4/23

Jean -
I wanted you to know what went out on this report as an FYI -
Mary Beth

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

EMBARGOED: 4 PM ET
April 23, 1998

Contact: CDC Press Office
(404) 639-3286

ASTHMA RATES IN U.S. INCREASE

More Americans than ever before say they are suffering from asthma, according to a report released today by the Centers for Disease Control and Prevention. In 1993 and 1994, an average of 13.7 million persons reported that they experienced asthma-related conditions. Based on trends for the past 15 years, CDC estimates that today more than 15 million Americans suffer from asthma. The increase in asthma cases and deaths affects all ages, spans across all racial groups and occurs throughout the U.S. However, higher rates of hospitalization and emergency room visits were reported in the northeast; and blacks reported higher rates of emergency visits, hospitalization and deaths.

In a special CDC report entitled, "Surveillance for Asthma -- United States, 1960-1995", CDC studied asthma from the perspective of how often people reported they had asthma; visited either their doctor's office or the emergency room; or were admitted to the hospital for treatment. Finally, researchers examined the number of asthma deaths that occurred throughout the U.S.

Asthma is a chronic lung disease characterized by temporary obstruction of airflow that leads to breathing difficulty, coughing, inflammation of the airways, and an increased sensitivity to a variety of triggers that can cause breathing difficulty.

CDC researchers also found that the overall picture of asthma is changing, and today's report recommended a comprehensive national monitoring system to identify these emerging trends on a state-by-state basis, especially to understand why some areas have lower rates of emergency room visits and hospitalization.

"Asthma is a complicated illness that adults and children live with daily. To prevent asthma, we need a

better understanding to unravel the mysteries of why some people develop it and others do not," said Claire V. Broome, M.D.,Acting Director of CDC. "Promoting healthy home environments and sharing proven prevention strategies with health care providers to define the problems and causes is a key step towards prevention of this serious illness."

Other key findings in this report included:

Self-Reported Asthma Cases

- Rates increased 75% between 1980 and 1994. This increase was evident across all races; both sexes; and all age groups. Self-reported rates were 50.8 per 1,000 among whites and, and 57.8 per 1,000 among blacks.

Office Visits

- The number of doctor's office visits to treat asthma more than doubled between 1975 and 1995. These increases were evident in all groups of races, both sexes, and all age groups.

Emergency Room Visits

- In 1995 there were more than 1.8 million emergency room visits made for asthma. The rate was 48.8 per 10,000 among whites and 228.9 per 10,000 among blacks.

Hospitalization

- Between 1979 and 1994, hospitalization rates were highest for those from birth to 4 years old and lowest among persons 15-34. Among whites, hospitalization rates were 10.9 per 10,000 and among blacks the rate was 35.5 per 10,000 visits.

Death Attributed to Asthma

- Asthma-related deaths vary substantially by age group with the highest rates appearing in the elderly. Deaths due to asthma as the underlying cause were 15.1 per million among whites, and 38.5 per million among blacks.

CDC's role in asthma prevention programs is to ensure that proven, comprehensive asthma interventions and surveillance programs are implemented by the states and their partners. CDC shares this information with state health officials so that they can adapt what has worked in other regions of the country to their communities. Through CDC's educational efforts, public health officials will have a greater understanding of the environmental interventions and medical management tools such as patient education, demonstrating behavior changes to avoid asthma triggers, using drug therapies, and frequent medical follow-up to treat and identify asthma patients.

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E.O.

(b) addressed numerous important issues today children consistent w/ our priority

→ Executive Order

+ Revised +

PRESIDENT WILLIAM J. CLINTON

ANNOUNCEMENT OF DIABETES INITIATIVES

WASHINGTON, D.C.

AUGUST 8, 1997

Acknowledgments: Sam Wiesel, [Wee-zil] Georgetown Cong. Furse Medical Center; Mary Delaney; Chief Joyce Dugan [Doogan]; Sandra Puczynski, [Poo-zin-skee]; Stephen Satalino, Chair of American Diabetes Association; Mary Tyler Moore, International Chair of Juvenile Diabetes Foundation; Joan Beaubaire, former head of the Juvenile Diabetes Foundation is here. Her son David works for me; doctors and scientists from our regional hospitals and research institutes; Dr. Philip Gorden, head of diabetes research at NIH, is with us today; diabetes patients, their families, activists and advocates.

Standing here at one of America's foremost medical facilities, I'm reminded of the miracles that modern medicine and science have wrought in our lives. Polio, mumps, diphtheria -- the diseases that robbed so many families of beloved infants and toddlers for centuries -- have been virtually eradicated. Premature babies who just a decade ago would not have had a chance at life beyond the intensive care unit are growing into happy and healthy children. Powerful treatments are prolonging the lives of AIDS patients across the country, raising new hope for those living with the disease.

But there are always new frontiers to conquer; and there are still too many among us whose lives and futures are dimmed by disease and illness. As we prepare for the 21st century, we must press on in our efforts to find cures and ease the suffering caused by our most dreaded diseases. This is especially true in our fight against diabetes, the seventh leading cause of death in our country.

The historic balanced budget legislation I signed on Tuesday is about more than balancing our books. It's about honoring our values and improving the lives of every American.

Today, I want to call attention to some little-known, but very important provisions in our new balanced budget that will take us a tremendous step forward in the fight against diabetes. These investments -- totaling more than two billion dollars over the next five years -- will strengthen our efforts to find a cure, help our most vulnerable citizens better manage the disease, and prevent some of its most traumatic, costly and life-threatening complications.

These landmark investments represent the committed efforts of many members of Congress and my Administration. Representative Elizabeth Furse, whose daughter has diabetes, led the bipartisan Congressional Diabetes Caucus in her tireless fight to include the investments in Medicare in the bill. And I wish Speaker Gingrich could have joined us today. Having watched his mother-in-law live with diabetes, the Speaker has been a great champion for people struggling with this disease -- and a tireless advocate for greater investments in diabetes research, prevention and care. I know he played a leading role in making these new initiatives part of our final budget deal and I thank him.

The new legislation will do three things: First, it expands Medicare benefits for the more than three million senior citizens diagnosed with diabetes. As we all know, early investments in prevention can save us millions in expensive treatments down the line. If left untreated, diabetes can lead to devastating complications such as blindness, amputation and kidney disease. The new benefit will make testing strips and other methods of monitoring blood glucose levels, as well as instruction on how best to manage this complicated disease, available to all Medicare beneficiaries with diabetes.

Through this benefit, we will empower Medicare patients to take better care of themselves at home and avoid complications that can lead to costly hospital stays and destroy their health.

Second, the new legislation will enable Health and Human Services Secretary Donna Shalala to boost funding for Type I -- or juvenile -- diabetes research by $150 million over the next five years. Nearly one million Americans have Type I diabetes, and as many as half of them are children. Even when the disease is managed carefully, these patients almost always experience further complications.

That's why we cannot rest until we find a cure that will free our children from this disease. This unprecedented grant will help us do just that.

Third, we will provide a five-year, $150 million grant to the Indian Health Service for diabetes prevention, research and treatment in our Native American communities. Native Americans are three times as likely as white Americans to have diabetes and far less likely to find adequate treatment for their condition. As Chief Dugan told us, too many Native Americans are suffering the grimmest complications of diabetes, losing limbs or even kidneys to the disease.

This grant will bring public health services, schools, and nutrition programs together to reach families and children living on reservations and provide them with the information and tools to prevent and manage diabetes.

I'd also like to announce that next month, our scientists at NIH will be hosting a workshop that will bring researchers from all across the country to share ideas and discuss the most promising avenues of diabetes research.

Finally, I am announcing a new, unprecedented public-private partnership that will bring our nation's leading health care providers, purchasers, and consumers together to develop uniform guidelines for diabetes care. Through these new guidelines, we can ensure that all doctors provide their patients with thorough and vigilant care -- such as regular eye and foot exams -- to stay as healthy as possible.

Taken together, these initiatives can make life changing differences for millions of Americans. In fact, I was very heartened to hear that the American Diabetes Association has called these initiatives as important for people with diabetes as the discovery of insulin in 1921.

Today, we bring new hope to the 16 million Americans living with diabetes and their families. The past half century has seen mankind split the atom, splice genes, conquer space. I have said that in science, the 21st century will be the age of biology. And with these new investments in our balanced budget, we have every reason to believe that new breakthroughs in diabetes prevention, education and research will not be far on the horizon.

Dr. Gibbons & Dr. Varmus

NEW DIABETES INVESTMENTS TO IMPROVE TREATMENT, PREVENTION, AND RESEARCH FOR AMERICANS WITH DIABETES

Today President Clinton highlighted a set of four initiatives that will improve the lives of the at least 8 million Americans who have been diagnosed with diabetes. Three of these initiatives were included in the balanced budget the President signed into law on Tuesday. The President also emphasized that this new investments emerged as a result of a strong bipartisan partnership with Speaker Gingrich. The American Diabetes Association (ADA) stated that "taken together, these new investments in diabetes, announced by President Clinton today, are as important for people with diabetes as the discovery of insulin in 1921." The President announced:

(1) **An important new Medicare benefit** which will help pay for the critically necessary supplies and self-management instruction which will help the 3.2 million older Americans who suffer from diabetes better manage their treatment.

(2) **A new $150 million investment in diabetes research to prevent and cure Type I (often known as juvenile) diabetes,** to be allocated by Health and Human Services Secretary Donna Shalala.

(3) **A new $150 million investment for prevention and treatment of diabetes among Native Americans**, who are almost three times as likely to suffer from the disease as others in the U.S. population;

(4) **A new public/private effort to assure and improve high quality care for Americans with diabetes.** This effort will review current treatments for diabetes to determine the degree to which they are effective, to recommend alternative approaches that ensure high quality care, and to develop more consistent quality measures for diabetes patients, health plans, and health providers across America.

A New Medicare Benefit to Help People With Diabetes Better Manage Their Care.
The balanced budget expands Medicare's coverage of benefits for people with diabetes by $2.1 billion over five years. In so doing, it expands the number of people able to take advantage of self-management tools will increase the number of Americans who properly manage their diabetes, thereby helping to prevent the debilitating and costly complications too often associated with the disease. Under the new balanced budget, Medicare will cover self-management training offered by physicians and other certified providers rather than only in hospital-based programs as it traditionally has. This will help ensure that more beneficiaries with diabetes can access the necessary education to manage this disease. In addition, Medicare will make blood glucose monitors (including testing strips) available to all beneficiaries with diabetes, whereas Medicare currently covers only insulin-dependent patients. Ensuring Medicare beneficiaries have access to these supplies will help improve their treatment and has great potential to reduce costs. This new legislation was introduced and strongly advocated by Rep. Furse, Rep. Nethercut, and Senator Breaux.

A New $150 Million Investment to Help Research a Cure for Type I (Juvenile) Diabetes.
The HHS Secretary is allocated $30 million annually for five years for research to help find the cure for diabetes. Americans with Type I diabetes with this disease often suffer severe consequences, even when they receive the best treatment and care. The HHS Secretary will have discretion to target the new funds to the best scientific opportunities. This represents the largest single new investment in Type I diabetes.

$150 Million Investment to Help Prevent and Treat Diabetes Among Native Americans. The HHS Secretary is allocated $30 million annually for five years to be used to provide services for diabetes prevention and treatment for Native Americans. The death rate from diabetes is almost three times higher in the Native American population than in the U.S. population as a whole. This new funding will go to help improve prevention efforts (such as improved diet, exercise and other factors that reduce the likelihood of diabetes) and help identify the disease as early as possible. It will also help more Native Americans with diabetes get the necessary information about managing diabetes, for example, by improving linkages between families, public health services, schools, and nutrition programs. Moreover, it will expand access to affordable treatment so that more Native Americans get the care they need to help reduce costly and extensive complications. IHS will work in partnership with Tribes, Urban Indian Health Centers Facilities, and other agencies within HHS, such as the CDC.

A New Diabetes Quality Improvement Project.
Numerous studies by organizations such as the ADA and National Committee on Quality Assurance (NCQA) have shown that many patients are not receiving the medical care known to reduce diabetes complications such as blindness and amputation. In fact, an NCQA study shows that the rate of an annual eye exam in managed care plans averages less than 40 percent. The multiplicity of report cards, each with their own measures, has created confusion and made it difficult to compare and improve care across all delivery systems.

The President announced a major year-long collaborative effort to review current treatments for diabetes to determine the degree to which they are effective, to recommend alternative approaches that ensure high quality care, and to develop more consistent quality measures for diabetes patients, health plans, and health providers across America. Such measures will monitor whether proper care was delivered (for example, an annual eye exam) or health outcomes were achieved (such as appropriate blood glucose levels).

