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Diabetes: Basic Information and Federal Funding

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Summary

An estimated 8 to 10 million Americans know they have diabetes mellitus, a metabolic disorder in which the body either fails to produce, or fails to properly use, the hormone insulin. It is the seventh leading cause of death in the United States,[1] the leading cause of adult-onset blindness, and a significant contributor to several debilitating health complications, including heart disease, stroke, kidney disease (nephropathy), nerve disease (neuropathy), and amputations. The American Diabetes Association estimates that direct and indirect costs of diabetes mellitus in the United States exceed $98.2 billion each year.[2] This report describes diabetes, current treatment and management, public health impact and cost, innovations in treatment, and federal spending on treatment and research. This report will be updated periodically.[3]

Background

Diabetes mellitus, or simply diabetes, is a disease that affects the way the human body uses food as fuel. This fuel, glucose, is a sugar which comes from other sugars and starches; human body cells convert glucose into energy to live and grow. Some cells can absorb glucose only in the presence of insulin. Insulin, a hormone made by the pancreas, is carried by blood to body cells. Insulin is produced by beta cells which are present in cell clusters called islets of Langerhans scattered throughout the pancreas. When someone is diabetic, either the body does not produce insulin or the body does not respond normally to insulin. When glucose cannot enter the cells, it builds up in the bloodstream, and causes a condition called high blood sugar, or hyperglycemia. When

[1] National Center for Health Statistics, *Advance Report of Final Mortality Statistics*, 1995, Monthly Vital Statistics Report, supplement 2, v. 45, no.11, 12 June 1998. Diabetes causes 2.6% of total deaths in the United States.

[2] Department of Health and Human Services Budget Office, *HHS and National Cost for Thirteen Diseases and Conditions*, 20 February 1998.

[3] This report replaces CRS Report 97-13 SPR, *Diabetes: An Overview*, by Christine Miller, 18 December 1996.

levels remain high (fasting plasma glucose of ≥126 mg/dl), a person is considered to have diabetes. Symptoms of diabetes include frequent urination, thirst, weight loss, and blurred vision. Untreated chronic hyperglycemia is gradually fatal.[4] Even when treated, it may result in diabetic complications, such as damage to the kidneys, eyes, nerves, or blood vessels. Diabetics are 2 to 6 times more likely to get heart disease than non-diabetics.

There are two types of diabetes. Type 1, or insulin-dependent diabetes mellitus (IDDM), develops when beta cells die off, and the pancreas does not produce insulin to control blood glucose concentrations. Type 1 diabetes, sometimes called juvenile diabetes, usually strikes children or young adults, and accounts for 7% to 10% of all diabetic cases.[5] Type 2, or non-insulin-dependent diabetes mellitus (NIDDM), develops when the body's cells resist insulin made by the pancreas and glucose remains in the blood stream. Type 2 diabetes usually develops later in life, and accounts for over 90% of all diabetes cases. Millions of people are unaware they have Type 2 diabetes.

Current Treatment and Management

Diabetes is incurable; a diabetics's goal is to keep blood sugar levels near normal, to avoid life-threatening high or low blood sugar incidents, and to stave off diabetic complications. Optimally, a diabetes management plan is developed by patient and doctor. The plan is periodically evaluated and altered as needed. Treating diabetes requires a life-long commitment by the patient to regular medical care.

Some diabetics can manage their condition by monitoring their blood glucose levels and balancing food intake against insulin and activity. Food raises blood sugar levels; insulin and exercise help lower them. Very low blood sugar, called "hypoglycemia," robs the brain of fuel, and can cause confusion, coma, and death if not detected and treated. Keeping blood glucose levels in a "normal" range can help diabetics avoid complications. Most patients are treated with insulin or with oral "hypoglycemic" agents.

