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The Case of the Diabetes Prevention Program

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Over a third of all deaths in the United States are associated with tobacco and obesity. Today, nearly 36 percent of adults are considered obese, and over 19 percent of teens and adults continue to smoke, which is over 45 million people.<sup>1</sup> Obesity rates among adults have doubled since the late 1980s, and exceed 36 percent today. While smoking rates have declined over time, the reduction in smoking prevalence has abated. Tobacco use increases the risk of a variety of cancers, including cancers of the lung, esophagus, larynx, and oral cavity, as well as cardiovascular disease. Approximately half of all long-term smokers die prematurely from smoking-related diseases.<sup>2</sup> Obesity is associated with a wide variety of chronic diseases. Being overweight or obese increases the risk of diabetes, hypertension, hyperlipidemia, and cardiovascular disease, among others.

Smoking and obesity add to our health care bill. Obesity is estimated to account for over 20 percent of total health care spending, nearly \$200 billion per year.<sup>3</sup> The doubling of obesity rates since the late 1980s accounted for nearly 10 percent of the rise in health care spending since the late 1980s.<sup>4</sup> Both smoking and obesity are potentially modifiable risk factors. Finding effective approaches to prevent teens and adults from starting to smoke and to help them quit smoking is an important public health objective. Similarly, identifying effective lifestyle interventions designed to prevent weight gain and assist in sustained weight loss is another key public health objective. Finding effective clinical treatments for chronic diseases associated with smoking, being overweight, and obesity represents another key health policy challenge.

Identifying evidence-based approaches that more effectively prevent, identify, and manage chronic diseases, most of which are linked to smoking and obesity, requires ongoing research. Historically, much of the research that has evaluated alternative lifestyle and smoking cessation interventions has been funded by the National Institutes of Health (NIH). Other federal funding sources, notably the Centers for Disease Control and Prevention (CDC), have also been an important source of research funding. Examples of critical research that the NIH in particular has funded, which has resulted in the identification of several key public health prevention breakthroughs, include:

- Funding the largest clinical randomized controlled trial to date of an intensive lifestyle intervention—the diabetes prevention program (DPP)—which resulted in critically important results showing that type 2 diabetes can be prevented or delayed (funding from the National Institute of Diabetes, Digestive and Kidney Diseases [NIDDK] at the NIH).<sup>5</sup>
- Funding a ten-year follow-up study of the DPP showing that the cumulative incidence of diabetes remains lower in the lifestyle-intervention group even a decade later.<sup>6</sup>
- Funding efforts to expand the DPP into community-based settings such as churches that largely serve African American communities.
- Funding the Search for Diabetes in Youth Study, which provided the first national data on the incidence and prevalence of diabetes in youth.<sup>7</sup>
- Funding for clinical trials that validated the use of hemoglobin A1C—a measure of average blood sugar control over a three-month period—allowing diabetics and prediabetics to more effectively monitor their blood sugar levels.<sup>8</sup>
- Funding trials that indicate that controlling blood pressure and lipids can reduce complications from diabetes by 50 percent.<sup>9</sup> These clinical trials have led to changes in clinical recommendations for treating hypertension and hyperlipidemia, contributing to the long-term reduction in cardiovascular mortality rates.
- Funding a wide variety of evaluations of smoking cessation programs that have resulted in publications and recommendations from the CDC regarding the design features of best-practice evidence-based interventions.<sup>10</sup> These best-practice programs have contributed to the long-term decline in smoking rates among teens and adults.

# The Underlying Issues and the Role of the NIH in Funding Research to Find Solutions for Obesity and Chronic Illness

The prevalence of treated chronic disease has increased sharply over the past 20 years. Table 1 presents trends in chronic disease prevalence between 1987 and 2009. Treatment for many conditions linked to rising rates of obesity has increased sharply. Between 1987 and 2009, treatment for abnormal cholesterol (a condition known as hyperlipidemia) increased by 13.6 percentage points, hypertension nearly 9 percentage points, mental disorders by over 8 percentage points, diabetes and pulmonary disease by approximately 4 percentage points each, and arthritis by 6 percentage points.

