Testimony Before the
Committee on Indian Affairs
United States Senate

Statement for hearing entitled, "A Way Out of the Diabetes Crisis in Indian Country and Beyond"

Statement of

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Mr. Chairman and Members of the Committee: I am Judith Fradkin, Director of the Division of Diabetes, Endocrinology, and Metabolic Diseases of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Our Institute has primary responsibility for diabetes research at the National Institutes of Health (NIH), an agency of the U.S. Department of Health and Human Services (HHS).

On behalf of the NIDDK and the other Institutes and Centers of the NIH, I am pleased to report that we are vigorously pursuing research on diabetes and its complications. Through collaborative and coordinated research, we are gaining important insights into the molecular mechanisms underlying disease, identifying and testing promising therapies to prevent and treat the disease and its complications, and striving for a cure.

Today I will provide an overview of NIH-supported diabetes research, including research supported by the Special Statutory Funding Program for Type 1 Diabetes Research (Special Diabetes Program), which is led by the NIDDK on behalf of the Secretary, HHS, and is conducted in collaboration with multiple other Institutes and Centers of the NIH and the Centers for Disease Control and Prevention (CDC). A parallel funding stream, the Special Diabetes Program for Indians, is administered by the Indian Health Service (IHS), to address through prevention and treatment the growing problem of diabetes in those communities.

ADVANCES FROM DIABETES RESEARCH

This year marks the NIDDK's 60th anniversary of conducting and supporting research to combat debilitating diseases within its mission, including diabetes. Diabetes is a devastating disease that affects approximately 23.6 million people in the U.S. and is the seventh leading cause of death.[1] Diabetes lowers average life expectancy by up to 15 years,[2] increases cardiovascular disease risk two-to four-fold, and is the leading cause of kidney failure, lower limb amputations, and vision loss in working age adults.[3] In addition to the human costs, the estimated total financial cost for diabetes in the U.S. in 2007 was $174 billion.[4]

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[1] CDC. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 2007. Atlanta, GA: U.S. Department of Health and Human Services, CDC, 2008.

[2] Portuese E and Orchard T: Mortality in Insulin-Dependent Diabetes. In Diabetes in America (pp. 221-232). Bethesda, MD: National Diabetes Data Group, NIH, 1995.

[3] CDC. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 2007. Atlanta, GA: U.S. Department of Health and Human Services, CDC, 2008.

[4] ibid

Diabetes is characterized by the body's inability to produce and/or respond appropriately to insulin, a hormone that is necessary for the body to absorb and use glucose, or sugar, as a cellular fuel. The most common forms of the disease are type 1 diabetes, in which the body loses its ability to produce insulin, and type 2 diabetes, which is due to a combination of insulin resistance and insufficient insulin production. Women can also develop gestational diabetes, a risk factor for type 2 diabetes, during pregnancy. Rarer forms of diabetes also exist.

To appreciate the tremendous progress that has been achieved in recent decades, we can look back at how diabetes was treated in 1950, at the inception of the Institute. Sixty years ago, patients monitored their blood glucose levels with urine tests, which recognized high but not dangerously low glucose levels and reflected hours-old, not current, glucose levels. People with type 1 diabetes relied on painful injections of animal-derived insulin. People with type 2 diabetes had few treatment options: injections of insulin or drugs that stimulated insulin release from the beta cells of the pancreas. Both of these therapies had associated risks. No proven strategies existed to prevent disease complications, such as blindness, heart disease, kidney disease, and nerve damage.

Insights gained from NIDDK- and NIH-supported research over the past 60 years have contributed to a knowledge base leading to improvements in survival and quality of life for people with diabetes. Doctors now use simple blood tests to diagnose diabetes and to assess long-term blood glucose control. People at high risk for type 2 diabetes can prevent or delay disease onset by losing a modest amount of weight through dietary changes and moderate exercise. People with type 1 diabetes can reduce their risk for complications by intensively controlling blood glucose levels. Doctors can prescribe new classes of oral drugs and combinations of drugs to treat people with type 2 diabetes. Patients can use new technologies, such as insulin pumps and continuous glucose monitors, to manage their diabetes. As a result of these past accomplishments, people with diabetes are living longer and healthier lives than ever before. I am pleased to provide you with a few specific examples of how NIH-supported research has contributed to these tremendous improvements in the health and quality of life of people with diabetes.

