diabetes-related problems
Identify external supporters for diabetes control activities	Inform, educate, and empower external supporters to control and prevent diabetes
Average CDC award to state health departments	**Average CDC award to state health departments**
$232,000	**$800,000**

CDC

"Those who suffer losses due to diabetes are not just statistics on a chart. They are people whose talents and wisdom are needed and whose problems deserve our unified efforts."

-- David Satcher, MD, PhD, Director
Centers for Disease Control and Prevention, 1994



Division of Diabetes Translation

Phone 770-488-5000
Internet http://www.cdc.gov/diabetes

THE NATIONAL DIABETES EDUCATION PROGRAM (NDEP)
A VISION FOR THE FUTURE
(April 4, 1997 Update)

Strong scientific evidence exists today to support aggressive intervention to reduce the medical, social and economic burden of diabetes among all populations especially minority groups who are at higher risk for this debilitating disease. Results of the National Institutes of Health's (NIH) Diabetes Control and Complications Trial (DCCT) clearly showed that persons with insulin dependent diabetes who maintain good control of their blood glucose levels can dramatically reduce their risk for long term medical complications. Other studies suggest that good blood glucose control has similar benefits for persons with non-insulin dependent diabetes and reduces the risk for heart attacks, strokes and peripheral vascular diseases. With so much scientific evidence to support intensified intervention efforts, the question becomes, "What could and should be done to improve the prognosis for all people with diabetes?"

A task force appointed by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) made recommendations in 1994 for translating the DCCT results into widespread practice. These recommendations are contained in the document "Metabolic Control Matters." Based on recommendations of the task force and the National Diabetes Advisory Board, the Centers for Disease Control and Prevention (CDC) and the NIH joined forces in 1995 to provide national leadership to develop and launch a major new initiative, the National Diabetes Education Program (NDEP). Substantial progress was made in planning this program in 1996.

A Steering Committee composed of leading clinical researchers, representatives of national diabetes organizations and federal agencies guides the planning and development of the NDEP. The NDEP provides a framework for the development of effective partnerships at the national, state and community levels to reduce the burden of diabetes as a public health problem especially among those at disproportionate risk including the elderly and minority populations. This program will involve collaboration with other Federal agencies; state health departments; multiple professional, voluntary health, minority, national, academic, and other public sector organizations; as well as the private sector (e.g., managed care organizations, corporations and small businesses, pharmaceutical companies, food and sports industries, national and local media including minority media, and others). The NDEP will be an "umbrella program" to coordinate national efforts to reduce the burden of diabetes.

During 1996, planning meetings with four key constituency groups elicited input on the existing barriers to good diabetes care (including diabetes education) and what a national program such as the NDEP should do. The four groups included:

- primary care providers (e.g., physicians, certified diabetes educators, and dietitians).
- payers and purchasers of health care (e.g., insurance industry, managed care organizations,

employer purchasers, and government health programs.).

- consumers and patient-advocates (e.g., organizations representing and that provide health or social services to target populations such as Latinos African Americans, Native Americans, Asians, and the elderly).

- public health providers (e.g., state and territorial diabetes control programs, public health educators, and public health nutritionists).

Using input from these planning meetings with constituents, a mission statement, goal and objectives for the NDEP have been developed by the Steering Committee. The mission states that, "the NDEP is a collaborative effort to improve the treatment and outcome of people with diabetes, promote early diagnosis, and ultimately, prevent the onset of this disease." Based on existing scientific evidence, the NDEP will focus on the implementation of secondary and tertiary prevention strategies proven effective in preventing or delaying progression of the debilitating and costly medical complications related to diabetes.

Broad target audiences identified for the NDEP include the general public, patients and their families, health professionals, and, policymakers and payers. The goal of the NDEP is, "to reduce the morbidity and mortality of diabetes and its complications." Four objectives for this goal are:

- "To increase public awareness of the seriousness of diabetes, its risk factors, and potential strategies for preventing diabetes and its complications."

- "To improve understanding of diabetes and its control among people with this disease, and promote effective self-management."

- "To improve understanding of diabetes and its control among health professionals, and promote an integrated approach to care."

- "To promote health care policies that improve quality and access to diabetes care."

Presently, a strategic plan is being drafted under the leadership of CDC and NIH with guidance from a formal NDEP planning committee and input from the four planning meetings with constituents. Six guiding principles for design of the NDEP were recommended to the Steering Committee. These principles are that the NDEP should: 1) be a comprehensive, ongoing program directed to multiple audiences; 2) be inclusive and establish broad based partnerships; 3) be flexible to meet diverse population and community needs; 4) identify and promote effective interventions; 5) build on the success of other national programs; and 6) set priorities and target intervention efforts for maximum impact.

The NDEP strategic plan will bring together existing and new prevention, early detection and diabetes control efforts to achieve improved intervention quality, continuity and effectiveness. It

will address priority target audiences and the needs of minority and other special populations; a broad array of prevention and public health strategies, and multi-discipline approaches; targeted educational messages and delivery channels; and suggestions for the full participation of public and private sector partners. The following are examples of intervention strategies that may be included in the NDEP strategic plan:

- conduct of targeted media and community-based diabetes awareness campaigns and education programs;
- dissemination of diabetes research on the efficacy of secondary and tertiary prevention, and information on the benefits of investing in prevention;
- promotion of the use of diabetes care guidelines by physicians and other health care providers;
- involvement of community organizations, lay health workers and family members in diabetes prevention and control programs;
- promotion of public/private sector partnerships at the national, state and community levels;
- promotion of the replication of effective diabetes intervention approaches or programs;
- improvement of the health service delivery system including the financing of diabetes care;
- and, the conduct of behavioral and other intervention research/demonstration projects.

Full implementation of the NDEP strategic plan will be contingent upon the resources available from Federal agencies and participating partners in this nationwide endeavor to reduce the burden of diabetes. The initial overall priority will be to focus on increasing awareness among the four target audiences that diabetes is serious, common and costly. Representatives of minority organizations and communities are actively involved in all phases of the development, implementation and evaluation of the NDEP to ensure their unique needs are addressed.

CDC will be responsible for coordinating implementation of the public health component of the NDEP. For example, CDC is proposing to develop a special emphasis program called "Business Responds to Diabetes," modeled after the highly successful "Business Responds to AIDS" and "Labor Responds to AIDS" programs. Additionally, CDC will have lead responsibility for addressing the needs of minority populations using a community-based and other effective approaches.

CDCdoc: ndepdesc.44

DIVISION OF DIABETES TRANSLATION: A PROFILE

Formed in 1988, the Division of Diabetes Translation (DDT) is a component of CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). Congress has assigned a dual responsibility to the Divsion, combining the implementation of a public health oriented diabetes control program with the translation of diabetes research findings into widespread clinical and public health practice -- both directed toward reducing the burden of diabetes in the United States.

DDT currently provides financial and technical assistance to 49 states, 4 territories, and the District of Columbia to support their efforts to develop program capacity to carry out a program for diabetes control within the existing and evolving health care system. In addition, two states are receiving enhanced funding to develop and implement comprehensive diabetes prevention and control programs. All DCPs focus on (1) defining and monitoring the burden of diabetes, (2) developing new, effective approaches for reducing the diabetes burden, (3) implementing specific measures to ensure the widespread application of accepted standards, and (4) coordinating the diabetes-related efforts of the health system by establishing linkages and networks.

All of the Division's programmatic activities emphasize populations, such as racial and ethnic minorities and older adults, which bear a disproportionate share of the diabetes burden. For example, Project DIRECT, a major demonstration of community-based interventions designed to prevent diabetes and its complications, has been undertaken in large urban African American community in North Carolina. Another example is the National Latino Diabetes Initiative for Action which was initiated to serve as a blueprint for the Division in framing interdisciplinary, culturally-relevant approaches to control diabetes in the U.S. Latino community.

The Division also conducts applied research which focuses on translating clinical/scientific research findings into various real world settings and program applications. Several studies are now underway to evaluate the cost-effectiveness of diabetes prevention and control strategies. DDT works closely with state-based partners to collect, analyze, and disseminate public health surveillance data for use in program and policy decision-making.

DDT has undertaken two major new efforts in collaboration with other federal and non-federal partners. The Division is sharing leadership with the Diabetes Division of the National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK) to plan, develop, and implement a National Diabetes Education Program (NDEP). Establishment of a NDEP was recommended in response to the strong scientific evidence from the Diabetes Control and Complications Trial supporting aggressive intervention to reduce the medical, social, and economic burden of diabetes. DDT is also collaborating with NIDDK on a randomized control trial to prevent non-insulin dependent diabetes, the Diabetes Prevention Program (DPP). The Division has lead responsibility for the analysis of the cost-effectiveness in the trial for primary prevention of diabetes.

