

The Special Diabetes Program: Past Success, Future Promise

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The diabetes epidemic in the United States continues to grow in magnitude. Nearly 26 million Americans have diabetes, and another 79 million have prediabetes. If current trends continue, one in three Americans will face a life with diabetes by 2050.¹

People with diabetes face acute and long-term complications in addition to the daily burden of managing the disease. In just 5 years, the financial cost of diagnosed diabetes and its complications increased by 41%, from \$174 billion in 2007 to \$245 billion in 2012.² One in three Medicare dollars is spent on diabetes.³

To combat the unacceptable trajectory of diabetes, a strong federal investment in diabetes research and prevention programs is required. Such an investment should include increased investment in the Special Diabetes Program (SDP).

Established in 1997 and based on the recommendations of the Congressional Diabetes Research Working Group, the SDP is composed of two initiatives: the Special Statutory Funding Program for Type 1 Diabetes Research (SDP Type 1) and the Special Diabetes Program for Indians (SDPI). Each was originally funded with \$30 million per year for 5 years. The goals of the funding were to accelerate research toward prevention, improved treatment, and a cure for type 1 diabetes and to address the disproportionate burden of type 2 diabetes in American Indian and Alaska Native

(AIAN) populations. Throughout the past 16 years, both SDP programs have shown a marked return on the investment of federal dollars.

SDP Type 1—Funded Research Initiatives

The SDP Type 1 funding, directed to the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), is the lifeblood of type 1 diabetes research. It has created and supported large-scale, collaborative research networks and consortia—involving scientists and clinicians across disciplines—that would not have been possible without a sustained federal commitment. Current understanding of type 1 diabetes—its epidemiology, natural history, disease etiology, and pathogenesis—has been informed by SDP Type 1-funded research. Treatment advances made possible through SDP Type 1 have helped people with diabetes live longer and healthier lives.⁴

Through the SDP Type 1-supported SEARCH for Diabetes in Youth study, we now know that, between 2001 and 2009, type 1 diabetes increased by 23%, while type 2 diabetes increased by 21% in Americans < 20 years of age.^{5,6} If left unaddressed, this represents a doubling in the prevalence of diabetes for each future generation.

SDP Type 1 funding for the Type 1 Diabetes Genetics Consortium has resulted in identification of > 60

genes that influence the risk for type 1 diabetes.⁴

SDP Type 1 also provides 100% of the funding for The Environmental Determinants of Diabetes in the Young (TEDDY) study.⁴ This study screened 425,000 newborns to identify and enroll > 8,000 infants at high genetic risk for type 1 diabetes. TEDDY will follow these children until the age of 15 years, collecting blood and stool samples, along with other dietary and health data. TEDDY represents the best hope to identify the environmental triggers that lead to type 1 diabetes and will ultimately result in pathways to prevent, delay, or reverse the disease in those at risk. Massive, long-term efforts such as TEDDY simply could not be sustained without SDP support.

SDP Type 1 funding also supports TrialNet, a national clinical trials network testing therapies to prevent the onset of type 1 diabetes in those at risk and delay the progression of type 1 diabetes in newly diagnosed patients.⁷ With more than 150 medical centers and physician offices participating in the network, TrialNet has screened > 100,000 people for diabetes risk and identified those who may benefit from current and future prevention therapies.⁷

SDP Type 1 funding has also been a key driver of advances in understanding of β -cell biology through the National Institute of Diabetes and Digestive and Kidney Disease's Beta Cell Biology Consortium, through which investigators are

making progress toward turning stem cells, or progenitor cells, into insulin-producing cells.^{4,8,9}

SDP Type 1 funding has also supported development of continuous glucose monitoring devices, a crucial component in progress toward an artificial pancreas, an automated closed-loop system that would reduce disease burden and help people with diabetes achieve the level of tight glycemic control associated with the delay and reduction of diabetes-related complications.⁴ Indeed, long-term SDP Type 1–funded research has identified tight glycemic control as the optimal treatment regimen and demonstrated that it can result in a reduction in end-stage renal disease (ESRD).^{4,10}

Other significant advances have been made in preventing, treating, and reversing some of the devastating complications of type 1 and type 2 diabetes. Notably, SDP Type 1–funded research recently led to the discovery that vision loss can be reversed in people with diabetic retinopathy through a combination of drug and laser therapy.⁴

SDPI Research Initiatives

SDP funding has had an equally powerful effect in reversing the course of diabetes in AIAN communities. Type 2 diabetes is a devastating problem in the AIAN population; with a type 2 diabetes rate of 16.1%, this population has the highest prevalence of diabetes among all racial and ethnic groups.¹ In some communities, > 50% of AIAN adults have type 2 diabetes.¹¹

The SDPI program has changed the picture of diabetes in the AIAN communities it has touched. The program is funded through the Indian Health Service (IHS), which issues competitive grants to 404 IHS tribal and urban Indian health programs across the nation. The program has two components: SDPI

demonstration projects and community-directed diabetes programs.

