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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. memo	Larry Soler to Nancy Hernreich and Mary Morrison re: Presidential Announcement on Juvenile Diabetes (partial) (1 page)	06/21/2000	P6/b(6)
002. fact sheet	re: Diabetes Research (partial) (1 page)	n.d.	P6/b(6)
003. fact sheet	re: Type 1 Diabetes (partial) (1 page)	10/1999	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Devorah Adler
OA/Box Number: 20463

FOLDER TITLE:
Diabetes [Folder 2]

2012-0463-S
rc740

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
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Freedom of Information Act - [5 U.S.C. 552(b)]

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A MAJOR ADVANCE IN THE TREATMENT OF DIABETES

TYPE 1 DIABETES: BACKGROUND INFORMATION

Type 1 diabetes is an "autoimmune" disease in which the immune system attacks and destroys the insulin-producing islet cells of the pancreas.

- ~ 1 million individuals with type 1 diabetes in the United States; ~ 30,000 new cases diagnosed each year
- One of the most common chronic disorders in children; onset in early childhood and teens; costly, life-long disease
- The leading cause of kidney failure, blindness in adults, and amputations

CURRENT THERAPIES ARE INSULIN INJECTIONS AND PANCREAS TRANSPLANTS

The most common treatment for diabetes is insulin.

- Requires multiple daily injections and careful attention to diet and activity; blood sugar levels must be measured several time a day by finger pricks
- Insulin injections are essential for survival, but do not prevent severe complications of diabetes such as blindness, kidney failure, stroke, and amputations
- Extremely difficult for patients, especially children, to maintain "tight" control of their blood sugar

Transplantation: ~250 pancreas transplants and 1000 combined kidney-pancreas transplants are performed each year in US.

- Difficult surgical procedure with high rate of complications. More than 65% of pancreas recipients reject their transplant within 3 years; rejections are also common with pancreas-kidney transplants
- Shortage of donor organs severely limits the number of diabetics who can receive a transplant; >20% of patients awaiting a pancreas transplant die while on the waiting list
- Transplant recipients require a lifelong regimen of immunosuppressive drugs that increases risks of infections and malignancies

Pancreatic islet cells transplants are being performed on an investigational basis.

- Pancreatic islet cells are isolated from a donor pancreas and injected into one of the blood vessels supplying the liver, where they lodge and produce insulin; compared to whole pancreas transplantation, this is a minimally invasive procedure
- However, long-term success of this procedure has been disappointing; of ~ 300 islet transplants performed in the last 10 years, more than 90% of recipients still require insulin injections
- Islet recipients also require a lifelong regimen of immunosuppressive drugs, including steroids, to prevent rejection. These drugs, especially steroids, appear to damage newly transplanted islet cells

RECENT ADVANCES IN ISLET CELL TRANSPLANTATION – THE "EDMONTON PROTOCOL"

- An islet transplant study was recently conducted in Edmonton at the University of Alberta in a small number of patients with severe type 1 diabetes; not funded by NIH; to be published in the New England Journal of Medicine (July 27, 2000; made available on NEJM website June 6, 2000 due to medical urgency; http://www.nejm.org/content/shapiro/1.asp)
- 4-15 months after transplantation, none of the patients treated under the "Edmonton protocol" require insulin injections

What are the differences between the Edmonton protocol and earlier studies?

- A new regimen of immunosuppressive drugs that is designed to eliminate the need for steroids
- Uses an increased number of islet cells that are prepared to maximize viability and transplanted rapidly

FOLLOW-UP & EXPANSION OF THE EDMONTON PROTOCOL BY THE IMMUNE TOLERANCE NETWORK

An international consortium of NIH- and JDF-funded investigators, designated the *Immune Tolerance Network*, will conduct a new study to confirm the Edmonton results in a larger number of patients transplanted by clinical research teams at multiple sites.

- The expansion and validation of the Edmonton Protocol (see JDF briefing materials for details on this NIH/JDF funded clinical trial) will provide a platform for future trials of new drugs and approaches that may eventually allow islet transplantation without immunosuppression
- This is the long-range goal of the Immune Tolerance Network – to test new therapies being developed by NIH-funded researchers and the biotechnology/pharmaceutical industry that will: a) eliminate the need chronic immunosuppression following transplantation; and b) treat or prevent autoimmune and allergic diseases, by selectively modulating immune responses to "foreign" or "self" antigens and allergens.

Contact:
Julie Kimbrough, JDF, 212-479-7536, jkimbrough@jdf.org
Jeff Matthews, Immune Tolerance Network, 604-512-3029, jmatthews@immunetolerance.org

DRAFT BACKGROUNDER/~~CONFIDENTIAL~~

NIH/JDF Immune Tolerance Network to Announce Clinical Centers for Upcoming Trials of the Edmonton Protocol

Last week, the New England Journal of Medicine published a study by Dr. James Shapiro and his research team at the University of Alberta on their work in successfully transplanting human pancreatic islets into eight people who had Type 1 diabetes. The new protocol is a very significant step forward in curing Type 1 diabetes. The protocol used in the clinical trial at the University of Alberta, now referred to as the Edmonton Protocol, uses a novel steroid-free combination of three drugs which together prevents rejection and also prevents the autoimmune diabetes from coming back.

The cells are extracted from the pancreases of organ donors and transplanted into the patients with Type 1 diabetes. The transplants involve a simple injection procedure which does not require surgery. The cells are placed into the liver through the portal vein. The cells then migrate to the liver where, even though they are in a different organ, take root and produce sufficient insulin and almost perfect control of blood sugar. The patients in the trial, aged 29-53, all had severe low blood sugar-induced blackouts (hypoglycemia). The patients continue to take an immunosuppressive drug therapy. The transplants are only recommended for people who have truly failed at injected insulin treatment. It is not for children and not for people in good control of their diabetes.

The Immune Tolerance Network (ITN), which is a joint initiative funded by the National Institutes of Health (NIAID and NIDDK) and the Juvenile Diabetes Foundation will replicate the Edmonton Protocol in 10 centers located in North America and Europe. **The list of the centers chosen to participate in the multicenter study have not yet publicly been announced.** In all, the ITN will use the new technique to perform at least 40 islet transplants in the ten centers over the next 18 months.

These selected centers are as follows:

- University of Alberta Clinical Islet Transplantation Program, Edmonton, Canada
- Diabetes Research Institute, University of Miami, Miami, Fl.
- Diabetes Institute for Immunology and Transplantation, University of Minnesota, Minneapolis, Minn.
- Juvenile Diabetes Foundation Center for Islet Transplantation, Harvard Medical School, Boston, Mass.
- Organ/Tissue Transplant Research Center, National Institutes of Health, Washington, D.C.
- Diabetes Research Training Center, Washington University, St. Louis, Missouri
- Virginia-Mason Research Institute, Seattle, Washington
- Geneva, Switzerland
- Islet Transplant Centre, Justis-Liebig University, Giessen, Germany
- San Raffaele Scientific Institute, University of Milan, Milan, Italy

The Immune Tolerance Network is a clinical research program headquartered at the University of Chicago and jointly sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) and the Juvenile Diabetes Foundation International. The project is a $144 million initiative led by over 70 world-leaders in immune tolerance from over forty hospitals and research institutions around the globe. Its aim is to bring new therapies to the clinic for kidney and islet transplantation, autoimmune diseases, such as diabetes, lupus, rheumatoid arthritis and multiple sclerosis, as well as allergy and asthma.

Hanna!

Lost your parents
phone —
call me!

Love
D

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Wednesday, June 21, 2000 3:

P6/(b)(6) 371-9106

Branch Chief

Laura breakthrough in diabetes

Steve Broaver

P6/(b)(6)

Juvenile Diabetes Foundation International
The Diabetes Research Foundation
Public Affairs

$15 million to replicate 10 centers 40 transplants over period of months

NIH | JDF immune tolerance network $144 m.

immediately fast track replicate trials on diabetes 10 centers

P6/(b)(6)

MEMORANDUM

To: Nancy Hernreich
Mary Morrison

From: Larry Soler
Director of Government Relations

Subject: Presidential Announcement on Juvenile Diabetes
Deadline: June 21 at 5:00 PM

Date: June 21, 2000

Pam Solo suggested that I call you to see if you can help us get a decision from the Administration by 5:00 PM today on a policy announcement regarding juvenile diabetes research.

You probably heard a few weeks ago about the breakthrough research in Canada that resulted in 7 individuals being cured of juvenile diabetes through transplantation of insulin producing drugs. The Administration is ready to announce that NIH is planning to fund 10 centers that will expand this research to see if it works in a broader population.

We have been working with OSTP to see if the President would make this announcement. We felt that this would be an opportunity for him to show that the Administration is speedily moving forward on what could turn out to be the biggest breakthrough in diabetes research since the discovery of insulin in the 1920s.

Our understanding is that the White House is very interested in doing this. However, we are running into a time problem. The news on which centers will get this project is beginning to leak, and the NIH grantees want to release the information. We have managed to get them to hold off until 5:00 PM today so we can try to get a commitment from the Administration to make the announcement. If we don't have that commitment by today, the NIH grantees will make the announcement tomorrow. If we do get it, we can have some more time.

Can you help us speed the decision process along? This would be a wonderful opportunity to show the Administration's commitment to curing juvenile diabetes and their quick action following the breakthrough.

Fauci

You can call me at 202-371-9746 x. 12 to discuss this. Again, we have a deadline of 5:00 PM today.

P6/(b)(6)

Thank your help.

Dan Rotrosen - Division Director for Allergy Imm. Transpl.

1400 I Street N.W. · Suite 530 · Washington, D.C. 20005 · 202-371-9746 · Fax: 202-371-2760

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Alan Spiegel

P6/(b)(6)

HIGHLIGHTS OF DIABETES RESEARCH AT THE NATIONAL INSTITUTES OF HEALTH

[0027]

Diabetes:
--Affects an estimated 16 million Americans, about one-third of whom do not know they have the disease.
--Sixth leading cause of death in the U.S.
--Causes debilitating and often life-threatening complications including blindness, irreversible kidney failure, heart attack, stroke, and lower limb amputations.

Type 1 diabetes:
--Usually diagnosed in childhood or young adulthood; affects an estimated one million Americans.
--Autoimmune disease–immune system destroys the insulin-producing cells of the pancreas.
--Patients require lifelong administration of insulin to survive.

Type 2 diabetes:
--Usually develops in middle age; most prevalent form of the disease.
--Characterized by reduced insulin secretion and by resistance of the body to the action of insulin.
--Disproportionately affects minority populations, including African Americans.
--Major risk factors include obesity, sedentary lifestyle and family history.
--Can usually be controlled with diet, exercise, and oral medications.

Progress Since 1993:
Funding increases, coupled with emerging scientific opportunities, have enabled the NIH to pursue many compelling avenues of diabetes research, and to implement a wide range of scientific recommendations from the Diabetes Research Working Group, a panel of diabetes experts. Patients have benefitted from unprecedented strides in biomedical research, which have increased understanding of the disease and spurred the development of new treatment and prevention strategies. Some achievements include:

--Identification of genes implicated in both type 1 and type 2 diabetes, thereby providing novel targets for treatment and prevention.

--Development of methods to predict with great accuracy those who are at high risk for developing type 1 and type 2 diabetes, thus enabling the initiation of major clinical trials that will soon demonstrate whether it is possible to prevent the development of diabetes in these individuals.

--Evidence that blindness, kidney failure and other dreaded complications of diabetes can be prevented or delayed through close control of blood glucose levels, as demonstrated in two major clinical trials.

--Development of several new drugs for treating type 2 diabetes and the definition of their mechanisms of action so that even more effective drugs can be developed in the future.

--Development of innovative methods to isolate insulin-producing cells and to prevent the body from rejecting them when they are transplanted into type 1 diabetes patients, thus facilitating this approach as an alternative to lifelong insulin treatment in these patients.

Type 2 Diabetes–Basic Research Advances of Relevance
--The technology revolution has produced an explosion of new knowledge about the genetics of obesity, a major risk factor for type 2 diabetes. Researchers have discovered important genes, such as the obesity gene that produces the protein leptin, which can affect appetite and metabolic rate. The identification of genes in spontaneous mouse models has helped to reveal new and intricate signaling pathways between fat tissue and the brain–pathways that regulates appetite and metabolism and points to possible targets for the development of new clinical interventions for type 2 diabetes.

P6/(b)(6)

–Major advances have been achieved in understanding the complex pathways of insulin action on its target cells. Research has defined many critical steps in insulin action–beginning with the binding of insulin to its cell receptors and continuing to its regulation of glucose transport and gene expression. These advances provide novel targets for drug therapy, which are being tested in mouse and other animal models in which the technology to knock out specific genes has been used to gain insights into the disease mechanisms of diabetes.

Type 2 Diabetes--Clinical Research Advances

--Genes implicated in rare forms of type 2 diabetes have been identified and the search for additional genes is proceeding rapidly–aided by the human genome project and the Type 2 Diabetes Linkage Consortium. At least five such genes, each involved in some aspect of regulation of insulin secretion or action, have already been identified. A striking example is the gene termed insulin promoter factor-1, in which subtle mutations may contribute to more common forms of type 2 diabetes by impairing insulin secretion. Progress in the development and application of genetic tools such as microarray technology will enable researchers to determine how these genes function in pancreas, fat, liver and other tissue highly relevant to type 2 diabetes.

--A major clinical trial (the United Kingdom Prospective Diabetes Study) demonstrated the effectiveness of close glucose control in preventing the microvascular complications of type 2 diabetes. The development of new drugs for therapy of type 2 diabetes and new methods of glucose monitoring have made it easier to maintain good glucose control and thus achieve these benefits.

--Several new and effective drugs have been developed for type 2 diabetes, thereby expanding the range of treatment options for patients. A new class of diabetes drugs that increase insulin sensitivity was shown to act on a cell receptor protein termed PPAR-gamma, which genetic evidence now implicates in some forms of type 2 diabetes. As new knowledge emerges from studies that reveal how genes are differentially expressed in diabetes patients, it may be possible to tailor drug therapies to individual patients to increase therapeutic benefits and reduce untoward effects.

Type 2 Diabetes--Initiatives in the FY 01 President's Budget Request
The President's Budget request will enable the NIH to undertake many important new initiatives to understand and combat diabetes, including intensified research efforts to:

--Understand and address recent alarming reports of increased incidence of type 2 diabetes in children from minority groups;
--Identify and address factors that may contribute to risk for development and progression of complications including inherent metabolic and genetic variations, medical care, socioeconomic status, and behavioral factors;
--Determine the reasons for disparities in the incidence of diabetes and its complications in minority racial and ethnic populations;
--Investigate normal cell signaling processes in the tissues affected by diabetes and how these processes are altered in this disease.
--Expand and speed the search for genes that predispose to type 1 and type 2 diabetes and their complications;
--Expand the public-awareness campaigns of the National Diabetes Education Program, with emphasis on culturally sensitive messages to disproportionately affected minority populations.
--Extend the duration of the Diabetes Prevention Program, a multicenter clinical trial in type 2 diabetes patients, with nearly 50% minority participation.