Senior Staff: Frank Vinicor, MD, MPH, Director
Kathy H. Rufo, MPH, Deputy Director
David F. Williamson, PhD, MS, Associate Director for Science
Faye L. Wong, MPH, RD, Associate Director for Diabetes Education
Michael M. Engelgau, MD, Chief, Epidemiology and Statistics Branch
Dara L. Murphy, MPH, Chief, Program Development Branch

MAJOR ACCOMPLISHMENTS AND ACTIVITIES

MAJOR ACCOMPLISHMENTS AND ACTIVITIES

DEFINING THE BURDEN: SURVEILLANCE

- The diabetes module of the BRFSS was developed to provide information regarding risk factors, care practices, and outcomes related to diabetes eye disease and foot disease. The number of states using the behavioral risk factor surveillance system (BRFSS) increased from 35 in 1995 to 38 in 1996. DDT has used BRFSS data from 22 states to develop indicators for surveillance of diabetes-specific preventive care practices among persons with diabetes. This analysis has provided unique population-based information on diabetes care. A manuscript is being prepared for publication.

- DDT sponsored a Regional Workshop on "State-based Analysis of Behavioral Risk Factor Surveillance System Diabetes-related Data" in Atlanta in September 1996. This workshop was a follow-up to recommendations produced during a special meeting at the Diabetes Translation Conference in 1995. Workshop participants developed recommendations on criteria for multi-state data aggregation, determining priorities for analysis of diabetes-related BRFSS data, and increasing the effective use of BRFSS data in decision-making. Participants included twenty DCP personnel and BRFSS State Coordinators from the 13 states in the Atlantic and southeast region.

- DDT has developed two major projects for identifying the burden of visual impairment among persons with diabetes. In collaboration with the Texas Diabetes Control Program (DCP) and researchers at the University of Wisconsin, validity studies on BRFSS questions related to visual impairment in white and minority populations are being conducted. DDT is also collaborating with the Massachusetts DCP and the Massachusetts Blindness Commission to identify recent trends in blindness and to better understand the factors associated with non-reporting to the blindness registry in Massachusetts. A report of this work was published in the MMWR.

- In collaboration with the Diabetes Unit at Grady Memorial Hospital, DDT has developed methods to estimate the prevalence of Type I and Type II diabetes in a population of African Americans with diabetes. Simple methods that yield unbiased estimates and only require information on insulin use, age at diagnosis, and body mass index were developed. Previous methods were developed in mostly white, non-Hispanic populations. Because of the different etiology for Type I and Type II, it is important to track these trends. Currently a manuscript is being prepared for publication.

- DDT is collaborating with 3 managed care organizations (MCOs) to develop surveillance systems that can assess the process of care, associated costs, and intermediate outcomes of care among persons with insulin-dependent and non-insulin dependent diabetes in MCOs. These systems will be valuable in describing the epidemiology and economic burden or diabetes, developing recommendations for implementing diabetes surveillance in managed care settings, identifying opportunities for quality improvement of diabetes care in MCOs, and providing insights into the potential reduction in costs that can be achieved by preventing complications.

- Through an ASPH cooperative agreement with the University of Minnesota and Dr. Marshall McBean, DDT is using Medicare claims data to enhance current surveillance efforts by generating national and state estimates of the prevalence and incidence of diabetes, the processes and outcomes of care, and the costs of diabetes care in the Medicare population. The project provides technical assistance for 3 states to develop a state-based medicare surveillance system. DDT is also working with Georgia Medicaid data to describe the prevalence of diabetes, care utilization and practices, and costs of care in the Medicaid population.

- DDT operates and maintains a national diabetes surveillance system that provides periodic and representative data about the burden of diabetes in the United States. Data from this system are widely disseminated through Diabetes Surveillance Reports which includes data on diabetes morbidity and mortality, hospitalizations, cardiovascular disease, and complications. The fourth edition of Diabetes Surveillance Reports will be published in the Fall of 1996. State Diabetes Fact Sheets, which include state-specific estimates of the burden of diabetes, were produced this year using data from the national surveillance system.

- Through an MOA with the National Center for Health Statistics, DDT has proposed the development of measures for diabetes in NHANES IV. Proposals for diabetes include measures for glycemia, lower extremity disease, and linkage of participants with birth certificate data. Data will be used to define the national diabetes burden and develop national strategies for control.

EXPANDING THE SCIENCE VISION

Cost and Cost-effectiveness

- The Diabetes Prevention Program (DPP) is an NIH-sponsored, multi-center, randomized controlled clinical trial designed to test the efficacy of drugs and physical activity/nutrition in the primary prevention of non-insulin dependent diabetes. The study includes an intensive lifestyle/behavioral arm, which focuses on diet and exercise, and two drug intervention arms. Recruitment of 4000 subjects began in June of 1996 and is scheduled to finish after 5 years. DDT is leading the economic evaluation component of this study, and a protocol has been developed. A cost-utility analysis will be used to estimate life-time marginal costs of clinical care per quality adjusted life year (QALY) gained for each intervention compared to a control group receiving standard care. This is the largest and most rigorous trial for the primary prevention of diabetes ever conducted. If successful, it will have enormous implications for chronic disease prevention policy at the local, state, and national levels.

- Recognizing that early detection of diabetes through screening has become an emerging health issue, DDT is working with Battelle to examine the cost-effectiveness of screening for diabetes. Costs of early detection and lifetime costs of care per quality adjusted life year (QALY) gained will be examined. Interest in screening for diabetes arises from research showing that the onset of diabetes occurs an average of 7 years before clinical diagnosis and that complications are often already present.

- DDT is working with Battelle to evaluate the cost-effectiveness of intervention strategies in the early detection and treatment of diabetic nephropathy, the leading cause of end-stage renal disease (ESRD). The study will estimate the marginal costs of various detection and treatment strategies per quality adjusted life year (QALY) gained. Because treatment of ESRD requires an enormous amount of resources, this will be valuable information for development of ESRD prevention and control strategies.

- DDT is developing an annotated economic bibliography that reviews all of the recent economic studies conducted in diabetes. This will be a tremendous resource for identifying gaps in the economic knowledge base and for determining areas in need of further research.

Screening and Diagnosis

- DDT is collaborating with the NIH-sponsored Diabetes Prevention Program (DPP) to develop screening strategies for detecting persons with impaired glucose tolerance. If the DPP is a successful trial, there will be a need to understand the performance of various screening strategies in order to translate findings into improved practice.

- DDT is collaborating with 3 Diabetes Control Programs, Rhode Island, Massachusetts, and North Carolina, in a prospective evaluation of a risk assessment questionnaire test and a random capillary glucose test for diabetes screening. This project will evaluate the performance of these tests in a population representative of the U.S. population. Screening information will be of importance to policy makers for developing strategies to detect the estimated 8 million Americans with undiagnosed diabetes.

- DDT is using data from the "Diabetes in Egypt" project to evaluate the effectiveness of screening for diabetic retinopathy by non-mydriatic camera in less developed countries where there is limited access to diabetes specialists or ophthalmologists. Screening with non-mydriatic camera has not yet been endorsed although it has been shown in many studies to be at least as effective as ophthalmoscopy. Study findings will be useful for determining health care policy related to implementation of widespread screening for diabetic retinopathy in developing countries.

- DDT is using data from the "Diabetes in Egypt" project, to compare the performance of three glycemic measures (fasting, 2 hr. glucose, and hemoglobin A1c) for diagnosing diabetes. Study results should prove valuable for determining the optimal tests and cut point values for diagnosing diabetes. A manuscript has been submitted to Diabetes Care.

PROGRAM PLANNING:

National Diabetes Education Program (NDEP)

- DDT and the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) are providing joint leadership to plan and implement a major new initiative, the National Diabetes Education Program (NDEP) in collaboration with other Federal agencies and public and private sector partners. Establishment of the a NDEP was recommended by the National Diabetes Advisory Board in response to the strong scientific evidence that exists today to support aggressive intervention to reduce the medical, social, and economic burden of diabetes among minority populations. The NDEP will be the centerpiece for Federal efforts to ensure that patients, providers, and the public become aware that diabetes is a very serious illness, and that its tragic and costly complications can be prevented with new and existing prevention and control strategies. Accomplishments and future plans include:

  - An NDEP Steering Committee has been established that is composed of leading clinical researchers, representatives on national diabetes organizations, and ex officio members from CDC, NIH, HCFA, and the Veterans Administration. The Steering Committee will develop a preliminary rationale and conceptual framework for the NDEP.