The performance and outcome measures are being developed by a coalition of four organizations: HCFA, the largest purchaser of health care for the diabetic population; the ADA, the largest voluntary health agency dedicated to improving the lives of people with diabetes; NCQA, which develops and maintains a set of standardized performance measures used by more than 90 percent of health plans; and the Foundation for Accountability (FACCT), an organization dedicated to ensuring that consumers have adequate information to make health care decisions. Together, these organizations will work to ensure that millions of consumers, purchasers, and health care providers utilize this new information to improve care.

8 Friday

10:00 AM - 10:30 AM Presidential Breifing on DIabetes

11:00 AM - 12:30 PM Diabetes Event at GT Hosp.

11:10 AM - 11:10 AM Car pick-up 3800 Reservior Rd, Entrance 3 — 11-83
Pre-clinical building

11:30 AM - 12:30 PM KIDS HEALTH in Dirksen, Room 106
for Ed Howard (Alliance for HC Reform)

12:30 PM - 1:30 PM Car pick at Dirksen Bldg to OEOB

1:30 PM - 2:30 PM Pediatric Labeling Mtg., Room 216

3:00 PM - 4:00 PM RaceMtg w/HHS (Bill Corr690-7431 rm 216) →

NEW DIABETES INVESTMENTS TO IMPROVE TREATMENT, PREVENTION, AND RESEARCH FOR AMERICANS WITH DIABETES

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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.**

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)

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

American Diabetes Association.

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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

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American Diabetes Association.
Diabetes Information Service Center
1660 Duke Street
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Tel: 800-232-3472

American Diabetes Association.

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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 practitioner how to test your urine for ketones. 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.

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).

Nutrition and Insulin-Dependent Diabetes

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

American Diabetes Association.

5/94 - 74M

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 in-

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

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

American Diabetes Association

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

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Phone:

CC:

From: Debra

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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.

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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.

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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

File: Diabetes Caucus

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

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Total Pages:	41	(including this cover sheet)	

Transmittal Message

Sara - more than you wanted! I will be in & out of the office until about 6PM (not 11PM!).

① pp 1-7: Brand New Diabetes #'s - to be officially released on Nov. 1. Only real new # is # diagnosed + undiagnosed. After new ADA diagnostic criteria only 1/3 (not 1/2) now undiagnosed, with new diagnosed!

② pp 8-19: 2 documents re NDEP

③ pp 20-22: CDC's proposals re: Type 1 $

④ pp 23-32: NIH's proposals re: Type 1 $

⑤ pp. 33-35: CDC's Brand New Satellite Broadcast - THURSDAY Oct 30 - to all states; >700 down-link sites with over 20,000 people

⑥ pp. 36-40: Very recent agenda of HCFA "Quality" Meeting; and ADA press release. NEXT Quality Meeting - Jan 98.

Frank V.

Islanders are at particularly high risk for type 2 diabetes.

Gestational diabetes develops in 2% to 5% of all pregnancies but disappears when a pregnancy is over. Gestational diabetes occurs more frequently in African Americans, Hispanic/Latino Americans, American Indians, and persons with a family history of diabetes. Obesity is also associated with higher risk. Women who have had gestational diabetes are at increased risk for later developing type 2 diabetes. In some studies, nearly 40% of women with a history of gestational diabetes developed diabetes in the future.

"Other specific types" of diabetes result from specific genetic syndromes, surgery, drugs, malnutrition, infections, and other illnesses. Such types of diabetes may account for 1% to 2% of all diagnosed cases of diabetes.

Complications of diabetes

Heart disease

-- Heart disease is the leading cause of diabetes-related deaths. Adults with diabetes have heart disease death rates about 2 to 4 times as high as that of adults without diabetes.

Stroke

- The risk of stroke is 2 to 4 times higher in people with diabetes.

High blood pressure

- An estimated 60% to 65% of people with diabetes have high blood pressure.

Blindness

- Diabetes is the leading cause of new cases of blindness in adults 20 to 74 years old.
- Diabetic retinopathy causes from 12,000 to 24,000 new cases of blindness each year.

Kidney disease

- Diabetes is the leading cause of end stage renal disease, accounting for about 40% of new cases.
- 27,851 people with diabetes developed end stage renal disease in 1995.
- In 1995, a total of 98,872 people with diabetes underwent dialysis or transplantation.

Nervous system disease

- About 60% to 70% of people with diabetes have mild to severe forms of nervous system damage (which often includes impaired sensation or pain in the feet or hands, slowed digestion of food in the stomach, carpal tunnel syndrome, and/or other nerve problems).
- 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 people with diabetes

--From 1993 to 1995, about 67,000 amputations were performed each year among people with diabetes.

Dental disease

♦ Periodontal disease (a type of gum disease that can lead to tooth loss) occurs with greater frequency and severity among people with diabetes. Periodontal disease has been reported to occur among 30% of people aged 19 years or older with type 1 diabetes.

Complications of pregnancy

♦ The rate of major congenital malformations in babies born to women with preexisting diabetes varies from 0% to 5% among women who receive preconception care to 10 % among women who do not receive preconception care.

♦ Between 3% to 5% of pregnancies among women with diabetes result in death of the newborn; this rate compares to that of 1.5% for women who do not have diabetes.

Other complications

- Diabetes can directly cause acute life-threatening events, such as diabetic ketoacidosis* and hyperosmolar non-ketotic coma.*

- People with diabetes are more susceptible to many other illnesses. For example, they are more likely to die of pneumonia or influenza than people who do not have diabetes.

* Diabetic ketoacidosis and hyper-osmolar non-ketotic coma are medical conditions that can result from biochemical imbalance in uncontrolled diabetes.

Cost

Total (direct and indirect): $92 billion (United States, 1992)

Direct medical costs: $45 billion

Indirect costs: $47 billion (disability, work loss, premature mortality)

This estimate is in contrast to higher estimates cited elsewhere that are based on all health care costs incurred by people with diabetes, including costs not resulting from diabetes. New cost estimates are expected to be released within 6 months.

New diagnostic criteria for diabetes*

The new diagnostic criteria for diabetes include the following changes.

- The routine diagnostic test for diabetes is now a fasting plasma glucose test rather than the previously preferred oral glucose tolerance test. (However, in certain clinical circumstances, physicians may still choose to perform the more difficult and costly oral glucose tolerance test)

- A confirmed** fasting plasma glucose value of greater than or equal to 126 mg/dl indicates a diagnosis of diabetes. Previously, a value of greater than or equal to 140 mg/dl had been required

for diagnosis.

- In the presence of symptoms of diabetes, a confirmed** non-fasting plasma glucose value of greater than or equal to 200 mg/dl indicates a diagnosis of diabetes.
- When a doctor chooses to perform an oral glucose tolerance test (by administering 75 grams of anhydrous glucose dissolved in water in accordance with World Health Organization standards and then measuring the plasma glucose concentration two hours later), a confirmed** glucose value of greater than or equal to 200 mg/dl indicates a diagnosis of diabetes.
- In pregnant women, different requirements are used to identify the presence of gestational diabetes.

* For further information about the new diagnostic criteria for diabetes, please refer to The Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, as referenced in the Appendix.

** Except in certain specified circumstances, abnormal tests must be confirmed by repeat testing on another day.

Treatment of diabetes

Diabetes knowledge, treatment, and prevention strategies advance daily. Treatment is aimed at keeping blood glucose near normal levels at all times. Training in self-management is integral to the treatment of diabetes. Treatment must be individualized and must address medical, psychosocial, and lifestyle issues.

Treatment of type 1 diabetes: Lack of endogenous insulin makes type 1 diabetes particularly difficult to control. Treatment requires a strict regimen that typically includes a carefully calculated diet, planned physical activity, home blood glucose testing several times a day and multiple daily insulin injections.

Treatment of type 2 diabetes: Treatment typically includes diet control, exercise, home blood glucose testing, and in some cases, oral medication and/or insulin. Approximately 40% of people with type 2 diabetes require insulin injections.

Impaired fasting glucose

Impaired fasting glucose is a new diagnostic category in which persons have fasting plasma glucose of 110-125 mg/dl. These glucose values are greater than the level considered normal but less than the level that is diagnostic of diabetes. It is estimated that 13.4 million persons, 7.0% of the population, have impaired fasting glucose. Scientists are trying to learn how to predict which of these persons will go on to develop diabetes and how to prevent such progression.

Appendix

How were the estimates in this fact sheet derived?

Periodically, the federal government conducts surveys to determine the health of Americans. Such surveys involve questionnaires and medical tests. The diabetes prevalence and incidence estimates presented in this fact sheet were developed by analyzing the newest available national survey data and then adjusting for changes in the population based on 1997 census estimates. The prevalence of diagnosed diabetes represents the number who said they had diabetes. The prevalence of undiagnosed diabetes represents the number of people who said they did not have diabetes, but when given a fasting plasma glucose test, they did in fact have abnormally elevated blood glucose levels (defined as fasting plasma glucose levels greater than or equal to 126 mg/dl). Other estimates presented in this Fact Sheet were based on individual surveys, research projects, and registry data. A listing of references and additional data sources appears on the next page.

Has the number of persons with diabetes changed since the previous National Diabetes Fact Sheet, which was issued in 1995?

Between the 1995 and 1997 fact sheets, the number of persons with diagnosed diabetes increased from 8 million to 10.3 million, but the number of persons with undiagnosed diabetes decreased. For the 1995 National Diabetes Fact Sheet, the number of persons with undiagnosed diabetes was estimated from research using the oral glucose tolerance test (OGTT) to identify undiagnosed diabetes. In contrast, for the 1997 National Diabetes Fact Sheet, the number of persons with undiagnosed diabetes was estimated from research using the fasting plasma glucose test (FPG) according to recently enacted recommendations. These tests are not equivalent, however, and fewer cases of undiagnosed diabetes are identified using the FPG under current recommendations. An enhanced national effort to identify previously undiagnosed persons may also have contributed to a decrease in the number of persons with undiagnosed diabetes. Continued efforts to identify persons with undiagnosed diabetes, the implementation of new guidelines for screening, and the use of an easier and less expensive diagnostic test are all likely to lead to even further decreases in the number of persons with undiagnosed diabetes and increases in the number of persons with diagnosed diabetes.

References

- American Diabetes Association. *Direct and Indirect costs of diabetes in the United States in 1992.* Alexandria, VA: American Diabetes Association, 1993.
- National Diabetes Data Group, National Institutes of Health. *Diabetes In America, 2nd Edition.* Bethesda, MD: National Institutes of Health, 1995. NIH Publication No. 95-1468.
- Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care* 1997 July;20(7):1183-97.
- Valway S, Freeman W, Kaufman S, Welty T, Helgerson SD, Gohdes D. Prevalence of diagnosed diabetes among American Indians and Alaska Natives, 1987. *Diabetes Care* 1993;16 (Suppl 1):271-276.

-- U.S. Department of Health and Human Services. Physical activity and health: a report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 1996.

- U.S. Renal Data System. USRDS 1997 Annual Data Report. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Disease, 1997.

Additional sources

- Calculations were performed by the National Institutes of Health and the Centers for Disease Control and Prevention using data from various surveys including the Third National Health and Nutrition Examination Survey (NHANES III), the National Health Interview Survey (NHIS), and U.S. Census estimates for current population. The national prevalence estimates for diabetes were based on Harris MI, Unpublished Data from NHANES III, 1988-1994.
- Information about Native Hawaiians was provided by the Hawaii Diabetes Control Program and is based on Wen M, Unpublished Analysis of Data from the Behavioral Risk Factor Surveillance System (BRFSS) from 1988 - 1995.

Acknowledgments

The following organizations collaborated in compiling the information for this fact sheet:

American Association of Diabetes Educators
http://www.diabetesnet.com/aade.html

American Diabetes Association
http://www.diabetes.org

Centers for Disease Control and Prevention
http://www.cdc.gov/diabetes

Department of Veterans Affairs
http://www.va.gov/health/diabetes/

Health Resources and Services Administration
http://www.hrsa.dhhs.gov

Indian Health Service
http://www.ihs.gov/IHSMAIN.html

Juvenile Diabetes Foundation International
http://www.jdfcure.com

National Diabetes Education Program
http://www.niddk.nih.gov/NDEP/NDEP.htm

National Institute of Diabetes and Digestive and Kidney Disease of the National Institutes of Health
http://www.niddk.nih.gov

U.S. Department of Health and Human Services, Office of Minority Health
http://www.omhc.gov

Reminder to all collaborating organizations: This draft document is intended for your review only and is not meant to be shared outside of your organization. It includes all changes through this point in the clearance process. Please let me know immediately if this draft is not ok.

Thank you again for all of your work.

Marc A. Safran, MD
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October 23, 1997

8

Changing the way diabetes is treated

Purpose

The National Diabetes Education Program is a Federally sponsored initiative that involves public and private partners to improve the treatment and outcomes for people with diabetes, to promote early diagnosis, and ultimately to prevent the onset of diabetes.