RESULTS OF MAJOR CLINICAL TRIALS AND TRANSLATING THOSE RESULTS TO IMPROVE PUBLIC HEALTH

One approach to combat the diabetes epidemic in the U.S. is to prevent the disease. A landmark clinical trial studying type 2 diabetes prevention was spearheaded by the NIDDK. The Diabetes Prevention Program (DPP) clinical trial showed that people with pre-diabetes–defined as having blood glucose levels that are higher than normal but not yet high enough to be diagnosed as diabetes—can dramatically reduce their risk of developing type 2 diabetes through lifestyle changes that achieve modest weight loss or through treatment with the drug metformin.[5] The interventions worked in all ethnic and racial groups studied, including American Indian participants, in both men and women, and in women with a history of gestational diabetes. Research now shows that, after a 10-year period of following DPP participants, the interventions result in long-term benefits: people still had a lower risk of developing type 2 diabetes and those who made lifestyle changes also had reduced cardiovascular risk despite taking fewer drugs to control their heart disease risk factors.[6] IHS diabetes programs were among the first to implement the DPP results into diabetes prevention programs for American Indians and Alaska Natives, with advice and guidance from NIDDK scientists. Results from IHS' ongoing evaluation are demonstrating the same outcomes that were achieved in the DPP study.

Building on these critically important results, the NIDDK supports research to translate DPP findings to improve public health and benefit the approximately 57 million Americans with pre-diabetes.[7] One successful research effort utilizes local YMCAs for delivering a group-based DPP lifestyle intervention. A pilot study showed that this group-based approach reduces costs to deliver the intervention, while achieving similar levels of weight loss in participants;[8] a larger trial is ongoing. Based on these impressive findings, earlier this year, United Health Group announced a partnership with YMCAs to offer a diabetes prevention program in six U.S. cities, with plans for a national roll out over the next couple of years.

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[5] Knowler WC, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 346:393-403, 2002.

[6] Diabetes Prevention Program Research Group, et al. 10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study. Lancet 374:1677-86, 2009.

[7] CDC. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 2007. Atlanta, GA: U.S. Department of Health and Human Services, CDC, 2008.

[8] Ackermann RT, et al. Translating the Diabetes Prevention Program into the community. The DEPLOY Pilot Study. Am J Prev Med. 35: 357-63, 2008.

Another way that the DPP results are being translated to the public and health care providers is through the National Diabetes Education Program (NDEP), which is a partnership between the NIDDK and the CDC. The NDEP developed the "Small Steps. Big Rewards. Prevent Type 2 Diabetes" education campaign to disseminate the DPP results. The IHS has been a critical NDEP partner, helping to create and disseminate culturally appropriate messages for American Indian and Alaska Native communities. The NIDDK and its collaborators remain dedicated to building on the tremendous successes to date in order to take advantage of new and emerging opportunities to expand type 2 diabetes prevention efforts, including to American Indian and Alaska Native populations.

Another NIDDK-led clinical trial has changed the face of type 1 diabetes management. The Diabetes Control and Complications Trial (DCCT), and its follow-on, the Epidemiology of Diabetes Interventions and Complications (EDIC) study, conclusively demonstrated that early and intensive blood glucose control prevented or delayed the debilitating complications of type 1 diabetes involving the heart, eyes, kidneys, and nerves.[9] These impressive findings, which were supported in part by the Special Diabetes Program, have revolutionized the management of type 1 diabetes, as physicians now recommend that people control their disease as early and intensively as possible. Intensive treatment is being translated into improved health, as researchers recently reported that the outlook for people with longstanding type 1 diabetes has greatly improved in the past 20 years.[10]