  - Two focus group meetings have been conducted-- the first with primary care providers and the second with payors and purchasers. Two additional focus group sessions are planned for December 1996-- one with patient advocacy groups and the other with public health representatives. Feedback has been overwhelmingly supportive of the NDEP effort. Results will be summarized and incorporated into the Plan.

  - Using input from the focus group meetings, an NDEP plan will be developed for implementation. The plan will incorporate and address the consensus key goals and objectives, educational messages, intervention strategies and activities, and Federal agency, public and private sector partnerships identified as important for an effective national program.

PROGRAM DESIGN, IMPLEMENTATION, AND EVALUATION:

Diabetes Control Programs

- Cooperative agreements for state and territorial Diabetes Control Programs (DCPs) to reduce the burden of diabetes were awarded to 49 states, 4 territories, and the District of Columbia. Currently, 47 of these awardees are using funds to develop program capacity and infrastructure to carry out a program for diabetes control. The remaining 2 states are funded to develop comprehensive, enhanced programs. Program emphasis continues to be on defining and monitoring the burden of diabetes, utilizing health system approaches coordinated by the DCPs, and developing and applying community-based interventions.

Managed Care Organization Activities

- Birch and Davis Associates, Inc. developed a strategic business plan for state-based program activities in the area of managed care. This plan is currently being used to refine and focus activities in the Program Development Branch, DDT. In FY97, the contractor will assist DDT in describing "success stories" related to health systems approaches of selected DCPs. This information will be used to develop a *Best Practices Manual* to be shared with other DCPs for translating and replicating successful diabetes prevention and control approaches.

- In September 1996, the Diabetes Symposium, co-sponsored by DDT and the HMO Group was held in Atlanta, Ga. The Symposium included plenary sessions, "showcasing" successful partnership strategies between managed care and state-based diabetes control programs, and group workshops. The Symposium successfully created learning opportunities for participants in the understanding of collaborative needs and roles between managed care organizations (MCOs) and state health departments in the context of diabetes prevention and control. Participants were charged with the identification and pursuit of collaborative opportunities between the public and private health sectors. More specifically, participants were challenged to explore and pursue collaborative opportunities in the areas of data systems, disease/case management and outreach efforts. Subsequent to the symposium, ongoing networks between MCOs and DCPs are being established and maintained.

Promoting Diabetes Care Among Vulnerable Populations

- Project DIRECT (Diabetes Intervention Reaching and Educating Communities Together) is a multi-year project designed to improve the health-related quality of life of an African-American community in Raleigh, North Carolina by reducing the burden of diabetes and its complications through a community-based intervention program. The project has an intervention component and an evaluation component.

  - Intervention Component: There are 3 major areas of intervention - diabetes care, outreach, and health promotion.

    Diabetes Care: The goals of the diabetes care intervention are to increase access to care, improve the quality of care provided to people with diabetes, and improve self-care practices related to diabetes management.

    Outreach: The goals are to detect previously undiagnosed diabetes, especially among African Americans, and to see that those previously diagnosed are in the health care system. The intent is to increase access to care and decrease preventable diabetes complications.

    Health Promotion: The goal is to reduce risk factors related to diabetes, especially by increasing physical activity and decreasing fat intake. This involves promoting lifestyle, environmental, and policy changes. The achievement of the project's goals will be measured and documented by the evaluation component of the project.

  - Evaluation Component: Evaluation will consist of (1) an assessment of the specific interventions implemented aimed at providing feedback and improving the process of delivery, and (2) a scientific evaluation of the impact of the entire program on population-based process and outcome indicators associated with diabetes and its complications. The evaluation will provide valuable insight into the effectiveness of a community-based diabetes intervention program, specifically in an African-American Community.

- The Latino Diabetes Initiative for Action, Latino DIA, focuses on developing appropriate diabetes prevention strategies for Latino communities in the U.S. This initiative promotes inter-disciplinary, culturally-relevant approaches for preventing diabetes and its complications in the U.S. and territorial Latino community. CDC has enlisted the assistance of a National Latino Expert Workgroup to collaborate with DDT in the planning, prioritization, implementation, promotion, and evaluation of strategic Latino DIA activities intended to address the disproportionate burden of diabetes in the Latino community. The expert workgroup convened 3 times in 1996 and is in the process of developing a formal report of their deliberations, thoughts, and expert views on how to effectively reach Latino populations.

- DDT has entered into an agreement with the National Council of La Raza to prepare and engage Latino communities and populations for active participation in the developing National Diabetes Education Program. The Council will hold strategic regional meetings with key stakeholders, voluntary organizations, and community-based organizations.

- DDT has established a cooperative agreement with the Congress of National Black Churches (CNBC) to develop a church-based nutrition and physical activity program targeting African American women who have or are at risk for developing diabetes. Technical assistance is being provided to CNBC by the Association of Black Psychologists and DDT. This intervention is unique in that it is framed out of an Afrocentric model intended to reflect and support the experiences of African-American women and will develop a conceptual model that is "culturally appropriate". When the intervention design and components are finalized, they will be disseminated to states for replication, where appropriate.

- DDT has completed a series of 27 focus groups among representatives of four populations disproportionately burdened by diabetes: African Americans, American Indians, Asian Americans, and Hispanics/Latinos. The major purpose is to develop an evaluation tool for persons with non-insulin dependent diabetes to learn their perspectives about health, diabetes, and culturally-relevant interventions. A moderator's discussion guide, aiming to gather an "insider's view" of personal and community perceptions was developed and modified for each community of participants. A final report will be available in December of 1996; and a book containing the moderator's guide, lessons learned, and general principles about qualitative research will be published and shared with participants at the annual Diabetes Conference in March 1997.

- In order to further define and address the diabetes burden in the Appalachian population, DDT is funding the University of West Virginia Chronic Disease Prevention Center to form a coalition of representatives from the 13 states with Appalachian counties. The coalition will provide additional information on the burden of diabetes and community efforts to reduce the burden in this area. Gaps in information will be identified, and the coalition will act as a critical player in influencing the health decisions of the region.

- A public health monograph, *Diabetes and Women's Health: A Public Health Perspective*, is being developed to highlight the effect of diabetes on the life cycle of women. The monograph describes the epidemiology of the disease in women and addresses community needs and psychosocial issues from a public health perspective.

- In recognition of National Diabetes Awareness Month, a satellite conference and accompanying state and local diabetes activities are being planned for November 1997, as are broadcasting, public service announcements for local communications. One of the main goals of the event is to help the states to build their health communications capacity through satellite conference activities.

- DDT has proposed diabetes-specific performance measures for HEDIS 3.0, Medicaid HEDIS, the Foundation for Accountability, and State and Federal programs. DDT has also consulted with NIH, HCFA, and the Veterans Administration on measuring processes of diabetes care.

- An evaluation strategy for the Diabetes Control Programs (DCPs) is being developed by Battelle. This strategy will support the development and implementation of a model for ongoing evaluation of the 49 state-based DCPs, four territories, and the District of Columbia. In order to develop such an evaluation strategy, data will be collected on the implementation of the paradigm for delivery of public health services that was inaugurated with the 1994 cooperative agreement. DDT and Battelle will collect and analyze information on four key areas of program implementation: (1) capacity building and infrastructure development, (2) surveillance and data collection, (3) health systems change, and (4) working with local programs.

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion
Division of Diabetes Translation
[Program Development Branch]
(770) 488-5046

Street Address
3000 Chamblee-Tucker Road
Atlanta, Georgia 30341-3724

Mailing Address
4770 Buford Hwy, NE (MS-K10)
Atlanta, Georgia 30341-3724

To:	Sarah Hurwitz	*Date:*	August 1, 1997
Telephone:		*From:*	Karen Rigler
FAX #:	(202) 456-5557	*Telephone:*	(770) 488-5012
Subject:	Diabetes Outreach Programs		FAX: 770-488-5966
Total Pages:	1	*(including this cover sheet)*	

Transmittal Message

Ms. Hurwitz

You called in reference to information on Diabetes Outreach Programs and Prevention Programs. You can call Dara Murphy, Chief, Program Development Branch, Division of Diabetes Translation at (770) 488-5632.

I did not have your telephone number (just your fax number) to get back in touch with you.