Need

Current scientific evidence demonstrates that much of the morbidity and mortality of diabetes can be eliminated by aggressive treatment with diet, exercise, and new pharmacology approaches to achieve tighter blood glucose levels. Unfortunately, a wide gap still exists between current and desired diabetes care and practices.

In addition, public awareness about diabetes is very low, despite the fact that the disease is one of the leading causes of death and disability in the United States--affecting an estimated 16 million Americans, including 8 million who are undiagnosed.

Goal

The goal of the program is to reduce the morbidity and mortality associated with diabetes and its complications.

Objectives

The National Diabetes Education Program's objectives 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 about diabetes and its control and to promote better self-management behaviors among people with diabetes.
- To improve health care providers' understanding of diabetes and its control and to promote an integrated approach to care.
- To promote health care policies that improve the quality of and access to diabetes care.

Sponsors

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) are jointly sponsoring the development of the program.

Audiences

The National Diabetes Education Program's target audiences include:

- General Public
- People with Diabetes and Their Families
- Health Care Providers
- Payers and Purchasers of Health Care and Health Care System Policy Makers

Strategies

The National Diabetes Education Program will:

- Create program partnerships with other organizations concerned about diabetes and the health status of their constituents.
- Develop and implement ongoing diabetes awareness and education activities.
- Identify, develop, and disseminate educational tools and resources, including those that address the needs of special populations.
- Review, support, and disseminate science-based diabetes care guidelines.
- Promote policies and activities to improve the quality of and access to diabetes care.

Timeline

The key dates are:

- Develop a National Diabetes Education Program Partnership Network – Fall 1997.
- Convene the National Diabetes Education Program Partnership Meeting – Winter 1998.
- Launch a Public Awareness Campaign – Winter 1998.

Steering Committee

The key organizations involved in implementing the program include:

• American Academy of Family Physicians • American Academy of Nurse Practitioners • American Association of Clinical Endocrinologists • American Association of Diabetes Educators • American College of Physicians • American Diabetes Association • American Dietetic Association • American Pharmaceutical Association • Association of American Indian Physicians • Association of Asian/Pacific Community Health Organizations • California Diabetes Control Program • Endocrine Society • General Motors Corporation • Juvenile Diabetes Foundation International • Links, Inc. • Lions Clubs International • Michigan Diabetes Research and Training Center • Mutual of Omaha Companies • National Coalition of Hispanic Health & Human Services Organizations • National Kidney Foundation • National Medical Association • Prudential Center for Health Research • Puerto Rican Association of Diabetes Educators • Kaiser Permanente (Stockton, CA)• Vanderbilt University Diabetes Research and Training Center • Wyoming Diabetes Control Program

Getting Involved

The program is forming partnerships with organizations concerned about diabetes and, the health status of their constituents. Your organization can work with the National Diabetes Education Program in a variety of ways. You can adopt the program's messages and tailor them for your members or constituents. You can also disseminate information, coordinate activities, and share resources with other partner organizations. You can work with other organizations to help promote integrated approaches to diabetes care.

For More Information

To learn more about the National Diabetes Education Program, please contact:

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PLANNING THE NATIONAL DIABETES EDUCATION PROGRAM

Executive Summary

June 1997

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a joint initiative of the
Centers for Disease Control and Prevention
and the National Institutes of Health

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Planning the National Diabetes Education Program
Executive Summary

Diabetes is one of the most common and serious chronic diseases in the United States. Presently, 16 million people in the U.S. have diabetes.[1] Half are undiagnosed, because diabetes is generally asymptomatic until complications develop. The prevalence of diabetes is rising for three reasons: the aging of the U.S. population; the growth in minority populations most susceptible to Type II diabetes; and the increasing prevalence of obesity.

The statistics regarding the morbidity and mortality from diabetes are staggering.

- Diabetes is one of the six leading causes of death by disease in the United States[2]
- It is the leading cause of adult blindness, end-stage renal disease, and non-traumatic lower extremity amputations.[3]
- People with diabetes are two to five times more likely to have coronary heart disease and stroke than people without diabetes.[4]
- Diabetes costs this country over $100 billion a year, accounting for 13 percent of total U.S. health care expenditures.[5]

Advances in diabetes research now provide the clinical and therapeutic means to improve outcomes for people with diabetes. The 1993 landmark study, the Diabetes Control and Complications Trial (DCCT), conclusively showed that improved glucose control can retard the onset and progression of diabetes complications affecting the eyes, kidneys, and nerves.[6] In addition, new medications are available to lower blood glucose and methods for measuring glucose levels have greatly improved.

Nonetheless, research advances in diabetes are not being communicated effectively and diabetes is not being managed aggressively. The U.S. is far from reaching the diabetes objectives set in the U.S. Department of Health and Human Services *Healthy People 2000*.[7] Physician practices often do not meet recommended standards of diabetes care. Many patients do not manage their diabetes well. Furthermore, the health care system, which is designed to treat acute and episodic illnesses, is poorly equipped to manage a complex, multisystemic chronic disease like diabetes. A national diabetes education program is needed to address the gap between current and desired diabetes care and practices.

The National Diabetes Education Program

What Is the National Diabetes Education Program (NDEP)?

The National Diabetes Education Program (NDEP) is a joint initiative sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health and the Centers for Disease Control and Prevention (CDC). It is also a partnership of public and private organizations that are concerned about the health status of their constituents. The purpose of the NDEP is to improve the treatment and outcomes for people with diabetes, to promote early diagnosis, and, ultimately to prevent the onset of diabetes.

NDEP Program Goal and Objectives

The NDEP planning process--which invited broad input from over 100 organizations concerned with diabetes and health-- developed the following program goal: ***To reduce the morbidity and mortality of diabetes and its complications.***

The following program objectives support the NDEP goal:

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

2. To improve understanding of diabetes and its control and to promote self-management behaviors among people with diabetes.

3. To improve health care providers understanding of diabetes and its control and to promote an integrated approach to care.

4. To promote health care policies and activities that improve quality and access to diabetes care.

NDEP Target Audiences

Program strategies and activities will be designed for four broad audiences:

- the general public
- people with diabetes and their families,
- health care providers, and
- payers and purchasers of health care and policy makers.

NDEP Program Strategies and Activities

The NDEP will employ a variety of strategies and activities to accomplish its program objectives.

1. The NDEP will develop partnerships.

There is a wealth of expertise and experience in the diabetes community--and beyond. The NDEP will develop partnerships with organizations concerned about diabetes and the health status of their constituents to enhance the program's effectiveness. The NDEP partnership will facilitate, coordinate, and promote diabetes initiatives and activities of the NDEP and other groups. Through the partnership, the NDEP will deliver a *consistent* set of messages to its audiences and it will integrate NDEP strategies and messages into existing systems of diabetes care, education programs, and community-based activities.

- The NDEP is a subcommittee of the Federal Government's Diabetes Mellitus Interagency Coordinating Committee. The NDEP organizational structure includes an Executive Committee, a Steering Committee, and a Partnership Network. The Steering Committee will be selected by the Executive Committee and comprised of representatives from key diabetes, health care, and ethnic minority organizations. The Steering Committee will help guide program implementation and address key program issues. The Partnership Network will be comprised of a broad range of professional associations, voluntary groups, and private sector companies interested in participating in the program.

- Members of the Steering Committee and Partnership Network will participate in the NDEP in key ways: developing diabetes education activities that use NDEP messages and materials; distributing NDEP messages and materials to their constituents; serving on task forces to address key program issues; putting diabetes on their organization's agenda and tapping NDEP's expertise and resources for program development; and co-sponsoring special events and activities.

2. The NDEP will develop and implement ongoing diabetes awareness and education activities.

The NDEP Partnership will build national support for diabetes through awareness and education campaigns targeted to each of the NDEP audiences. Messages will emphasize that diabetes is serious, common, costly, and controllable. Messages will be clear, consistent, action-oriented, and based on scientific evidence. They will be communicated widely through multiple, targeted mass media channels. To enhance the effectiveness of

NDEP strategies and messages in communities, the NDEP will engage the Steering Committee, the Partnership Network and other community-based groups in planning, implementing, and evaluating education activities.

- Educational activities for the general public will be designed to generate a national climate of diabetes awareness, promote healthy lifestyle behaviors, and reduce the alienation and discrimination often directed toward people with diabetes. Community-based interventions will reinforce media messages and facilitate behavior change.

- Educational activities for people with diabetes and their families will increase understanding of diabetes and promote practice of appropriate diabetes self-management skills.

- Educational activities for health care professionals will focus on the seriousness of diabetes and the importance of blood glucose control, patient education, and patient support using a team approach. Activities will provide guidance on treatment duration, frequency of screening for complications, and associated risk factors.

- Educational activities for payers, purchasers, and policy makers will increase awareness of the short- and long-term economic and clinical benefits of quality diabetes care, particularly the important role of good blood glucose control, screening for diabetes-related complications, patient education, and reduction of cardiovascular disease risk factors among people with diabetes.

3. The NDEP will identify, collect, develop, and disseminate educational tools and resources.

The NDEP will work with the National Diabetes Information Clearinghouse of the NIDDK to serve as a central coordinator for a wide range of diabetes information and educational resources, statistical data, and current research information. Working through the partnership, the program will survey the availability of materials and diabetes resources, promote access to them, and work with partners to develop educational tools where gaps exist.

- For the general public, the NDEP will promote and disseminate information about populations at risk, diabetes risk factors, and symptoms.

- For people with diabetes and their families, the NDEP will translate new research findings on diabetes treatment, prevention, and issues specific to special populations into materials that are sensitive to cultural, linguistic, and community differences. The NDEP will identify and/or develop tools and educational materials to promote self-management and enhance the community=s and family=s ability to support people with diabetes. The NDEP will identify and promote existing programs and support groups for patients and their caregivers.

- For health care providers, the NDEP will identify and disseminate materials and tools such as train-the-trainer programs, interactive computer programs for clinical and academic settings, and new curricula in undergraduate and graduate education programs.

- For payers, purchasers, and policy makers, the NDEP will identify and disseminate best practice models from a variety of settings as well as strategies to improve the efficiency and cost-effectiveness of delivering diabetes care.

4. The NDEP will review, support, and disseminate science-based diabetes care guidelines.

Health care providers, insurers, industry groups, and even patients need information on diabetes care guidelines that reflect quality diabetes care. The NDEP will review, adopt, and disseminate guidelines that are scientifically based, include definable and measurable outcomes, represent a consensus of multiple provider groups, and include alternatives to allow for use in different practice settings.

5. The NDEP will promote policies and activities to improve quality and access to diabetes care.

- The NDEP will strive to focus attention on the economic and clinical benefits of quality diabetes care, especially the role of secondary and tertiary prevention. Program efforts will be directed toward maximizing access to and the quality of diabetes care.

- For people with diabetes covered by programs such as Medicare and Medicaid, the NDEP and its partners will develop information and educational materials to help patients understand their diabetes care benefits and provide guidance on using primary care services effectively.

- Working with the NDEP's health care provider partners, the NDEP will promote an integrated team approach to diabetes care directed by the primary care provider with referrals to allied health care providers and specialists. The partnership will address important issues such as improving access for uninsured or underinsured people with diabetes.

- For payers, purchasers and policy makers, the NDEP will explore ways to: encourage reimbursement for care provided by qualified nonphysicians such as diabetes educators; document problems of access; and identify model diabetes benefits packages that incorporate all of the features and services of quality diabetes care.

6. The NDEP will evaluate its activities.

The diabetes objectives set by the U.S. Department of Health and Human Services forthcoming *Healthy People 2010* will be reviewed and considered as a benchmark to measure the impact of the NDEP. The program will conduct process and outcome evaluations of NDEP activities and use the evaluations to plan and revise future activities.

Next Steps

1. Establish the NDEP Steering Committee.

The new NDEP Steering Committee will be appointed during the summer of 1997 and its first meeting will be held in the Fall of 1997.

2. Develop the NDEP Partnership Network.

The NDEP will identify voluntary organizations and private companies as potential partners. The NDEP will obtain information about these groups current and future diabetes/health education program plans and explore ways to establish mutually beneficial partnerships.

3. Develop the NDEP Communication Plan.

The NDEP staff will develop the program's communication plan, which will include ways to convey messages, achieve awareness, and educate each of the four NDEP audiences. The NDEP will conduct target audience research to develop program messages, select communication channels, and produce materials. A timeline for implementing activities

and an evaluation plan also will be developed. The program will be launched with a mass media awareness campaign in early 1998.

4. **Finalize the Strategic Plan.**

The Steering Committee will review the NDEP Planning Report and prioritize the activities and identify new ones, if necessary. The Strategic Plan will describe the specific steps to implement the activities, required resources, and evaluation activities.