Note: Several of these initiatives are part of the new NIH-wide Health Disparities Strategic Plan.

Type 1 Diabetes–Initiatives Undertaken with Special Funds Provided by Balanced Budget Act
The BBA of 1997 provided a total of $150 million for a special five-year initiative on research to prevent and cure type 1 diabetes. These funds have been used productively to fuel new initiatives addressing areas that would maximally impact on the prevention and treatment of type 1 diabetes, including ways to:

--Achieve normal blood glucose regulation and to effect improvements in glucose sensors in order to enable more careful and continuous monitoring of blood glucose levels.

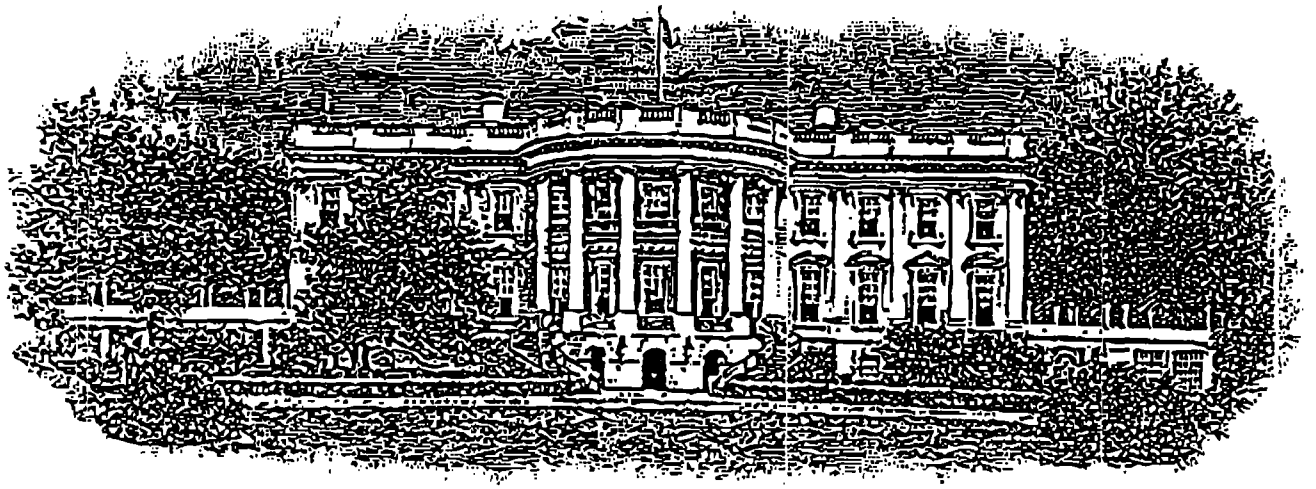
--Develop innovative methods to prevent type 1 diabetes by finding ways to understand and address abnormalities of the immune system that underlie this disease and how the functioning of genes in the developing pancreas may affect this process.

–Combat the complications of type 1 diabetes by undertaking pilot and feasibility studies to develop innovative research approaches; by focusing renewed efforts on the under-served research area of neurologic complications; and by propelling new studies that focus research attention on the onset and treatment of diabetes complications.

Importantly, these funds have attracted new research talent to the study of diabetes. Twenty-six percent of the awards provided under this initiative in FY 1998 were to first-time NIH grantees. Thirty-seven percent of these awards were made to established investigators who were new to the diabetes field. Additional new efforts in FY 01 and 02 will focus on methods to increase understanding of the insulin-producing beta cell; regional resource centers to supply insulin-producing cells to researchers for clinical trials of islet-cell transplantation, in order to follow-up on recent successful studies in this area; and a consortium for improved animal models of diabetes complications.

Note: Only a small proportion of total federal diabetes efforts is exclusively relevant to either type 1 or type 2 diabetes. Research applicable to both forms of diabetes includes studies of complications of diabetes; of the cells that produce insulin and how insulin is released; and fundamental aspects of insulin action. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) leads NIH diabetes research efforts.

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: DR ALAN SPIEGEL

FAX NUMBER: 301 402 2125

TELEPHONE NUMBER:

FROM: DEVORAH ADLER

TELEPHONE NUMBER: 2024563560 / fax 2024565557

PAGES (INCLUDING COVER):

COMMENTS: Can you please review asap? Thanks - it's the diabetes section of the press paper for tomorrow. Call or fax back edits —

NIDDK CHANGES
7/12/00 5PM
CAROL FELD 301-496-2420
PER DR. SPIEGEL

INSERT HEADLINE
July 13, 2000

Today, at the National Conference of the NAACP, the President will announce that the National Institutes of Health will immediately release $5 million to 10 research sites worldwide to fund new clinical trials attempting to replicate the breakthrough "islet transplantation" protocol that has effectively cured a small number of individuals with Type 1 diabetes. He will also highlight that the Administration's Mid-Session review budget commits another $300 million over five years for research on and prevention of all types of diabetes. In addition, the President's FY 2001 budget provides at least another $65 million for research on Type 2 diabetes, contributing to a total of $561 million for research applicable to both types of diabetes over the next year. As he discussed this major new financing commitment, the President will unveil findings from a new report, entitled "America's Children: Key National Indicators of Well-Being 2000" indicating that the health and well being of American children continues to improve. However, the President will also note that racial disparities in health status persist, and in so doing, highlight the Administration's strong commitment to improving health outcomes for all populations and urge the Congress to fully fund the Administration's FY 2001 race and health initiative. Today, the President will:

ANNOUNCE SIGNIFICANT NEW FUNDING INVESTMENT IN DIABETES RESEARCH AND PREVENTION. Approximately 16 million people nationwide have diabetes, a chronic disease with no cure that costs the health care system approximately $98 billion annually. Diabetes is the leading cause of new cases of blindness in people aged 20 to 74, affecting up to 24,000 people each year. It is also the leading cause of non-traumatic lower-limb amputations – more than 56,000 a year. In addition, people with diabetes are more than twice as likely to have heart disease or a stroke than people without the disease.

- **New investment in breakthrough clinical trials treating Type 1 Diabetes.** Today, President Clinton announced that the National Institutes of Health would invest $5 million in 10 sites worldwide in an attempt to replicate the breakthrough islet transplantation technique demonstrated to have effectively cured Type 1 diabetes in a small number of patients. There are approximately one million individuals with Type 1 diabetes nationwide, approximately 25 percent of which are minorities, and 30,000 new cases are diagnosed every year – 13,000 in children.

- **Highlighted new investment of $150 million over 5 years in research on Type 1 diabetes proposed in mid-session review.** The President's Mid-Session review budget includes $150 million over five additional years at the National Institutes of Health for new research on treatment and prevention of Type 1 diabetes, including ways to understand and address the immune system abnormalities that cause the disease and combat complications of the disease.

- **Highlighted new investment of $150 million over five additional years to prevent and treat diabetes in Native American populations.** The President's Mid-Session review budget includes approximately $ 150 million for over 300 tribal grant programs to prevent the development of Type 2 diabetes in individuals at risk and enhance the diabetes care and education provided at Indian Health Service clinics through the creation of new diabetes clinics and teams of health care professionals dedicated to diabetes care.

(in new or expanded initiatives)

- **Highlighted investment of at least $65 million dedicated to research on and prevention of Type 2 diabetes in his FY 2001 budget.** President Clinton announced that his FY 2001 budget proposes to dedicate at least $65 million to research on Type 2 diabetes, as part of an overall investment of $561 million in diabetes research. This new funding will be used to fund clinical trials aimed at developing more effective treatment; prevention strategies and national education efforts for Type 2 diabetes; research on risk factors for development and progression of complications for diabetes; and the reasons for racial disparities in the incidence of diabetes. This funding will also be used to expand and speed the search for genes indicating a predisposition to Type 2 diabetes and basic scientific research on the molecular basis for the disease.

(65) (at NIH)

RELEASE A NEW REPORT INDICATING THAT THE WELL BEING OF AMERICA'S CHILDREN CONTINUES TO IMPROVE, BUT MORE MUST BE DONE TO ADDRESS RACIAL DISPARITIES. Today, the President will release a new report by the National Institute of Child Health and Human Development detailing that the health and well-being of American children continues to improve, but that more must be done to eliminate racial health disparities. Key findings include:

(must be cleared with NICHD)

- **Childhood immunization status.** In 1998, approximately 80 percent of children aged 19 to 35 months had received the full complement of vaccines, an increase of approximately X percent since 1990. However, only 73 percent of African-American children received the full complement of vaccines as opposed to 82 percent of white, non-Hispanic children.

- **Infant mortality.** In 1998, the national infant mortality rate was 7.2 deaths per 1000 births, X percent lower than the 1990 rate. However, African-American children have consistently higher mortality rates than white children – although their infant mortality decreased from X to Y per 1000 births since 1993, their rates are still Z percent higher than infant mortality rates for white children.

- **Adolescent birth rates.** In 1998, the national rate of adolescent births was X per 1000 young women, Y percent lower than 1990 – a record low for the nation. However, the adolescent birth rates for African American teenagers is X per 1000 young women, Y percent higher than the rate among white adolescents.

- **Low-birthweight babies.** Although low-birthweight rates are rising for children of all races, in part because of the higher number of twin and triplet births has increased, 13.2 percent of African American children were born at a low birthweight in 1998 as opposed to 7.6 percent of white children.

MUST BE CLEARED WITH NICHD

In addition, the President will note that African Americans are 40 percent more likely to die from heart disease than whites. Native Americans suffer significantly higher rates of infant mortality and heart disease. And Asian Americans are as much as five times more likely to die from liver cancer associated with hepatitis.

URGE THE CONGRESS TO FULLY FUND THE ADMINISTRATION'S RACE AND HEALTH INITIATIVE. In order to address these and other racial health disparities, President Clinton launched a new initiative in 1998 that set a national goal of eliminating by the year 2010, longstanding disparities in health status that affect racial and ethnic minority groups in six key areas: infant mortality; 2) diabetes; 3) cancer; 4) heart disease; 5) HIV/AIDS and 6) immunizations. The President's FY 2001 Budget includes $35 million for these demonstration projects. The House has fully responded to the President's request, while the Senate has provided only $30 million. The President reiterated his call to the Congress to fully fund this critical initiative.

NOTE: IT IS IMPORTANT TO MAKE CLEAR THAT 65 MILLION ~~FOR~~ IN 2ND BULLET OF P2 DOES NOT REPRESENT ALL TYPE 2 DIABETES RESEARCH. IT IS FOR SOME MAJOR NEW OR EXPANDED INITIATIVES. THERE IS A LOT OF TYPE 2 RESEARCH IN

Guay-Broder, Colleen (NIDDK)

From: Harris, Maureen (NIDDK)
Sent: Wednesday, July 12, 2000 3:16 PM
To: Guay-Broder, Colleen (NIDDK)
Subject: type 1 diabetes and minorities

Colleen,

Minorities (Hispanics, blacks, Asian/Pacific Islanders, Native Americans/Eskimo/Aleuts) comprise 36% of those age 0-17 years. If we estimate that the rate of type 1 diabetes in minorities is approximately 2/3rds the rate in non-Hispanic whites, then we can estimate that, of people age 0-17 years who have type 1 diabetes, 27% are of minority race-ethnicity.

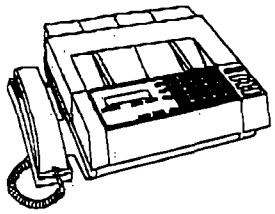
(The proportion would be similar in people age 0-24 years because in this age group, minorities comprise 35% of the population.)

For the layman, it might be useful to say that one in every four children and young adults with type 1 diabetes is of minority race-ethnicity.

OFFICE OF SCIENTIFIC PROGRAM AND POLICY ANALYSIS

National Institute of Diabetes & Digestive & Kidney Diseases

July 12, 2000



FAX TRANSMITTAL SHEET

FROM:

PHONE: (301) 496-6623

Fax: (301) 480-6741

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Rewrite of last paragraph of WH release

o **Highlighted investment of at least $ 50 million (4 large ticket items described separately), which is dedicated to major research initiatives on the treatment and prevention of Type 2 diabetes in his FY 2001 budget.** President Clinton announced that his FY 2001 budget proposes to dedicate a total of $561 million at the National Institutes of Health toward research aimed at treating and preventing all forms of diabetes and its complications. These funds will be used to continue and expand support for a wide range of high priority basic and clinical research studies across the many institutes and centers of the NIH. This budget will help to spur the application of new technolgies to yield important fundamental insights about diabetes and its complications–research equally relevant to both type 1 and type 2 diabetes. Specifically targeted to type 2 diabetes in FY 01 is over $50 million for three major multicenter clinical trials aimed at developing more effective treatment and prevention strategies for this disease, as well as for national education efforts to combat type 2 diabetes. The $561 million diabetes funding level will also enable the NIH to undertake many other initiatives related to type 2 diabetes in FY 2001 including new research efforts to address recent reports of an increasing incidence of type 2 diabetes in minority children; the reasons for racial disparities in the incidence of type 2 diabetes; and the search for genes that predispose individuals to type 2 diabetes.

DRAFT

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Highlights of "Large-Ticket" Type 2 Diabetes Initiatives
FY 01 Investments and Total Investments

1. Diabetes Prevention Program (DPP)–Nearing completion, the DPP is a multicenter randomized clinical trial in 27 medical centers across the U.S. to determine whether type 2 diabetes can be prevented or delayed in a population of high-risk individuals through lifestyle interventions and/or medications. This trial is sponsored by several NIH Institutes (NIDDK, NICHD, NIA, Office of Research on Minority Health, Office of Research on Women's Health), as well as the CDC, industry, and the private sector (American Diabetes Association). Approximately 45% of the patients participating in this trial are from minority groups.

Expenditure estimated for FY 01 based on President's Budget: $ 20 million
Expenditure estimated over life of trial from 1994-2001: $160 million

2. National Diabetes Education Program (NDEP)--The NDEP is a joint partnership of the NIDDK, the Centers for Disease Control and Prevention and over 150 public and private sector partners. The program's purpose is to improve the treatment and outcomes for people with diabetes, to promote early diagnosis, and, ultimately to prevent onset of the disease. The participation of representatives of African American organizations and groups representing other minority communities is a key feature of the NDEP Partnership to ensure that public awareness messages are culturally sensitive and tailored to specific audiences. As research advances are made with respect to new treatment and prevention approaches to type 2 diabetes, the NDEP will be an increasingly important conduit of health information messages to the public. For example, as the DPP nears completion, the NDEP will serve as a conduit for the dissemination of the results and recommendations.

Expenditure estimated for FY 01 based on President's Budget: $ 5 million
Expenditure estimated since inception of NDEP--1994-2001: $ 21 million

The NIH is launching two major multicenter clinical trials in FY 01 aimed at reducing cardiovascular mortality in type 2 diabetes–the major cause of death in this disease.