The NIDDK-supported United Kingdom Prospective Diabetes Study showed that people with type 2 diabetes also benefit from improved glucose control early in the course of the disease with respect to reducing rates of disease complications.[11] However, in people with long-standing type 2 diabetes who also are at high risk for heart disease, more intensive blood glucose control than is currently recommended by treatment guidelines can be dangerous, as demonstrated in the ACCORD clinical trial, which is led by NIH's National Heart, Lung, and Blood Institute.[12] The

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[9] The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 329: 977–986, 1993; Nathan DM, Cleary PA, Backlund JY, et al. Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study Research Group. Intensive diabetes treatment and cardiovascular disease in type 1 diabetes mellitus. N Engl J Med 353: 2643–2653, 2005.

[10] DCCT/EDIC Research Group, et al. Modern-day clinical course of type 1 diabetes mellitus after 30 years' duration: the diabetes control and complications trial/epidemiology of diabetes interventions and complications and Pittsburgh epidemiology of diabetes complications experience (1983-2005). Arch Intern Med 169:1307-16, 2009.

[11] Holman RR, et al. 10-year follow-up of intensive glucose control in type 2 diabetes. N Engl J Med 359:1577-89, 2008.

[12] Action to Control Cardiovascular Risk in Diabetes Study Group, et al. Effects of intensive glucose lowering in type 2 diabetes. N Engl J Med 358: 2545-49, 2009; ACCORD Study Group, et al. Effects of intensive blood-pressure control in type 2 diabetes

trial found that lowering blood pressure to normal levels did not significantly reduce the risk of cardiovascular events overall, although it may reduce the risk of stroke. In the lipid trial, combination therapy of a statin and a fibrate appeared to be safe, but did not lower the risk of heart attack, stroke, or death from heart disease more than statins alone. The ACCORD findings indicate that people who have longstanding type 2 diabetes and are at high risk for a cardiovascular event and are well controlled as per current recommendations do not need to be treated more intensively to reduce heart attacks, strokes, and other cardiovascular events. Thus, such controlled patients can be spared from unnecessary additional medications. These key results from type 2 diabetes clinical trials suggest that, rather than a one-size-fits-all approach, recommendations for treating people with type 2 diabetes can be personalized. Again, with advice and guidance from NIDDK scientists, IHS has successfully translated these results into practice in American Indian and Alaska Native communities through an intensive case management approach called the Healthy Heart Project through the Special Diabetes Program for Indians.

Further insights into the management of type 2 diabetes are expected to emerge from the NIDDK-led Look AHEAD (Action for Health in Diabetes) clinical trial, which is examining the health effects of a lifestyle intervention designed to achieve and maintain weight loss over the long term in over 5,000 overweight and obese adults with type 2 diabetes. Encouraging results are already emerging. After following participants for 1 year, researchers found that people in the intensive lifestyle arm showed improved diabetes, blood pressure, and lipid control, with reduced medication use and costs.[13] After 4 years, researchers observed a sustained effect of the lifestyle intervention on weight loss, as well as improved glucose control with reduced medication use.[14] Participants continue to be followed to assess longer-term outcomes. The trial includes American Indian participants, and the IHS has been an important partner in conducting the trial. These are just a few examples of the NIH-supported clinical trials that have provided unprecedented insights into diabetes prevention and management.

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mellitus. N Engl J Med 362:1575-85, 2010; ACCORD Study Group, et al. Effects of combination lipid therapy in type 2 diabetes mellitus. N Engl J Med 362: 1563-74, 2010.

[13] Redmon JB, et al. Effect of the look AHEAD study intervention on medication use and related cost to treat cardiovascular disease risk factors in individuals with type 2 diabetes. Diabetes Care 33: 1153-8, 2010.

[14] The Look AHEAD Study: Design of the Lifestyle Intervention and Four-Year Weight Losses. Presented at the American Diabetes Association 69th Scientific Sessions, June 2009. Publication in press, Archives Int Medicine.