Condition	1987	2009	Change in prevalence
Hyperlipidemia	1.0%	14.6%	13.6%
Hypertension	9.6%	18.4%	8.8%
Mental Disorders	4.2%	12.5%	8.3%
Diabetes	2.9%	6.7%	3.8%
Pulmonary Disease	8.4%	12.7%	4.3%
Arthritis	5.4%	11.4%	6.0%

### Table 1. Trends in the Prevalence of Chronic Disease, Adults 18+, 1987–2009

Source: Tabulations from the Medical Expenditure Panel Survey.

In addition to their impact on morbidity, rising rates of chronic disease represent an important driver of health care spending increases over time. In light of these data, finding effective lifestyle interventions to reverse these trends is a key priority.

The following section highlights the critical role that NIH funding has played in identifying interventions that both prevent the rise in obesity and chronic illness and provide more

effective control of these diseases to keep patients healthier. I focus on the largest clinical trial to date—the Diabetes Prevention Program—which evaluated the effect of a structured lifestyle intervention on both weight loss in general and the reduction in the incidence of weight-related chronic diseases in particular.

#### **The Diabetes Prevention Program**

The DPP conducted a randomized trial of 3,234 overweight and obese pre-diabetic adults at 22 sites throughout the country and divided them into three groups. The first group was given standard advice and practice about weight loss—plus participants were given a placebo. The second group was given standard lifestyle recommendations plus metformin, an oral antidiabetic drug, and the third group was given an intensive program of lifestyle modification. The goal for those enrolled in the intensive lifestyle program was a sustained loss of 7 percent of baseline body weight. The intensive program consisted of several interventions, including engaging in at least 150 minutes per week of moderate physical activity and eating a healthy, low-calorie, and low-fat diet. At the core of the interventions was a 16-week, one-on-one curriculum during the first 24 weeks that covered diet, exercise, and behaviorial modification tools and skills designed to assist in meeting the weight loss goals. This was followed up by at least monthly reinforcements.

After an average tracking and follow-up of 2.8 years, average weight loss in the intensive lifestyle program was 7 percent, with 75 percent of participants meeting the 150-minutes-perweek exercise goals. Of particular interest was the outcome that weight loss was greatest among participants aged 60 and older. At 24 months, mean weight loss within this age group was 7.4 percent, compared to 5 percent for those under age 45 and 5.4 percent for those aged 45 to 59.

Relative to the placebo group, the lifestyle group achieved a 58 percent reduction in the incidence of diabetes, and the group receiving metformin and standard advice had a 31 percent reduction in diabetes incidence. Reflecting their larger percentage of weight loss, those aged 60

and older had a 71 percent lower incidence of diabetes. Weight loss was found to be the most important predictor of the reduction in diabetes incidence. The study found that each kilogram of weight loss was associated with a 16 percent reduction in diabetes incidence.

Also of interest were the results among those who met the exercise targets but did not achieve the 7 percent weight loss goal. This group still had a 44 percent reduction in diabetes incidence, which was lower than those with the weight loss but still higher than those receiving the metformin.

The intensive lifestyle intervention group showed broader impacts on other chronic health care conditions. For instance, 30 percent of all participants in the overall trial had hypertension at study entry. Hypertension prevalence increased in both the placebo and metformin groups. In contrast, hypertension prevalence significantly decreased among participants in the intensive lifestyle group. In addition, triglyceride levels decreased significantly more in the intensive lifestyle group than in the other groups. Finally, the intensive lifestyle group significantly increased HDL (the good) cholesterol levels. So overall, the intervention after the initial 2.8 years of follow-up generated significant reductions in diabetes incidence as well as in a broader set of cardiovascular risk factors.<sup>11</sup>