The Steering Committee will form working groups to help plan, implement, and evaluate the wide array of activities that are needed. The committee also will coordinate activities and facilitate action with other diabetes organizations.

Conclusion

Developing the National Diabetes Education Program is a major step toward closing the gap between current and desired diabetes care and practices. The advice and recommendations of the many diabetes and health education experts who participated in planning the NDEP have been invaluable. The challenge ahead is to begin implementing the program so that it truly makes a difference for people with diabetes.

The National Diabetes Education Program

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Internet Web Site:
CDC: http://www.cdc.gov/diabetes
NIH: http://www.niddk.nih.gov
NDEP: under development

Other source for NDEP updates:
NIH: 1-800-GET-LEVEL (1-800-438-5383)

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Proposal by the Centers for Disease Control and Prevention for

(20)

Special Diabetes Programs for Type 1 Diabetes

BACKGROUND

Type 1 diabetes mellitus (DM- previously referred to as IDDM) remains a challenging disorder in terms of pathogenesis, prevalence, seriousness and cost. Reflecting both a strong genetic predisposition coupled with environmental factors, Type 1 DM a) varies in incidence world-wide; b) appears to be increasing within the United States (U.S.); c) can be predicted several years prior to clinical onset with a combination of genetic, immunologic, and insulin secretory testing. Once Type 1 DM is clinically diagnosed, existing efficacious and cost-effective secondary and tertiary prevention programs can be utilized to limit the development of associated complications. Unfortunately, these strategies are not being applied uniformly or effectively in daily clinical practice, with resultant unnecessary eye, kidney, foot and cardiovascular disease.

A multi-component effort is now being directed to Type 1 DM which includes a) expanded genetic, immunologic, biochemical, clinical, epidemiologic and health services research; b) primary prevention trials for Type 1 DM in Europe and in the U.S. (DPT-1); and c) structured and systematic efforts to improve access to efficient and quality preventive care for those with Type 1 DM. Though activities are ongoing in all these areas, expanded programs and new initiatives are needed to both understand the challenges and reduce the burden of Type 1 DM.

PROPOSED PROGRAMS

Based on findings from recent scientific and clinical studies, deliberations at a recent National Institute of Health conference on diabetes, and the unique expertise, experience and responsibility of the Centers for Disease Control and Prevention (CDC), the CDC proposes to use new funds for Type 1 DM efforts for the following programs:

1. National Diabetes Laboratory

Because of the extensive experience that the CDC has in establishing and providing assistance on reference laboratories, the CDC is proposing to develop a National Diabetes Laboratory. Within the National Center for Environmental Health at CDC, the Division of Environmental Health Laboratory Science's (EHLS) mission includes a responsibility "to assist disease-prevention programs that need special or unusual laboratory expertise." Biomonitoring, standardization of laboratory measurements, quality control and performance evaluation for state public health laboratories, research into the relationship between genetics and environmental exposure in causes of disease, and sophisticated nutrient, toxic, protein and biologic measurements represent activities of EHLS. Researchers within EHLS collaborate with government agencies, including the NHLBI and NCI at NIH; health departments, academic institutions, and international organizations. Also, because of a special interest in cardiovascular disease, the CDC has established an international reputation in the standardization and quality control of many lipid assays.

The proposed National Diabetes Laboratory would focus on 3 main laboratory activities supportive of the emerging scientific efforts in Type 1 DM described above, would build upon existing expertise at CDC, and would consist of genetic and immunologic laboratory measurements; reference measurements of glycosylated proteins, including hemoglobin A1C and advanced glycation endproducts (AGEs); and quality storage mechanisms for essential samples from scientific clinical trials.

a. Genetic and Immunologic Laboratory: Several clinical trials and individual studies relevant to prevention of Type 1 DM are now underway. Genetic research has identified multiple sites associated with Type 1 DM, e.g. IDDM1, the major histocompatibility complex (MHC)HLA region on chromosome 6p21; IDDM2, the insulin gene region on chromosome 11p15. These two regions contribute approximately 42 and 10% respectively of the observed familial clustering of the disease. Eighteen other chromosome regions show some positive evidence of linkage to the disease, with some combination of genes being risk factors across ethnic groups, while other combinations being specific to certain groups. In addition, certain "immunological markers" are being used broadly to identify those individuals are at increasing risk for Type 1 DM. The National Diabetes Laboratory would provide reference measurements, control materials, and technical consultation for genetic and immunologic laboratory measurements that help identify effective clinical preventive approaches for type 1 DM.

b. Recent studies, especially the DCCT, have established the efficacy and cost-effectiveness of glycemic control for improvement of long-term health in Type 1 DM. In addition, pathogenetic mechanisms of tissue damage related to hyperglycemia are now being identified. For day to day clinical decisions, comparability ("standardization") of clinical laboratory results is a fundamental reason for measurement reference systems. For example, the present National Glycohemoglobin Standardization Program uses the BioRex 70 HPLC method. More recently, a more accurate reference method based on isotope-dilution mass spectrometry (ID/MS) has been developed for HbA1c measurements, but whose results are 40% lower than the BioRex 70 HPLC method. In a similar manner, scientific studies indicate the importance of AGEs as both a mechanism of microvascular complications, as well as a possible better index of long-term glucose control. The National Diabetes Laboratory would establish reference methods for glucose, appropriate HbA1c assays, and analytical methods for AGEs, as well as technical consultation assistance.

c. For rigorous and scientific studies of Type 1 DM, appropriate storage facilities for tissue, blood, protein and DNA samples would be critical in facilitating extant scientific investigation, as well as future opportunities for investigation upon new study findings relevant to Type 1 DM. The presence of state-of-the-art storage facilities at CDC, already existing and soon to be completed, will provide an important opportunity for storage of samples from rigorous scientific studies for continued and future investigation.

Requested support: $3 million/year

2. <u>Enhanced Surveillance System for Type 1 DM:</u>

The extent and distribution of type 1 DM in the U.S. remain incompletely understood. Furthermore, several studies indicate that care for this disease is sub-optimal despite convincing science of the efficacy of glycemic control (secondary prevention) as well as early microvascular complication detection and treatment (tertiary prevention). In order to improve epidemiologic information about Type 1 DM, as well as a) identify potential opportunities for fundamental research opportunities; and b) track and eventually improve the care being provided in order to limit preventable complications, CDC will use its expertise in surveillance to establish pilot "enhanced surveillance systems" of Type 1 DM in selected populations. For example, an increasing number of individuals with DM, including Type 1 DM, are receiving their initial and long-term care in managed care organizations (MCOs). The CDC has established cooperative epidemiologic programs with several large MCOs, and would improve and use these expanding data sources to establish surveillance systems for Type 1 DM. Identification of new onset Type 1 DM, as well as characterization of care patterns, and predictors of complications - particularly using the resources of the CDC Laboratory described above - will permit an

evaluation of this new type of surveillance system. If, upon careful evaluation, the "enhanced Type 1 DM surveillance system" were determined to be an efficient and useful method to identify and track individuals with new onset as well as existing Type 1 DM, the program would be expanded to other MCOs throughout the U. S., as well as other systems of care delivery.

Requested support: $2 million/year

3. Demonstration Trials to Translate Research Into Better Diabetes Care for Type 1 Diabetes:

Data indicate that care for Type 1 diabetes is inadequate, despite convincing science of its efficacy (DCCT). Remedying this problem requires determining *why* Type 1 diabetes care is inadequate. The answers can be found through demonstration and intervention trials designed to address "gaps in care" for Type 1 diabetes programs. The trials can be conducted within CDC's well-established network of state-based diabetes control programs, managed care organizations, community-based organizations, and other service providers. CDC would implement demonstration projects (multi-site, randomized trials) regarding implementation of glycemic control, reducing the risk of complications, and providing better preventive care among persons with Type 1 diabetes. These demonstrations would address cultural factors, patient and provider characteristics, access factors (such as integrating prevention and control with school systems and family-centered education), and integration with a range of delivery systems. Results would then be disseminated and implemented through CDC's state-based diabetes control programs.

Requested support: $1 million/year

SUMMARY:

Type 1 DM presents both challenges and opportunities to better understand the pathogenesis and management of this increasingly common disorder. This information can result in more effective primary, secondary and tertiary prevention efforts in order to reduce the devastation associated with the disease. Improved efforts to identify and track individuals with Type 1 DM; as well as augmented laboratory programs for quality control of assays relevant to Type 1 DM; development of new laboratory procedures and tests; and storage of blood, genetic and tissue samples from rigorous scientific studies, will all supplement the important NIH research activities directed to Type 1 DM. This collaborative interaction between CDC and NIH will further expand our existing programmatic coordination, and provide a stronger synergistic effort to control the burden of Type 1 DM.

TOTAL PROPOSED FUNDING:

1. National Laboratory - $3 million/year

2. Enhanced Surveillance - $2 million/year

3. Demonstration Trials - $1 million/year

Total - $6 million/year

(23)

Vinicor, Frank

From: Eastman, Richard C.
To: Alexander, Duane; Anthony Fauci; Audrey Penn; Bill Foster; Carol Feld; Charles Wells; Cheryl Sherman; Claude Lenfant; Daniel Rotrosen; Earl Laurence; Francis Collins; Grave, Gilman; Joan Harmon; Judith Fradkin; Kupfer, Carl; Peter Savage; Phillip Gorden; Richard Farishian; Richard Hodes; Stanley Slater; Vaitukaitis, Judith; Vinicor, Frank
Subject: Initial Action on Type 1 Diabetes Initiative
Date: Tuesday, October 14, 1997 7:32AM

Special Advisory Panel Members:

I have attached the summary slides from the October 7 Advisory meeting on the Type 1 diabetes Initiative. We are prodeeding with 4 RFAs:

1. Islet cell transplantation and other cellular therapies
2. Glucose sensors
3. Pathogenesis of microvascular complications with emphasis on growth factors and glucotoxicity
4. Immunopathogenesis of type 1 and basic mechanisms for antigen presentation in human cells

I have asked Judy Fradkin (594-8814) and Joan Harmon (594-8814) to organize the writing of these 4 RFAs by November 1. We welcome and request your assistance and participation, and thank you in advance for your assistance.

We propose to create working groups to develop further the initiatives on ESTs, viral factors, the humanized mouse model, and noninvasive methods for assessing beta cell mass and inflammation. In addition, a working group will develop a strategy for the nephropathy genes initiative. More to follow on these efforts in the near future.

Please let me know if you have any questions. Thank you in advance for your help.

Richard C. Eastman M.D.

<<File Attachment: Type1Dia.doc>>

Type 1 Diabetes Prevention and Cure

FY 1998-2003 Initiative
Advisory Meeting
October 7, 1997

Categories of Research Initiative

Category 1 Patient Oriented Innovative Research
Category 2 Regular RFAs
Category 3 Investigator Initiated Research
Category 4 Supplements to Existing Programs
Category 5 Major Clinical Trials

Category 1: Patient Oriented Innovative Research

2 year funding

- ability to compete for continuation funding after pilot and feasibility phase
- review process innovative and rapid
- encompasses short term development of established systems

Therapy Breakout Group Summary Report (1)

Behavioral research to improve adherence with complex treatment regimens

- Biologic and Cellular Approaches to Euglycemia
  - islet transplantation
  - stem cell technology
  - islet growth and development

Therapy Breakout Group Summary Report (2)

Mechanical Approaches to Euglycemia
- emphasis on non-optical sensors that are non-invasive or minimally invasive

Pharmacologic Approaches to Euglycemia
- prevention of hypoglycemia
- -beta cell growth and development

Microvascular Complications Breakout Group Summary Report (1)

Develop Expressed Sequence Tag libraries for tissues involved in diabetes complications
- pericyte, mesangial cell, nerve, endothelium

Genetics of nephropathy
- polymorphisms in candidate genes

Microvascular Complications Breakout Group Summary Report (2)

Effects of growth factors in diabetes complications
- e.g. VEGF, NGF, TGF-ß

Mechanisms of glucose toxicity
- effect on growth factors
- -other mechanisms

Mechanism of hypoglycemia unawareness

Macrovascular Complications Breakout Group Summary Report (1)

Define natural history of CVD in Type 1 diabetes using non-invasive techniques
- EDIC (DCCT cohort)
- other existing patients

Apply to identifying high risk individuals with subclinical disease for clinical trials
- High CVD risk without classical dyslipidemia
- pathogenesis of CHF

Macrovascular Complications Breakout Group Summary Report (2)

Need for animal models to study interaction and mechanisms of injury of
- glycation
- -oxidation
- -thrombogenesis

Clinical trial including Type 1 and 2
- role of glycemic control relative to other risk factors (BP, lipids, smoking)

Etiology and Pathogenesis Breakout Group Summary Report (1)

Viral and environmental role
- recruit virologists to the diabetes field
- make Type 1 diabetes a reportable disease

Genetics
- mechanism of antigen presentation and role in pathophysiology
- DQ6 protective mechanism
- non-HLA genetic factors

Etiology and Pathogenesis Breakout Group Summary Report (2)

Need to obtain human lymphoid tissue from patients to study antigen presenting cells, T and B cells
- Need for supply of autoantigens

proinsulin, GAD etc.