DISPROPORTIONATE IMPACT ON MINORITY POPULATIONS

Type 2 diabetes occurs more frequently among racial and ethnic minority groups in the U.S., including American Indians, African Americans, Hispanic/Latino Americans, and Asians/Pacific Islanders.[15] In fact, American Indians have the highest rates of type 2 diabetes in this country.[16] Because of this disparity, the NIH has included large numbers of minority participants in its type 2 diabetes studies. For example, nearly half of the DPP participants were from minority groups, and the interventions worked in all groups. Those results are being translated in culturally appropriate ways through the NDEP and other translational research efforts.

Type 2 diabetes is an emerging health problem in youth, particularly minority youth, being driven by the obesity epidemic. The NIH and its partners are tackling this issue on many fronts. For example, just this week, researchers announced results from the NIDDK-led HEALTHY clinical trial, which examined whether a middle-school based intervention could lower risk factors for type 2 diabetes. The study was conducted in schools with a high enrollment of minority children and youth from low-income families. The intervention was found to lower the obesity rate in students at highest risk for type 2 diabetes—those who started out overweight or obese in sixth grade. However, schools that implemented the program did not differ from comparison schools in the study's primary outcome—the prevalence of overweight and obesity combined—which had declined by 4 percent in both the intervention and control schools by the end of the 3-year study.[17] These results are important for informing future school-based efforts to reduce overweight and obesity in children, and the IHS can use and build upon these results as they consider approaches to improve health in their young populations.

Another school-based effort is the Diabetes Education in Tribal Schools (DETS) Project, on which NIDDK and IHS partner. The DETS Project is a K-12 curriculum focused on increasing American Indian/Alaska Native students' understanding of health, diabetes, and maintaining life in balance; understanding and application of scientific and community knowledge; and interest in science and health professions. DETS provides an opportunity to reach beyond supporting diabetes-related research to provide the resources to support the

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[15] CDC. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 2007. Atlanta, GA: U.S. Department of Health and Human Services, CDC, 2008.
[16] ibid
[17] Presented at the American Diabetes Association 70th Annual Sessions, June 2010.

translation of science to the community to have a more long-term beneficial impact on the health of American Indians and Alaska Natives. IHS has played a critical role in the development and dissemination of the DETS curriculum throughout the Indian health system. The NIDDK is currently building on the success of the DETS Project to develop a K-12 curriculum for African American and Hispanic students.

For children who already have type 2 diabetes, the NIDDK supports the Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY) clinical trial at centers around the country, to test three different treatment regimens for type 2 diabetes in children 10-17 years of age. A large percentage of children who are enrolled in this study are from minority groups disproportionately burdened with type 2 diabetes; the TODAY center at the University of Oklahoma is enrolling American Indian youth into the trial. Through TODAY and other studies, the NIDDK hopes to ameliorate type 2 diabetes and its complications in this most vulnerable population.

Gestational diabetes mellitus (GDM) also disproportionately affects minority groups. Although this form of diabetes generally goes away after the baby is born, it leaves both mother and child at increased risk for developing type 2 diabetes. Important insights about GDM have emerged from the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study, which is led by NIH's *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). The HAPO study showed that the higher a pregnant woman's blood glucose is, the higher her risk of pregnancy complications—whether or not her blood glucose reached the level at which GDM was diagnosed at the time of the study.[18] The effect is significant enough that a recent panel of experts has recommended changing the diagnostic criteria for GDM to be less stringent, such that under the proposed new guidelines, the prevalence of GDM will more than double.[19] The good news is that the DPP showed that a healthy diet and exercise can help prevent later type 2 diabetes in women who have had GDM. For this reason, the NDEP, in collaboration with the NIH Office of Research on Women's Health, recently expanded its educational campaign for women with a history of GDM to raise awareness of the health risks for these women and their offspring.

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[18] HAPO Study Cooperative Research Group, et al. Hyperglycemia and adverse pregnancy outcomes. N Engl J Med 358: 1991-2002, 2008.

[19] International Association of Diabetes and Pregnancy Study Groups Consensus Panel. International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. Diabetes Care 33: 676-82, 2010.