Type 1 diabetes is treated with two or more daily insulin injections, exercise, and strictly regulated diet. Patients may use disposable plastic syringes or pre-filled injection pens to inject insulin into the body. Some utilize insulin pumps, mechanical devices attached to or inserted into the body to deliver insulin more continuously. Type 2 diabetes is treated with exercise, diet, blood sugar monitoring, and oral medication or injected insulin. Over half of Type 2 diabetics do not require injected insulin. The likelihood that a Type 2 diabetic will need injected insulin increases with the duration of the disease.[6]

Patients with diabetes are at risk for diabetic complications. A major clinical trial, the Diabetes Control and Complications Trial (DCCT) supported by the National Institutes of Health's (NIH), National Institute of Diabetes and Digestive and Kidney

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[4] National Institute of Diabetes and Digestive and Kidney Diseases, *Diabetes Overview*, NIH Publication No. 94-3235, 1994.

[5] IDDM is the most common chronic disease in U.S. children affecting about one in every 400-500 children.

[6] National Diabetes Data Group, *Diabetes in America*, NIH Publication No. 95-1468, 1995, 2d ed., 528.

Diseases (NIDDK), tested 1,441 Type 1 patients to determine if strictly controlled blood glucose levels over several years could delay the onset of complications. In the DCCT, diabetics who maintained near normal blood sugar levels could dramatically reduce onset and progression of long-term diabetes complications. For example, there were 40% to 70% reductions in the incidences of kidney, eye, and nerve diseases. The cost for this close glucose-monitoring approach was double the cost of other treatments, however. The test group also experienced more hypoglycemia, and showed modest weight gain, so this strict protocol might not be suitable for patients under 13, the elderly, or overweight diabetics.[7] Any sustained normalization of blood sugar helps slow the progression toward diabetic complications, and possible side effects must be balanced against the great benefit in delaying such complications.

Public Health Impact and Cost

Diabetes is the seventh leading cause of death in the United States, the leading cause of adult-onset blindness, and a significant contributor to debilitating health complications, including heart disease, stroke, kidney disease (nephropathy), nerve disease (neuropathy), and amputations. Half of the lower limb amputations in the United States are among diabetics; diabetes also predisposes people to periodontal (gum) disease, tooth loss, and skin infections. About a third of diabetics remain undiagnosed, and therefore are not receiving treatment for their condition, putting them at risk for long term adverse health effects.

Estimates of economic costs of diabetes vary considerably, and its contribution to other diseases makes cost estimating difficult. The American Diabetes Association estimated for 1997 that the direct and indirect cost of diabetes mellitus in the United States exceeded $98.2 billion annually. This total contains estimates of $44.1 billion in direct medical costs, for treatment and monitoring, and $54.1 billion in lost productivity due to illness and premature death.[8]

In the United States, African-Americans, Hispanics, Native Americans, Asian Americans and Pacific Islanders, have a greater likelihood of developing Type 2 diabetes. White Americans are more likely to get Type 1 diabetes than are non-whites. In 1997, the total prevalence of known, diagnosed cases of diabetes was estimated to be between 8-10 million. At the same time, undiagnosed cases are estimated to be between 4-5 million. An additional 13 million people are estimated to have impaired fasting glucose (glucose of between $\geq$110 and 126 mg/dl) and 21 million to have impaired glucose tolerance (a precursor to Type 2 diabetes.)

Risk factors for diabetes include a varied ethnic and racial background, being overweight, having a family member with diabetes, physical inactivity, and increasing age. In the United States, increasing numbers of people are overweight, and elderly and

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[7] The Diabetes Control and Complications Trial Research Group, "The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications," *New England Journal of Medicine*, v. 329, 30 September 1993, 977-86.

[8] American Diabetes Association, "Economic Consequences of Diabetes Mellitus in the U.S. in 1997," *Diabetes Care* 21(1998):296-309.

minority populations are growing as a percentage of the overall population, so for Americans as a whole, the number of people with diabetes is likely to increase.

Innovations in Treatment and Management

The underlying causes of diabetes are unknown, although genetic predisposition, behavior, and environmental factors are believed to play roles. Diabetes may be caused by various genes, all resulting in high blood sugar. Several chromosomes have been identified as possible sites for genes which predict or even cause diabetes, but no specific genes have been determined to be causal. Research continues to try to clarify the underlying genetic, molecular or cellular causes of diabetes. Also there is ongoing research on the prevention of the disease. NIH's Diabetes Prevention Program is testing whether life style and drug interventions can prevent or delay the onset of Type 2 diabetes in at-risk individuals including minority populations.

