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# Preventing Type 2 Diabetes in Communities Across the U.S:

**The National Diabetes Prevention Program** 

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# Abstract

There are as many as 79 million people in the U.S. with prediabetes, and their risk of developing type 2 diabetes is four to 12 times higher than it is for people with normal glucose tolerance. Although advances in diabetes treatment are still needed, there is a critical need to implement effective strategies to stem the current and projected growth in new cases of type 2 diabetes. RCTs and translation studies have demonstrated that type 2 diabetes can be prevented or delayed in those at high risk, through a structured lifestyle intervention that can be delivered cost effectively. In order to bring this compelling lifestyle intervention to communities across America, Congress authorized the CDC to establish and lead the National Diabetes Prevention Program. Several aspects of the etiology of type 2 diabetes suggest that strategies addressing both those at high risk and the general population are necessary to make a major impact on the diabetes epidemic.

# Introduction

Diabetes affects almost 26 million Americans.<sup>1</sup> Currently one in nine U.S. adults has diabetes, and the CDC estimates that as many as one in five could have the disease by 2025 if current trends continue.<sup>2</sup> As many as 79 million people in the U.S. have prediabetes,<sup>1</sup> representing more than one third of adult Americans and half of all adults aged 65 years. The yearly incidence of type 2 diabetes is 5%–10% in people with prediabetes, compared to about 1% per year in the general adult population.<sup>3</sup>

The implications of increased diabetes prevalence are extensive, because of the well-known risks of cardiovascular disease, vision loss, amputation, end-stage renal disease (ESRD), disability, and mortality.<sup>1</sup> It is promising that the U.S. National Diabetes Surveillance System has documented several important improvements in diabetes complications for the average person with diabetes.<sup>4</sup> The rates of amputations have declined by more than half since the mid-1990s, from a peak of nine per 1000 in 1996 to three per 1000 in 2009.<sup>5</sup> Similarly, annual rates of ESRD declined from 3.1 to 1.9 cases per 1000 between 1995 and 2008.<sup>6</sup> However, as the average risk of major diabetes-related complications has declined, rising prevalence of diabetes has increased the risk of these complications in the total population.<sup>7</sup> Overall, national diabetes surveillance data make it clear that advances in

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diabetes treatment are still needed because of the continued high rates of diabetes complications, but there is an equal need to implement primary prevention efforts to stem the current and projected growth in new cases of type 2 diabetes.

The current article summarizes the evidence for lifestyle change programs to prevent or delay type 2 diabetes and describes the National Diabetes Prevention Program (National DPP) that has been constructed based on this evidence. The National DPP provides a critical opportunity to organize lifestyle prevention efforts in the country in order to reduce the incidence of type 2 diabetes. In addition, strategies addressing the general population are discussed because it is likely that these must also be undertaken to make a major impact on trends in the diabetes epidemic.

# Evidence for Lifestyle Change Prevention Programs

Fortunately, it is now well established that type 2 diabetes can be prevented or delayed in high-risk adults. At least five major RCTs, conducted in the U.S., China, Finland, Japan, and India, have documented 30%–60% reductions in diabetes incidence in high-risk adults.<sup>8–10</sup> At least three of the RCTs have conducted additional follow-up measurements of participants to examine the extended, "legacy" effect of the interventions long after the intervention has ended.

The Finnish Diabetes Prevention Study found a significant 43% reduction in diabetes incidence 3 years after the completion of the trial.<sup>11</sup> The Da Qing diabetes prevention study found a 43% reduction 14 years following the intervention (20 years after baseline).<sup>12</sup> Most recently, the Diabetes Prevention Program (DPP) study reported a 24% reduced incidence 8 years following the completion of the trial (10 years after baseline).<sup>13</sup> In the only trial to examine the effects on long-term complications of diabetes, Gong et al.<sup>14</sup> found a significant reduction in incidence of severe retinopathy associated with the intervention.

Successful RCTs of the impact of lifestyle intervention on type 2 diabetes incidence have several key elements in common. All were conducted among adults with impaired glucose tolerance and/or impaired fasting glucose. Each study consisted of relatively intensive one-on-one or small-group intervention using a structured curriculum for 6 months to 1 year, and included an extended "maintenance" period to prevent and manage relapses and encourage sustained behavior change.

Each major intervention achieved substantial reductions in total dietary intake, total and saturated fat intake, and achieved increases in leisure-time physical activity, and in some cases, increased fiber intake. Each study integrated behavioral principles and self-monitoring using diet and exercise diaries to assist behavior change. Weight loss after 1 year in these trials ranged from 0 to 7 kg per year. The DPP, the largest efficacy trial in diabetes prevention, showed that people with impaired glucose tolerance who lost 5%–7% of their body weight and achieved 150 minutes of moderate physical activity per week through a structured lifestyle change program reduced their chance of getting type 2 diabetes by 16 percentage points per year.<sup>8</sup>

The RCTs have provided invaluable information to guide practical implementation, but they also included elements that pose challenges to achieve the same results in the broader prediabetes population and economic sustainability. For example, the DPP lifestyle intervention included one-on-one "core" sessions delivered by highly credentialed research staff. The core sessions were followed by twice-monthly in-person "maintenance" sessions and telephone contact between sessions.