Karen Rigler

FAX

Date 08/04/97

Number of pages including cover sheet

TO: Sarah Hurwitz
Domestic Policy Council
White House

Phone 202 456 5594
Fax Phone 202 456 5557

FROM: Paul Bollinger
American Diabetes Association

Phone 703 299 2053
Fax Phone 703 549 8748

CC:

REMARKS: ☐ Urgent ☒ For your review ☐ Reply ASAP ☐ Please Comment

Ms. Hurwitz:

Here is some initial information. I will look for some more of the statistical type information that you requested. However, I thought this would be a good start.

DIABETES FACTS

Diabetes in Youth

What is diabetes?

There are 16 million people in the United States who have diabetes. Diabetes is actually a general term for a number of separate but related disorders. Insulin-dependent, or type I, diabetes results from the body's failure to produce insulin -- the hormone that "unlocks" the cells of the body, allowing glucose to enter and fuel them. Type I diabetes usually begins during childhood.

- Diabetes is a chronic disease that has no cure. It is the fourth-leading cause of death by disease in the United States; this year, more than 178,000 will die from diabetes and its related complications.
- There are an estimated 700,000 people with type I diabetes in the United States today.

How are young people affected?

- The risk of developing type I diabetes is higher than virtually all other severe chronic diseases of childhood.
- Peak incidence occurs during puberty, around 10 to 12 years of age in girls and 12 to 14 years of age in boys.
- Type I diabetes tends to run in families. Brothers and sisters of children with type I diabetes have about a 10% chance of developing the disease by age 50.
- The identical twin of a person with type I diabetes has a 25-50% higher chance of developing type I diabetes than a child in an unaffected family.
- There is a higher incidence of type I diabetes in whites than in other racial groups.
- The symptoms for type I diabetes can mimic the flu in children.

(over)

What are the complications of diabetes?

The complications of diabetes include heart disease, stroke, vision loss/blindness, amputation and kidney disease.

- **Cardiovascular disease** caused by atherosclerosis (excess buildup on the inner wall of a large blood vessel, restricting the flow of blood) accounts for approximately **25 percent of deaths** among patients with onset of diabetes before 20 years of age.

- **Blindness** due to diabetic retinopathy. Diabetic retinopathy is a more important cause of **visual impairment** in younger-onset people than in older-onset people. Males with younger-onset diabetes develop retinopathy more rapidly than females with younger-onset diabetes.

- **Kidney disease** due to diabetic nephropathy. Ten to twenty-one percent of all people with diabetes develop kidney disease. Diabetic nephropathy is the most common cause of end-stage renal disease (ESRD), a condition where the patient requires dialysis or a kidney transplant in order to live. In people with type I diabetes who develop proteinuria (protein in the urine), **ESRD or death usually follows** after about 5-10 years.

- **Diabetic ketoacidosis** (DKA) is one of the most serious outcomes of poorly controlled diabetes, and primarily occurs in type I individuals. DKA is marked by high blood glucose levels along with ketones in the urine. DKA is responsible for about **10 percent of diabetes-related deaths** in individuals with diabetes under age 45.

What is needed for young people with diabetes?

In ideal circumstances, patients with diabetes will have their disease under good control and have universal access to quality diabetes treatment including frequent monitoring by a health care team knowledgeable in the care of diabetes.

- **Access to quality treatment is important.** People with diabetes need affordable health care. Medicare and Medicaid, as well as many private health care providers that follow their lead, do not offer comprehensive coverage of the necessary supplies, services and education. The following changes are needed: prohibit pre-existing condition exclusions; provide coverage for prescription drugs and insulin, diabetes-related supplies, equipment and education; and provide a mandate for community rating.

- **Health care team education is vital.** Because people with diabetes have a multi-system chronic disease, they are best monitored and managed by highly skilled health care professionals trained with the latest information on diabetes to help ensure early detection and appropriate treatment of the serious complications of the disease. A team approach to treating and monitoring this disease serves the best interests of the patient.

- **Patient education is critical.** People with diabetes can reduce their risk for complications if they are educated about their disease, learn and practice the skills necessary to better control their blood glucose levels, and receive regular checkups from their health care team.

- People with diabetes, with the help of their health care providers, should **set goals for control of blood glucose levels, as close to the normal range as is possible for them.**

1/96

For more information

Call us at 1-800-232-3472 for your *free* publications catalog. Also ask about ADA's *free* quarterly newsletter for people with diabetes.

What is Insulin-Dependent Diabetes?

(Type I Diabetes)

es Rights and Responsibilities Rig
ems Health-care Systems Health-ca
es Community Resources Communi
eneral Facts General Facts General
oping Coping Coping Coping Copir
amily Family Family Family Family
utrition Nutrition Nutrition Nutritio
xercise Exercise Exercise Exercise
ledications Medications Medication
Balance: Food, Exercise, Medicines
esting Testing Testing Testing Test
mia Hyperglycemia/Hypoglycemia
lness Illness Illness Illness Illness
omplications Complications Compli
ersonal Habits Personal Habits Per
ies Rights and Responsibilities Rig
tems Health-care Systems Health-c
ces Community Resources Commun
eneral Facts General Facts General
oping Coping Coping Coping Copir
y Family Family Family Family Fan

American Diabetes Association
Diabetes Information Service Center
1660 Duke Street
Alexandria, VA 22314
Tel: 800-232-3472

Copyright © 1989 by the American Diabetes Association, Inc.

American Diabetes Association.

6/94 - 124M

American Diabetes Association.

What is insulin-dependent diabetes?

Insulin-dependent diabetes is a disease that affects the way your body uses food. Insulin-dependent diabetes is also called type I diabetes or insulin-dependent diabetes mellitus (IDDM, for short).

Type I diabetes starts when your body stops making insulin or makes only a tiny amount. Your body needs insulin to use food for energy. Without insulin, your body cannot control blood levels of sugar. And without insulin, you would die. So people with type I diabetes give themselves at least one shot of insulin every day.

Type I diabetes usually strikes children and young adults. But it can occur at any age. It used to be called juvenile-onset diabetes. More than 300,000 Americans have this type of diabetes. That is about 10 percent of all Americans diagnosed with diabetes.

Why insulin shots?

You must inject insulin under the skin — in the fat — for it to work. You cannot take insulin in a pill. The juices in your stomach would destroy the insulin before it could work. Scientists are looking for new ways to give insulin. But today, shots are the only method.

What are the signs and symptoms of type I diabetes?

Type I diabetes often appears suddenly. Signs and symptoms are:

- high levels of sugar in the blood
- high levels of sugar in the urine
- frequent urination (and/or bed-wetting in children)
- extreme hunger
- extreme thirst
- extreme weight loss
- weakness and tiredness
- feeling edgy and having mood changes
- feeling sick to your stomach and vomiting

What causes type I diabetes?

We do not know exactly what causes diabetes. We do know that people inherit a tendency to get diabetes. But not all people who have this tendency will get the disease. Other things such as illnesses must also come into play for diabetes to begin.

Diabetes is not like a cold. Your friends and family cannot catch it from you.

What does living with diabetes mean?

People with type I diabetes can live happy, healthy lives. The key is to follow your diabetes treatment plan. The goal of this plan is to keep your blood-sugar level as close to normal as possible (good blood-sugar control). Your treatment plan will probably include:

1. *Insulin*, which lowers blood sugar. Your health-care practitioner will prescribe how much and when to take insulin and what kinds.
2. *Food*, which raises blood sugar. Most people with type I diabetes have a *meal plan*. A registered dietitian makes a plan for you. It tells you how much food you can eat and when to eat it. Most people have three meals and at least two snacks every day. Your meal plan can have foods you enjoy.
3. *Exercise*, which lowers blood sugar. Like insulin, exercise also helps your body to use blood sugar. So exercise will probably be prescribed for you. Your health-care practitioner can help you fit exercise safely into your daily routine.
4. *Blood and urine testing*. Testing your blood lets you know if your blood-sugar level is high, low, or near normal. The tests are simple. You prick your finger to get a drop of blood. A nurse-educator can teach you how to do this test and use the test results.

You may need to test your urine for ketones. Ketones in the urine may mean that your diabetes is not under good control. A nurse-educator can teach you how to test ketones.

Problems you may have

Type I diabetes can cause problems that you should be prepared for. There are three key problems:

Hypoglycemia, or low blood sugar; sometimes called an insulin reaction. This occurs when your blood sugar drops too low. You correct this problem by eating some sugar — such as 3 glucose tablets, 6 ounces of regular soda, or 5 or 6 Lifesavers™ Your health-care practitioner will teach you the signs of hypoglycemia and show you how to treat it.

Hyperglycemia, or high blood sugar. This occurs when your blood sugar is too high. It can be a sign that diabetes is not well controlled. Your health-care practitioner will explain the signs and symptoms and the best way to treat hyperglycemia.