3. Study of Health Outcomes of Weight Loss (SHOW)–This new trial will be entering its large-scale phase in FY01. It is a large, multicenter trial in obese type 2 diabetes patients. Researchers are studying the impact of lifestyle and pharmacological interventions on sustained weight loss and on cardiovascular mortality.

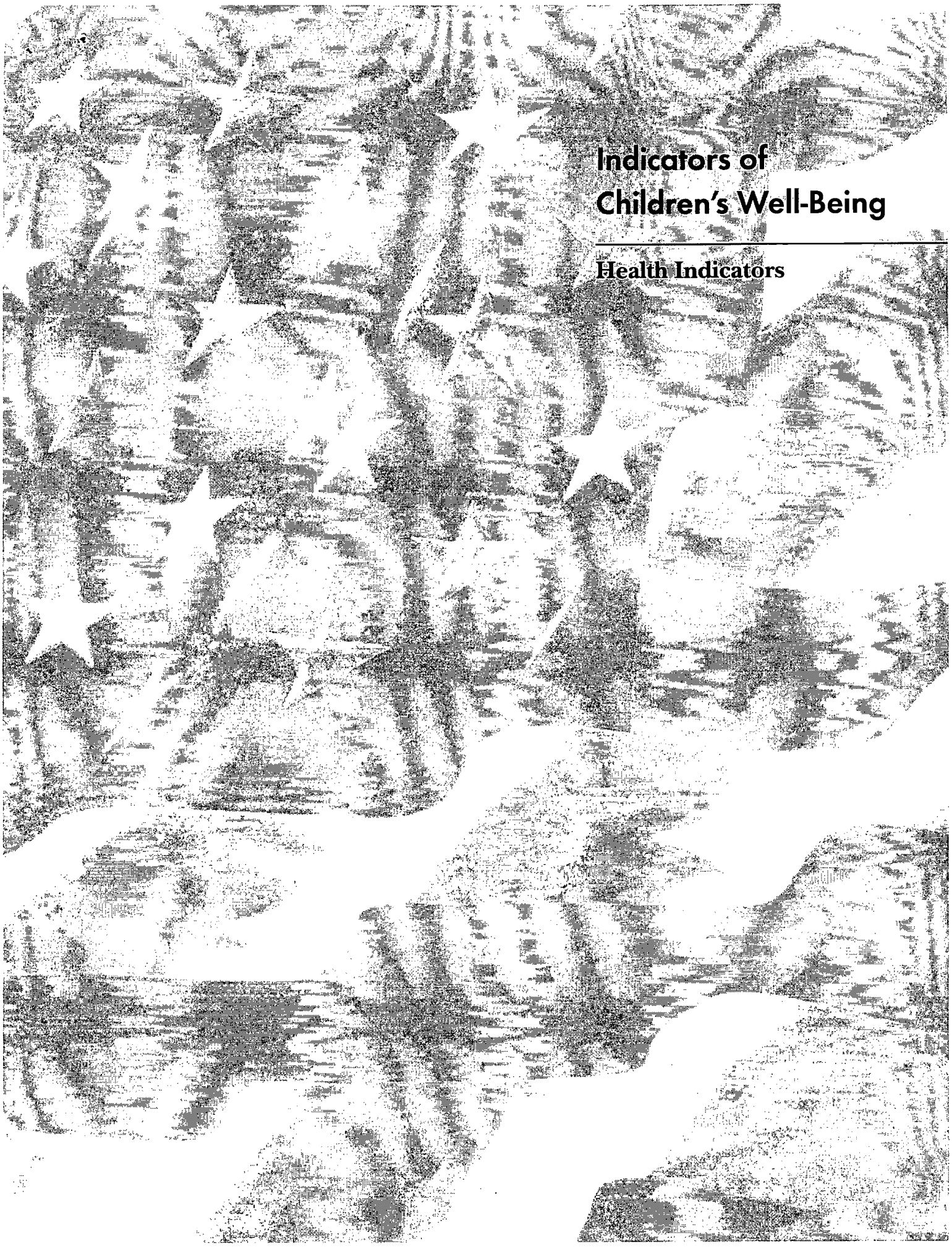
Expenditure estimated for FY 01 based on President's Budget: $ 21 million
Expenditure estimated over life of trial from 1999-2010: $180 million

4. Action to Control Cardiovascular Risk in Diabetes (ACCORD)– This large, multicenter trial will focus on ways to control the multiple risk factors faced by type 2 diabetes patients, including blood glucose levels and lipid levels with a view toward reducing cardiovascular mortality.

Expenditure estimated for FY 01 based on President's Budget: $ xx million
Expenditure estimated over life of trial from xxxx-xxxx $ xxx million

DIABETES RESEARCH

	NIDDK	NIH
FY 1991	$175,114,000	$261,519,000
FY 1992	184,500,000	278,412,000
FY 1993	187,100,000	285,894,000
FY 1994	191,409,000	293,615,000
FY 1995	193,597,000	295,185,000
FY 1996	197,542,000	298,920,000
FY 1997	211,626,000	319,539,000
FY 1998	230,084,000	387,236,000
FY 1999	267,500,000	457,600,000
FY 2000 Estimate	313,500,000	525,100,000
FY 2001 President's Budget	338,600,000	561,000,000

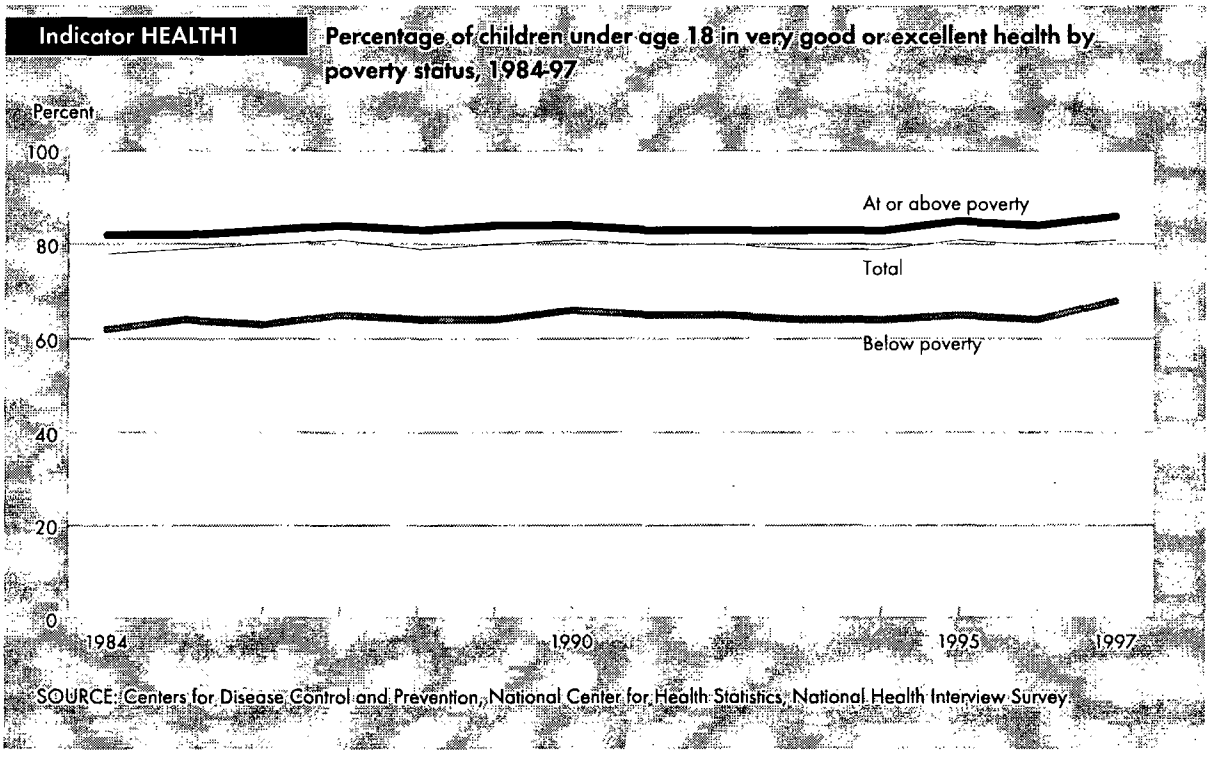


Indicators of Children's Well-Being

Health Indicators

General Health Status

The health of children and youth is basic to their well-being and optimal development. Parental reports of their children's health provide one indication of the overall health status of the Nation's children. This indicator measures the percentage of children whose parents report them to be in very good or excellent health.



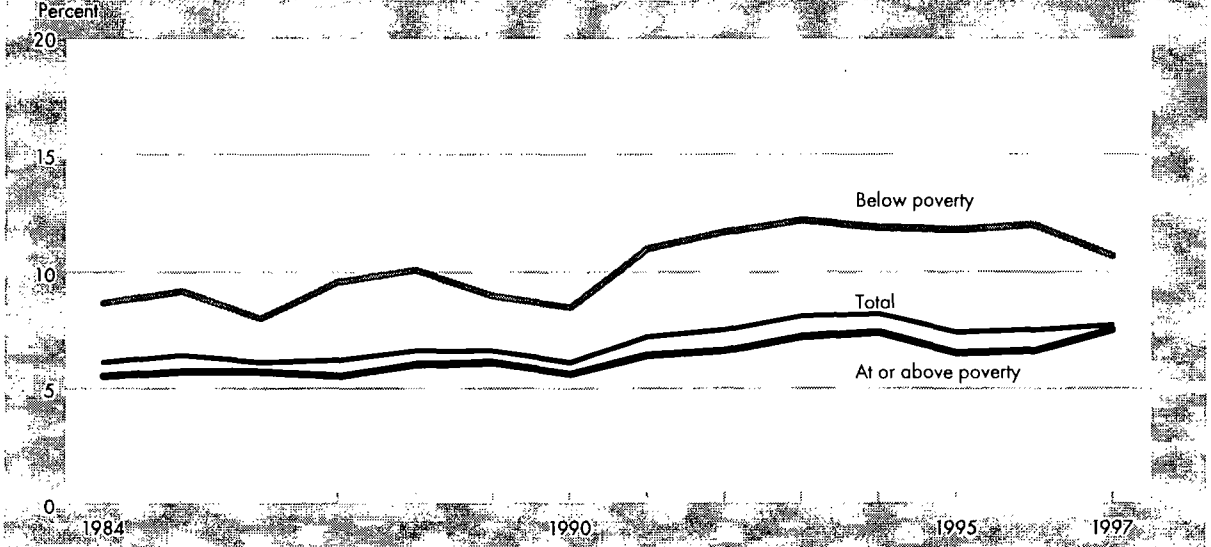
- In 1997, about 81 percent of children were reported by their parents to be in very good or excellent health.
- Child health varies by family income. Children living below the poverty line are less likely than children in higher-income families to be in very good or excellent health. In 1997, about 68 percent of children in families below the poverty line were in very good or excellent health, compared with 86 percent of children in families living at or above the poverty line.
- Children under age 5 are about as likely to be in very good or excellent health as children ages 5 to 17.
- The percentage of children in very good or excellent health remained stable between 1984 and 1997. The health gap between children below and those at or above the poverty line also did not change during the time period. Each year, children at or above the poverty line were about 20 percentage points more likely to be in very good or excellent health than children whose families were below poverty.

Bullets contain references to data that can be found in Table HEALTH1 on page 85. See indicator ECON1.A and ECON1.B on pages 14 and 15 for a description of child poverty.

Activity Limitation

Children whose activities are limited by one or more chronic health conditions may need more specialized health care than children without such limitations. Their medical costs are generally higher; they are more likely to miss days from school; and they may require special education services.[34] Researchers use parental reports on limitations associated with chronic conditions to determine the prevalence of activity limitations. Chronic conditions (such as asthma, hearing impairment, or diabetes) included in this measure usually have a duration of more than 3 months. Activities include going to school, playing, and any other activities of children.

Indicator HEALTH2 **Percentage of children ages 5 to 17 with any limitation in activity resulting from chronic conditions by poverty status, 1984-97**



NOTE: In 1997, the National Health Interview Survey was redesigned. Data for 1997 are not strictly comparable with earlier data.
SOURCE: Centers for Disease Control and Prevention, National Center for Health Statistics, National Health Interview Survey.

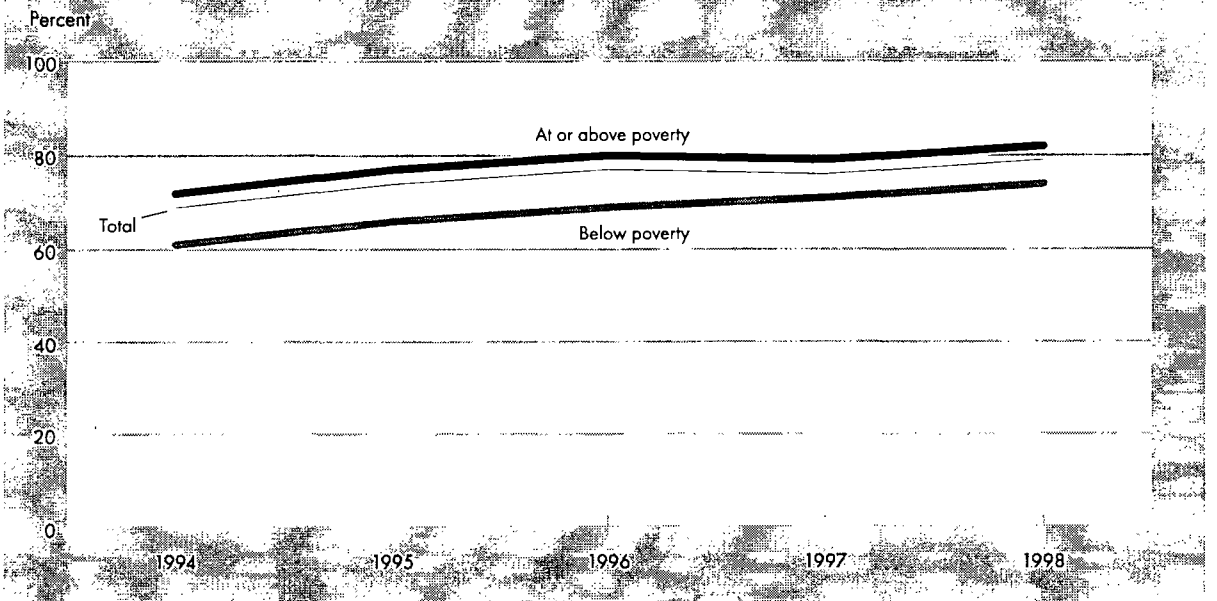
- In 1997, 8 percent of children ages 5 to 17 were limited in their activities because of one or more chronic health conditions, compared with 3 percent of children younger than 5. Children and youth ages 5 to 17 have much higher rates of activity limitation than younger children, possibly because some chronic conditions are not diagnosed until children enter school.
- Children and youth in families living below the poverty line have significantly higher rates of activity limitation than children in more affluent families. Among children and youth ages 5 to 17, 11 percent of children living below poverty had activity limitations due to chronic conditions, whereas 8 percent of children in families at or above poverty had a limitation in 1997.
- From 1984 to 1997, activity limitation increased from 9 to 11 percent among children ages 5 to 17 in families living below the poverty line. Among children ages 5 to 17 in families at or above the poverty line, activity limitation increased from 6 to 8 percent.
- The difference in activity limitation by income is also present among preschool-age children. Children ages birth to 4 in families below poverty had a rate of activity limitation that was higher than for children in families at or above poverty.
- Males ages 5 to 17 were more likely than females in the same age group to have activity limitations for all years from 1984 to 1997.