After completion of the original trial, all DPP participants were offered enrollment in the intensive lifestyle program which was followed for several additional years. Whereas the original trial was conducted with one participant per researcher, the new program was conducted in groups of several participants per researcher and held in quarterly sessions. Participants in the follow-up study (DPP Outcome Study [DPPOS]) were tracked for an additional 6.8 years. While there was some weight regained in the intensive lifestyle group over the ten years (initial loss of 7 kilograms and at ten years 2 kilograms), the cumulative incidence of diabetes in the lifestyle group was 34 percent lower than in the placebo group.<sup>12</sup>

Collectively, this body of research, which was funded through the NIH (NIDDK), found that a structured, intensive lifestyle intervention can reduce incidence rates of diabetes and other

cardiovascular risk factors in a short time period (one year) and that the results can persist for at least a decade. The research has proven that structured lifestyle interventions can prevent or delay the onset of diabetes and related complications.

The study demonstrated that intensive lifestyle interventions can reduce the incidence of several cardiovascular risk factors. However, because the 16-week sessions were one-on-one, the intervention was quite expensive—approximately \$1,800 per person. Early (and likely low) estimates of the health care savings were on the order of \$450 per participant, generating a net increase in costs. Thus, NIH funding has focused on approaches for translating the DPP protocol to community-based group settings. This line of work is designed to see if the same weight loss and reductions in chronic disease incidence can be produced outside the one-on-one counseling at a lower cost. One recent study funded by the NIDDK is a five-year translation of the protocol, called the Church-Based Diabetes Prevention and Translation Study. This is an ongoing line of research.

The original NIH-funded trial has generated substantial innovations in developing communitybased alternatives, such as the establishment of the National Diabetes Prevention Program (NDPP), which is housed in the CDC. The NDPP is tasked with developing community-based programs using the DPP model. The two initial partners with the CDC in developing communitybased versions of the protocol are the YMCA of the USA (Y-USA) and the UnitedHealthGroup (UHG). Some funding for the program (approximately \$6 million in fiscal year 2012) has been provided through the Prevention and Public Health Fund, established as part of the Affordable Care Act. The UHG is also providing funding to the YMCA to do the training and establish the data measurement and collection systems. Most recent, the Y-USA received funding through the Center for Medicare and Medicaid Innovation for \$12 million over the next three years to continue to build community-based versions of the DPP for 10,000 Medicare beneficiaries.

Early evaluations of the community-based versions of the DPP are showing considerable promise. Participants in the community-based lifestyle version of the program lost 6 percent of baseline body weight after 6 months and at 12 months. Similar results were found at 28

months, and the study is still tracking.<sup>13</sup> It is encouraging that even though the YMCA version of the DPP has a smaller sample size, it has produced weight loss results similar to those of the original trial. And the cost of the intervention is a fraction of the original protocol, approximately \$300 per capita compared to \$1,400. Based on these data, it is likely that enrollment in the DPP program would improve health outcomes and result in lower health care spending. Medicare, for instance, would save well over \$7 billion over ten years if overweight and obese pre-diabetic adults were enrolled in the community-based program.<sup>14</sup>

#### Future Funding Needs from the NIH on Lifestyle Prevention Programs

Many areas of prevention research need to be pursued over the next several years, including, but not limited to

- Identifying approaches to increase participation among eligible populations in behaviorial change programs like the DPP
- Finding cost-effective approaches for identifying at-risk populations that would most benefit from intensive lifestyle programs
- Identifying new approaches for preventing and treating diabetes and other related chronic conditions in children
- Researching the factors influencing the progression of diabetes complications to better tailor personalized treatment strategies.

## Discussion

NIH funding has provided a wealth of information about best-practice smoking cessation interventions and recently regarding intensive weight loss and lifestyle programs. While the discussion has focused on the largest clinical trial, the DPP, the importance of NIH funding more broadly in shaping what we know about modifying risk factors cannot be understated. Funding provided through the NIDDK to develop and evaluate the impact of the largest randomized lifestyle intervention program in the world has fundamentally influenced prevention policy. As a result of this study, the Congress sought to scale and replicate community-based versions of the DPP funded through the National Diabetes Prevention Program at the CDC. Funding for the initiative has largely been provided through the Affordable Care Act.