Type 2 diabetes is often treated with oral medications. Four classes of oral drugs are now available. The oldest, called "sulfonylureas," work by stimulating the pancreas to produce more insulin. Maintaining a normal weight, which helps control NIDDM, becomes more difficult when taking sulfonylureas. A newer class of oral medication for Type 2 patients, biguanides, includes metformin, which lowers cells' resistance to insulin produced by the liver. Glucosidase inhibitors, which include acarbose and miglitol, slow the digestion of carbohydrates and delay the absorption of glucose from the intestine. The fourth class, as represented by troglitazone, allows diabetics to make better use of their own insulin by resensitizing body tissues to the insulin. In March 1998, researchers found that metformin and troglitazone work even better in combination than they do alone for hard-to-treat cases of diabetes.[9]

Currently being tested in clinical trials is a finely powdered insulin which, when inhaled into the lungs, goes directly into the blood stream. Although it may be two years before it can be marketed, patients in the trials appear to prefer this new application over injections. So far there have been no detectable negative side effects reported.[10]

Type 1 diabetes is an autoimmune disease, in which the body misidentifies its own beta cells as foreign, and destroys them. This autoimmune response may stem from a viral infection to which the body over-responds, or from some other cause.[11] Prevention in susceptible individuals is being researched, as well as replacement of damaged beta cells by transplantation of new pancreatic tissue. The main impediment to transplantation is the body's immune system. Once it detects the transplanted cells, it attacks and kills them, a process called "rejection." Diabetics who develop kidney failure may be

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[9] S.E. Inzucchi et al., "Efficacy and Metabolic Effects of Metformin and Troglitazone in Type II Diabetes Mellitus," *The New England Journal of Medicine*, v. 338, 26 March 1998, 867.

[10] Thomas H. Maugh II, "Inhaled Form of Insulin Seen as a Breakthrough," *Los Angeles Times*, Wednesday, 17 June 1998, A1,A7.

[11] M. Trucco, and R. LaPorte, "Exposure to Superantigens as an Immunogenic Explanation of Type 1 Diabetes Mini-epidemics," *Journal of Pediatric Endocrinology and Metabolism*, 8(1), January-March 1995, 3-10.

candidates for kidney transplantation, and some may receive a new pancreas at the same time. They receive immunosuppressant medication to prevent rejection of both organs.[12]

An entire transplanted human pancreas is not necessary for insulin production. Technologies are being developed to introduce clusters of beta cells into areas of the body without triggering an immune response. Transplant ideas being researched include: (a) implanting small perforated plastic containers of beta cells, which render the cells invisible to the immune system, (b) introducing beta cells into the eyes or testes, where immunoresponse is less, (c) implanting human fetal beta cells, which produce lower immunoresponse, and (d) simultaneous implants, in which beta cells are transplanted along with protective tissue which destroys particular immune cells.[13]

NIH is currently conducting the Diabetes Prevention Trial (DPT-1) to test whether lifestyle changes and prophylactic administration of insulin can prevent or delay the onset of Type 1 diabetes in at risk individuals, particularly children. Participants are being treated with daily oral medications or with exercise and diet modification.

Diabetes-Related Funding

Federal funding for diabetes treatment, prevention education and research will total about $16.8 billion in FY1999, and is spread throughout the federal government. (See Table 1.) The Health Care Financing Administration (HCFA) of the Department of Health and Human Services (DHHS) spends the largest share in the Medicare and Medicaid programs to help pay medical expenses for eligible diabetics. The Balanced Budget Act of 1997 extended to those Medicare beneficiaries coverage of outpatient self-management training services so they could learn how to better control their condition. The Act's purpose was to increase Medicare savings over time by reducing hospitalizations and complications arising from diabetes. The Department of Veterans' Affairs (VA) also provides health care benefits to diabetics. Treatments for VA patients accounted for 12% of the 1994 VA's medical care budget, and at least 24% of all VA pharmacy outpatient costs were diabetes related.[14] In 1996, the VA served 375,000 diabetic veterans through its health care system. A total of $2 billion was spent in 1996 for their medical care.