RESEARCH SUPPORTED BY THE SPECIAL DIABETES PROGRAM

Through support from the Special Diabetes Program, the NIH is supporting a wide range of diabetes research efforts that are having a far reaching impact. For example, the NIH supports research to improve diabetes treatment strategies, to help patients achieve blood glucose control associated with reduced rates of complications and to reduce the burden of diabetes self-care. Research supported by the Special Diabetes Program contributed to the development of continuous glucose monitoring technologies, which reveal dynamic changes in blood glucose levels by assessing glucose levels hundreds of times per day and displaying trends. The NIH is committed to capitalizing on this technology and supports research on "artificial pancreas" technology to "close the loop" and link insulin delivery to continuous glucose measurements. This technology has the potential to benefit people with both forms of diabetes.

The NIDDK also supports research on cell replacement therapy for people with diabetes, which could potentially restore the body's ability to produce sufficient levels of insulin and properly control blood glucose levels. The NIDDK-led Beta Cell Biology Consortium is making significant progress in understanding beta cell biology and development toward the goal of generating unlimited supplies of beta cells in the laboratory for transplantation, or promoting growth of new beta cells in the pancreas. Because impaired function of the beta cell is central to both type 1 and type 2 diabetes, this research can inform treatment strategies for people with both forms of the disease.

Although the DPP identified effective strategies to prevent or delay type 2 diabetes, disease prevention remains a major goal of type 1 diabetes research. The NIDDK-led Type 1 Diabetes TrialNet is tackling this goal by conducting prevention trials, including a trial testing whether oral insulin could prevent the disease in people who have high levels of antibodies to insulin (a pre-clinical marker of disease). TrialNet plans to launch a second prevention trial with an agent proven to slow beta cell loss in new onset type 1 diabetes. An NICHD-led clinical trial, called TRIGR (Trial to Reduce the Incidence of Type 1 Diabetes in the Genetically at Risk), is determining whether weaning newborns at risk for type 1 diabetes to extensively-hydrolyzed formula, as compared to standard cow's milk formula, will reduce the risk of developing type 1 diabetes.

Type 1 diabetes has a strong genetic basis that is modified by environmental factors. The last few years have seen unprecedented discoveries in type 1 diabetes genetics research. Recent research through the Type 1 Diabetes Genetics Consortium and their collaborators has identified over 40 genes or genetic regions associated with type 1 diabetes.[20] The NIDDK is now supporting research to pinpoint the exact genes involved and to understand their function in health and disease. New insights about the genetic underpinnings of type 1 diabetes can inform new strategies for prevention or treatment, and even on a personalized or customized basis.

With respect to environmental factors, The Environmental Determinants of Diabetes in the Young (TEDDY) study has recently completed recruitment of over 8,000 newborns at high genetic risk for type 1 diabetes and is now following them to age 15 to identify environmental triggers of disease. Identification of a dietary or infectious cause of type 1 diabetes could have an enormously positive impact on public health through a diet change or vaccine for disease prevention, for example. To maximize the return on the investment in TEDDY, samples from the study will be made widely available to researchers worldwide. Importantly, TEDDY may also contribute to understanding the development of celiac disease, which is an autoimmune disease primarily affecting the gastrointestinal tract. Some genes confer susceptibility to both celiac disease and type 1 diabetes, and many people have both diseases. Thus, TEDDY may benefit not only people with, or at-risk for, type 1 diabetes, but also people with celiac disease and other autoimmune diseases.