Need to understand the role of the fetal immune system in pathogenesis in humans

Etiology and Pathogenesis Breakout Group Summary Report (3)

Immunomodulation trials

anti-CTLA4, IFA-GAD

– explore recruitment of DPT-1 patients who are diabetic before randomization, or who are otherwise excluded from the trial

CDC Reference lab for Type 1 related immunology assays (ICA, GAD), T cell assays

Etiology and Pathogenesis Breakout Group Summary Report (4)

Develop metabolic/immune surrogates for progression to diabetes to make pilot studies of novel interventions feasible and meaningful

DPT-1 ancillary study on immunopathogenesis

– noninvasive or invasive measures of beta cell mass/function/inflammation

Crosscutting Issues Summary Report (1)

Develop techniques for noninvasive measurement of islet mass/function

- NIH facilitation of sharing of genomic data
- Develop humanized mouse model to Type 1 diabetes
- Develop EST libraries for human islet, endothelium, insulin responsive tissues, lymphocytes

Crosscutting Issues Summary Report (2)

Need for high technology resources for clinical and basic studies

NMR

Training and career development

- Industry -academia - NIH - JDFI collaboration

Discussion of CDC Proposals

There was great enthusiasm for a reference laboratory for assays related to the prevention and cure of Type 1 diabetes, including antibodies to autoantigens, DNA sequencing, and insulin

The proposal for a HbA1c reference lab was felt to be duplicative of the existing efforts towards standardization that have been taken by the AACC in collaboration with the DCCT study group. CDC should explore the role it might play in this ongoing effort

There was also enthusiams for the proposed storage facility for samples

There was less enthusiasm for the enhanced surveillance system for Type 1 diabetes. The proposal would define health care delivery, but was felt unlikely to result in a paradigm shift in the approaches to achieving euglycemia

There was also less enthusiasm for the proposal for translational research. While some felt that this would lead to useful results during the time span of the initiative, others felt that the funds should be used to achieve a more fundemental breakthrough in the prevention and cure of Type 1 diabetes.

Summary of Priorities (1)

Request for Applications

1. Cellular therapy and islet cell growth
2. Glucose sensors (biologic and other novel)
3. EST data bases for diabetes relevant tissues
   human islet, endothelium, muscle, adipose tissue
4. Basic studies of growth factors on complications
5. Viral/environmental factors biology in IDDM
6. "Humanized" mouse model of Type I DM
7. Basic mechanisms for antigen presentation in human cells
8. Non-invasive or minimally invasive methods
   for beta cell mass and inflammation

Other Priority Areas

9. Explore recruitment of DPT-1 subjects and excluded subjects to identify volunteers for new clinical trials
10. Identification of genes for nephropathy

Develop animal models for macrovascular disease

Cellular therapy and islet cell growth

The goal of this initiative is to develop therapies to achieve euglycemia in people with diabetes. The scope includes islet and beta cell transplantation, engineering of regulated insulin secretion in non-beta cell precursors, development of stem therapy, and development of technologies to preserve beta cell function and stimulate beta cell regeneration.

Glucose sensors (biologic and other novel)

The goal of this initiative is to develop a glucose sensor to create a closed-loop system for regulating blood glucose. Commercial development of needle based sensors and minimally invasive sensors is underway. Optical approaches are appealing, but are unlikely to yield a functioning sensor in the near future. Development of other novel technologies may be stimulated by an RFA in this area.

EST data bases for diabetes relevant tissues

The goal of this initiative is to create a resource for use in investigating the etiology, pathogenesis, and complications of diabetes. Sequencing of existing libraries is needed. For some tissues, libraries may need to be created. Human islet, endothelium, muscle, and adipose tissue were identified as the key target tissues for which EST sequence libraries should be created.

Basic studies of growth factors on complications

The goal of this initiative is to elucidate the role of various growth factors in the pathogenesis of complications. VEGF, NGF, and TGF-ß are of particular interest. The scope includes the effect of glycemia, glycation, and other mechanisms on the pathophysiology of complications. Understanding the mechanisms underlying complications could lead to novel therapeutic approaches.

Viral/environmental factors biology in IDDM

The goal of this initiative is to elucidate the role of viral/environmental triggers of Type 1 diabetes. A secondary goal is to recruit virologists to the diabetes field, particularly those involved with retroviral and other chronic disease infectious

mechanisms.

"Humanized" mouse model of Type I DM

The goal of this initiative is develop a "humanized" mouse model for Type 1 diabetes. The current NOD mouse model is extremely sensitive to nonspecific interventions, with respect to preventing diabetes. A model is needed that is less sensitive to nonspecific factors, which can be used to test new interventions for preserving beta cell function and preventing diabetes.

Basic mechanisms for antigen presentation in human cells

The goal of this initiative is to understand the role of antigen presentation in the pathogenesis of Type 1 diabetes. Studies of DQ and DR alleles that confer increased risk, as well as those that are protective (DQ 6) are needed. The scope encompasses the role of the fetal immune system in pathogenesis. Understanding basic mechanisms will lead to novel approaches to immunomodulation and immunoprevention.

Non-invasive or minimally invasive methods for beta cell mass and inflammation

The goal of this initiative is to develop methods to assess beta cell mass and islet inflammation. Development of this technology would allow smaller pilot studies of immunomodulation, using these endpoints as surrogates for progression to diabetes. This capability would allow testing of more therapeutic approaches than is currently possible because of the expense of recruiting large numbers of patients and following them to diabetes.

DIABETES
CONTROL IS PREVENTION

Via Satellite Broadcast
October 30, 1997
1-3 PM EST

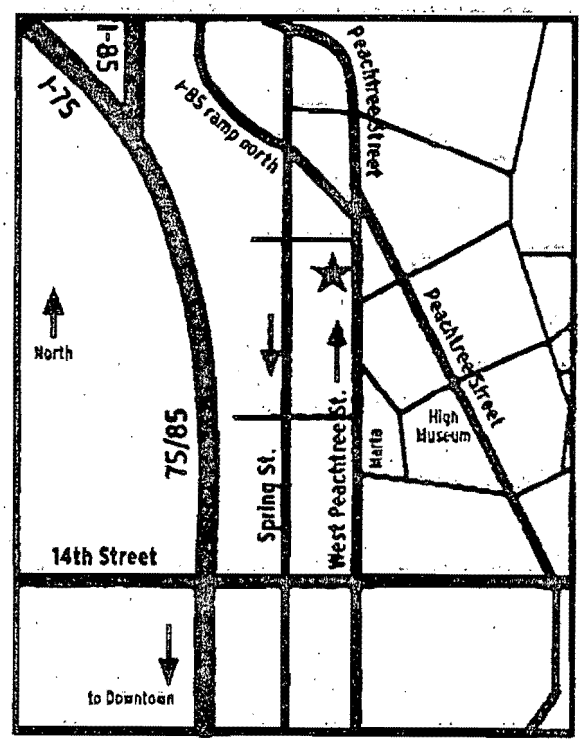
Location
Center Stage Television Theatre is conveniently located in Midtown Atlanta and is easily accessible from the Interstate, surface roads or MARTA. Less than 1/4 mile from the 14th Street Exit on the I-75/I-85 Connector, Center Stage is also three blocks from MARTA's Art Center Station on the North-South rapid transit line.

Directions
Driving: Take the I-85/I-75 connector to the 10th Street/14th Street exit. Head east on 14th Street to West Peachtree Street.

Turn left (north) on West Peachtree Street. Center Stage is on the left at #1374.

MARTA : Take the north/south line to the Arts Center station. The theatre is three blocks north.

Parking
Ample parking is available for events at Center Stage. In addition to many street lots and substantial metered parking near the building, Center Stage has a 140-space parking deck on premises.



Booking The Theatre
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Guy H. Tuttle at (404) 522-8008 or
W. Bruce Harlan at (404) 352-0464.

Box Office
For information on tickets or event schedules call the box office line **(404) 872-6622**.

Center Stage Television Theatre

1374 West Peachtree Street NW
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AGENDA
Meeting of the
DIABETES QUALITY IMPROVEMENT PROJECT
October 20, 1997
Washington, DC

8:30-9:00	*Continental Breakfast Available*	
9:00-9:15 (Tab 1)	**Approval of Minutes** **Discussion of Meeting Objectives**	Barbara Fleming, MD, PhD
9:15-9:30 (Tab 2)	**HCFA Contract for DQIP**	Barbara Fleming, MD, PhD
9:30-10:15	**Discussion of Measurement Set Evaluation Criteria**	Barbara Fleming, MD, PhD
10:15-10:30	*Break*	
10:30-11:15 (Tab 3)	**Discussion and Approval of Measure Evaluation Criteria**	Barbara Fleming, MD, PhD
11:15-12:00 (Tab 4)	**Presentation and Discussion of Existing Consumer Focus Group Research**	Christina Bethell, PhD, MBA
12:00-12:45	*Working Lunch* **Issues Involved in a Diabetes Patient Self-Management Measure**	Christina Bethell, PhD, MBA Jonathan Brown, PhD
12:45-1:30 (Tab 5)	**Presentation of Findings from the RWJ Chronic Care Initiative Diabetes Project and Discussion of Implications for Diabetes Measurement**	David Larsen, RN Patty McDermott, RN Doug Roblin, PhD
1:30-3:00 (Tab 6)	**Approval of Proposed Measures for Diabetes Measurement Set**	Barbara Fleming, MD, PhD
3:00-3:15	*Break*	
3:15-4:00	**Potential for Secondary Data Analyses from Existing Diabetes Measure Projects**	Faruque Ahmed, MD, PhD
4:00-4:15	**Process for Steering Council and Panel Meeting Work**	Barbara Fleming, MD, PhD
4:15-4:30	**Work Plan and Schedule**	Joshua Seidman, MHS

American Diabetes Association.

ional Service Center 1660 Duke Street Alexandria, Virginia 22314 (703) 549-1500 Telex: 901132 Fax: (703) 549-6294

News Release

For Release Embargoed
August 8, 1997- 11AM

Contact: Kenneth Inchausti
703/299-5506

PRESIDENT'S ANNOUNCEMENT OF NEW PUBLIC/PRIVATE DIABETES QUALITY IMPROVEMENT COALITION CAPS DRAMATIC WEEK FOR MILLIONS WITH DIABETES

American Diabetes Association Also Applauds Bi-Partisan Efforts Resulting In Dramatic Spending To Improve Diabetes Treatment and Prevention

ALEXANDRIA, VA (August 8, 1997) – Today, President Clinton announced a groundbreaking initiative spearheaded by the American Diabetes Association, bringing together leading public and private sector organizations to develop universal criteria intended to improve the health care outcomes of people with diabetes. He also took this opportunity to recap dramatic diabetes initiatives outlined in the Balanced Budget Act, signed August 5.

The Diabetes Quality Improvement Project aims to improve diabetes care in America by establishing a set of diabetes-specific performance and outcome measures that providers and plans must strive to achieve for their diabetes patients. Currently, a universal set of outcomes measures does not exist, leaving diabetes patients unable to determine if the care they receive is adequate.

The members of the Diabetes Quality Improvement Project are the American Diabetes Association, the Health Care Finance Administration (HCFA), the National Committee for Quality Assurance (NCQA), and the Foundation for Accountability (FACCT). This coalition – consisting of the nation's largest diabetes advocacy organization, the nation's largest health care payor, and the leading organizations that develop and implement outcome criteria – will set diabetes care on an unprecedented course, where providers will be accountable for the diabetes care they deliver, and give diabetes patients confidence in the quality of health care they receive.

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"President Clinton's announcement today ends an extraordinary week in the history of diabetes in America," said Stephen J. Satalino, Chair of the American Diabetes Association. "Because of the President's support of bi-partisan initiatives, nearly $3 billion of new money will be invested into research and treatment. Finally, diabetes is getting the recognition its deserves as a major public health problem facing America."

President's Signature Expands Medicare Diabetes Policy

Due to a six year advocacy effort by the American Diabetes Association, Medicare will now spend $2.4 billion in additional services over five years by expanding its reimbursement of diabetes supplies and self-management training for over three million senior citizens with diabetes.

Previous Medicare regulations restricted reimbursement only to diabetes recipients treated with insulin despite the fact that not all diabetes cases require insulin. Many Medicare recipients with diabetes are treated with an exercise and diet regimen, oral medications, or both. They could not qualify for coverage necessary to help prevent devastating and costly complications, such as amputations, kidney disease, heart disease, stroke, or blindness.

