The NEW ENGLAND JOURNAL of MEDICINE

Perspective

SEPTEMBER 27, 2012

What's Preventing Us from Preventing Type 2 Diabetes?

Judith E. Fradkin, M.D., B. Tibor Roberts, Ph.D., and Griffin P. Rodgers, M.D., M.B.A.

The Diabetes Prevention Program (DPP) clinical trial and its 10-year outcomes study (DPPOS), both sponsored by the National Institutes of Health (NIH), showed that certain interventions could prevent or substantially delay the onset of type 2 diabetes both safely and cost-effectively.[1,2] Yet diabetes prevention is not widely practiced in the United States, and the disease's staggering human and financial costs continue to grow. It is therefore essential to identify the factors impeding the full realization of the DPP interventions' potential for preventing diabetes.

The DPP was a comparative effectiveness trial involving 3234 overweight or obese adults with impaired glucose tolerance (prediabetes). Forty-five percent of the participants belonged to racial or ethnic minority groups that have an increased risk of type 2 diabetes. Participants were assigned to receive one of three interventions: lifestyle intervention aimed at modest weight loss through diet and exercise, treatment with generic metformin, or a placebo control. DPP findings published in 2002 indicated that, relative to placebo, lifestyle intervention and metformin reduced the rate of conversion to diabetes by 58% and 31%, respectively, over 3 years.[1] Subgroup analyses showed that lifestyle intervention was effective in both sexes, across all racial and ethnic groups, and in people with a genetic predisposition to diabetes. Lifestyle intervention worked best in participants 60 years of age or older, a group in which metformin did not provide a significant benefit. Metformin worked well among younger participants and was particularly effective in women with a history of gestational diabetes. Most DPP participants (88%) enrolled in the DPPOS, in which continued follow-up demonstrated that the 10-year risk reduction for type 2 diabetes was 31% for lifestyle intervention and 18% for metformin.[2]

Beyond reducing diabetes risk, lifestyle intervention led to substantial health benefits and health care cost savings. Even though these interventions were initially delivered by highly trained professionals who conducted individual sessions, the net 10-year cost was quite modest; although metformin conferred fewer benefits and prevented fewer cases of diabetes, thanks to its lower cost it yielded net savings.[2]

To translate clinical research into practice, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) established a program to adapt efficacious diabetes and obesity interventions, including the DPP's lifestyle intervention, to real-world settings. In one promising trial, lifestyle intervention delivered by YMCA fitness trainers in a group setting greatly reduced per-patient costs and validated one practical

approach for reaching many of the estimated 79 million Americans with prediabetes.

Building on NIDDK research, which we sponsored, the Centers for Disease Control and Prevention (CDC) created the National Diabetes Prevention Program (NDPP) to assemble a sizable workforce well-trained in the methods pioneered through the DPP and YMCA–DPP studies. Quality assurance and credentialing provide payers with confidence that interventions are safe and effective, and the program is increasing the number of intervention sites and employing marketing strategies that highlight program availability. Through cooperation with public and private partners, including the YMCA and UnitedHealth Group, group-based lifestyle intervention is now available at more than 100 CDC-recognized sites in 25 states.[3]

Despite the strong evidence of benefit and the increasing capacity for delivering group-based lifestyle intervention, most payers do not cover services for preventing type 2 diabetes. The Affordable Care Act requires the Centers for Medicare and Medicaid Services (CMS) and private insurers to cover preventive medical services that receive a grade of B or better from the U.S. Preventive Services Task Force (USPSTF). Since the USPSTF has not issued a recommendation on diabetes-prevention services, lifestyle intervention is not covered. CMS recently began covering intensive behavioral therapy for obesity, which is a risk factor for diabetes. But this coverage has limited efficacy for diabetes prevention, since overweight, nonobese persons with prediabetes are not covered, and few primary care physicians who provide obesity counseling are trained in lifestyle intervention.

CMS lacks statutory authority to reimburse nontraditional care providers, such as lifestyle coaches. Private payers, on the other hand, have fewer constraints. Recognizing the health and financial benefits of lifestyle intervention for participants with prediabetes, UnitedHealth Group and Medica do cover these preventive services, and other private payers are considering doing the same. Recently, the YMCA received a CMS Health Care Innovation Award to pilot diabetes-prevention services for 10,000 Medicare beneficiaries with prediabetes in 17 communities. Such a program could be a model for more widespread intervention coverage. Unfortunately, the great majority of Americans with prediabetes remain undiagnosed or unaware of their condition, and few have access to an accredited lifestyle-intervention provider.[3]

Given its efficacy, potential for cost savings, and excellent safety profile, metformin offers another approach to diabetes prevention, particularly in people less than 60 years of age and in women with a history of gestational diabetes. It is difficult, however, to know how often the drug is prescribed off-label for diabetes prevention. Lack of Food and Drug Administration (FDA) approval for this indication hampers education about its potential benefits: it is unlawful for industry to advertise drugs for unapproved indications, and professional societies and insurers are reluctant to recommend unapproved agents in guidelines and educational materials. Only holders of an original new drug application (NDA) may file for FDA approval of new indications. From a business perspective, a pharmaceutical company may have difficulty justifying the cost of a supplemental NDA if a medication is available in generic form.