Public Health Service (PHS) programs for diabetes education and prevention are supported by the Centers for Disease Control and Prevention (CDC) and the Indian Health Service (IHS).

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[12] J. D. Pirsch, et al., "Pancreas Transplantation for Diabetes Mellitus," *American Journal of Kidney Disease*, 27 (3), March 1996, 444-450.

[13] National Institute of Diabetes and Digestive and Kidney Diseases, *Diabetes Overview*, NIH Publication No. 94-3235, 1994.

[14] This figure includes all VA medical care for the diabetic veteran, even care not directly diabetes-related. It does not include $7.946 million spent on research in 1996. Other federal entities, such as the Federal Employee Health Benefits (FEHB) program, fund diabetes health care benefits. Information on total FEHB diabetes care funding levels is not available. TRICARE, the Department of Defense health care organization, also provides a small amount of funding for diabetes care.

The majority of federal diabetes research funding is administered through NIH and agencies within PHS. Research funding has increased substantially since FY1997 because, in the Balanced Budget Act of 1997, Congress committed $150 million, ($30 million each year over 5 years FY1998 through FY2002), for medical research focusing on Type 1 diabetes. This commitment is in addition to the annual appropriations for NIH. The Act also included $150 million for diabetes prevention and treatment for Native Americans. The Act specified that the Secretary of DHHS must evaluate these two diabetes grant programs and report to Congress with an interim report on or before January 1, 2000, and with a final report on or before January 1, 2002.

Table 1. Department of Health and Human Services (HHS) Funding of Diabetes Treatment and Related Research, FY1994 - FY1998, With an Estimate for FY1999.
($ in Thousands)

Agency	FY1994	FY1995	FY1996	FY1997	FY1998	FY1999[d]
NIH	293,615	295,142	298,920	319,539	373,215[a]	414,856[a]
NIDDK	191,409	193,597	197,542	211,626	229,000	256,641
NEI	22,605	22,001	21,509	21,604	23,172	25,844
NHLBI	19,779	20,393	21,010	21,270	22,744	28,504
NCRR	18,577	19,501	17,952	19,461	20,784	21,387
NICHD	12,329	12,631	13,373	16,042	17,100	17,596
Other NIH	28,896	27,019	27,534	29,536	60,415	64,884
CDC	17,910	19,770	22,991	26,277	48,977[a]	53,788[a]
IHS[b]	6,722	7,701	7,701	7,701	41,001	41,001
AHCPR	1,210	2,733	2,382	2,135	2,000	2,100
TOTAL PHS	312,735	317,645	324,293	355,652	465,193	511,745
HCFA[c]	8,713,000	10,303,000	11,951,000	13,269,000	14,611,000	16,278,000
TOTAL HHS	9,025,735	10,620,645	12,275,293	13,624,652	15,076,193	16,789,745

Sources: HHS Budget Office, "HHS and National Cost for Thirteen Diseases and Conditions," Feb. 20, 1998; HHS Budget Office, FY1999 Moyer Cross-Cutting Material, Feb. 1998. Budget Office, National Institute of Diabetes, and Digestive, and Kidney Disease, National Institutes of Health, Jan. 6, 1998.

[a] Includes transfer of $27 million to NIH and $3 million to CDC for Type 1 diabetes research in accordance with the Balanced Budget Act of 1997. [b]Includes a grant of $30 million each year for FY1998 through FY2002 in accordance with the Balanced Budget Act of 1997. [c]These totals include the total Medicare reimbursement for a diabetic beneficiary as well as the calculated direct and indirect costs for diabetes. [d] = Estimate.

Acronyms mean the following: NIH = National Institutes of Health; NIDDK = National Institute of Diabetes and Digestive and Kidney Disease; NEI = National Eye Institute; NHLBI = National Heart, Lung and Blood Institute; NCRR = National Center for Research Resources; NICHD = National Institute of Child Health and Human Development; CDC = Centers for Disease Control and Prevention; IHS = Indian Health Service; AHCPR = Agency for Health Care Prevention and Research; PHS = Public Health Service; HCFA = Health Care Financing Administration.