Now, all Medicare recipients with diabetes will qualify for reimbursement for the purchase of blood glucose monitors and their accompanying strips, regardless of their use of insulin. As before, Medicare will not reimburse for medications or insulin.

Additionally, Medicare will reimburse certified providers who offer training services in an outpatient setting meeting certain quality standards. Such education and training will have to be deemed necessary to diabetes care by the patient's physician. Previously, only educational services provided within a hospital setting were covered.

"By investing now in the tools and services that can help seniors manage their diabetes, we anticipate that Medicare can help reduce the enormous human and financial cost that accompanies diabetes complications," said Satalino. "This is a dramatic step forward since Medicare traditionally has paid for diabetes-related hospitalizations, but not for the means that would help keep seniors out of the hospital."

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These new policies will take effect on July 1, 1998. Quality standards for providers, as well as outcome measures ed to review the entire Medicare package, will be designed by the Secretary of Health and Human Services in consultation with the American Diabetes Association and other diabetes organizations.

President's Signature Gives Diabetes Programs Dramatic Boost

The Balanced Budget Act will dramatically increase the level of spending on diabetes by the Department of Health and Human Services. Grants totaling $150 million will be awarded over five years towards research into the prevention and cure of type 1 diabetes.

An additional $150 million in grants over five years will be awarded by the Department of Health and Human Services for providing services for the prevention and treatment of diabetes among the Native American population. Programs benefiting will include the Indian Health Service (IHS) and other programs operated by tribes or tribal organizations in cooperation with IHS.

"With this critical investment for research and a new concerted effort to improve care, these measures may be as important as the discovery of insulin in 1921," said Satalino. "Thank you, President Clinton, for your leadership in making these measures a reality. And our thanks to Speaker Gingrich, Congresswoman Furse, Congressman Nethercutt and all of our allies in Congress for your outstanding leadership in providing people with diabetes the support and resources necessary to help stop diabetes' incredible devastation."

In the United States, 16 million people have diabetes – eight million of whom are diagnosed. At least three million of the diagnosed are senior citizens. Nearly 1 million Americans have type 1 diabetes. Finally, diabetes disproportionately affects the Native American population at rates as high as 50 percent in some tribes.

Each year, diabetes drains the economy of $92 billion in direct health care and indirect productivity costs. Diabetes patients make up only 9 percent of Medicare's recipients, while their care, under previous regulations, eats away nearly 25 percent of Medicare's budget.

Diabetes is a group of serious diseases characterized by high blood sugar levels that result from defects in the 's ability to produce and/or use insulin.

(40)

The American Diabetes Association is the nation's leading voluntary health agency supporting diabetes research, information and advocacy. Founded in 1940, the Association is a community-based organization that provides services in every region of the country.

For more information on the American Diabetes Association's advocacy program, *Delegates for Diabetes*, or on diabetes, visit us on the world wide web at www.diabetes.org or call toll-free at 1-800-DIABETES (1-800-342-2383).

# # #

File Diabetes

August 28, 1997

Note to Sarah Bianchi:

Sarah,

I just found out that Congressman First has scheduled a "mini-session" tomorrow (Aug. 29) to discuss screening for diabetes in African Americans and Hispanics. I thought you would want to know this. I'm also faxing you some summary documents on the new diagnostic classification criteria and some Q and A's, for your info.

Frank Vinicor

Sarah, Just how do (P) To Sarah

ConferenceCommittees

departments of Commerce, Justice, State and the federal judiciary.

Time and room TBA **date TBA**

Agenda:

HR 2267 - A bill making appropriations for the departments of Commerce, Justice, and State, the Judiciary, and related agencies for the fiscal year ending Sept. 30, 1998, and for other purposes.

Senate Conferees: GREGG, R-N.H.; STEVENS, R-Alaska; DOMENICI, R-N.M.; MCCONNELL, R-Ky.; HUTCHISON, R-Texas; CAMPBELL, R-Colo.; COCHRAN, R-Miss.; HOLLINGS, D-S.C.; BYRD, D-W.Va.; INOUYE, D-Hawaii; BUMPERS, D-Ark.; LAUTENBERG, D-N.J.; and MIKULSKI, D-Md

House Conferees: ROGERS, R-Ky.; KOLBE, R-Ariz.; TAYLOR, R-N.C.; REGULA, R-Ohio; FORBES, R-N.Y.; LATHAM, R-Iowa; LIVINGSTON, R-La.; MOLLOHAN, D-W.Va.; SKAGGS, D-Colo.; DIXON, D-Calif.; OBEY, D-Wis.

EXPORT-IMPORT BANK REAUTHORIZATION

Conferees will meet on legislation (S 1026) that would reauthorize the Export-Import Bank of the United States.

Time and room TBA **date TBA**

Senate Conferees: TBA

House Conferees: LEACH, R-Iowa; CASTLE, R-Del.; BEREUTER, R-Neb.; LAFALCE, D-N.Y.; FLAKE, D-N.Y.

OTHER EVENTS FutureListings

Those wishing to have events listed in this section should fax a notice to 202-835-1695 Attn: Bob Hanly. Only events related to Congress will be considered. All notices must include a telephone contact number. The CQ Monitor reserves the right to edit or reject any item submitted.

NOTE: Deadline is Noon, two days prior to the date of issue: i.e. Noon Monday for the Wednesday issue; Noon Thursday for the Monday issue.

U.S.-CHINA RELATIONS ★

Rep. Christopher Cox, R-Calif., chairman of the House Policy Committee will discuss China policy in a speech before the Center for Security Policy.

8pm Roosevelt Room, ANA Hotel, 24th and M Sts. N.W. **Oct. 28**

Contact: Paul Wilkinson at 202-225-4841

NORTHEAST DAIRY COMPACT

Sen. Rod Grams, R-Minn., and Citizens Against Government Waste will sponsor a policy briefing on the Northeast Dairy Compact. The compact was created by the 1996 farm bill and created a mechanism to allow farmers to set the wholesale price of milk and dairy products.

2pm SD-562 Dirksen Bldg. **Oct. 28**

Contact: John Campi at 202-467-5300

DIABETES ISSUES AND SCREENING

The Foot Health Foundation of American in conjunction with Rep. Marcy Kaptur, D-Ohio, and Rep. Elizabeth Furse, D-Ore., will sponsor an event to highlight the need for diabetes screening, especially among Hispanic, African-American and Native American populations, that have a higher-than-average rate of diabetes.

9:30am foyer, Rayburn Bldg. **Oct. 29**

Contact: Cynthia Gears at 202-944-6137

GLOBAL CLIMATE CHANGE DISCUSSION

Policy Insiders program of the U.S. Chamber of Commerce will sponsor a breakfast meeting with Sen. Chuck Hagel, R-Neb., and Rep. John Dingell, D-Mich., who will discuss global climate change.

8am U.S. Chamber of Commerce, 1615 H St. N.W. **Oct. 29**

Contact: 202-463-5604

Note:

There is a $40 charge for this event for non-members.

SHOULD LAND MINES BE BANNED? ★

Cato Institute will sponsor a policy form on land mines, focusing on the treaty banning land mines that is scheduled to be signed in December. The United States has declined to sign the treaty, because it did not contain exemptions for anti-personnel land mines, particularly in Korea.

4pm Cato Institute, 1000 Massachusetts Ave. N.W. **Oct. 29**

Contact: James Markels at 202-789-5256

GATT AFTER 50 YEARS ★

The Cato Institute will sponsor a seminar on the occasion of the 50th anniversary of the original signing of the GATT (General Agreement on Tariffs and Trade) treaty. Sessions will focus on trade and harmonization, regional trade agreements and anti-dumping laws.

10am Cato Institute, 1000 Massachusetts Ave. N.W. **Oct. 30**

Contact: James Markels at 202-789-5256

WOMEN'S ACCESS TO CONTRACEPTIVE TECHNOLOGY ★

Congressional Caucus for Women's Issues along with Del. Eleanor Holmes Norton, D-D.C., and Rep. Nancy Johnson, R-Conn., will hold a news conference to review the limitations and related consequences of contraceptive options available to women. The session will focus on recommendations to address and remove barriers to new technologies.

8am 345 Cannon Bldg. **Oct. 30**

Contact: Joan Clark at 202-225-4476 or Erin Prangley at 202-225-8050.

POLL OF WOMEN VOTERS ★

EMILY's list (Early Money Is Like Yeast) will hold a news briefing to discuss a a national poll of women voters.

1:30pm National Press Club, 529 14th St. N.W. **Nov. 3**

Contact: Karin Johanson at 202-326-1400

WELFARE TO WORK ★

The Employment Policy Foundation will sponsor a forum on welfare to work issues. There will be panel discussions on: the job market facing former welfare recipients; the characteristics of the welfare population; successful welfare-to-work strategies; potential employment policy obstacles.

8:30am Sheraton Carlton Hotel, 16th and K Sts. N.W. **Nov. 12**

Contact: Teri Shaffer at 202-789-8685

"AFTER THE BALANCED BUDGET AGREEMENT" ★

American Association for Budget and Program Analysis will sponsor a symposium focusing on "After the Balanced Budget Agreement."

8am Washington Hilton Hotel, 1919 Connecticut Ave. N.W. **Nov. 12**

Note:

703-941-4300

LABOR ISSUES ★

Labor and Human Resources Task Force of Women In Government Relations will sponsor a luncheon meeting to hear Deputy Secretary of Labor Kathryn "Kitty" Higgins discuss the administration's labor agenda for the months ahead.

Noon National Democratic Club, 30 Ivy St. N.W. **Nov. 17**

Contact: For information: Erin Kramer at 202-289-6700 For reservations WGR office at 202-347-5432

Note:

There is a charge for this event of $35 for members and $50 for non-members.

OUTLOOK FOR LABOR ISSUES

Labor and Human Resources Task Force of Women in Government Relations will sponsor a luncheon meeting to hear Deputy Secretary of Labor Kathryn "Kitty" O'Leary Higgins discuss the Clinton Administration's labor agenda.

Noon National Club Association, 3rd floor, 30 Ivy St. S.E. **Nov. 17**

Contact:

For information: Erin Kramer at 202-289-6700

For reservations: WGR office at 202-347-5432

Note:

There is a charge for this event of $35 for members and $50 for non-members.

★ New Listing

☎ Event available live by phone on *Hearings-On-The-Line®* for information call 202-[illegible]

(1) IUF - Age adjusted
(3) Diagnosis - 1° Care

DRAFT/DRAFT/DRAFT

1. Who developed the new guidelines for the diagnosis and classification of diabetes, and what was CDC's role?

An international Expert Committee on the Diagnosis and Classification of Diabetes Mellitus working under the sponsorship of the American Diabetes Association (ADA) developed the new guidelines and published their report in *Diabetes Care* 1997 20:1183-97. The Committee had 17 members and was comprised of clinicians and researchers from academia, NIH, and the ADA. CDC was not represented on the Committee. CDC was consulted during the process, reviewed and commented on preliminary drafts of the report, and provided some epidemiological data to the Committee. CDC's data, previously published, was used to establish the diagnostic criteria. Similar recommendations are soon to be released for public comment by the WHO.

2. What are the major recommendations/changes in the report for the diagnosis and classification of diabetes?

The major recommendations in the report include:

A. For classification:
Eliminate the use of insulin dependent diabetes mellitus (IDDM) and non-insulin diabetes mellitus (NIDDM) because these terms are confusing. Replace these terms with type 1 to describe diabetes characterized by an absolute deficiency of insulin (currently termed IDDM or juvenile onset diabetes); and type 2 to describe diabetes characterized by insulin resistance (ie ineffective in target tissue) and inadequate compensatory insulin secretory response (currently termed NIDDM or adult onset diabetes). "Other Specific Types" was a 3rd. category where specific genetic defects, surgery, drugs, etc. are known to have caused hyperglycemia. The Committee retained the term Gestational Diabetes Mellitus (GDM) to describe diabetes that develops during pregnancy.

B. For diagnosis:
Lower the current fasting diagnostic criteria from ≥140 mg/dl (7.7 mmol/l) to ≥126 mg/dl (7.0 mmol/l). Eliminate the routine use of the oral glucose tolerance tests (OGTT). The OGTT is performed using a 75-g glucose meal and measuring the plasma glucose 2 hours after consumption and is more difficult and more expensive to perform than fasting glucose test. Subjects with single positive diagnostic tests, as currently recommended, should continue to have a repeat positive test before the diagnosis is made.

DRAFT/DRAFT

C. For testing:
Testing for diabetes should be considered for all persons 45 years and older and, if normal, it should be repeated at 3-year intervals. Testing should be considered at a younger age or be carried out more frequently in indivduals who are at high risk for diabetes (ie, those who are obese, have a family member with diabetes, are members of high risk ethnic groups [African Americans, Hispanics, American Indians], have delivered a baby weighing 9 pounds or were diagnosed with GDM, are hypertensive, or have a blood lipid abnormally). For GDM, it was recommended that individuals at "low risk" for this condition not be screened.