One important and unavoidable consideration is that the deadly, debilitating, and costly complications of diabetes do not appear immediately after disease onset. Although the peak incidence of the disease occurs between 50 and 60 years of age, complications typically emerge a decade or more later (with enormous implications for Medicare). The duration and extent of hyperglycemia predict complications, and controlling diabetes becomes more difficult over time. Thus, it may take decades to fully realize the health and financial benefits of diabetes prevention. Even the substantial benefits achieved through glycemic control in the NIH's landmark Diabetes Control and Complications Trial and the Epidemiology of Diabetes Interventions and Complications studies were not immediate: an average of 6.5 years of intensive blood-glucose management dramatically reduced early signs of microvascular complications of diabetes, but effects on clinical events such as myocardial infarction and kidney failure emerged over decades.[4]

Such results demonstrate the importance of following patients to assess long-term outcomes in key clinical trials, particularly for chronic diseases such as diabetes. Since the effects of interventions on the most serious consequences of diabetes are not immediate, the health and financial benefits of preventing or delaying diabetes are expected to accrue slowly at first, then accelerate over time. Achieving modest cost savings with metformin within a decade and the near cost neutrality of even the original, individually administered lifestyle intervention over that same period are therefore remarkable. Under the Con-

gressional Budget Office's standard scoring of policy proposals on the basis of their 10-year budgetary impact, diabetes prevention appears to be on the cusp of fiscal benefit, in addition to being of enormous health benefit.[5] Given a longer-term perspective, however, the value of applying DPP results to diabetes prevention is clear cut.

Although research has provided tools for preventing or delaying type 2 diabetes, health policies limit their application. Industry needs incentives for obtaining FDA approval of new uses of generic drugs, or we must design alternative pathways for approval. Benefits and costs must be assessed over meaningful timelines for diseases that stretch across decades. Finally, instituting mechanisms for compensating NDPP-certified ancillary health care providers and integrating them into the broader public health infrastructure may cost-effectively stem the tide of diabetes and improve our nation's health.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Division of Diabetes, Endocrinology, and Metabolic Diseases (J.E.F.), the Office of Scientific Program and Policy Analysis (B.T.R.), and the Office of the Director (G.P.R.), National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Bethesda, MD.

1. Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 2002;346:393-403.
2. *Idem*. The 10-year cost-effectiveness of lifestyle intervention or metformin for diabetes prevention: an intent-to-treat analysis of the DPP/DPPOS. Diabetes Care 2012;35:723-30.
3. Centers for Disease Control and Prevention. National Diabetes Prevention Program (http://www.cdc.gov/diabetes/prevention/).
4. The DCCT/EDIC Research Group. Intensive diabetes therapy and glomerular filtration rate in type 1 diabetes. N Engl J Med 2011;365:2366-76.
5. Huang ES, Basu A, O'Grady MJ, Capretta JC. Using clinical information to project federal health care spending. Health Aff (Millwood) 2009;28:w978-w990.

DOI: 10.1056/NEJMp1208169

Cutting Family Planning in Texas

Kari White, Ph.D., Daniel Grossman, M.D., Kristine Hopkins, Ph.D., and Joseph E. Potter, Ph.D.

Four fundamental principles drive public funding for family planning. First, unintended pregnancy is associated with negative health consequences, including reduced use of prenatal care, lower breast-feeding rates, and poor maternal and neonatal outcomes.[1,2] Second, governments realize substantial cost savings by investing in family planning, which reduces the rate of unintended pregnancies and the costs of prenatal, delivery, postpartum, and infant care.[3] Third, all Americans have the right to choose the timing and number of their children. And fourth, family planning enables women to attain their educational and career goals and families to provide for their children. These principles led to the bipartisan passage of Title X in 1970 and later to other federal- and state-funded programs supporting family planning services for low-income women.

Despite the demonstrated positive effects of these programs, political support and funding for them have begun to erode. Recently, efforts to expand access to contraception through the Affordable Care Act ignited a broad debate regarding the proper role of government in this sphere, and proposals have been put forth to eliminate Title X.

Several states have already taken substantial steps to reduce public funding for family planning and other reproductive health services. In 2011, Texas enacted the most radical legislation to date, cutting funding for family planning services by two thirds — from $111 million to $37.9 million for the 2-year period. The remaining funds were allocated through a three-tiered priority system, with organizations that provide comprehensive primary care taking precedence over those providing only family planning services (see pie charts). The Texas legislature also imposed new restrictions on abortion care and reauthorized the exclusion of organizations affiliated with abortion providers from participation in the state Medicaid waiver program, the Women's Health Program (WHP), which was due for renewal in January 2012. Although the exclusion had not previously been enforced by the state Health and Human Services Commission, it runs contrary to federal policy, and the renewal of the WHP was declined by the Centers for Medicare and Medicaid Services. In 2010, the WHP provided services to nearly 106,000 women 18 years of age or older with incomes below 185% of the federal poverty level who had been legal residents of Texas for at least 5 years. Almost half of these women were served at Planned Parenthood clinics.

To implement the legislation and funding cuts, the Texas Department of State Health Services reduced the number of funded family planning organizations