Ketoacidosis, or diabetic coma. This is very serious. Discuss its signs with your health-care practitioner.

Ketoacidosis

For more information

Call us at 1-800-232-3472 for your *free* publications catalog. Also ask about ADA's *free* quarterly newsletter for people with diabetes.

es Rights and Responsibilities Rig
ems Health-care Systems Health-ca
es Community Resources Commun
eneral Facts General Facts General
oping Coping Coping Coping Copi
amily Family Family Family Family
utrition Nutrition Nutrition Nutritic
xercise Exercise Exercise Exercis
ledications Medications Medicatior
Balance: Food, Exercise, Medicines
esting Testing Testing Testing Tes
mia Hyperglycemia/Hypoglycemia
lness Illness Illness Illness Illnes
omplications Complications Compl
ersonal Habits Personal Habits Per
ies Rights and Responsibilities Rig
tems Health-care Systems Health-c
ces Community Resources Commur
eneral Facts General Facts General
oping Coping Coping Coping Copi
y Family Family Family Family Far

American Diabetes Association®
Diabetes Information Service Center
1660 Duke Street
Alexandria, VA 22314
Tel: 800-232-3472

Copyright © 1989 by the American Diabetes Association®, Inc.

American Diabetes Association®

10/94 - 15M

American Diabetes Association®

Ketoacidosis (key-toe-as-i-DOE-sis) is a serious condition that can lead to diabetic coma (passing out for a long time) and even death. Ketoacidosis may happen to people with insulin-dependent (type I) diabetes.

Ketoacidosis does not occur in people with non-insulin-dependent (type II) diabetes. But some people — especially older people — with type II diabetes may experience a different serious condition. It's called hyperosmolar nonketotic coma (hi-per-oz-MOE-lar non-key-TOT-ick KO-ma). This pamphlet is not about this condition.

Ketoacidosis means dangerously high levels of ketones. Ketones are acids that build up in the blood. They appear in the urine when your body doesn't have enough insulin. Ketones can poison the body. They are a warning sign that your diabetes is out of control or that you are getting sick.

Treatment for ketoacidosis usually takes place in the hospital. But you can help prevent ketoacidosis by learning the warning signs and testing your urine and blood regularly.

What are the warning signs of ketoacidosis?

Ketoacidosis usually develops slowly. But when vomiting occurs, this life-threatening condition can develop in a few hours. The first symptoms are:

- thirst or a very dry mouth
- frequent urination
- high blood-sugar levels
- high levels of ketones in the urine

Next, other symptoms appear:

- constantly feeling tired
- dry or flushed skin
- nausea, vomiting, or abdominal pain (Vomiting can be caused by many illnesses, not just ketoacidosis. If vomiting continues for more than 2 hours, contact your health-care practitioner.)
- a hard time breathing (short, deep breaths)
- fruity odor on breath
- a hard time paying attention, or confusion

Ketoacidosis is dangerous and serious. If you have any of the above symptoms, contact your health-care practitioner IMMEDIATELY, or go to the nearest emergency room of your local hospital.

How do you know if you have large amounts of ketones?

A simple urine test can detect ketones. You use a test strip, like a blood-testing strip. Ask your health-care

Many experts advise to check your urine for ketones when your blood sugar is more than 240 mg/dl.

When you are ill (when you have a cold or the flu, for example), test for ketones every 4 to 6 hours. And test every 4 to 6 hours when your blood sugar is more than 240 mg/dl.

Also, test for ketones when you have any symptoms of ketoacidosis.

What if you find higher-than-normal levels of ketones?

If your health-care practitioner has not told you what levels of ketones are dangerous, then call when you find moderate amounts after more than one test. Often, your health-care practitioner can tell you what to do over the phone.

Call your health-care practitioner at once if:

- your urine tests show large ketones
- your urine tests show large ketones and your blood-sugar level is high
- you have vomited more than twice in 4 hours and your urine tests show large ketones

Do NOT exercise when your urine tests show ketones and your blood sugar is high. High levels of ketones and high blood sugars can mean your diabetes is out of control. Check with your health-care practitioner about how to handle this situation.

What causes ketoacidosis?

Ketones mean your body is burning fat to get energy. Moderate or large amounts of ketones in your urine are dangerous. They upset the chemical balance of the blood.

Commonly, the flu, a cold, or other infections may sometimes bring on ketoacidosis.

Here are three basic reasons for moderate or large amounts of ketones:

1. Not getting enough insulin. Maybe you did not inject enough insulin. Or your body could need more insulin than usual because of illness. If there is not enough insulin, your body begins to break down body fat for energy.

2. Not enough food. When people are sick, they often do not feel like eating. Then, high ketones may result. High ketones may also occur when someone misses a meal.

3. An insulin reaction (low blood sugar). When blood-sugar levels fall too low, the body must use fat to get energy. If testing shows high ketones in the morning, the person may have had an insulin reaction while asleep.

ks I've selected.
'd like a free catalog.

Total

DM @
nonmember _____
MOM2 @
nonmember _____
MOM3 @
nonmember _____
MOM4 @
nonmember _____
MOM5 @
nonmember _____
SHHS @
nonmember _____
#CCBF1 @
10 nonmember _____
#CCBF2 @
10 nonmember _____
#CCBF3 @
10 nonmember _____
#CCBF4 @
10 nonmember _____
tions Subtotal _____
4.5% sales tax _____
e chart below) _____
please add $15
mail shipment _____
TOTAL DUE _____
CH79403

oney order)
MasterCard ____ Amex
_____ Exp. _____

hipping & Handling
p to $30.00.....add $3.00
30.01-$50.00...add $4.00
bove $50.00...add 8%

ping & handling for each extra
in U.S. funds, drawn on a U.S.

AUG-04-1997 11:10 P.09/09

Managing Through Meal Planning

Just as your physician prescribes your medications, your dietitian will prescribe a meal plan to meet *your* daily nutritional needs. Your dietitian will work with you to create a meal plan that matches your food preferences with your activity level and insulin. Your dietitian may ask you to do self-monitoring of blood glucose (test your blood sugar) to make certain your food is matching with your insulin and activity.

Meal plans are not written in stone, so if the initial plan isn't right for you, don't hesitate to go back and work out another plan—just as you would return to a tailor to have a good suit fitted to you. And you can look to your dietitian for continued guidance and support as your dietary habits and meal plans change.

Because consistency is so important for IDDM, you'll probably be advised to follow an "exchange" diet. Exchange diets are based on the booklet *Exchange Lists for Meal Planning*. Each list contains foods that have about the same amount of carbohydrate, protein, fat, and calories. So they can be substituted—or "exchanged"—one for another. The six lists are: starch/bread, meat and meat substitutes, vegetables, fruit, milk, and fat.

With the exchange lists, your dietitian can help you plan meals that are just as appealing and appetizing as you want to make them.

How to Learn More

The American Diabetes Association publishes numerous materials about diabetes, as well as cookbooks, nutritional guides, and other publications suitable for anyone interested in good nutrition. Please refer to the attached card or contact your local ADA affiliate (listed in the white pages of your telephone book).

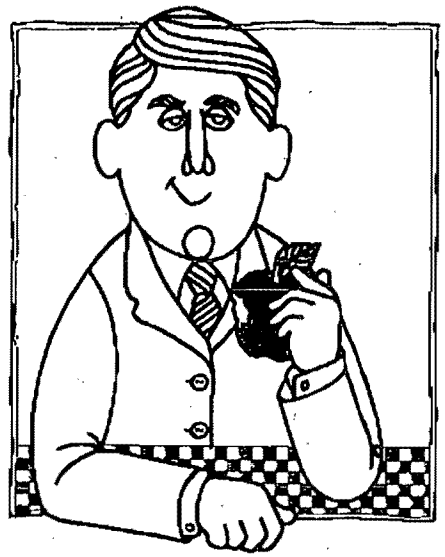
American Diabetes Association®
Diabetes Information Service Center
1660 Duke Street
Alexandria, VA 22314
Tel.: 800-232-3472

Copyright © 1993 by the American Diabetes Association®, Inc.

American Diabetes Association®

6/94 - 74M

Nutrition and Insulin-Dependent Diabetes



American Diabetes Association®

Food does more than satisfy our appetites; it contains the nutrients essential for good health. So, eating the proper foods places *you* in control of your health. And that's particularly important because diabetes interferes with the way the body uses food. This makes diet one of the cornerstones of diabetes management.

What Is Insulin-Dependent Diabetes?