3. What is CDC's positions in regard to the recommendations made by the Expert Committee?

CDC strongly recommends that the new diagnostic and classification criteria be adopted, promulgated, and implemented by all individuals and organizations that identify and care for persons with diabetes. The new criteria are based on sound scientific evidence. On balance, patient should benefit by having a greater opportunity to be diagnosed and receive treatment before complications develop. However, more data is necessary to support the Committee's recommendation on testing of all persons 45 years and older every 3 years. In addition, the entire issue of GDM needs further investigation and discussion.

4. What scientific research has been done to support these recommendations?

For classification:
The committee considered the data and rationale for the current classification system adopted in 1979 along with research findings of the last 18 years in proposing the new classification system.

For diagnosis:
Data from several population-based studies (including the US National Health and Nutritional Examination Survey III) were used on which to base the recommendations for the new fasting diagnostic values.

For testing:
As mentioned above, very little data support the testing of persons 45 years and older every 3 years. However, this was the consensus reached among the Committee members and was deemed logical and reasonable, based upon the DCCT, the pilot phase of the VA Study on type 2 DM, the UKPDS, and the WESDAR data.

Succeeding Diagnostic

DRAFT/DRAFT

5. What is the rationale for screening persons 45 years and over every 3 years?

The Committed cited the steep rise in the diabetes incidence after age 45 years and the negligible likelihood of developing complications from diabetes with a 3-year interval of a negative test as the reason for this recommendation on testing.

6. What are the public health implications and challenges?

Using data from the NHANES III survey (a US population-based survey), the new diagnostic criteria (ie using the new fasting measurement alone with no OGTT) lowers the estimated total diabetes prevalence in persons 40-74 years of age to 12.3% compared to 14.3% found applying the World Health Organization's current diagnostic criteria (which uses both a fasting values of ≥140 mg/dl and the OGGT measurement).

However, the new fasting diagnostic criteria will facilitate detection of asymptomatic persons with undiagnosed diabetes because of the utility and ease of obtaining fasting measurements compared to awkward OGTTs. A shift in persons from having undiagnosed to diagnosed diabetes may potentially increase the total number of persons with diagnosed diabetes by 2 million, from 8 million to 10 million.

Public health challenges include addressing issues for newly diagnosed persons and issues for the health care system. Patient anxiety, personal economic impact, insurability, and employability will need attention. However, these concerns possibly will be overshadowed by the benefit to the individual in terms of the potential of a more healthy life and living fewer years with disabling diabetic complications.

Issues for the health care system include concerns for provider work overload with newly identified cases and using this opportunity to ensure that newly diagnosed persons with sugars get appropriate treatment aimed at preventing the micro- and macro-vascular complications. It critically important to ensure that evidence-based, cost-effective interventions be used in order to maximize the nation's investment value.

7. What are the economic implications?

The use of the new fasting criteria will result in a larger proportion of those with diabetes who are currently undiagnosed, being identified. As noted, an estimated increase of approximately 2 million persons with diabetes may be diagnosed. This may initially result in an increase in the expenditures for diabetes. However, over the lifetime, the cost of caring for persons with diabetes diagnosed using the new criteria may be decreased because disease will be diagnosed at earlier stage and complications may be easier to prevent, .No scientific study has been carried out to support or refute these conjectures.

DRAFT/DRAFT

8. What impact will these recommendations have on CDC's Diabetes Control Programs?

The new recommendations will tend to result in persons with mild, undiagnosed diagnosis diabetes being diagnosed more frequently. Most of these new case will have no or few diabetic complications. Identification of milder cases provides an opportunity and greater "potential" for prevention of micro- and macro-vascular complications. DCPs will need to place emphasis on use of the fasting criteria to diagnose cases and on aggressive prevention of complications in persons newly diagnosed along with those with diabetes of longer duration.

9. What impact will these recommendations have on the National Diabetes Education Program?

These recommendations may require that the NDEP develop initiatives that focus on adopting, promulgating, and implementing the new recommendations including the classification system, the diagnostic criteria, and the testing algorithm. In addition, it will be important to emphasize quality care of patients with newly diagnosed diabetes and consideration of the role of diet and physical activity as an aggressive treatment option.

10. What activities are presently being carried out by CDC to further understand those recommendation?

Currently, most of CDC's focus is on important public health research issues. Activities include:
A)Dedicating a DDT Translation Advisory Committee meeting for review of the public health issues related to screening and early detection of diabetes. Public health screening issues related to research, programs, and policies were explored in detail. This effort has been supportive of CDC's current research agenda. — copies of
B) Performing an epidemiologic study to examine the effect that screening and early detection has on development and progression of diabetic complications. This critical question has not been studies directly.
C. Conducting studies to characterize the performance of various screening test for detecting undiagnosed diabetes. This information is critical for cost-effectiveness studies.

D. Collaboration with DCP to develop and characterize the performance of various population-based diabetes screening strategies.
E. Using statistical models to conduct cost-effectiveness studies of screening for undiagnosed diagnosed diabetes and the benefit it may have compared to typical clinical diagnosis .

The finding of this research agenda should enhance our ability to support an effective, efficient, and appropriate public health response to the burden of diabetes in the US.

American Diabetes Association.

National Center 1660 Duke Street Alexandria, Virginia 22314 (703) 549-1500 Fax: (703) 549-6294

Backgrounder

EMBARGOED
until Monday, June 23, 1997
10 am EDT

Contact: Jane Agate, 703/299-2055
Elizabeth Miller, 703/299-2056
NEWS ROOM June 21-24, 1997:
Room 102, Hynes Convention Center, Boston
617/954-3566

NEW RECOMMENDATIONS FOR THE DIAGNOSIS AND CLASSIFICATION OF DIABETES MELLITUS

INTRODUCTION

Why are new guidelines for the diagnosis and classification of diabetes needed?
It has been nearly twenty years since the last guidelines were released. Published in 1979, these guidelines were developed by the National Diabetes Data Group, under the auspices of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health. Over the years, considerable research has provided greater insight into how and why diabetes and its complications develop.

Who developed and who approved the new guidelines?
In 1995, the American Diabetes Association convened a committee, composed of 17 international experts in diabetes, to review fifteen years of research and develop a report. Their report was reviewed widely in the diabetes community prior to completion. The guidelines are published in the July 1997 issue of *Diabetes Care*, together with a supportive editorial. Another supportive editorial will appear in the August 1997 issue of *Annals of Internal Medicine*. In addition to the American Diabetes Association, the report's recommendations have been accepted and are supported by the Division of Diabetes Translation of the Centers for Disease Control and Prevention, and the NIDDK. Other organizations are currently reviewing the Expert Committee's report and there is indication of wide support of the guidelines in the diabetes and broader medical communities.

NEW DIAGNOSTIC RECOMMENDATIONS

What tests are recommended to diagnose diabetes?
Any one of three tests can be used: fasting plasma glucose (FPG), a simple blood test done after not eating for eight hours; a casual plasma glucose, a simple blood test done at any time, regardless of eating; or an oral glucose tolerance test (OGTT), in which blood sugar levels are evaluated two hours after the person is given a drink containing 75g of anhydrous glucose dissolved in water.

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Is there a preferred test?
In the past, the OGTT was preferred. Today, the experts say the FPG is preferred -- with the cutpoint lowered to 126 vs. 140 mg/dl -- because it is simpler, less expensive and more acceptable to patients and, therefore, more likely to be offered on a regular basis. The casual plasma glucose test can be used for diagnosis if diabetes symptoms, such as increased thirst, frequent urination and unexplained weight loss, are present. Generally, two abnormal test results using any of the three tests -- on two different days -- are needed to make the diagnosis of diabetes.

Why is a lower level of fasting plasma glucose recommended as the point for diagnosis?
Data from new population-based research studies indicated that microvascular complications of diabetes were occurring in people with FPG values in the low-to-mid 120s -- and not at 140, the old diagnosis cutpoint for diabetes. The Expert Committee decided to recommend a diagnostic cutpoint of 126 as a reasonable value given the new research data.

Why is it important to identify diabetes at this new, lower FPG value of 126?
Type 2 diabetes -- the more common form of the disease -- is often called a "silent killer" because people with high blood glucose levels may be asymptomatic or have symptoms that are so subtle they go unrecognized until complications like vision or heart problems set in. With type 2 diabetes, patients typically go 7 years or more with the disease before it is diagnosed. That's 7 years of high blood sugar levels doing damage to the small and large blood vessels.

It is important, therefore, to identify people with diabetes early on in the progression of their disease. In addition, results of the Diabetes Control and Complications Trial (DCCT), a 10-year landmark study which ended in 1993, proved that good control of blood glucose in those with type 1 can reduce the risk of getting diabetic eye, nerve, and kidney disease by 50% to 75%. Other studies support the belief that good control for people with type 2 diabetes would also yield beneficial results. Implementing treatment at this earlier stage in the disease should help prevent or delay the complications of diabetes.

Won't this markedly increase the numbers used to report the prevalence of diabetes?
The overall number of people with diabetes -- estimated at 16 million -- will not change. The 16 million figure is derived from estimates of 8 million diagnosed and 8 million undiagnosed with diabetes.
The estimate of 8 million undiagnosed individuals was made by the federal government based on a projection using the OGTT test, and not the FPG test. Because the 126 FPG cutpoint value approximately equals the cutpoint on the OGTT test, the total projected number of people with diabetes (both diagnosed and undiagnosed) will not change. What will change, however -- with consistent, universal use of the FPG test -- is the number of diagnosed people. More people will move from being "undiagnosed" to "diagnosed." This shift is important to the public health of America. As we get more people appropriately into treatment, we will begin to reduce the long-term human and medical costs of the serious complications of diabetes.

Page 3, Backgrounder
Classification/Diagnosis of Diabetes

NEW NAMING SYSTEM

Why have the names been changed?
To clarify what is being diagnosed. The committee recommended eliminating the old categories of "insulin-dependent diabetes mellitus" (IDDM) and "non-insulin-dependent diabetes mellitus" (NIDDM) because they are based on treatment which can vary considerably and do not necessarily indicate the underlying problem (e.g., many people with type 2 do indeed need to take insulin injections). Further, in discussing the different types of diabetes, the use of Arabic rather than Roman numerals is recommended to prevent confusion (i.e., type II being read as "type eleven").

What constitutes type 1 diabetes?
Type 1 (formerly known as IDDM) is characterized by destruction of the beta cells in the pancreas that produce insulin, usually leading to absolute insulin deficiency -- a total failure to produce insulin. It has two forms.) Immune-Mediated Diabetes Mellitus results from an autoimmune destruction of the beta cells. It typically starts in children or young adults who are slim, but can arise at any age. Idiopathic type 1 refers to rare forms of the disease that have no known cause. Altogether, type 1 afflicts about 700,000 Americans.

What constitutes type 2 diabetes?
Type 2 (formerly known as NIDDM) usually arises because of insulin resistance, in which the body fails to use insulin properly, combined with a relative (rather than absolute) deficiency in the production of insulin. People with type 2 diabetes can range from predominantly insulin resistant with relative insulin deficiency, to predominantly deficient in insulin secretion with some insulin resistance. Type 2 typically occurs in those over 45, overweight, sedentary, and with a family history of the disease. This is the much more common type of the disease. Approximately 15.3 million Americans have type 2 although about half are undiagnosed.

What constitutes gestational diabetes (GDM)?
A condition of abnormal glucose metabolism that arises during pregnancy, gestational diabetes complicates about two to four percent of all U.S. pregnancies. Although it disappears after birth, gestational diabetes may signal an increased risk for type 2 later in life. The Expert Committee has not recommended changes in the definition of gestational diabetes; however, they have recommended changes regarding screening for who should be tested (see question under "New Testing Guidelines" on page 4.)

-more-

IMPAIRED GLUCOSE HOMEOSTASIS

What is impaired glucose homeostasis?
Impaired glucose homeostasis is a state between "normal" and "diabetes," in which the body is no longer using and/or secreting insulin properly. The committee recognized two categories of impaired glucose homeostasis that are considered risk factors for future diabetes and cardiovascular disease:

- Impaired Fasting Glucose (IFG), a new category, when fasting plasma glucose is ≥110 but <126 mg/dl;
- Impaired Glucose Tolerance (IGT), an existing category, when results of the more complicated oral glucose tolerance test are ≥140 but <200 mg/dl (in the two-hour sample).

Why is impaired glucose homeostasis a problem?
Research has shown that people with impaired glucose homeostasis are at high risk for developing diabetes and macrovascular complications, such as heart attacks and strokes, and therefore should be closely monitored. A major multi-center clinical trial, the Diabetes Prevention Program, is now underway to determine whether early treatment can prevent or delay the development of diabetes in people with impaired glucose homeostasis. The study will be incorporating the Committee's recommendations into the trial's protocol.