Bullets contain references to data that can be found in Table HEALTH2 on page 86. Endnotes begin on page 58.

Childhood Immunization

Adequate immunization protects children against several diseases that killed or disabled many children in past decades. Rates of childhood immunization are one measure of the extent to which children are protected from serious vaccine-preventable illnesses. The combined immunization series (often referred to as the 4:3:1:3 combined series) rate measures the extent to which children have received four key vaccinations.

Indicator HEALTH3 **Percentage of children 19 to 35 months of age with the combined 4:3:1:3 series of vaccinations by poverty status, 1994-98**



NOTE: Vaccinations included in the combined series are 4 doses of diphtheria and tetanus toxoids and pertussis vaccine (DTP)/diphtheria and tetanus toxoids (DT) vaccine, 3 doses of polio vaccine, 1 dose of a measles-containing vaccine (MCV), and 3 doses of *Haemophilus influenzae* type b (Hib) vaccine.

SOURCE: Centers for Disease Control and Prevention, National Immunization Program and National Center for Health Statistics, National Immunization Survey.

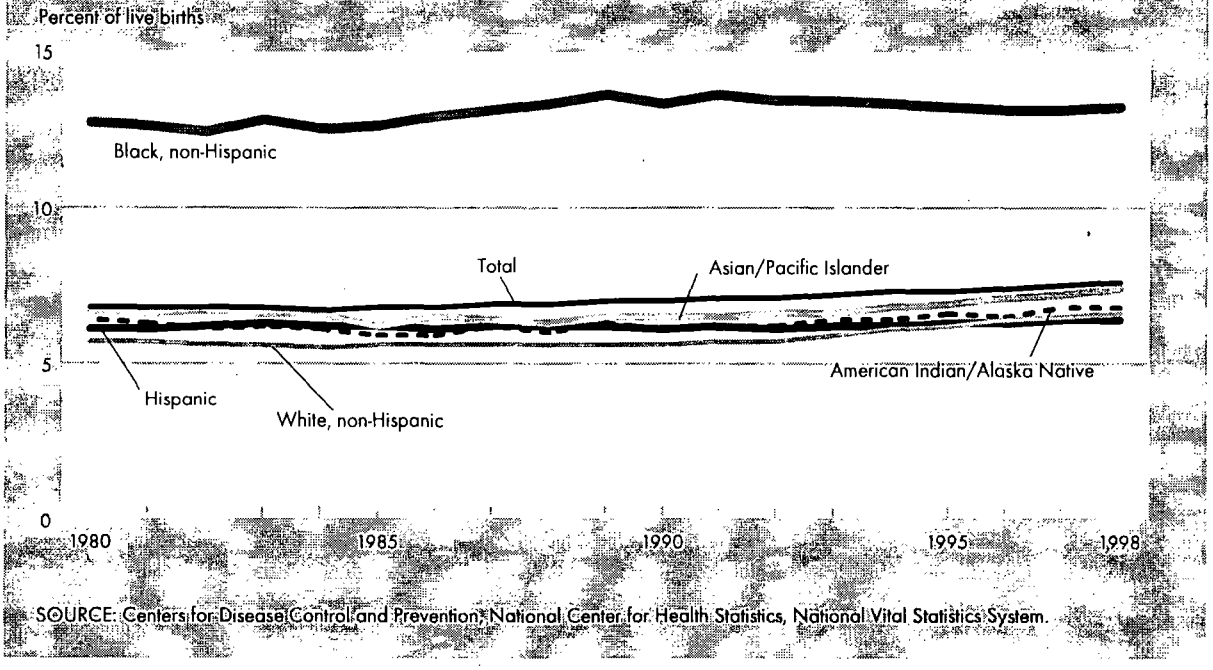
- In 1998, 79 percent of children ages 19 to 35 months had received the combined series of vaccines (often referred to as the 4:3:1:3 combined series).
- Children with family incomes below the poverty level had lower rates of coverage with the combined series than children with family incomes at or above the poverty line—74 percent of children below poverty compared with 82 percent of higher-income children.
- Overall and for children living above and below the poverty level, coverage with the combined series increased 3 percentage points between 1997 and 1998. However, the gap in coverage between children in families living above and below the poverty level remained stable at 8 percentage points.
- Coverage with three or more doses of Hib vaccine among children ages 19 to 35 months remained relatively stable at 93 percent.
- In 1998, coverage with three or more doses of hepatitis B vaccine among children ages 19 to 35 months increased 3 percentage points, to 87 percent.
- Rates of coverage with the full series of vaccines were higher among white, non-Hispanic children than among black, non-Hispanic or Hispanic children. Eighty-two percent of white, non-Hispanic children ages 19 to 35 months received these immunizations compared with 73 percent of black, non-Hispanic children and 75 percent of Hispanic children.
- In 1998, coverage with varicella vaccine among children ages 19 to 35 months increased substantially, from 26 percent to 43 percent. Gains in coverage for varicella vaccine were seen among all children regardless of race or ethnicity and poverty level; however, children living at or above the poverty line had higher coverage levels.

Bullets contain references to data that can be found in Table HEALTH3 on page 87.

Low Birthweight

Low-birthweight infants (infants born weighing less than 2,500 grams, or about 5.5 pounds) are at higher risk of death or long-term illness and disability than are infants of normal birthweight.[35,36] Low-birthweight infants are a diverse group: some are born prematurely, while others are small for their gestational age.

Indicator HEALTH4 **Percentage of infants born of low birthweight by race and Hispanic origin, 1980-98**



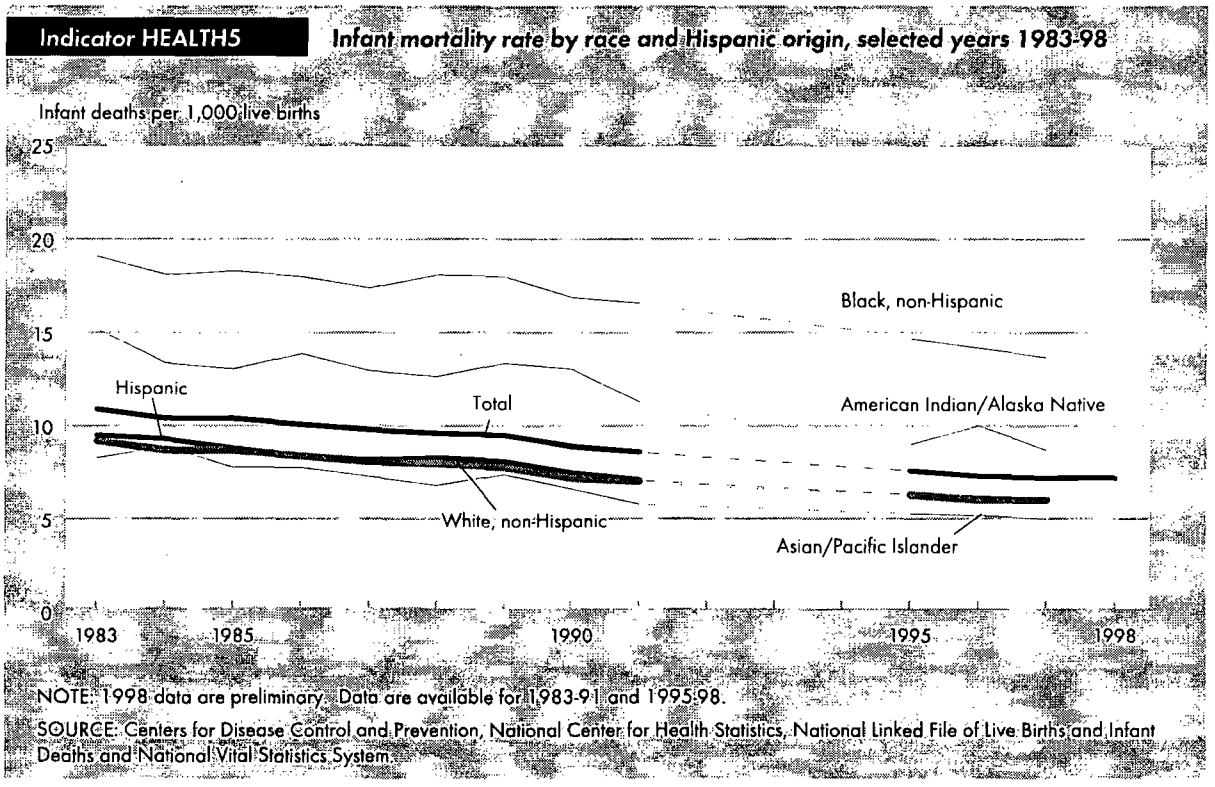
SOURCE: Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System.

- The percentage of infants born of low birthweight was 7.6 in 1998, up slightly from 7.5 percent in 1997. The low-birthweight rate has increased slowly but steadily since 1984. The 1998 rate is the highest since 1973.[5]
- The low-birthweight rate for black, non-Hispanic infants declined during the 1990s, to 13.1 percent in each year, 1996 and 1997, before rising slightly to 13.2 in 1998, but is still higher than levels reported for the early to mid-1980s. The low-birthweight rate has risen during the 1990s for white, non-Hispanic infants, from 5.6 percent in 1990 to 6.6 percent in 1998. The rate of low birthweight among Hispanic infants remained at 6.4 percent in 1998. The rate of low birthweight for American Indian/Alaska Native infants was 6.8 percent, and the overall rate for Asian/Pacific Islander infants was 7.4 percent in 1998.
- The percentage of low-birthweight births varies widely within Hispanic and Asian/Pacific Islander subgroups. Among Hispanics, women of Mexican origin had the lowest percentage of low-birthweight infants (6.0 percent) and Puerto Ricans the highest (9.7 percent). Among Asian/Pacific Islander subgroups, low birthweight was lowest for births to women of Chinese origin (5.3 percent) and highest for women of Filipino origin (8.2 percent).
- About 1.4 percent of infants were born with very low birthweight (less than 1,500 grams) in each year between 1996 and 1998, up from 1.3 percent in each year between 1989 and 1995, and 1.2 percent in each year between 1981 and 1988.
- One reason for the increase in low birthweight over the past several years is that the number of twin, triplet, and higher-order multiple births has increased.[5,37,38] Twins and other multiples are much more likely than singleton infants to be of low birthweight; 54 percent of twins and 94 percent of triplets, compared with 6 percent of singletons, were of low birthweight in 1998.[5]

Bullets contain references to data that can be found in Table HEALTH4 on page 88. Endnotes begin on page 58.

Infant Mortality

Infant mortality is defined as the death of an infant before his or her first birthday. The infant mortality rate is an important measure of the well-being of infants, children, and pregnant women because it is associated with a variety of factors, such as maternal health, quality of access to medical care, socioeconomic conditions, and public health practices.[39] In the United States, about two-thirds of infant deaths occur in the first month after birth and are due mostly to health problems of the infant or the pregnancy, such as preterm delivery or birth defects. About one-third of infant deaths occur after the first month and may be influenced by social or environmental factors, such as exposure to cigarette smoke or access to health care.[40]



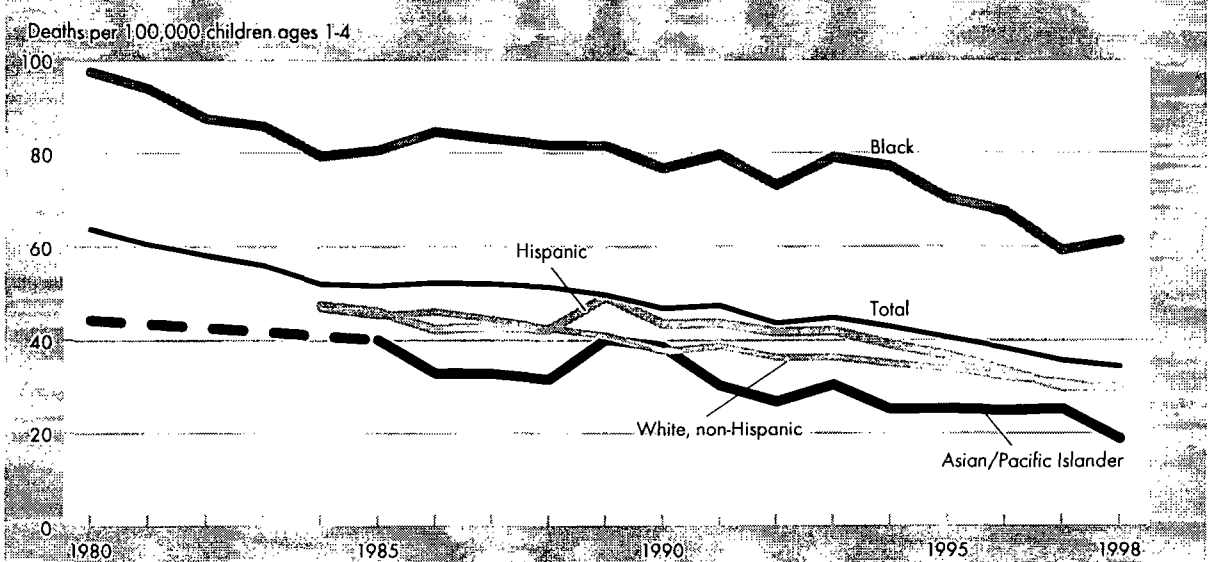
- The 1998 infant mortality rate for the United States, according to preliminary data, was 7.2 deaths per 1,000 births, substantially below the 1983 rate of 10.9.
- Infant mortality data are available by mother's race and ethnicity through 1997.[41] Black, non-Hispanics have consistently had a higher infant mortality rate than white, non-Hispanics. In 1997, the black, non-Hispanic infant mortality rate was 13.7, compared with 6.0 for white, non-Hispanics.
- Infant mortality has dropped for all race and ethnic groups over time, but there are still substantial racial and ethnic disparities in infant mortality. In 1997, black, non-Hispanic and American Indian/Alaska Native infants had significantly higher infant mortality rates than white, non-Hispanic, Hispanic, and Asian/Pacific Islander infants. In 1997, infant mortality rates varied from 5.0 among Asian/Pacific Islander infants and 6.0 among Hispanics to 8.7 among American Indians/Alaska Natives.
- Infant mortality rates also vary within race and ethnic populations. For example, among Hispanics in the United States, the infant mortality rate ranged from 5.5 for infants of Central and South American and Cuban origin to a high of 7.9 for Puerto Ricans. Among Asians/Pacific Islanders, infant mortality rates ranged from 3.1 for infants of Chinese origin to 5.8 for Filipinos.