In insulin-dependent (IDDM or type I) diabetes mellitus, the pancreas does not produce enough insulin to meet the body's needs. Insulin is a hormone that allows the body to use glucose for energy. Without insulin, the body is unable to properly use glucose and it builds up in the blood, leading to the high blood-glucose (blood-sugar) levels that are the hallmark of untreated diabetes.

Insulin injections allow your body to use glucose (which your body produces from the foods you eat) for energy; this keeps blood-glucose levels from becoming elevated. But the amount and kind of insulin you take must be balanced with your food and

What Is Good Nutrition?

Good nutrition involves eating a variety of foods because no one food can supply *all* the nutrients your body needs to stay healthy and active. Vary the types of fruits, vegetables, starches, and proteins you eat from day to day.

Healthy diets are high in complex carbohydrates. Carbohydrates come in two forms: **simple carbohydrates or sugars** (cakes, pastries, and candy, for example), which tend to raise blood-glucose levels very high and rather quickly, and often provide little nutrition and no fiber; and **complex carbohydrates** (vegetables, dried beans and peas, brown rice, and whole grain flours, breads, and cereals, for example), which tend to raise blood glucose gradually over a longer period of time, and contain a variety of vitamins and minerals as well as fiber.

Good nutrition also means limiting fat and cholesterol from foods such as gravies, sauces, dressings, fatty meats, and fried foods, as well as eggs and some dairy products. Fat and cholesterol have been linked to atherosclerosis (fatty build-up inside blood vessel walls), and can contribute to heart disease and stroke. Some people may be encouraged to limit salt, as well.

Dietary Goals for People With IDDM

Consistency: How much you eat is as important as when you eat. Your meal plan will help you maintain day-to-day consistency in the amount of carbohydrate, protein, and fat you eat at each meal. It will also help you establish a schedule for meals and snacks. Your meal plan will guide your food choices so you'll have a consistent mix of foods while still enjoying variety.

Balance: A consistent food intake will help ensure that there is glucose in the bloodstream at the times when your insulin is peaking (working the hardest), or during those times when you will be most active, such as exercise class. Never skip a meal if you have taken your insulin—or you risk upsetting this balance.

Maintain Proper Weight: Your body's ability to use insulin, as well as your overall health, will be best when you are at a reasonable body weight. Your meal plan will take into account whether you need to lose, gain, or maintain weight.

Special Considerations

Insulin Reactions: Insulin reactions, also called low blood sugar or hypoglycemia, are usually caused by too much insulin, too much exercise, or too little food (a skipped meal). Symptoms appear suddenly and may include any of the following: sudden hunger, inappropriate crying or laughing, clumsy actions, dizziness, shakiness, headaches, "butterflies" in the stomach, sleepiness, nightmares, sweatiness, irritability, fatigue, or weakness. Learn to recognize these symptoms and ALWAYS carry some form of concentrated sugar (such as fruit juice, sugar cubes, a commercially prepared glucose product to treat reactions, or hard candy) to treat the problem. It's crucial to discuss reactions with your dietitian to see if your meal plan needs adjusting and how you can best treat reactions.

Illness: You may not feel like eating when you are sick, but your body is under stress, which can cause blood-glucose levels to soar. ALWAYS take your insulin; in fact, you may need more than usual. Work out a plan with your doctor in advance about how to handle medications on sick days. Work with your dietitian to establish eating guidelines for when you have little appetite, or trouble keeping food down.

Unusual Activity: A certain amount of activity is accounted for in your daily regimen, but if you are unusually active one day, you will need to eat to avoid low blood sugar. Activity such as light walking should not require additional food. Work with your dietitian to learn how to handle special situations, such as heavy exercise or an all-day outing.

Delayed Meals: For those times when you cannot eat on schedule, have a carbohydrate source, such as crackers or bread sticks, to prevent your blood glucose from dropping too low while waiting for

Dig
Recipe-P
Cookbooks a

Month of Meals (

Need help choosing th
calorie level? *Month of M*
choose from 28 days' wort
menus to fit 1200, 1500, a
of the more complicated n
menu planner has complet
can mix and match from a
of choices. Yes, *thousand*

Month of Meals: Oven-Fri
Month of Meals 2: Beef B
Month of Meals 3: McDon
Month of Meals 4: Meatlo
Month of Meals 5: Veggy
Each menu planner:
Member: $9.95 Nonme

The Healthy Hom

Now you can beef up y
weigh you down. *The Hea*
with dozens of kitchen-tes
ribs selections. Just like gr
that fat!

Choose from Chicken
Sweet and Sour Meatballs,
tips will help you choose b
margarine, freeze bananas
store sales, create a homen
egg, and more. Alphabetiz
favorites in a snap. Special
free reference while you c
Member: $9.95 Nonmen

Family Cookbook

Choose from a family c
each with more than 200 s
mouth-watering recipes. A
breakdown for each recipe
Exchange Lists for Meal P
hardcover for long-life and
recipe after recipe, year aft

Family Cookbook 1: Ginge
Family Cookbook 2: Veal
Family Cookbook 3: Broil
Family Cookbook 4: Bost

FAX

Date 08/04/97

Number of pages including cover sheet

TO: Sarah Hurwitz

Phone 202 456 5594
Fax Phone 202 456 5557

FROM: Paul Bollinger
American Diabetes Association

Phone 703 299 2053
Fax Phone 703 549 8748

CC:

REMARKS: ☐ Urgent ☒ For your review ☐ Reply ASAP ☐ Please Comment

Ms. Hurwitz:

(703) 299-5506 → Ken Inchausti

Here is some initial information. I will look for some more of the statistical type information that you requested. However, I thought this would be a good start.

127,000 kids w/ Diabetes → if teens don't control diabetes in middschool/HS → catches up in future = complications
day-to-day → Hypoglycemia, too little blood glucose in bloodstream → body shuts down, kid can pass out → if severe enough = life threatening
healthcare costs = 5-fold per yr.
few cases of kids having complications
complications later in life if NOT controlled
daily struggle parents deal with: parent = patient = difficult

DIABETES FACTS

Diabetes in Youth

What is diabetes?

There are 16 million people in the United States who have diabetes. Diabetes is actually a general term for a number of separate but related disorders. Insulin-dependent, or type I, diabetes results from the body's failure to produce insulin -- the hormone that "unlocks" the cells of the body, allowing glucose to enter and fuel them. Type I diabetes usually begins during childhood.

- Diabetes is a chronic disease that has **no cure**. It is the **fourth-leading cause of death by disease** in the United States; this year, **more than 178,000 will die** from diabetes and its related complications.
- There are an estimated **700,000** people with type I diabetes in the United States today.

How are young people affected?

- The risk of developing type I diabetes is **higher** than virtually all other severe chronic diseases of childhood.
- **Peak incidence occurs during puberty**, around 10 to 12 years of age in girls and 12 to 14 years of age in boys.
- Type I diabetes tends to run in families. Brothers and sisters of children with type I diabetes have about a **10%** chance of developing the disease by age 50.
- The identical twin of a person with type I diabetes has a **25-50% higher chance** of developing type I diabetes than a child in an unaffected family.
- There is a higher incidence of type I diabetes in whites than in other racial groups.
- The symptoms for type I diabetes can **mimic the flu** in children.

(over)

American Diabetes Association

D.C. Office: 1211 Connecticut Avenue, N.W.; Suite 501
Washington, D.C. 20036

MD Office: 407 Central Avenue
Reisterstown, MD 21136

FAX

Until There's A Cure,
There's The American Diabetes Association

Date: 7/30/97

Number of pages including cover sheet: 8

To: Sarah Hurwitz

Fax phone:

Phone:

CC:

From: Debra

Fax phone: D.C. (202) 331-1402
MD (410) 526-4995

Phone: D.C. (202) 331-8303, ext.____
MD (410) 526-2900, ext.____

REMARKS: ☐ Urgent ☐ For your review ☐ Reply ASAP ☐ Please comment

Per your request.

Tom Westmoreland
202-662-9595

United Way

NVHA

DIABETES FACTS

PROFILE OF THE DIAGNOSED

There are nearly 14 million people in America who have diabetes. Diabetes is actually a general term for a number of separate but related disorders. These disorders fall into two main categories: type I, which usually occurs during childhood or adolescence, and type II, the most common form of the disease, usually occurring after age 30.

What is type I (insulin-dependent) diabetes?

Type I (insulin-dependent) diabetes is a disease which results from the body's failure to produce insulin -- the hormone that "unlocks" the cells of the body, allowing glucose to enter and fuel them. This is most often the result of an autoimmune process in which the body's immune system attacks and destroys the insulin producing cells of the pancreas. Since glucose cannot enter the cells, it builds up in the blood and the body's cells literally starve to death. People with type I diabetes must take daily insulin injections and regularly monitor blood sugar levels.