Demonstration projects

In 2004, Congress directed the SDPI program to translate research on diabetes prevention and cardiovascular disease risk reduction for the AIAN community. This resulted in the SDPI demonstration projects known as the SDPI Diabetes Prevention Program and the SDPI Healthy Heart Project. For 6 years, 66 SDPI demonstration projects, serving 110 tribal communities, received grant funding.¹²

The SDPI Diabetes Prevention Program was based on the landmark NIH Diabetes Prevention Program, which provided evidence that the onset of type 2 diabetes can be prevented or delayed in individuals at high risk for the disease.¹³ Adapting the NIH lifestyle intervention for the 36 grantee sites produced similar results, demonstrating a 58% reduction in risk among participants.¹² The SDPI Healthy Heart Demonstration focused on reducing cardiovascular disease risk behaviors and improving clinical outcomes in people with diabetes through intensive case management, both medical intervention and patient education.¹² In the 30 grantee sites, progress was measured both in terms of lifestyle behavior changes and changes in blood pressure and blood lipid levels. Results at the end of the third year showed an increase in the percentage of participants engaged in healthy eating and increased physical activity as well as improved blood pressure and blood lipid targets. These valuable programs have transitioned into ongoing SDPI initiatives to produce continued results in the AIAN community.

An example of the clinical outcomes achieved in SDPI demonstration projects can be found in the story of a 62-year-old male participant. He began the SDPI Diabetes

Prevention Program in May 2012, when he was diagnosed with pre-diabetes and hypertension. By September 2012, he had completed the 16-week intensive core program and achieved a weight loss of 62 lb and a decrease in waist circumference of 4 inches. His blood glucose and blood pressure returned to normal ranges. This participant remains active with the program and attends monthly follow-up meetings. As of March 2013, he had lost 80 lb, and his hypertension medications have been discontinued.

Community-directed diabetes programs

The other half of the SDPI program—community-directed diabetes programs—respond to the local needs and priorities of the AIAN community by providing funding to develop and maintain quality, evidence-based diabetes treatment and prevention programs. The services vary based on local need and capacity, but all include direct medical services, the purchase of diabetes medications and supplies, diabetes education, and lifestyle intervention programs focused on youths and adults.

These programs have lowered average blood glucose levels, as measured by A1C, from 9.0% in 1996 to 8.1% in 2010.¹² According to the CDC, every 1-percentage-point decrease in A1C results in a 40% reduction in risk for complications such as heart disease, blindness, amputations, and kidney failure.¹

Among the many improvements in clinical outcomes of SDPI-supported programs, reduction of diabetes-related kidney failure stands out for its individual and economic impact. Between 1999 and 2006, the incidence of diabetes-related ESRD among AIANs declined by 28%, the largest decline in any racial and ethnic group.¹² The decreased number of new ESRD cases provides enormous cost savings to the health system,

and particularly to Medicare, which is the main payer for dialysis treatment.¹²

Together, the SDP Type 1 and SDPI initiatives are evidence that strategically targeted federal resources can produce enormous gains in the effort to combat diabetes and its complications. Through the years, funding has grown for the entire SDP program, but the renewal periods have been truncated, leaving promising research and prevention program efforts in flux. The highest and longest allocation of funding to date was \$150 million per program for a 5-year renewal period in 2002.

In January 2013, SDP funding was renewed through 30 September 2014 for a total of \$300 million (\$150 million per program). Although this renewal is significant, substantial increases in both the length of the renewal period and the funding levels are foundationally important to the continued success of the program. With short-term renewal periods of 1–2 years and the uncertainty of renewed funding, SDP-funded researchers and health care professionals are in a perpetual cycle of wondering whether their efforts to stop diabetes will be able to continue. This makes innovation and progress challenging, increases the risk of promising investigators leaving the field, and delays or jeopardizes our ability to capitalize on the fruits of past SDP investments.

SDP works. It wisely invests in research that has increased our understanding of how to prevent, and ultimately cure, type 1 diabetes. It has resulted in improved treatments and outcomes for the disease and has brought vision to those who would otherwise be in the dark. It has saved kidneys and prevented amputations in AIAN communities. Sustained and expanded investment in this success-

ful program is crucial if we are serious about stopping diabetes.

Health care professionals concerned about the diabetes epidemic have an important perspective to share and need to add their voices to the cadre of advocates seeking to renew and increase funding for this important program. Visit the ADA Advocacy Web site (www.diabetes.org/advocate) to become a diabetes advocate. More information about the SDP Type 1 program is available at <http://t1diabetes.nih.gov/about.shtml>. Information about the SDPI program can be found at <http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=programsSDPI>.

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