Bullets contain references to data that can be found in Table HEALTH5 on page 89. Endnotes begin on page 58.

Child Mortality

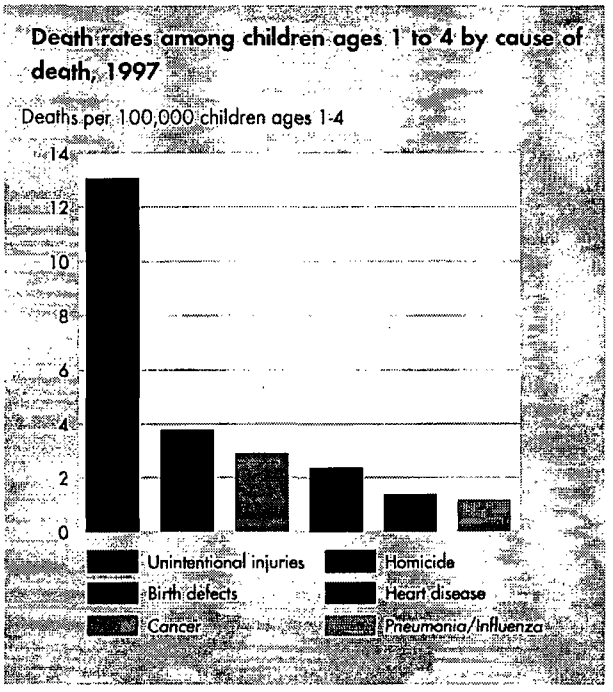
Child mortality rates are the most severe measure of ill health in children. These rates have generally declined over the past two decades. In 1997, unintentional injuries, birth defects, and cancer were the leading causes of death among children ages 1 to 4, while at ages 5 to 14, unintentional injuries, cancer, and homicide were the leading causes of death.

Indicator HEALTH6.A **Death rate among children ages 1 to 4 by race and Hispanic origin, 1980-98**



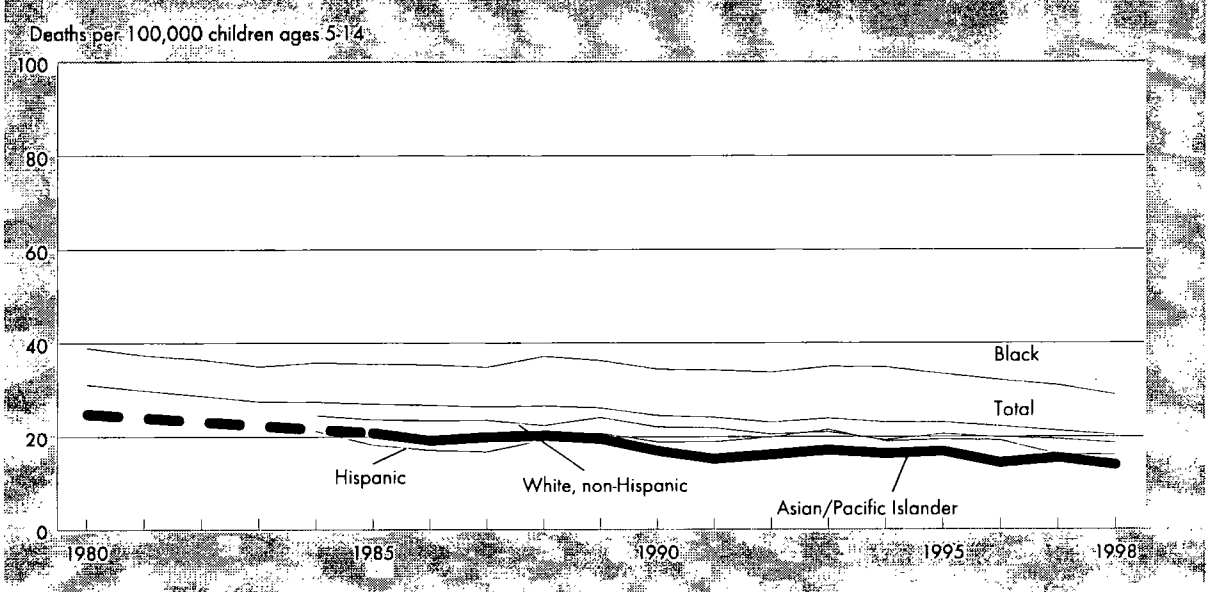
NOTE: Total includes American Indians/Alaska Natives. Mortality rates for American Indians/Alaska Natives are not shown separately because the numbers of deaths were too small for the calculation of reliable rates. 1998 data are preliminary.

SOURCE: Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System.



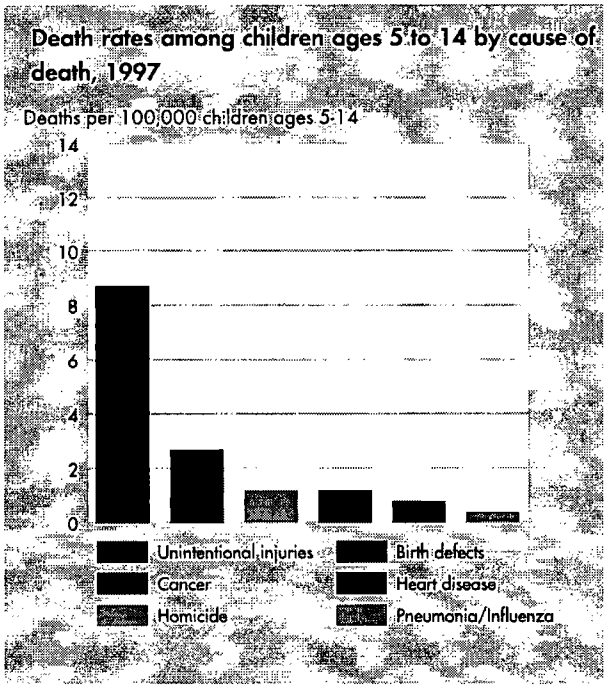
- In 1998, the death rate for children ages 1 to 4 was 34 per 100,000 children, according to preliminary data.
- Among children ages 1 to 4, black children had the highest death rate in 1998, at 61 per 100,000 children (preliminary data). Asian/Pacific Islander children had the lowest death rate, at 19 per 100,000.
- Between 1980 and 1998, the death rate declined by almost half for children ages 1 to 4.
- Among children ages 1 to 4, unintentional injuries were the leading cause of death, followed by birth defects. The mortality rate from unintentional injuries in 1997 was about half of what it was in 1980, having declined from about 26 to 13 per 100,000. Mortality from birth defects also declined by about half, from 8 deaths per 100,000 in 1980 to 4 in 1997.
- Most unintentional injury deaths among children result from motor vehicle traffic crashes. Use of child restraint systems, including safety seats, booster seats, and seat belts, can greatly reduce the number and severity of injuries to child occupants of motor vehicles. In 1997, 66 percent of child occupants ages 1 to 4 who died in crashes were unrestrained.[42]

Indicator HEALTH6.B **Death rate among children ages 5 to 14 by race and Hispanic origin, 1980-98**



NOTE: Total includes American Indians/Alaska Natives. Death rates for American Indians/Alaska Natives are not shown separately because the numbers of deaths were too small for the calculation of reliable rates. 1998 data are preliminary.

SOURCE: Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System.

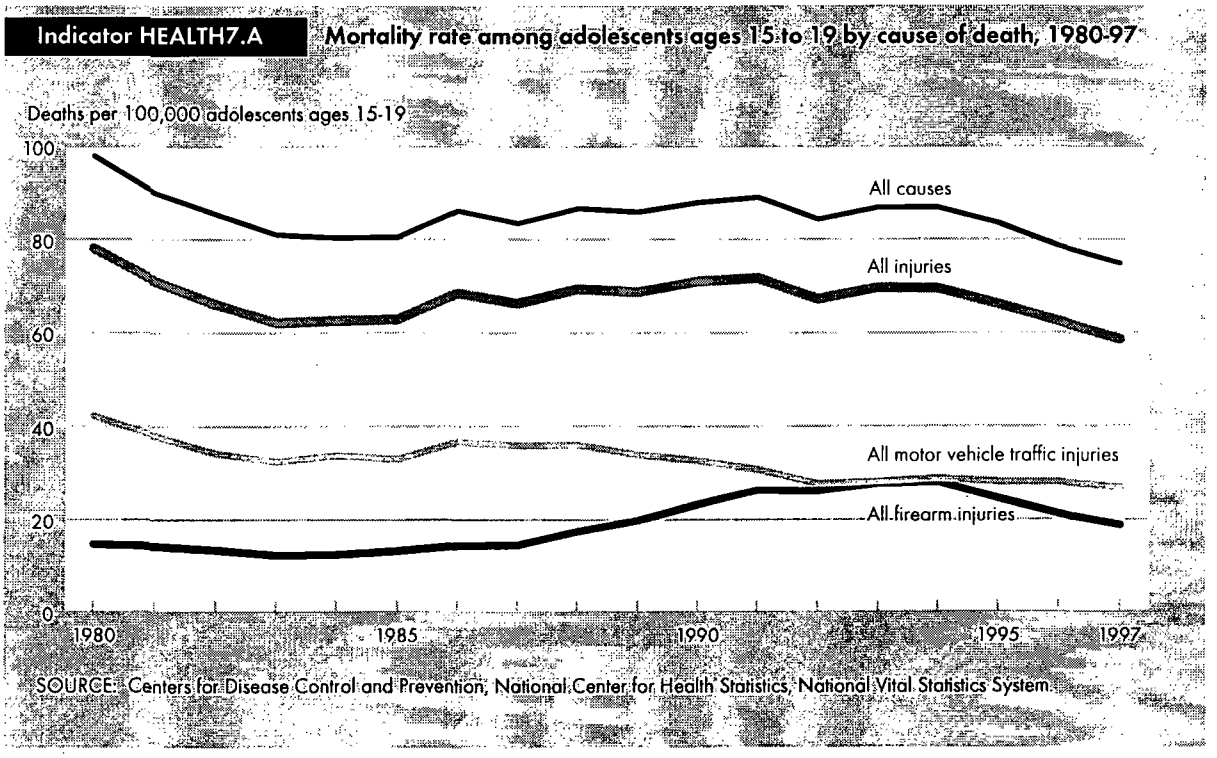


- The death rate in 1998 for children ages 5 to 14 was 20 per 100,000 children, according to preliminary data.
- Among children ages 5 to 14, black children had the highest death rates in 1998 at 29 deaths per 100,000 (preliminary data), and Asians/Pacific Islanders had the lowest death rate at 14.
- Between 1980 and 1998, the death rate declined by almost one-third, from 31 to 20 deaths per 100,000 children ages 5 to 14.
- Among children ages 5 to 14, unintentional injuries were the leading cause of death, followed by cancer, homicide, and birth defects.
- The majority of unintentional injury deaths among children ages 5 to 14 result from motor vehicle traffic crashes. Over 75 percent of children ages 5 to 14 who died in traffic crashes in 1997 were not wearing a seatbelt or other restraint.[42]

Bullets contain references to data that can be found in Tables HEALTH6.A and HEALTH6.B on pages 90 and 91. Endnotes begin on page 58.

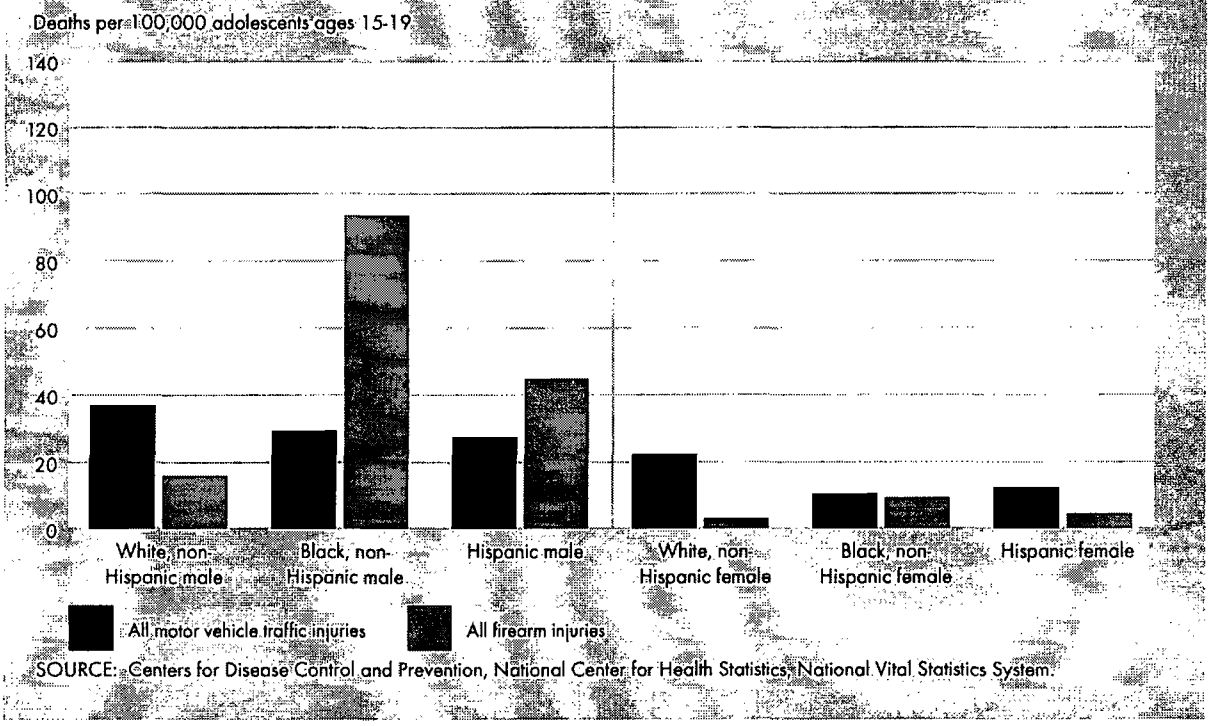
Adolescent Mortality

Compared with younger children, adolescents ages 15 to 19 have much higher mortality rates. Adolescents are much more likely to die from injuries sustained from motor vehicle traffic accidents or firearms.[43] This difference illustrates the importance of looking separately at mortality rates and causes of death among teenagers ages 15 to 19.