- There are an estimated **700,000** people with type I diabetes in the United States today.
- The risk of developing type I diabetes is **higher** than virtually all other severe chronic diseases of childhood.
- **Peak incidence occurs during puberty**, around 10 to 12 years old in girls and 12 to 14 years old in boys.
- The symptoms for type I diabetes can **mimic the flu** in children.
- Type I diabetes tends to run in families. Brothers and sisters of children with insulin-dependent diabetes have about a **10%** chance, or a **20-fold increased risk**, of developing the disease.
- The identical twin of a person with insulin-dependent (type I) diabetes has **at least 50 times** the risk of developing type I diabetes than a child in an unaffected family.
- In type I diabetes, incidence is highest among whites. Scandinavian countries have the highest incidence in the world, approximately 30 cases per 100,000 children.

What is type II (non-insulin-dependent) diabetes?

Type II (non-insulin-dependent) diabetes results from the body's inability to make enough or properly use insulin. Often type II diabetes can be controlled through dieting and exercise alone, but sometimes these are not enough and either oral medications or insulin must be used. The fact that few people with type II diabetes require insulin has led to the myth that this is a "mild" form of the disease.

- Of the nearly 14 million Americans with diabetes, **more than 95%** have type II diabetes.
- People with type II diabetes **often develop the disease after age 30**, but are not aware they have diabetes until treated for one of its serious complications.
- The risk for type II diabetes increases with age. By ages 65 to 74, nearly **17%** of the United States white population, **25%** of African Americans, and more than **33%** of Hispanics have type II diabetes.
- Studies indicate that diabetes is generally under reported on death certificates, particularly in the cases of older persons with multiple chronic conditions such as heart disease and hypertension. Because of this, the toll of diabetes is believed to be **much higher** than officially reported.

What are the complications of diabetes?

With its complications, diabetes is the fourth leading cause of death by disease in the United States. Each year, more than 160,000 people die as a result of diabetes and its complications.

- **Blindness** due to diabetic retinopathy. Each year 15,000 to 39,000 people lose their sight because of diabetes. Diabetes is the leading cause of new blindness in people ages 25-74.
- **Kidney Disease** due to diabetic nephropathy. Ten percent of all people with diabetes develop kidney disease. Diabetic nephropathy is the most common cause of end-stage renal disease, a condition where the patient requires dialysis or a kidney transplant in order to live.
- **Heart Disease and Stroke**. People with diabetes are two to four times more likely to have heart disease (more than 77,000 deaths due to heart disease annually). And, they are five times more likely to suffer a stroke, with more than 1,000 deaths each year.
- **Nerve Damage** due to diabetic neuropathy. Approximately 50% of all those who have diabetes for over 25 years have evidence of nerve damage. This can lead to loss of feeling, muscular weakness, amputation and impotence.
- **Amputations**. Diabetes is the most frequent cause of non-traumatic lower limb amputations. The risk of a leg amputation is 27.7 times greater for a person with diabetes.
- **Impotence** due to diabetic neuropathy or artery blockage. Impotence afflicts more than one third of all men who have diabetes.

DIABETES FACTS

Diabetes Among African Americans

Today, African Americans compose 12% of the United States population or more than 30 million people.

- It is estimated that more than **2 million** African Americans have diabetes.
- African Americans are **1.6 times more likely to have diabetes.**
- Nearly **6%** of African American men and nearly **8%** of African American women have diabetes.
- African Americans experience **higher rates of at least three of the serious complications of diabetes:** blindness, amputation and end stage renal disease (kidney failure).

9/93

DIABETES FACTS

Diabetes Among Native Americans

Today, there are more than 2 million Native Americans in the United States, a 37% increase from 1980.

- It is estimated that in excess of **47,000 Native Americans** in the United States have diabetes.
- One tribe, the Pimas of Arizona, have the **highest rate of diabetes in the world.** About 50% of Pimas ages 35 years or older have diabetes.
- Today, diabetes has reached **epidemic proportions** among Native Americans. Complications from diabetes are major causes of death and health problems in most Native American populations.
- Early reports by physicians working with Native Americans indicated that diabetes was rare. By the mid-1980's Native Americans were more than **10** times more likely than the general population to develop diabetes.
- The serious complications of diabetes are **increasing** in frequency among Native Americans. Of major concern are increasing rates of kidney failures, amputations, and blindness. More than **60%** of the Arizona Pimas develop diabetes-related kidney disease.

10/93

DIABETES FACTS

Diabetes Among Hispanics

There are more than 22 million Hispanics in the United States, an increase from close to 15 million in 1980. Hispanics are the fastest growing population in the country.

- It is estimated that in excess of **1 million Hispanics** in the United States have diabetes.
- Approximately **one in every 10** Hispanic adults has diabetes.
- Nearly **10%** of both the Cuban American and Mexican American populations have diabetes.
- Approximately **one quarter** of Mexican Americans and Puerto Ricans between the ages of 45-74 have diabetes.
- Nearly **16%** of Cuban Americans between the ages of 45-74 have diabetes.
- Population studies among Hispanic women with diabetes show **significantly higher death and complication rates** during pregnancy.
- Cuban Americans are **one and a half times more likely** than the general population to have diabetes.
- Both Mexican Americans and Puerto Rican Americans are **twice as likely** as the general population to have diabetes.

2/94

DIABETES FACTS

Diabetes in Youth

Children usually develop insulin-dependent (type I) diabetes which requires daily insulin injections and regular monitoring of blood sugar levels.

- There are about **1.7** cases of insulin-dependent (type I) diabetes **per 1,000 people under age 20** in the United States.
- There are more than **123,000 children and teenagers** with diabetes in the United States today.
- The risk of developing insulin-dependent (type I) diabetes is **higher** than virtually all other severe chronic diseases of childhood.
- **About 18 out of every 100,000 people under 20 years of age** will develop diabetes. Peak incidence is around 10 to 12 years old in girls and 12 to 14 years old in boys.
- The symptoms for diabetes can **mimic the flu** in children.
- Insulin-dependent (type I) diabetes tends to run in families. Brothers and sisters of children with insulin-dependent (type I) diabetes have about a **10%** chance, or a **20-fold increased risk**, of developing the disease.
- The identical twin of a person with insulin-dependent (type I) diabetes has **at least 50 times** the risk of developing type I diabetes as a child in an unaffected family.

9/93

DIABETES FACTS

Diabetes in Seniors

Diabetes prevalence appears to increase with age. There are more than 31 million people, aged 65 years or older, in America.

- Of the nearly 14 million Americans with diabetes, **more than 95%** have non-insulin-dependent (type II) diabetes.
- People with non-insulin-dependent (type II) diabetes often develop the disease **after age 30**, but are not aware they have diabetes until treated for one of its serious complications such as heart disease, stroke, blindness, amputation or kidney disease.
- By ages 65 to 74, nearly **17%** of the United States white population, **25%** of African Americans, and more than **33%** of Hispanics have diabetes.
- Studies indicate that diabetes is generally under reported on death certificates, particularly in the cases of older persons with multiple chronic conditions such as heart disease and hypertension. Because of this, the toll of diabetes is believed to be **much higher** than officially reported.

9/93

INDIAN HEALTH SERVICE

Division of Financial Management

Parklawn Building, Room 5A-54
5600 Fishers Lane
Rockville, MD 20857

Phone: (301) 443-1270
Fax: (301) 443-9157

This transmission consists of 2 pages (with cover page).

Date: 8/4/97

Deliver to: Sarah Hurwitz / White House

Phone: 202-456-5594

From: Carl Fitzpatrick / R Tracy DFM

Subject: Diabetes Funding between FY'93 and FY'97, as requested

Comments:

INDIAN HEALTH SERVICE
Diabetes Program

REQUEST: Ms. Sarah Hurwitz, with the White House, requested information on funding allocation for diabetes program for American Indians and Alaska Natives from fiscal years 1993 through 1997.

RESPONSE: The cost of care for diabetes and diabetes related complications among American Indians and Alaska Natives is extremely high. Most of these costs (e.g., hospitalization, foot care, eye care, dental care, laboratory, etc.) are covered in the IHS clinical and contract health care budgets, and it is not feasible to track separately the cost of diabetes treatment. However, the Model Diabetes program funding is allocated separately, as provided in the table below. The IHS allocated a total of $36,708,500 over the past 5 years to the 12 Area Offices (regional offices) for the Model Diabetes program. The Model program allocations do not include all costs associated with diabetes prevention and treatment services. The following table shows the allocation by fiscal years.