NEW TESTING GUIDELINES

Which pregnant women should be tested for gestational diabetes?
The new guidelines recognize variability in risk. Therefore, rather than universal screening of all pregnant women in their third trimester, the committee now recommends that women at low risk need not be screened. This includes women who satisfy all of the following criteria: less than 25 years of age, normal body weight, have no family history of diabetes, and are not a member of an ethnic group with a high prevalence of diabetes (Hispanic, Native American, African American, Asian).

Other than pregnant women, who should be tested for diabetes -- and when?
Testing presumably healthy people for type 1 diabetes for immune markers that indicate potential for, or early onset of, the disease is not recommended outside of clinical trials. The scientific community has not yet agreed on what markers are appropriate and there is no treatment available to prevent type 1 diabetes, so testing would not be cost effective.

-more-

(Who should be tested for diabetes, cont.)
However, testing for type 2 diabetes should be considered in all asymptomatic adults age 45 and over and, if normal, be repeated at three-year intervals. Testing should be considered at a younger age or be done more often in people who have particular risk factors for the disease, including individuals who:

- are obese (more than 20% above their ideal body weight);
- have a first degree relative with diabetes;
- are members of a high-risk ethnic population (African American, Hispanic, Native American, Asian);
- delivered a baby weighing more than nine pounds or were diagnosed with gestational diabetes
- are hypertensive (blood pressure at or above 140/90);
- have an HDL cholesterol level (the "good" cholesterol) of 35 mg/dl or lower and/or a triglyceride level of 250 mg/dl or higher;
- or, on previous testing, had IFG or IGT.

IMPACT

What impact will the new recommendations have on people who have already been diagnosed with diabetes?
Largely none. The new recommendations do not affect treatment criteria or goals of therapy. These recommendations only revise criteria for diagnosis. For the diagnosed, it simply means at most a name change for their disease.

What impact will the new recommendations have on the families of people with diabetes?
It is hoped that the guidelines will call their attention to their greater risk of diabetes because diabetes has a genetic component -- and will encourage them to have periodic diagnostic screening for the disease. Further, relatives of people with type 2 diabetes should seek to reduce their risks, such as by maintaining normal weight, increasing physical activity, and controlling blood pressure and blood fat levels.

What impact will the new recommendations have on health care providers?
First, the recommendations urge them to use a simpler, quicker test (fasting plasma glucose) to screen for diabetes. Second, the testing recommendations are meant to urge providers to be "thinking diabetes" when routinely assessing the health and well-being of all patients age 45 or older, especially those with risk factors for the disease -- including family history, ethnicity, age, body weight, and presence of related problems, such as hypertension and lipid problems.

What impact will the new recommendations have on managed care organizations?
In the long run, the diagnostic and testing recommendations should save them money. First, they are now encouraged to use the simpler FPG to test for and confirm diagnosis of diabetes. It is hoped that such testing will become a regular part of their protocols for people age 45 and over, and that they will develop protocols for identifying and testing more often people who are at high risk for the disease. Second, by diagnosing and treating the disease at the lower cutpoint, it is believed that the cost of such treatment will be offset by the dollars saved by preventing complications.

Won't this mean that pharmaceutical firms will sell more drugs -- with more people diagnosed earlier?
Not necessarily. Earlier diagnosis and treatment do not imply that drug therapy will necessarily begin earlier. In its early stages, type 2 diabetes can often be effectively treated with a healthy diet and regular physical activity. Recent research is helping the medical community understand how to tailor such diet and exercise programs to the individual's overall health, age, ethnic background, tastes, etc., so that the patient is more apt to follow the treatment plan. The American Diabetes Association has long recommended that anyone with diabetes consult with a registered dietitian and/or a diabetes educator to develop a nutritional and physical activity regimen best suited to the patient's health and lifestyle.

INFORMATION DISSEMINATION

How does the American Diabetes Association intend to promulgate these new recommendations?
The American Diabetes Association is taking the lead in coordinating the efforts of the diabetes community to translate and disseminate the Expert Committee's recommendations. This process has begun with the distribution of the information to the media to reach the public, patients and health care providers. Activities are now being planned to continue outreach efforts in the years ahead.

The American Diabetes Association is the nation's leading voluntary health organization supporting diabetes research, information, and advocacy. Founded in 1940, the Association supports affiliate offices in every region of the country, providing services in more than 800 communities. For more information, call 1-800-DIABETES (1-800-342-2383) or visit the Association's website at www.diabetes.org.

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News Release

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NEW RECOMMENDATIONS TO LOWER THE DIABETES DIAGNOSIS POINT COULD MEAN UP TO 2 MILLION MORE WITH THIS SERIOUS DISEASE

Other Recommendations: Testing for Diabetes Should Be Considered in Adults Over 45 Every Three Years, More Often and/or Younger if at High Risk; Change Nomenclature for Diabetes

Boston (June 23, 1997) -- An international Expert Committee has recommended lowering the number for diagnosis on the most commonly used test for diabetes and has urged that consideration be given to wide-scale screening and testing in order to detect diabetes at an earlier stage and help prevent or delay the onset of serious and costly complications, according to reports here today at the American Diabetes Association's 57th Annual Scientific Sessions. The Committee's report appears in the July 1997 issue of *Diabetes Care*.

"These recommendations serve as a powerful tool to contain the havoc wreaked by this often silent killer," said James R. Gavin, III, MD, PhD, of the Howard Hughes Medical Institute and chair of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. "We now have conclusive data from population-based research that show serious complications of diabetes begin earlier than previously thought. A value of 126 mg/dl on the easy-to-use, low priced fasting plasma glucose (FPG) test, confirmed by repeat testing on a different day, is a wake-up call to patients and health care professionals that diabetes is present and cannot be ignored."

For the first time, the Committee also recommends the health care community consider testing for diabetes in all adults at age 45 and above, and if normal, repeat testing at three-year intervals. Testing should be considered at a younger age, or be carried out more frequently, in individuals at high risk for diabetes.

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Approximately 16 million Americans have diabetes, but only half are diagnosed. Widespread and consistent use of the FPG test, with appropriate screening and re-testing, could help identify up to 2 million of the 8 million undiagnosed Americans with diabetes, according to Frank Vinicor, MD, MPH, of the Centers for Disease Control and Prevention (CDC), and Richard Eastman, MD, of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), in an accompanying editorial in *Diabetes Care*.

The Expert Committee's work is an update of a similar process last undertaken in 1979 by the National Diabetes Data Group, and its recommendations are based on a two-year review of more than 15 years of research. The Expert Committee was convened under the auspices of the American Diabetes Association and its recommendations have been accepted and are supported by the Association, NIDDK, and the Division of Diabetes Translation of the CDC. Other organizations are currently reviewing the Expert Committee's report.

Name Changes

To clarify what is being diagnosed, the Committee recommended eliminating the old categories of "insulin-dependent diabetes mellitus" (IDDM) and "non-insulin-dependent diabetes mellitus" (NIDDM) because they are based on treatment which can vary considerably and does not indicate the underlying problem. Further, in discussing the types of diabetes, the use of Arabic (type 1 and type 2) rather than Roman (type I and type II) numerals is recommended to prevent confusion (e.g., type II being read as "type eleven").

Approximately 700,000 Americans have type 1 diabetes (formerly known as IDDM), a disease characterized by destruction of the pancreatic beta cells which produce insulin, usually leading to absolute insulin deficiency -- that is, a total failure to produce insulin. It has two forms. Immune-Mediated Diabetes Mellitus results from an autoimmune destruction of the beta cells; it typically starts in children or young adults who are slim, but can arise in adults of any age. Idiopathic type 1 refers to rare forms of the disease that have no known cause.

NEW RECOMMENDATIONS MEAN TWO MILLION MORE WITH DIABETES 3

Type 2 diabetes (formerly known as NIDDM) usually arises because of insulin resistance, in which the body fails to use insulin properly, combined with relative (rather than absolute) insulin deficiency. People with type 2 can range from predominantly insulin resistant with relative insulin deficiency to predominantly deficient in insulin secretion with some insulin resistance. It typically occurs in those over 45, overweight and sedentary, with a family history of diabetes. Approximately 15.3 million Americans have type 2 diabetes.

Simplified Testing and Diagnosis

The Expert Committee stated that diabetes can be diagnosed in any one of the following three ways, confirmed on a different day by, again, any one of these three tests:

- An FPG of ≥126 mg/dl (after no caloric intake for at least 8 hours); or
- A casual plasma glucose (taken at any time of day without regard to time of last meal) ≥200 mg/dl with the classic diabetes symptoms of increased urination, increased thirst and unexplained weight loss; or
- An oral glucose tolerance test (OGTT) value of ≥200 mg/dl in the two-hour sample.

But the Committee clearly states that the FPG is the preferred test and recommends moving toward its universal use for testing and diagnosis because of its ease of administration, convenience, acceptability to patients, and lower cost (compared to the OGTT).

The Expert Committee notes that the hemoglobin A1c test (also known as HbA1c or glycosylated hemoglobin) is not, at this time, recommended for diagnosis. It should also be noted that the finger-prick test used by people with diabetes to monitor their blood glucose levels, and sometimes used at health fairs and diabetes risk assessments among the general public, is not considered a diagnostic procedure.

New State Defined Between "Normal" and "Diabetes"

The Committee defined a value of 110 mg/dl on the FPG as the upper limit of normal blood glucose. The Committee also recognized two categories of impaired glucose metabolism (or impaired glucose homeostasis) that are considered risk factors for future diabetes and cardiovascular disease:

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- Impaired Fasting Glucose (IFG), a new category, when fasting plasma glucose is ≥110 but <126 mg/dl;
- Impaired Glucose Tolerance (IGT), an existing category, when results of the more complicated oral glucose tolerance test are ≥140 but <200 mg/dl (in the two-hour sample).

"Research has shown that people with impaired glucose homeostasis are at high risk for developing diabetes and macrovascular complications, such as heart attacks and strokes, and therefore should be closely monitored," cautioned Dr. Gavin.

Dr. Gavin mentioned that a major multi-center clinical trial, the Diabetes Prevention Program, is now underway by the NIDDK to determine whether early treatment can prevent or delay the development of diabetes in people with impaired glucose homeostasis. NIDDK will be incorporating the Committee's recommendations into the trial's protocol.

Who Should Be Tested – and When

The Committee recommends that testing for diabetes should be considered in all adults at age 45 and above, and if normal, be repeated at three-year intervals. Physicians should consider testing at a younger age, or more frequently, those who are at higher risk of diabetes, including people who:

- are obese (more than 20% above their ideal body weight);
- have a first degree relative with diabetes;
- are members of a high-risk ethnic group (African American, Hispanic, Native American, Asian);
- delivered a baby weighing more than nine pounds or were diagnosed with gestational diabetes mellitus (GDM), a condition that can arise during pregnancy and usually disappears thereafter but tends to lead to type 2 in later years;
- are hypertensive (blood pressure at or above 140/90);
- have an HDL cholesterol level (the "good" cholesterol) of 35 mg/dl or lower and/or a triglyceride level of 250 mg/dl or higher;
- or, on previous testing, had IFG or IGT.

Special Recommendations for Pregnant Women

While the category of gestational diabetes (which complicates about four percent of U.S. pregnancies) is retained, the recommendation for screening of all pregnant women has been dropped. Again, recognizing risk factors identified in recent research, the committee now recommends that women at low risk not be screened. This includes women who satisfy all of the following criteria: less then 25 years of age, normal body weight, have no family history of diabetes, and are not a member of an ethnic group with a high prevalence of diabetes.

Impact of the New Recommendations

Dr. Gavin sees a major impact of these recommendations on American public health. "Adults in America -- especially family members of people with diabetes and other high risk individuals -- should be more vigilant in getting checked for this disease on a regular basis and should try to reduce their risk by maintaining ideal weight and seeking to control blood pressure and blood fat levels," he said. "Only then can we have hope of stopping the ever-upward spiral of blindness, kidney failure, amputations, heart disease and stroke caused by this insidious disease."

Dr. Gavin emphasized that earlier diagnosis and treatment does not imply that drug therapy will begin earlier. "In its early stages, type 2 diabetes can often be effectively treated with a healthy diet and regular physical activity," he explained.

Diabetes is a group of serious diseases characterized by high blood sugar levels that result from defects in the body's ability to produce and/or use insulin. It is the fourth-leading cause of death by disease in the U.S.

The American Diabetes Association is the nation's leading voluntary health organization supporting diabetes research, information and advocacy. Founded in 1940, the Association supports affiliate offices in every region of the country, providing services in more than 800 communities. For more information, call 1-800-DIABETES (1-800-342-2383) or visit the Association's website at www.diabetes.org.

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