- In 1997, the death rate for adolescents ages 15 to 19 was 75 deaths per 100,000. After increasing to 89 per 100,000 in 1991, the rate declined again and continues to be substantially lower than the rate in 1980. Injury, which includes homicide, suicide, and unintentional injuries, continues to account for nearly 4 out of 5 deaths among adolescents.
- Injuries from motor vehicles and firearms are the primary causes of death among youth ages 15 to 19. Motor vehicle traffic-related injuries accounted for 36 percent of deaths in this age group during 1997, while injuries from firearms accounted for 25 percent.[44]
- Motor vehicle injuries were the leading cause of death among adolescents for each year between 1980 and 1997, but the death rate declined by one-third during the time period. Little change, however, has occurred since 1992.
- In 1980, motor vehicle traffic-related deaths among adolescents ages 15 to 19 occurred almost three times as often as firearm injuries (intentional and unintentional).
- Motor vehicle traffic-related and firearm death rates have followed different trends since 1980. From 1980 to 1985, both rates declined; in the following years, however, the motor vehicle traffic death rate continued to decline modestly while the firearm death rate increased markedly. During the years 1992-94, the two rates differed only slightly. However, since 1994, the firearm death rate has decreased by one-third while the motor vehicle death rate has only decreased slightly, increasing the relative difference between the two causes again.
- Most of the increase in firearm injury deaths between 1985 and 1992 resulted from an increase in homicides. The firearm homicide rate among 15- to 19-year-olds more than tripled from 5 to 18 per 100,000 between 1983 and 1993. At the same time, the firearm suicide rate rose from 5 to 7 per 100,000. From 1994 to 1997, the firearm homicide rate declined by nearly one-third and the firearm suicide rate declined by about one-fourth.

Indicator HEALTH7.B **Injury death rate among adolescents ages 15 to 19 by gender, race, Hispanic origin, and type of injury, 1997**



SOURCE: Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System.

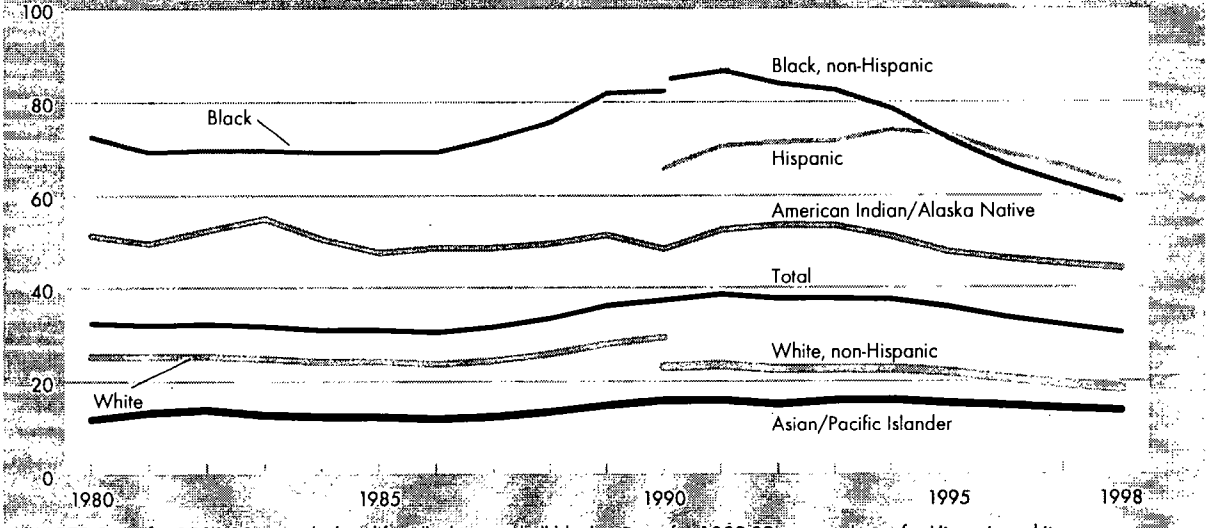
- Motor vehicle and firearm injury deaths were both more common among male than among female adolescents. In 1997, the motor vehicle traffic death rate for males was nearly twice the rate for females, and the firearm death rate among males was seven times that for females.
- Among adolescents in 1997, motor vehicle injuries were the most common cause of death among white, non-Hispanic males and females; black, non-Hispanic females; and Hispanic females. Firearm injuries were the most common cause of death among black, non-Hispanic and Hispanic males. Black, non-Hispanic males were three times as likely to die from a firearm injury as from a motor vehicle traffic injury.
- Deaths from firearm suicides were more common than deaths from firearm homicides among white, non-Hispanic adolescents. Deaths from firearm homicides were more common than deaths from firearm suicides among black, non-Hispanic and Hispanic adolescents.
- Motor vehicle and firearm mortality declined more for males than for females between 1994 and 1997.
- Deaths from firearm injuries among teenagers declined substantially between 1994 and 1997, particularly among black, non-Hispanic and Hispanic males. From 1994 to 1997, the firearm homicide rates for Hispanic and black, non-Hispanic adolescent males declined substantially to 33 and 81 per 100,000, respectively.

Bullets contain references to data that can be found in Table HEALTH7 on page 92. Endnotes begin on page 58.

Adolescent Births

Bearing a child during adolescence is often associated with long-term difficulties for the mother, her child, and society. The birth rate of adolescents under age 18 is a measure of particular interest because the mothers are still of school age. Compared with babies born to older mothers, babies born to adolescent mothers, particularly young adolescent mothers, are at higher risk of low birthweight and infant mortality.[5,36] They are more likely to grow up in homes that offer lower levels of emotional support and cognitive stimulation, and they are less likely to earn high school diplomas. For the mothers, giving birth during adolescence is associated with limited educational attainment, which in turn can reduce future employment prospects and earnings potential.[45] These consequences are often attributable to poverty and the other adverse socioeconomic circumstances that frequently accompany early childbearing.[46]

Indicator HEALTH8 **Birth rate for females ages 15 to 17 by race and Hispanic origin, 1980-98**



NOTE: Rates for 1980-89 are calculated for all whites and all blacks. Rates for 1980-89 are not shown for Hispanics; white, non-Hispanics or black, non-Hispanics because estimates for these populations were not available.

SOURCE: Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System.

- In 1998, the adolescent birth rate was 30 per 1,000 young women ages 15 to 17. There were 173,231 births to these young women in 1998. The 1998 rate was a record low for the Nation.[5]
- The birth rate among teenagers ages 15 to 17 declined from 39 to 30 births per 1,000 between 1991 and 1998. This decline follows a period of substantial increase between 1986 and 1991. During the early 1980s, the rate declined slightly and reached a low in 1986.
- There are substantial racial and ethnic disparities in birth rates among adolescents ages 15 to 17. In 1998, the birth rate for this age group was 14 per 1,000 for Asians/Pacific Islanders, 18 for white, non-Hispanics, 44 for American Indians/Alaska Natives, 59 for black, non-Hispanics, and 62 for Hispanics.
- The birth rate for black, non-Hispanic females ages 15 to 17 dropped by nearly one-third between 1991 and 1998, essentially reversing the increase from 1986 to 1991. The birth rate for white, non-Hispanic teens declined by more than one-fifth during 1991-98. In contrast, the birth rate for Hispanics in this age group did not begin to decline until after 1994; the rate fell by one-sixth from 1994 to 1998.
- In 1998, 87 percent of births to young teenagers were births to unmarried mothers, compared with 62 percent in 1980.
- While nearly four-fifths of all adolescent births are first births, the steepest decline in birth rates for young teenagers in the 1990s has been for second births to adolescents who have already had one child.[5,47]
- The pregnancy rate (the sum of births, abortions, and fetal losses per 1,000) declined by one-sixth for teenagers ages 15 to 17 during 1990-96, reaching a record low of 68 per 1,000 in 1996. Rates for births, abortions, and fetal losses declined for young teenagers in the 1990s.[48]
- Declines in overall teenage birth rates are greater than the reductions observed for unmarried teenagers (POP6A). Birth rates for married teenagers have fallen sharply in the 1990s, but relatively few teenagers are married.[49]

Bullets contain references to data that can be found in Table HEALTH8 on page 93. Endnotes begin on page 58.

Indicators Needed

Health

National indicators in several key dimensions of health are not yet available because of difficulty in definitions and measurement, particularly through survey research. The following health-related areas have been identified as priorities for indicator development by the Federal Interagency Forum on Child and Family Statistics:

- *Disability.* Research continues toward the development of improved measures of disability among children that can be derived from regularly available data. Disability in children may involve chronic health conditions or limitations in mobility and physical movement, sensory and communicative ability, activities of daily living, or cognitive and mental health functions. Many definitions of disability are currently in use by policy-makers and researchers, but there is little agreement regarding which components should be included, or how they are best measured. Parental or individual perceptions of limitations, the severity and impact of the limitation, and access to health care and services affect any estimate of disability among children.
- *Mental health.* Efforts are currently underway to evaluate data from a mental health indicator that could be used in national surveys to estimate the number of children with mental, emotional, and behavioral problems. The National Institute of Mental Health and the Center for Mental Health Services in the Substance Abuse and Mental Health Services Administration are working with other Forum agencies and academic researchers to determine data needs on mental health for children as well as the best methods of obtaining the data.
- *Child abuse and neglect.* Also needed are regular, reliable estimates of the incidence of child abuse and neglect that are based on sample surveys rather than administrative records. Since administrative data are based on cases reported to authorities, it is likely that these data underestimate the magnitude of the problem. Estimates based on sample survey data could potentially provide more accurate information; however, a number of issues still persist, including how to effectively elicit this sensitive information, how to identify the appropriate respondent for the questions, and whether there is a legal obligation to report abuse or neglect.

Date: 7/11/00

FAX

Health Division

Office of Management and Budget
Executive Office of the President
Washington, DC 20503

To: Devorah

From: Pat

Number of Pages (excluding cover) 2

Subject: Diabetes

Comment: per my email

Voice Numbers:		*Fax Numbers:*
Health Division (Front Office)	*(202) 395-4922*	*(202) 395-3910*
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Health Financing Br	*(202) 395-4930*	*(202) 395-7840*

Executive Summary

The Balanced Budget Act of 1997 provided $150 million over 5 years to Indian Health Service (IHS) for the establishment of a ***Grants for Special Diabetes Program for Indians*** focused on "the prevention and treatment of diabetes." The IHS was instructed to conduct an evaluation of the grant program and provide an interim (year 2000) and final (year 2002) report to the Congress.

The challenge is great. Significant and positive changes in diabetes activities have occurred in American Indian/Alaska Native (AI/AN) communities as a result of the diabetes grant funds. Here is a list of accomplishments:

Tribal Consultation

Grant program development involved the full participation of tribes and tribal leaders, urban Indian organizations, and IHS staff. The IHS Director established the Tribal Leaders Diabetes Committee to create a partnership between tribes and IHS for ongoing input and guidance on diabetes issues.

Grant Awards

Grants were awarded to 318 programs under 286 administrative organizations within the 12 IHS Areas. There were 27 grants awarded to IHS programs, 33 grants awarded to urban programs, and 258 distributed to tribal programs.

Diabetes Prevention

- Sixty-seven percent of the grant programs are focused on primary and secondary diabetes prevention. Thirty-two percent are focused on tertiary diabetes prevention.
- More diabetes prevention efforts now focus on elders (75%); young adults (68%); adolescents (55%); school age children (42%); and preschool age children (33%).
- Three-fourths of programs now focus more on clients with newly diagnosed diabetes; 68% of grant programs focus more on family members of people with diabetes; and 37% focus more on pregnant women as a result of the grant funds.
- More emphasis is now placed on addressing preventive measures in adults who are overweight (71.5%), people with high blood pressure (70%), children who are overweight (56%), and on tobacco users (42.6%).

Enhancement of Diabetes Care and Education

As a result of these grant funds, programs have both enhanced existing diabetes activities and developed new ones. These activities are known to improve diabetes care to patients.

- A significant number of programs use traditional approaches in their diabetes programs, including story-telling (34%), talking circles (35%), and use of traditional herbs or medicines (28%). Traditional approaches help support and influence positive diabetes self-management behaviors within communities.
- AI/AN communities established new diabetes teams (29%) and improved existing diabetes teams (42%).
- AI/AN communities created new diabetes registries (42%) and improved existing diabetes registries (48%).
- AI/AN communities established new diabetes clinics (21%) and improved existing diabetes clinics (43%).

Community Involvement

The diabetes grant funds have afforded tribes the opportunity to address diabetes prevention where it needs to be addressed--at the tribal community level. Significant advances in the development of diabetes programs have been made. New diabetes care networks have formed within and between tribal communities. They are learning from each other which diabetes prevention strategies work in AI/AN communities. This grant opportunity has allowed tribal communities to move further along their paths to wellness and diabetes prevention. But these funds were "seed money," just enough to get programs started. Five years is not nearly enough time to accomplish the goal of diabetes prevention.

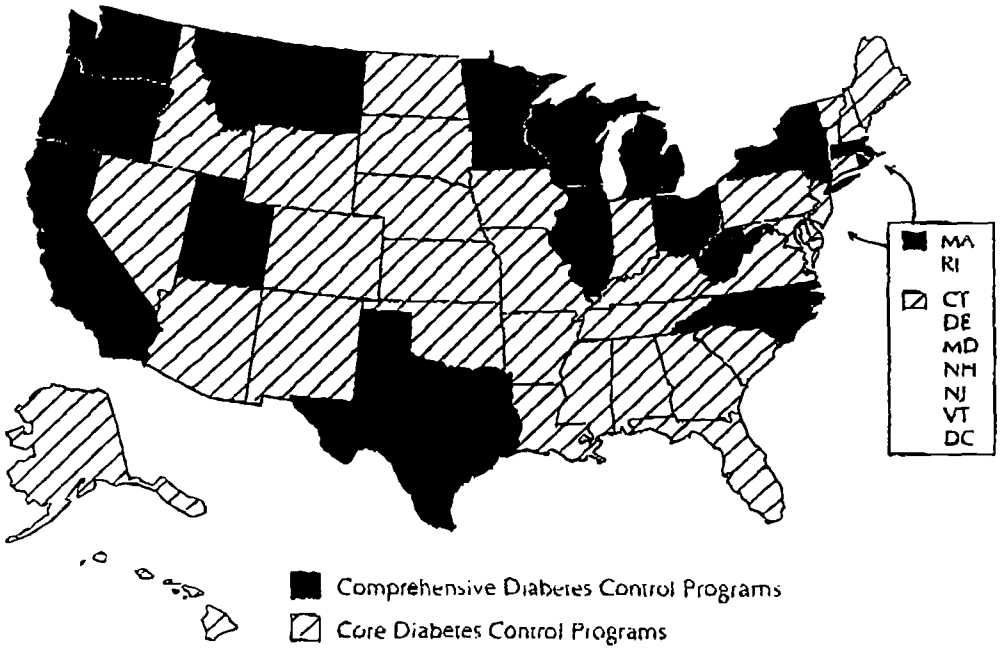
The advances achieved in AI/AN communities as a result of these funds will be lost without the means to continue and expand the established programs. AI/ AN communities will need continued funding beyond the five years allowed through the Balanced Budget Act of 1997 to continue to implement and expand upon the valuable lessons learned through this process. Diabetes prevention on all levels should bring the health of this population to the same level as that of all Americans in the next millennium. With these grants, American Indian and Alaska Native communities are finding their own paths to diabetes control and better health.