Fiscal Year	Recurring	Non-Recurring	Total Allocation
1993	$ 6,661,900	$ 60,000	$ 6,721,900
1994	6,783,000	100,000	6,883,000
1995	6,952,200	749,000	7,701,200
1996	7,701,200	-0-	7,701,200
1997	7,701,200	-0-	7,701,200
Total:	**$ 35,799,500**	**$ 909,000**	**$ 36,708,500**

Background of the Model Diabetes Program: In recognition of the growing burden of diabetes in American Indians and Alaska Natives, the National Commission on Diabetes recommended that IHS develop a special diabetes program. In 1979, Congress authorized and funded the IHS Model Diabetes program. The program has grown from 5 model care diabetes programs in rural, isolated Indian communities to a nationwide program of 19 model care diabetes programs in 23 sites and regional network of 12 area diabetes coordinators reaching patients, health providers in the 176 IHS, tribal and urban facilities, and leaders in over 500 Indian communities. Diabetes control efforts in IHS focus on primary, secondary and tertiary activities combining scientifically-based standards of care with clinical implementation strategies. A unique surveillance system monitors the implementation of these preventive care practices.

FAX COVER SHEET

OFFICE OF LEGISLATIVE & INTER-GOVERNMENTAL AFFAIRS

Number of Pages: 2 + cover page

Date: 8/04/97

To:	From:
Sarah Hurwitz White House	JOAN STIEBER Medicare Part B Analysis Division
Fax: (202) 456-5594 Phone: (202) 456-5557	Fax: (202) 690-8168 Phone: (202) 690-6884

REMARKS:

NOTE: this is an UNAUTHORIZED DRAFT: It can't leave our office - it's VERY unofficial

HEALTH CARE FINANCING ADMINISTRATION
200 Independence Ave., SW
Room 341-H, Humphrey Building
Washington, DC 20201

DRAFT

EXPANDED DIABETES BENEFITS INCLUDED IN THE PRESIDENT'S FY 98 BUDGET PROPOSAL AND IN THE BALANCED BUDGET ACT OF 1997

- Expansion of coverage for diabetes outpatient self-management training

  Under prior law, Medicare covered outpatient diabetes self-management training in hospital-based programs. The Balanced Budget Act expands Medicare coverage of outpatient self-management training to non-hospital-based programs, effective 7/1/98.

- Expansion of coverage for blood glucose monitors and testing strips

  Under prior law, Medicare covered blood glucose monitors (including testing strips) for insulin-dependent diabetics. The Balanced Budget Act expands coverage of blood glucose monitors (including testing strips) to all diabetics, effective 7/1/98.

- Reduction in payment for strips used with blood glucose monitors

  Payment for durable medical equipment (including testing strips used with blood glucose monitors) is based on statutorily prescribed fee schedules. The fees for testing strips are excessive when compared with retail prices and prices paid by the VA. The Balanced Budget Act reduces payment for this item by 10 percent, effective 1/1/98. The savings from this reduction will partially offset the cost of expanding coverage of glucose monitors and testing strips for non-insulin-dependent diabetics.

ADDITIONAL PROVISION INCLUDED IN BALANCED BUDGET ACT OF 1997 (NOT IN THE PRESIDENT'S FY 98 BUDGET PROPOSAL)

- Establishment of outcome measures and recommendations to Congress

  The Balanced Budget Act also calls for the Department of Health and Human Services to establish outcome measures for evaluating improvements in the health status of Medicare beneficiaries with diabetes, and to periodically submit recommendations to Congress on modifications to coverage of services for diabetics.

DRAFT

NOTES ON COVERAGE OF DIABETES-RELATED SERVICES 4/01/97

What we cover:

Diabetes-specific:

- eye exams
  - o no national policy but BPD encourages carriers to cover (based on model policy developed by carrier medical directors)
  - o coded as "evaluation & management " or "eye exam" (considered diagnostic)
- foot care for patients under doctor's care for a "systemic condition", including diabetes (manual section being revised, criteria tightened)
- therapeutic shoes (one pair per year)
  - o demo mandated by Congress, savings results inconclusive, but coverage extended beyond demo anyway, as of 5/01/93
- self-management training in hospital OPD's — now expanded to other outpatient settings
- blood glucose monitors and testing strips for insulin-dependent diabetics — now expanded to all diabetics

Not diabetes-specific:

- other medically necessary diagnostic and treatment items and services (hospitalization, physician services, DME, laboratory tests, etc.)

What we don't cover:

- insulin or drugs (self-administered)
- insulin pumps
- routine screening exams and procedures, absent a diagnosis or sign of possible disease

(603) 526-7713
(3)

FACSIMILE TRANSMISSION

FROM:

The
National Institute of Diabetes and Digestive and Kidney Diseases

National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

FROM: Name: Lisa Schwartzbach
Office: OHRR, NIDDK
Building: 31 Room: 9A04
Phone: (301) 496-3583 FAX: (301) 496-7422

(6) Joan Steiber — find out medicare policy → why good for diabetes → preventive benefits — tell RE: event

Date: 8/1/97

Please contact the addressee below for delivery of this communication.

TO: Name: Sara Hurwitz
Office: Domestic Policy
Institution:
Address:
Phone: 202-456-5594 FAX: 202-456-7431

Ref: OA Center (703) 549-1500 ext. 2059 60

(1) Trajr implications for kids — die younger, miss school, states are low bad (ADA)

(2) Peter Buxbein → S.B. out-of-town, summary of what they're doing → announcing new in research in drab. HHFA-ADA trying we'd like 1-pager, hold be invited — tomorrow

(4) 443-1860 France (311) Fax: (5) Per RE: Oral Commission Meet 12:00 in June → what persons → Congressional Staff → Call staff

(3) THS diab. Fax: 5 # Jul — 5 # Jul

Number of pages in this transmission including this cover sheet: 2

(M)(3) Jen Klein — Chris + Sally [illegible] worked policy issues w/ OMB → ped. labeling, call Chris if need be

Department of Health and Human Services

National Institutes of Health

DIABETES FUNDING - Fiscal Years 1994 - 1998

	1994 Actual	1995 Actual	1996 Actual	1997 Estimate	1998 House Level
National Institute of Diabetes and and Digestive and Kidney Diseases	$191,409,000	$193,597,000	$197,542,000	$209,100,000	229,000,000
National Cancer Institute	1,279,000	1,070,000	938,000	981,000	1,050,000
National Heart, Lung and Blood Institute	19,779,000	20,393,000	21,010,000	22,275,000	23,500,000
National Institute of Dental Research	2,505,000	2,577,000	2,395,000	2,568,000	2,721,000
National Institute of Neurological Disorders and Stroke	5,717,000	4,535,000	3,793,000	3,972,000	4,150,000
National Institute of Allergy and Infectious Diseases	4,898,000	4,737,000	5,545,000	5,767,000	5,766,000
National Institute of General Medical Sciences	1,704,000	1,762,000	1,850,000	1,955,000	2,065,000
National Institute of Child Health and Human Development	12,329,000	12,631,000	13,373,000	14,200,000	15,000,000
National Eye Institute	22,605,000	22,001,000	21,509,000	22,855,000	24,327,000
National Institute of Environmental Health Sciences	415,000	318,000	358,000	374,000	387,000
National Institute on Aging	6,666,000	6,652,000	7,598,000	7,830,000	8,070,000
National Institute of Mental Health	2,036,000	1,230,000	1,668,000	1,801,000	1,930,000
National Institute on Alcohol Abuse and Alcoholism	329,000	302,000	0	0	0
National Center for Research Resources	18,577,000	19,501,000	17,952,000	19,044,000	19,698,000
National Institute for Nursing Research	1,130,000	1,276,000	718,000	770,000	800,000
National Human Genome Research Institute	2,181,000	2,603,000	2,671,000	2,800,000	2,910,000
Fogarty International Center	56,000	0	0	0	0
Total, NIH	293,615,000	295,185,000	298,920,000	316,292,000	341,374,000

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion
Division of Diabetes Translation

Street Address
3005 Chamblee-Tucker Road
Atlanta, Georgia 30341-3724

Mailing Address
4770 Buford Hwy, NE (MS-K10)
Atlanta, Georgia 30341-3724

To:	Sara Herwitz	*Date:*	8/5/97
Telephone:		*From:*	Kathy Rufo
FAX #:	202-456-5557	*Telephone:*	
Subject:		**FAX: 770-488-5966**	
Total Pages:		*(including this cover sheet)*	

Transmittal Message