New insights about diabetes in youth are stemming from the CDC-led SEARCH for Diabetes in Youth study, which is a multicenter epidemiological study identifying cases of diabetes in children and youth less than 20 years of age in six geographically dispersed populations that encompass the ethnic diversity of the United States. SEARCH is defining the incidence and prevalence of diabetes in youth, including American Indian youth, which is important for informing public health efforts. Because of SEARCH, for the first time we know how many children in the U.S. have diabetes, and we will be able to see how the rates are changing over time. This knowledge could help to explain the findings from HEALTHY showing that overweight and obesity rates seemed to fall in both the intervention and control schools; SEARCH could help us determine if this trend is also being seen on a broader level. In

[20] Barrett JC, et al. Genome-wide association study and meta-analysis find that over 40 loci affect risk of type 1 diabetes. Nature Genetics 41: 703–707, 2009.

addition, SEARCH has found that, for Asian/Pacific Islander and American Indian youth aged 10–19 years, the rate of new cases of type 2 was greater than the rate for type 1 diabetes.[21] IHS is currently working with the CDC to develop a national diabetes in youth registry, using SEARCH criteria, in order to track the rates amongst many tribes. With ongoing surveillance through SEARCH we may be able to see the effects of programs, such as the DETS curriculum, NDEP campaigns, and IHS efforts, on the health of American Indian/Alaska Native youth.

Although most children are accurately diagnosed with type 1 or type 2 diabetes, a subset of children may have clinical characteristics that overlap between the two major forms of diabetes, making it difficult for physicians to easily determine diabetes type. To address this issue, SEARCH is also leading an effort to classify diabetes type in youth by developing clinical definitions and epidemiologic definitions of diabetes type, which is important not only for SEARCH research, but also for clinical purposes to ensure that all children with diabetes are accurately diagnosed and given the proper treatment.

Contributing to these efforts is a research program to standardize the measurement of autoantibodies in blood that are predictive of type 1 diabetes. This standardization has enabled improved characterization of childhood diabetes through the SEARCH study and an appreciation of the existence of hybrid forms of diabetes having characteristics of both type 1 and type 2. Accurate antibody measurement has also benefited enrollment in the TODAY clinical trial, which, as I mentioned earlier, is testing different treatment options for type 2 diabetes in youth. More precise antibody measures have allowed more patients to enroll into the trial because eligibility excluded those with autoimmunity, and previous assays were non-specifically falsely identifying some potential participants as having autoimmunity.

Another program is improving standardization of hemoglobin A1c (HbA1c), which is a measurement that provides information on a person's average blood glucose levels for the past 2-3 months. This standardization program has been critical to IHS's efforts to improve type 2 diabetes control in the populations it serves. Standardization has permitted the IHS to compare people's HbA1c levels over time and across different sites, to evaluate the impact of their programs and demonstrate substantial improvements in diabetes care in American Indian/Alaska Native populations. In addition, building on the success of the standardization program, the

[21] CDC. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 2007. Atlanta, GA: U.S. Department of Health and Human Services, CDC, 2008.

American Diabetes Association recently recommended HbA1c as a more convenient approach to diagnose type 2 diabetes.[22] Last month the IHS incorporated these new recommendations into its Standards of Care for Diabetes, used throughout the Indian health system to guide the diagnosis and treatment of diabetes. Thus, this standardization program, as well as numerous other research efforts supported by the Special Diabetes Program, are not only benefiting people with type 1 diabetes, but are having a far-reaching impact toward improving health.

DIABETES PROGRAMS IN INDIAN COUNTRY

Currently, the IHS Division of Diabetes Treatment and Prevention (DDTP) provides leadership and programmatic oversight to the diabetes teams and programs that exist in most communities served by the Indian health system. The mission of DDTP is to develop, document, and sustain a public health effort to prevent and control diabetes in American Indians/Alaska Natives. This mission is accomplished by promoting collaborative strategies for the prevention of diabetes and its complications to over 1.9 million American Indians and Alaska Natives through an extensive American Indian and Alaska Native diabetes network. The network consists of a national program office; Area Diabetes Consultants in each of the 12 IHS Areas; 19 Model Diabetes programs in 23 different IHS and Tribal sites, and over 500 diabetes teams and programs at local IHS, Tribal and Urban (ITU) Indian health settings, both Special Diabetes Program for Indians (SDPI) grant programs and non-SDPI programs. This extensive diabetes network supports these diabetes teams and programs by providing administrative and programmatic support, training and technical assistance, and the dissemination of the latest scientific findings and "best practices" to the programs. The IHS combines both clinical and public health approaches to address the problem of diabetes and its complications.