Diabetes:

A Serious Public Health Problem

AT-A-GLANCE
2000

CDC's Diabetes Control Programs, 1999*



*CDC also funds the following territories for core diabetes control programs: American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, Palau, Puerto Rico, and U.S. Virgin Islands

"Those who suffer losses due to diabetes are not just statistics on a chart. They are people whose talents and wisdom are needed and whose problems deserve our unified efforts. Together we can join to make life more just and more joyful for generations to come."

David Satcher, MD, PhD
Assistant Secretary for Health and Surgeon General

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Diabetes: A Serious Public Health Problem

What Is the Health Burden?

The facts about diabetes leave no doubt about its seriousness. The seventh leading cause of death in the United States,* diabetes contributes to more than 193,000 deaths each year. Currently, an estimated 10.3 million people in the United States have been diagnosed with diabetes—a sixfold increase over the past four decades—and another 5.4 million people have undiagnosed diabetes. These people are all at increased risk for serious health complications, including

- **Blindness.** Diabetes is the leading cause of new cases of blindness in adults aged 20–74 years.
- **Kidney failure.** Diabetes is the leading cause of end-stage (chronic, irreversible) kidney disease.
- **Amputations.** Diabetes is the leading cause of lower-extremity amputations not related to injury.
- **Cardiovascular disease.** People with diabetes are 2–4 times more likely to develop heart disease or stroke than people without diabetes.

Diabetes and its complications occur among Americans of all ages and racial and ethnic groups. The burden of this disease is heavier among elderly Americans—more than 18% of adults over age 65 have diabetes—and certain racial and ethnic populations, including African Americans, Hispanics/Latinos, and American Indians and Alaska Natives. For example, American Indians and Alaska Natives are 2.8 times more likely to have diagnosed diabetes than non-Hispanic whites of similar age. Several studies have also shown increased rates among certain Asian and Pacific Islander populations.

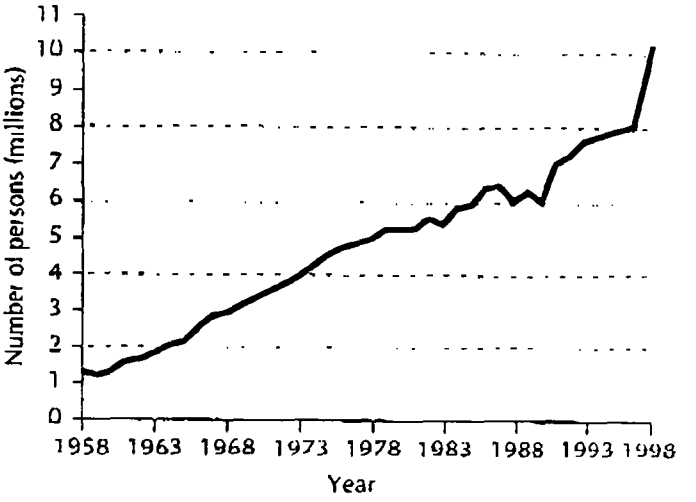
What Are the Economic Costs?

Diabetes imposes a heavy economic burden each year. The American Diabetes Association estimates that the nation spends more than $98 billion annually on the direct and indirect costs of diabetes.

The full burden of diabetes—in terms of death, complications, and costs—is not easy to measure. Mortality records often fail to reflect the role of diabetes in premature deaths, and the costs related to undiagnosed diabetes are unknown. Furthermore, for families and communities, the loss of people's lives and abilities transcends numerical measures.

*When heart disease and stroke are combined (as part of total cardiovascular disease), diabetes is the sixth leading cause of death.

Number of Persons With Diagnosed Diabetes



Source National Institutes of Health and Centers for Disease Control and Prevention, 1998.

What Is Diabetes?

The term *diabetes* describes either a deficiency of insulin or a decreased ability of the body to use insulin, a hormone secreted by the pancreas. Insulin allows glucose (sugar) to enter cells and be converted to energy. Insulin is also needed to synthesize protein and store fats. In uncontrolled diabetes, glucose and lipids (fats) remain in the bloodstream and, with time, damage vital organs and contribute to heart disease.

Diabetes is classified into two main types: type 1 and type 2. Between 5% and 10% of people with diabetes have type 1, which most often appears in childhood or the teenage years. Type 2 affects 90%–95% of people with diabetes and usually appears after age 40.

Some women develop diabetes during pregnancy. Known as gestational diabetes, this condition occurs in 2%–5% of all pregnancies. Other, less common types of diabetes, which together may account for 1%–2% of all diagnosed cases, result from specific genetic syndromes, surgery, drugs, malnutrition, infections, and other illnesses.

Many Complications of Diabetes Can Be Prevented

What Are the Opportunities for Prevention?

The increasing burden of diabetes and its complications is alarming, but the good news is that much of the burden of this major public health problem can be prevented with early detection, improved delivery of care, and better education on diabetes self-management. The following are examples of diabetes-related complications that could be prevented or reduced:

Eye Disease and Blindness

Each year, an estimated 12,000–24,000 people become blind because of diabetic eye disease. Early detection and treatment can prevent up to 90% of this blindness. If all people with diabetes received recommended screening and follow-up for eye disease, the annual savings to the federal budget could exceed $470 million.

Kidney Failure

Each year, about 33,000 people with diabetes develop kidney failure, and more than 100,000 people with diabetes receive treatment for this condition. Medicare costs for this treatment average $51,000 per person; total Medicare expenditures for treating diabetic kidney failure exceed $5.1 billion each year. Because the rate of kidney failure is rapidly increasing, these costs are expected to rise. At least half of the new cases of diabetes-related kidney failure each year could be prevented. The total first-year cost of treating these preventable cases is about $842 million.

Lower-Extremity Amputations

About 86,000 people undergo diabetes-related lower-extremity amputations each year. These amputations cost more than $860 million annually in hospitalization costs alone. Over half of these amputations could be prevented.

Complications of Pregnancy

Women with preexisting diabetes give birth to more than 18,000 babies each year. For every $1 invested in preconception care for these mothers, $1.86 can be saved by preventing adverse maternal and infant health outcomes associated with diabetes.

Poorly Controlled Glucose Levels

Results from a recent study in the United Kingdom indicate that intensive treatment to control glucose levels in people with type 2 diabetes reduces the risk of complications significantly more than diet therapy alone. Because 90%–95% of people with diabetes have type 2, these findings can help prevent many serious complications. Similarly, the Diabetes Control and Complications Trial—a national 10-year study of people with type 1 diabetes—confirmed that intensive therapy to control blood glucose levels can significantly prevent the onset or delay the progression of eye, kidney, and nerve damage.

Preventing Blindness Caused by Diabetes

- **Diabetes is the leading cause of new cases of blindness among adults aged 20–74 years.**
- **Twenty-five percent of adults with diabetes, or about 1.6 million people, report that they are visually impaired.**
- **Early detection and treatment could prevent up to 90% of diabetes-related blindness.**
- **Only 60% of people with diabetes are receiving annual dilated eye examinations—a key strategy for preventing blindness caused by diabetes.**

Source: Centers for Disease Control and Prevention, 1998.

CDC's National Leadership

CDC joins with state and territorial health departments and other partners to focus efforts on all populations at increased risk for diabetes and its complications. With fiscal year 2000 funding of $51 million, CDC provides leadership for a coordinated, multifaceted approach targeting diabetes. Goals are to increase awareness and education about diabetes, promote early detection of diabetes and treatment of its complications, improve the quality of diabetes care, and enhance access to diabetes care by improving and expanding services.

Implement Effective State Programs Nationwide

CDC supports state- and territorial-based diabetes control programs to reduce the complications associated with diabetes. In fiscal year 1999, CDC provided limited support to 34 states, 8 territories, and the District of Columbia for core diabetes programs and more substantive support to 16 states for comprehensive programs. The core programs do not address needs statewide; however, they serve as the framework on which states build more comprehensive programs. When resources become available, CDC plans to expand its comprehensive programs to additional states.

Examples of state activities include the following:

- The California Diabetes Control Program conducted a diabetes project to assess the effects of case management on blood glucose levels among MediCal (Medicaid) patients. Blood glucose levels had declined significantly at 18 months of follow-up among patients who received diabetes care guidelines, patient follow-up, blood glucose monitoring instruction, and nutrition education in addition to usual care from primary care providers. Improved glucose control decreases the patient's risk of complications and ultimately decreases health care costs.
- The Maine Diabetes Control Program worked with local diabetes educators to administer a comprehensive diabetes self-management education program in 90% of Maine's hospitals and many health centers. Participants reported significant reductions over a 5-year period in diabetes-related hospitalizations (43%), emergency room visits (36%), and illness-related physician visits (31%). They also reported increases in visits to eye care providers (12%) and podiatrists (51%).
- The Michigan Diabetes Control Program's Upper Peninsula Diabetes Outreach Network established a diabetes care and education program with hospitals, health departments, and home care agencies. Participants in the program experienced a 45% lower rate of hospitalizations, a 31% lower rate of lower-extremity amputations, and a 27% lower death rate than nonparticipants. This program has been replicated in five new outreach networks throughout the state.
- The Utah Diabetes Control Program works with local partners to ensure that people with diabetes throughout the state have access to education on self-care to help minimize the development of debilitating complications of diabetes. Partly as a result of these efforts, the percentage of Utahns with diabetes who never monitored blood glucose levels decreased from 33% in 1991 to 12% in 1997, and the percentage of those who had received a dilated eye examination in the past year increased from 46% in 1991 to 71% in 1997.

Implement the National Diabetes Education Program

CDC and the National Institutes of Health jointly sponsor the National Diabetes Education Program (NDEP). Through collaboration with over 100 public and private partners, this program seeks to improve the treatment and outcomes of people with diabetes, promote early detection, and ultimately prevent the onset of diabetes.

The NDEP develops educational tools and community-based interventions and establishes public and private sector partnerships to address the needs of people with diabetes and raise general awareness about the disease. Recently, the NDEP launched its first public awareness campaign with the theme, "Control Your Diabetes. For Life." Included in the campaign are public service announcements targeting general audiences, as well as messages directed toward Hispanic/Latino communities. Campaigns addressing the needs of African Americans, American Indians, and Asian Americans/Pacific Islanders are currently being developed.

Better Define the Diabetes Burden

Understanding how diabetes is distributed in the population is essential to effectively targeting prevention efforts. CDC uses multiple sources of data to track diabetes, including its Behavioral Risk Factor Surveillance System, which provides state-specific information on risk factors and health care practices related to diabetes. CDC also uses the National Health and Nutrition Examination Survey and the National Health Interview Survey. In addition, CDC maintains a national system that provides data about diabetes; these data are widely disseminated through diabetes surveillance reports. CDC will also explore new methods for tracking diabetes among special populations.

CDC develops projections of the economic burden of diabetes by examining how Medicare and Medicaid data can be used to generate information on diabetes trends and the anticipated costs of treatment and preventive services. To help focus future research, CDC has published a comprehensive, annotated bibliography of all recent economic studies of diabetes.

Translate Science Into Quality Care

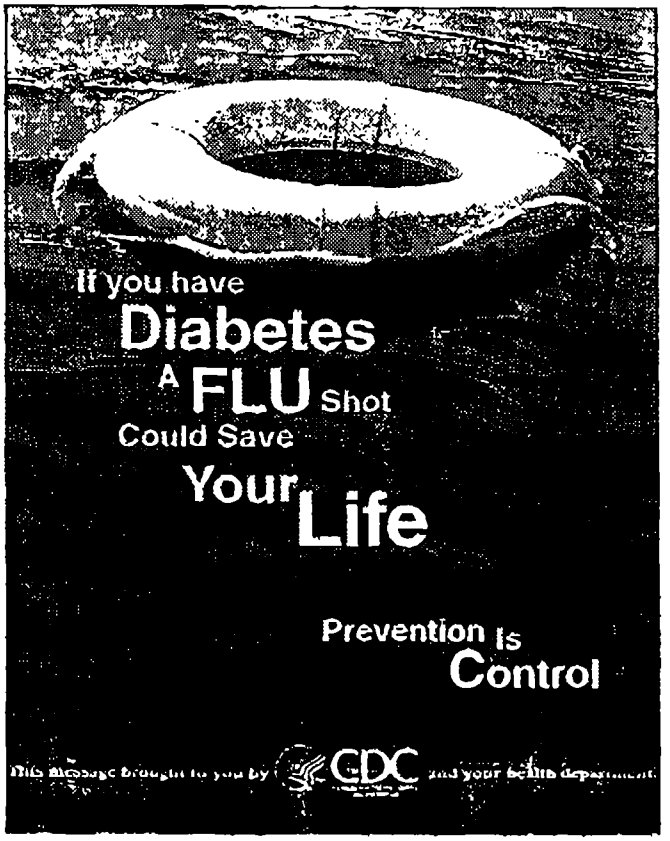
CDC is working with partners in managed care to determine how to improve care for people with diabetes. Through Diabetes Translational Research Centers and a supporting Data Coordinating Center, CDC is

- Assessing how health care providers and delivery systems implement accepted standards of care.
- Exploring variations in the implementation of quality diabetes care.
- Developing and testing strategies to close the gap between existing practices and optimal standards of care.

CDC has dedicated $3 million to the National Diabetes Laboratory to support scientific studies that will improve the lives of people with diabetes. Current research includes efforts to find noninvasive ways to monitor blood glucose to prevent hypoglycemia, which can cause comas; to improve instruments that measure blood glucose; and to better understand the role of autoantibodies in the development of type 1 diabetes.

Develop Innovative Approaches

- Diabetes and Flu/Pneumococcal Campaign—Although people with diabetes have an increased risk of death from influenza and pneumonia, only 50% get an annual flu shot. As part of CDC's ongoing public service campaign *Diabetes. One Disease. Many Risks*, the Diabetes and Flu/Pneumococcal Campaign educates people with diabetes about the importance of getting flu and pneumonia shots. CDC develops campaign kits that it disseminates through national media channels, health systems, and state diabetes control programs. Individual states can tailor these materials (available in English and Spanish) to their own populations.



- Diabetes Today—This program provides health professionals and community leaders with the skills needed to mobilize communities and to develop appropriate interventions to prevent diabetes complications and improve diabetes care. One outcome of this educational program is the development of a strategic plan that is community owned and culturally relevant to the local population. Two Diabetes Today centers—one for the continental United States and Alaska and the other for Hawaii and the Pacific basin—will provide training and technical assistance.