The private sector has also recognized the value and efficacy of averting disease. The UHG has partnered with the YMCA of the USA to provide the DPP as a benefit in certain jurisdictions. Performance-based per capita payments are made to the YMCA based on actual results. Other private health plans either have or are currently looking at this model.

Rising health care costs are largely driven by increases in potentially preventable chronic health care conditions. The NIH has successfully funded a variety of research efforts designed to identify best-practice approaches to reducing smoking and promoting weight loss. The research agenda has found several promising approaches that are being replicated in communities throughout the country. But much more work needs to be done. Slowing the growth in health care spending and improving the quality of care represent two critical health policy issues. Thanks to NIH-funded research, we now have some answers and tools for making progress on both fronts. Future research funding in these areas is a critically important investment for the country in order to continue to make progress on the two health care issues.

# Endnotes

<sup>1</sup> http://www.cdc.gov/tobacco/quit\_smoking/how\_to\_quit/you\_can\_quit/alone/; http://www.cdc.gov/nchs/data/databriefs/db82.htm

<sup>2</sup> http://www.cdc.gov/Features/VitalSigns/AdultSmoking/

<sup>3</sup> Cawley, John, and Chad Meyerhoefer. "The Medical Care Costs of Obesity: An Instrumental Variables Approach." *Journal of Health Economics*, 2012, 31(1): 219–230.

<sup>4</sup> See http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/118xx/doc11810/09-08-obesity\_brief.pdf. I have produced similar estimates.

<sup>5</sup> Diabetes Prevention Program Research Group. "Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin." *New England Journal of Medicine*, 2002, 346(6): 393–403.

<sup>6</sup> Diabetes Prevention Program Research Group. "10-Year Follow-Up of Diabetes Incidence and Weight Loss in the Diabetes Prevention Program Outcomes Study." *The Lancet*, 2009, 374: 1677–1686.

<sup>7</sup> Mayer-Davis, E. J., C. Davis, J. Saadine, R.B. D'Agostino Jr., D. Dabelea, L. Dolan, S.Garg, J. M. Lawrence, C. Pihoker, B. L. Rodriguez, B. E. Klein, R. Klein, The SEARCH for Diabetes in Youth Study Group. "Diabetic Retinopathy in the SEARCH for Diabetes in Youth Cohort: A Pilot Study." *Diabetic Medicine: A Journal of the British Diabetic Association*, 2012, 29:1148–1152. PMID: 22269205. http://www.ncbi.nlm.nih.gov/pubmed/22269205

<sup>8</sup> http://diabetes.niddk.nih.gov/dm/pubs/A1CTest/#1

<sup>9</sup> http://www.cdc.gov/diabetes/pubs/factsheets/atwork.htm

<sup>10</sup> http://www.ncbi.nlm.nih.gov/books/NBK63943/

<sup>11</sup> Diabetes Prevention Program Research Group. "Impact of Intensive Lifestyle and Metformin Therapy on Cardiovascular Disease Risk Factors in the Diabetes Prevention Program." *Diabetes Care*, 2005, 28(4): 888–894.

<sup>12</sup> Diabetes Prevention Program Research Group. "10-Year Follow-Up of Diabetes Incidence and Weight Loss in the Diabetes Prevention Program Outcomes Study." *The Lancet*, 2009, 374: 1677–1686.

<sup>13</sup> Ackermann, R. T., et al. "Translating the Diabetes Prevention Program into the Community. The DEPLOY Pilot Study." *American Journal of Preventive Medicine*, 2008, 35(4): 357–363.

<sup>14</sup> Thorpe, Kenneth E., and Zhou Yang, "Enrolling People with Pre-Diabetes Ages 60 to 64 in Proven Weight Loss Program Could Save Medicare \$7 Billion or More." *Health Affairs*, 2011, 30(9): 1673–1679.



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