Congress created the IHS Diabetes Program in 1979 in response to the growing epidemic of diabetes. Much has been achieved since then. Over the years IHS, together with its Tribal and urban partners, has worked toward a common purpose, to prevent and control diabetes, sharing information and lessons learned along the way. The IHS has shown, through its public health evaluation activities, that the ITU programs that have evolved over the years have been very successful in improving diabetes care and outcomes, as well as in launching primary prevention

[22] International Expert Committee. International Expert Committee report on the role of the A1C assay in the diagnosis of diabetes. Diabetes Care 32: 1327-34.

efforts, on reservations and in urban clinics. An evaluation of the SDPI and diabetes clinical measures suggests that population-level diabetes-related health is better among our American Indian/Alaska Native patients since the implementation of SDPI. The greatest benefit for American Indians and Alaska Natives with diabetes has likely been in the reduction in microvascular complications—eye, kidney and nerve diseases—due to improvement in long-term high blood sugar levels. Further reducing microvascular and macrovascular complications—atherosclerosis, coronary heart disease, stroke, and peripheral vascular disease—will require continued efforts to improve glucose, blood pressure and cholesterol values. However, the greatest long-term benefit will most likely be from the diabetes primary prevention activities now becoming commonplace in American Indian and Alaska Native communities. In its thirty one years, the IHS Diabetes Program has demonstrated the positive public health impact that is possible when Tribal and Congressional initiatives are focused on a common outcome. Here are some examples:

Key clinical outcome measures have significantly improved, such as:

- The mean long-term blood sugar control level (A1C) overall improved significantly from A1C=9.00 percent (1996) to A1C=8.02 percent (2009).
- The mean LDL cholesterol level decreased 24 percent from 118 mg/dl (1996) to 94.5 mg/dl (2009)

Since the start of SDPI, there are:

- 49% more weight management programs for adults
- 58% more nutrition education programs for adults
- 66% more physical activity programs for adults
- 34% more diabetes clinics
- 47% more diabetes registries
- 73% more primary prevention programs for children and youth
- 49% more weight management programs for children and youth
- 44% more school-based healthy eating programs for children and youth
- 45% more school-based physical activity programs for children and youth

In its SDPI Diabetes Prevention and Healthy Heart Demonstration Projects, IHS has demonstrated that:

- People are losing weight.
- Body mass index is going down
- Blood pressure is going down
- Blood sugars are going down
- Blood lipids are going down
- Smoking is decreasing
- Participation in physical activity is increasing.

The IHS has addressed a chronic disease in partnership with Tribes and other Indian organizations as well as collaborative involvement of other federal agencies and private organizations. Positive signs, such as a 33.4% decrease in the incidence of diabetes-related new dialysis cases among American Indians and Alaska Natives nationwide since 1999 as reported by the U.S. Renal Data Service, suggest the positive achievements developed under the program.

COORDINATING RESEARCH ACROSS THE GOVERNMENT

Diabetes research is effectively coordinated throughout the government toward a common goal of improving health. One important venue for coordination is the statutory Diabetes Mellitus Interagency Coordinating Committee (DMICC), which is chaired by the NIDDK and includes other components of NIH and other HHS and federal agencies that support diabetes-related activities, including the IHS.[23] The DMICC facilitates cooperation, communication, and collaboration on diabetes among these government entities. DMICC meetings help members identify emerging issues and opportunities and develop ways in which different government components can work together and build upon each other's expertise and resources. This approach helps ensure that federal diabetes activities are coordinated and not duplicated, and also stimulates collaborations.

The DMICC, with leadership by the NIDDK, has undertaken a diabetes research strategic planning process to help guide federal investment in diabetes research. The draft Plan is

[23] See http://www2.niddk.nih.gov/AboutNIDDK/CommitteesAndWorkingGroups/DMICC/Default.htm for list of DMICC members.

currently posted on the NIDDK website and is expected to be finalized later this summer. The Plan was developed as a collaborative effort across federal agencies and with input from the external research and patient advocacy communities. It includes a section on "Special Needs for Special Populations," which specifically addresses issues related to combating diabetes in minority populations and other special populations including children and pregnant women. The Plan will guide the NIH, other federal agencies, and the investigative and lay communities in our pursuit of a common goal of conquering diabetes.