Target Special Populations

- National Diabetes Prevention Center—American Indian populations have a high incidence and prevalence of diabetes and its complications. In 1998, CDC funded a center in Gallup, New Mexico, to promote diabetes prevention and control among the Navajo Nation and the Zuni Pueblo. The center will develop culturally relevant prevention strategies through focused intervention research, surveillance, program evaluation, training, and tribal capacity-building activities. Research findings, strategies, and benefits will ultimately be applicable to other American Indian tribes and similar populations.
- National Minority Organizations—In 1998, CDC selected six national minority organizations to support NDEP programs to reach African American, Hispanic/Latino, American Indian, and Asian American/Pacific Islander populations with culturally and linguistically appropriate diabetes prevention and control messages. These organizations are developing and delivering diabetes care messages through trusted community channels and developing partnerships with other national organizations that serve these groups.
- National Hispanic/Latino Diabetes Initiative for Action—This special population initiative develops diabetes prevention strategies that are relevant to U.S. Hispanic/Latino communities. CDC is incorporating strategic recommendations from an expert consultant group into the new 5-year funding cycle for state diabetes control programs.
- Diabetes and Women's Health Monograph—CDC is developing a monograph, *Diabetes and Women's Health Across the Life Stages: A Public Health Perspective*, to highlight the effect of diabetes on the life cycle of women. The monograph will describe the epidemiology of the disease, address community needs, and examine psychosocial issues related to women with diabetes.
- Project DIRECT—Project DIRECT is a multiyear community diabetes demonstration project in a predominantly African American community of 25,000 in southeast Raleigh, North Carolina. Community outreach, health promotion activities, and quality improvement strategies for local health care providers are the key program intervention components. Diabetes management and nutrition courses, organized walking programs, and diabetes screenings are being implemented to improve the health-related quality of life for this community. Lessons learned will be incorporated into CDC's 59 state- and territorial-based diabetes control programs.

Build National Partnerships

Committed to building strong national partnerships to reduce the burden of diabetes, CDC collaborates with its partners to provide data for sound public health decisions, inform the public about diabetes, and ensure optimal diabetes care and education for all people with diabetes in the United States. One product of these partnerships is the *National Diabetes Fact Sheet: National Estimates and General Information on Diabetes in the United States, produced by* CDC in collaboration with the following organizations: American Association of Diabetes Educators, American Diabetes Association, Department of Veterans Affairs, Health Resources and Services Administration, Indian Health Service, Juvenile Diabetes Foundation International, National Council of La Raza, National Diabetes Education Program, National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health, and the U.S. Department of Health and Human Services' Office of Minority Health.

Offer International Treatment Options

By 2025, 300 million people worldwide will have diabetes. Because most of these cases will be in developing countries and among poorer people, CDC is helping develop low-cost treatment options. As a World Health Organization Collaborating Center for Diabetes, CDC is working with the Pan American Health Organization to implement the Declaration of the Americas, which includes developing guidance documents for international diabetes control programs.

For more information or additional copies of this document, please contact the Centers for Disease Control and Prevention,
National Center for Chronic Disease Prevention and Health Promotion, Mail Stop K–10,
4770 Buford Highway NE, Atlanta, GA 30341-3717.
Toll-free 1-877-CDC-DIAB
diabetes@cdc.gov http://www.cdc.gov/diabetes

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00097]

Uniform Population-Based Approach to Case Ascertainment, Typology, Surveillance, and Research Childhood Diabetes

Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 20 funds for a cooperative agreement program to develop a multi-center and uniform population-based app to case ascertainment, typology, surveillance, and research on childhood diabetes (diagnosis before the a of 20 years). This program addresses the "Healthy People 2010" focus area of Diabetes. For the confere copy of "Healthy People 2010," visit the internet site: <http://www.healthypeople>. In view of the importance of racial and ethnic health disparity issues, the purpose of the program is to use a uniform m center approach in diverse populations for multiple purposes:

1. Using existing data of known prevalent cases of childhood diabetes, develop a uniform typolog the prevalent cases, obtain type-specific prevalence estimates, and describe characteristics of the different types of childhood diabetes;

2. Based on the extensive collection of new cases of childhood diabetes, develop a uniform typolo of the incident cases, obtain accurate and precise population-based estimates of the type-specific incidence and secular trends of new cases, and describe the characteristics of the different types o childhood diabetes;

3. Develop a uniform approach to follow incident cases of childhood diabetes to ascertain change typology, characteristics and outcomes, and to maintain a "pool" of incident cases of childhood diabetes.

Characterization of types of childhood diabetes should include a description of potential risk factors (including family history, maternal diabetes, race/ethnicity, sex, weight and height, birth-weight, etc), ot characteristics (including presence of acanthosis nigricans, symptoms and circumstances at or preceding diagnosis, treatment and response to treatment, HbA1c, lipids, and blood pressure levels, etc), potential laboratory measurements (C-peptide and insulin levels, immunological markers, etc), potential complica (including microalbuminuria, hypertension, retinopathy, neuropathy, infections, etc), and quality of med care (including screening frequencies for HbA1c, lipid profiles, microalbuminuria, retinal and foot examinations, blood pressure checks, nutrition counseling, rates of hospitalization for complications, etc

This collaborative program will consist of two phases. Phase I (12 months) - - Planning, developing networks of care providers and other partnerships, and collaboration on the development of the protocol Institutional Review Board clearances. Phase II (48 months) - - Data collection, monitoring, analyses, an collaborative reporting of the results, on a yearly basis.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and th agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofi organizations, State and local governments or their bona fide agents, and federally recognized Indian tri governments, Indian tribes, or Indian tribal organizations.

Note: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Reven Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately $500,000 is available in FY 2000 to fund approximately 2 to 3 awards. It is expected tha average award will be $200,000 ranging from $150,000 to $250,000. It is anticipated that additional fun may be available in FY 2001-2004 to increase the average award to approximately $500,000 in Years 2- ranging from $400,000 to $600,000. It is expected that the awards will begin on or about September 30, 2000, and will be made for a 12-month budget period within a project period of up to 5 years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progres evidenced by required reports and the availability of funds.

Use of Funds

Funds are awarded for a specifically defined purpose and must be targeted for implementation and management of the project. Funds can support personnel, activities directly related to the project, and th purchase of software for data collection, analysis, and project management and evaluation purposes.

Prohibited Uses: Cooperative agreement funds under this program announcement cannot be used for (1) construction, (2) renovation, (3) the purchase or lease of passenger vehicles or vans, (4) to supplant non federal funds that would otherwise be made available for this purpose, or (5) cost of regular patient care

Funding Priority

In making awards, priority consideration will be given as follows. Due to the high prevalence of type 2 diabetes in American Indian children, funding priority will be given to at least one center which will hav access to American Indian populations. In addition, approved applications may also be ranked and funde based on populations with racial/ethnic and socio-economic diversity to achieve geographic, socio-econ and racial/ethnic representation of the U.S. population, and a minimum mix of the different types of childhood diabetes (at least 20% type 2).

Minimum requirement

Applications for the development of a multi-center and uniform population-based approach to case ascertainment, typology, surveillance, and research on childhood diabetes in diverse populations require access to information on large numbers of children with diabetes (minimum of 50 incident cases per yea and their referent populations (minimum of 300,000 children under the age of 20) with racial/ethnic and

socio-economic diversity, including under-insured.

Institutions may apply as a single entity or in collaborative partnership or network(s). However, only on institution will be named as the recipient of funds in a partnership/network.

Eligibility characteristics for review must be clearly specified with appropriate documentation in the Application Requirements section of your application (see Application Content).

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (C Activities).

1. Recipient Activities

a. Establish and sustain networks or partnerships with health care providers and health care systems have access to information on cases of childhood diabetes. Collaborate with other health organiza community groups, State Health Department, Diabetes Control Programs etc., as necessary to accomplish program activities.
b. Establish a Steering Committee that will be the primary governing body of the study and will be comprised of each of the Principal Investigators from each center. The Steering Committee will h primary responsibility for developing manual(s) of operations and common study protocols, submitting the protocols for CDC and other Institutional Review Boards, and coordinating resolut of Institutional Review Board issues, facilitating the conduct of the study and on-going data colle analyses, and reporting of study results.
c. Participate in the methodology and protocol development, on-going data collection and follow-up quality control, data analysis and interpretation, the preparation of peer-reviewed publications, an presentation of findings.
d. Work cooperatively with the other Centers, and agree to follow the common protocol(s) and manu of operations developed in Phase I of the study by the Steering Committee.
e. Maintain an effective and adequate management and staffing plan. Staff should have the educatio background, and experience to successfully conduct the activities proposed in this application. As part of the application, the existing staff and all proposed positions should to be included.

2. CDC Activities

a. Support the recipients' activities by collaborating and providing scientific and public health consultation and assistance in the development of activities related to the cooperative agreement a coordination sharing.
b. Assist in facilitating communication among recipients development of common multi-center proto (s), quality control, interim data monitoring, data analysis, interpretation, reporting, and coordinat
c. Assist in the development of a research protocol for IRB review by all cooperating institutions participating in the research project, including CDC IRB.
d. Serve as a consultant to the Steering Committee.

E. Application Content

Competing Applications

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria section

the announcement and the Errata Sheet in the application to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan.

The outcome of this program should provide reliable estimates of the prevalence, incidence and secular trends of the different types of childhood diabetes, and should enable the development of case definition characterization at diagnosis and follow-up of the different types of childhood diabetes. More specifical the following questions should be answered:

1. Using existing data of known prevalent cases of childhood diabetes, how could prevalent cases be classified, and what are the type-specific prevalence estimates and the characteristics (including medical care received) of the different types of childhood diabetes?
2. Based on the extensive collection of new data, how could incident cases of childhood diabetes be classified, and what are the accurate and precise population-based estimates of the type-specific incidence and secular trends, and the characteristics (including medical care received) of the diffe types of diabetes.
3. How could incident cases of childhood diabetes be followed in a uniform approach, and what are characteristics, outcomes and quality of care at follow- up? How could a "pool" of incident cases maintained for studying secular trends in incidence and factors associated with causation?

Emphasis should be on rigorous scientific approaches and methodologies that should yield access to populations of diverse ethnicity, socioeconomic status and insurance coverage, produce reliable populat based estimates that should adequately address ascertainment biases, and should assure sustainability to provide data for secular trend assessment and follow-up for the different types of childhood diabetes.

Each applicant must describe the proposed populations, the methodology and study designs that best ad the objectives of this program, as well as the networks and partnerships that should help achieve these objectives. Applications should propose a uniform and multi-center approach, which considers the prob of racial/ethnic health disparities.

Collaborative protocol(s) to study the above questions should be developed by a Steering Committee composed of the recipients. The collaborative study protocol(s) should move into the implementation st with the concurrence of the Steering Committee. It is not the intent of this Program Announcement to so elaborately detailed research plans for the above proposed collaborative project because the final protoc should be collaboratively developed by the investigators during the planning phase (Phase I).

Eligibility characteristics must be clearly specified with appropriate documentation in the Application Requirements section of your application.

The application narrative must include the following sections in the order presented below:

a. Description and rationale of (a) the population source (including size, age, ethnicity, medical insuranc status, socio-economic status, geographic), and

b. The partnership/network(s) which will provide access to information on the cases within this populati source (not to exceed 5 pages).

(1) When describing the population source, indicate the degree to which racial and ethnic minority socio-economically disadvantaged populations are included, and how the population is sufficientl typical of children with diabetes around the country or accurately represents special groups of chi with the disease.

(2) When describing the partnership/network(s), detail the various types of providers which are included.

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
003. fact sheet	re: Type 1 Diabetes (partial) (1 page)	10/1999	P6/b(6)

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Devorah Adler
OA/Box Number: 20463

FOLDER TITLE:
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2012-0463-S
rc740

RESTRICTION CODES

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P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Type 1 Diabetes Fact Sheet

More than one million Americans have Type 1 (juvenile) diabetes. It can occur at any age, but is most commonly diagnosed in childhood. In Type I diabetes, a person's pancreas produces little or no insulin. Although the causes are not entirely known, scientists believe the body's own immune system attacks and destroys insulin-producing cells in the pancreas. Because insulin is necessary for life, people with Type 1 diabetes must take several insulin injections a day for the rest of their lives.

The Truth About Type 1 Diabetes

- ***AFFECTS YOUNG CHILDREN:*** It's one of the most costly, chronic diseases of childhood and one you never outgrow.
- ***INSULIN IS NOT A CURE***: While insulin allows a person to stay alive, it does not prevent the complications of diabetes, including blindness, heart attack, kidney failure, stroke, nerve damage, and amputations.
- ***NEEDS CONSTANT ATTENTION***: To survive, people with Type 1 diabetes must take multiple insulin injections daily and test their blood sugar by pricking their fingers for blood six or more times per day. While trying to balance insulin injections with their amount of food intake, people with Type 1 diabetes must constantly be prepared for potential hypoglycemic (low blood sugar) and hyperglycemic (high blood sugar) reactions which are life threatening.
- ***OTHER FACTORS AFFECTING CONTROL***: Despite rigorous attention to maintaining a healthy diet, exercise regimen, and always injecting the proper amount of insulin, many other factors can adversely affect a person's blood-sugar control including: stress, hormonal changes, periods of growth, illness or infection and fatigue.

Statistics and Warning Signs

- Life expectancy of people with diabetes averages 15 years less than people who don't have it.
- Each year 30,000 Americans are diagnosed with Type 1, over 13,000 of whom are children. That's 35 children each and every day.
- Common symptoms of Type 1 diabetes include: *excessive thirst, constant hunger, excessive urination; sudden weight loss for no reason; rapid, hard breathing; sudden vision changes or blurry vision, drowsiness or exhaustion; fruity odor on breath.* These symptoms may occur suddenly.

What is it like to have Type 1 Diabetes?

Ask people who have Type 1 diabetes. It's difficult. It's upsetting. It's life threatening. It doesn't go away.

-- Actress Mary Tyler Moore, JDF's International Chairman

"I've had Type 1 diabetes for over 30 years. It changes everything about a child's and a family's life. And to add to the day-in, day-out hassles of living with diabetes – the balancing of diet, exercise, and insulin, the shots, the terrible episodes of low blood sugar, the weird feelings of high blood sugar – is the knowledge that even if you do all you can to be as normal as possible, you're not, you're different, and you face the uncertainty of an adulthood visited upon by early blindness, kidney failure, amputation, heart attack or stroke."

-- P6/(b)(6) [0031]

"My grandmother died, along with many other family members who had diabetes. I am terrified of dying from diabetes."

-- P6/(b)(6)

"I could become blind, have a heart attack or kidney disease. When I get old, I might even have to get an amputation. If there's a cure, then I don't have to worry."

-- P6/(b)(6)

"Even though I work really hard at controlling my blood sugar, I can't do it perfectly and when I am high I feel lousy and when I am low I feel terrible and can't think straight or concentrate."

JDF is the world's leading nonprofit, nongovernmental funder of diabetes research. It was founded in 1970 by parents of children with diabetes. JDF's mission is to find a cure for diabetes and its complications through the support of research, and since its inception has given more than $326 million to diabetes research worldwide. For more information visit our website at www.jdf.org or call 800-JDF-CURE.

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