FUTURE DIRECTIONS FOR RESEARCH

As the NIDDK reflects on the past 60 years of supporting and conducting research on diabetes, it is clear that the scientific progress achieved during that time period has been remarkable. People with the disease are living longer and healthier lives than they did a few short decades ago. However, diabetes still places an enormous personal and economic toll on our country, so it is critically important to continue the pursuit of research to make further improvements in patients' health and quality of life.

Looking to the future, the NIDDK will continue to build on the landmark scientific discoveries of the past to foster new research breakthroughs. Vital to this effort is the continued vigorous support of basic, pre-clinical, and clinical research, including research to address disparities in minority populations disproportionately burdened by diabetes. NIDDK enjoys a special relationship with IHS, providing ongoing scientific expertise and guidance in translating new research breakthroughs into the real world settings of American Indian and Alaska Native communities. We will continue to foster that relationship in order to ensure that this population has access to cutting-edge science in its fight to prevent and treat diabetes. We will also continue to develop educational materials to disseminate new research findings to patients, their families, and health care providers. Strategic planning and collaboration, including the new Diabetes Research Strategic Plan, will continue to guide future research directions. The NIH will remain steadfast in our goal to support and conduct research that can continue to improve the health of people with and at risk for diabetes.

In closing, thank you Mr. Chairman and members of the Committee for the opportunity to share with you a few highlights of NIH-supported diabetes research efforts. I am pleased to answer any questions you may have.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute of Diabetes and Digestive and Kidney Diseases
Biographical Sketch
Judith E. Fradkin, M.D.

Dr. Judith E. Fradkin became the Director of the Division of Diabetes, Endocrinology, and Metabolic Diseases (DEMD) at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) in 2000. She had previously served as the Deputy Director of the Division, Chief of the Endocrinology and Metabolic Diseases Programs Branch, Acting Chief of the Diabetes Research Programs Branch, and Director of the Cystic Fibrosis Research Program within the Division.

Dr. Fradkin graduated magna cum laude from Harvard College, received her medical degree from the University of California at San Francisco, and completed her internship and residency in internal medicine at Harvard's Beth Israel Hospital in Boston. She came to NIDDK as a clinical associate in 1979 after an endocrinology fellowship at Yale University. Dr. Fradkin is board-certified in Internal Medicine and in Endocrinology and Metabolism.

In her 31-year career at NIDDK, Dr. Fradkin has created or directed a diverse array of high-impact clinical and basic research programs, including multi-centered clinical trials to evaluate new approaches to prevent and treat diabetes and its complications, scientific consortia to define the genetic and environmental triggers of diabetes, and diabetes research centers. She is responsible for a major series of diabetes initiatives focused on beta cell development and function, improved glucose control through development of continuous glucose monitors and an artificial pancreas, and research on obesity, insulin action, and animal models of diabetes.

Under Dr. Fradkin's leadership of DEMD, major new clinical research networks have been created to conduct trials for prevention or delay of progression of type 1 diabetes, prevention of development of risk factors for type 2 diabetes in children, and comparison of treatment approaches to type 2 diabetes in children, and the landmark Diabetes Prevention Program clinical trial was successfully completed.

Dr. Fradkin serves as Chair of the Diabetes Mellitus Interagency Coordinating Committee, which is charged with facilitating collaboration on diabetes among Federal entities.

She also serves the on the Executive Committee providing leadership for the National Diabetes Education Program.

In addition to her oversight of major biomedical research programs, she has served as an endocrinology consultant at the National Naval Medical Center in Bethesda, Maryland, since 1984.

The recipient of numerous NIH and Public Health Service awards, Dr. Fradkin is also the 2003 recipient of the American Medical Association's Dr. Nathan Davis Award for outstanding public service in the advancement of public health.