In addition, participants were given several lifestyle modification tools including access to exercise facilities and meal replacements. The cost to deliver the DPP lifestyle intervention in the first year was \$1400 per participant, an expense too great to be scaled in a sustainable manner.<sup>15</sup> As efforts are made to reduce the cost of diabetes prevention, it is important to not lose sight of the fact that in 2007 the annual per capita healthcare expenditure for a person with diabetes was \$11,700.<sup>16</sup>

A major focus of subsequent research for type 2 diabetes prevention has been how best to use limited resources to deliver the lifestyle intervention, while ensuring that weight loss is adequate to decrease future cases of type 2 diabetes. Several published research studies, carried out in real-world settings, have implemented modified versions of the lifestyle intervention used in the DPP research study. Ali and colleagues<sup>17</sup> conducted a systematic review and meta-analysis of 28 U.S.-based studies that adapted the DPP lifestyle intervention in real-world settings at lower cost.<sup>17</sup> Because the DPP study established that weight loss was the single most important factor in reducing type 2 diabetes incidence, Ali et al. examined the weight loss achieved in these translation studies. They also examined program characteristics that influence weight loss and cost, including number of core sessions and type of intervention staff.

The studies took place in diverse settings, including community centers, recreation centers, faith-based organizations, and healthcare facilities; four studies used electronic media. In total, 3797 participants were enrolled in interventions, and of these, 2916 participants had complete follow-up data and were included in the analysis. Mean weight change across all studies was about 4% at the 12-month follow-up. A 4% weight loss might seem modest, but it is only slightly less than what was achieved in the most-effective RCTs.<sup>18</sup>

Change in weight was similar regardless of whether the intervention was delivered by medical and allied health professional or lay community personnel.<sup>17</sup> The number of core sessions attended was strongly correlated with the number of core sessions offered. There was a dose–response association between the number of sessions and amount of weight loss, such that there was a 1% greater weight loss for every four sessions attended. Qualitative information from studies included in the analysis indicated that attrition was not related to program length, but was related to the effectiveness of behavioral modification techniques and participants' perceptions of how likely they were to develop type 2 diabetes.

# National Diabetes Prevention Program

Moving diabetes prevention from research to implementation in communities is a major undertaking. A concerted focus on building the infrastructure for and delivery of the adapted DPP lifestyle change program had not been done in the U.S. until 2010 when Congress

authorized the CDC to establish and lead the National DPP. The National DPP is more than a program. It represents an approach to increase a low-cost intervention based on the DPP in communities across America. Its foundation is a results-driven partnership that includes community-based organizations, health insurers, employers, healthcare systems, academia, and government agencies. By serving as the backbone for bringing this effective lifestyle intervention across the country, the National DPP puts in place the elements for reaching the large-scale implementation necessary to reduce the incidence of type 2 diabetes. The CDC's strategic approach to the National DPP has the following four core elements, each of which is discussed below, and is summarized in Figure 1: training, recognition program, lifestyle change program sites and payment model, and health marketing.

#### Training

A trained workforce that can deliver the lifestyle change program cost effectively is necessary. The number of people with prediabetes requires that the workforce be expanded to meet the demand. As demonstrated in the meta-analysis by Ali et al.,<sup>17</sup> health professionals and lay community workers can effectively deliver the lifestyle change program.

In response to this training need, the CDC established the Diabetes Training and Technical Assistance Center (DTTAC) at Emory University (www.dttac@emory.edu). The DTTAC provides comprehensive training services across the country for lifestyle coaches to prepare them to effectively deliver the lifestyle change program. Following in-person training, the DTTAC provides an ongoing learning community that features webinars and conference calls with program experts and opportunities to share information and exchange best practices. Other organizations conduct training, and those who chose to use these other services should examine them to be sure they provide a level of training that will allow an organization's lifestyle change program to meet CDC recognition program standards.

#### **Recognition Program**

The CDC Diabetes Prevention Recognition Program (DPRP) is a key component of the National DPP. The objectives of the DPRP are to (1) ensure the quality, consistency, and broad dissemination of the lifestyle change program for people at high risk for type 2 diabetes; (2) develop and maintain a registry of organizations that are recognized for their ability to deliver an effective lifestyle change program; and (3) provide technical assistance to organizations that have applied for recognition to help them deliver an effective lifestyle change program and (3) provide technical assistance to organizations that have applied for recognition. The DPRP Standards (required components for type 2 diabetes prevention lifestyle change programs) are used to ensure consistent quality which can help individuals at risk in deciding to participate, healthcare professionals considering whether to refer a patient, or an insurance provider considering whether to pay for the program. The CDC is responsible for the DPRP, and there is no cost to apply for recognition. For more information about the DPRP or to apply for recognition, go to www.cdc.gov/diabetes/prevention/recognition.

#### Lifestyle Change Program Sites and Payment Model

The most prominent core element of the National DPP is delivery of the lifestyle change program. The program is being offered at many locations, including community-based organizations, worksites, and healthcare facilities. Several of these sites have recently completed the application process for program recognition.

Payment is a critical component to ongoing delivery of the lifestyle change program. The Nation's largest private health insurer—United Health Group (UHG)—and largest lifestyle program provider—the YMCA (Y is now the preferred usage)—were the first organizations to formally partner with the CDC in the National DPP. The Y and UHG (under the Diabetes Prevention and Control Alliance [DPCA]) represent a new model for sustainable delivery of the lifestyle change program. The Y is receiving payment on a pay-for-performance basis from the UHG, self-funded employers, and other insurers who purchase services through DPCA. In this model, UHG serves as not only an insurance provider but also a service provider that created and operates the technology, business processes, and infrastructure that support participant identification, engagement, and enrollment. The CDC is working to bring more partners into the National DPP, including more organizations to deliver the lifestyle change program and other insurers to cover the cost of participation.

#### **Health Marketing**

Even the best lifestyle change programs will not succeed without adequate uptake. National DPP partners are working on strategies to increase referrals to and participation in lifestyle change programs. Various participant engagement strategies are being evaluated, as well as methods to increase healthcare professionals' understanding and support of the lifestyle change program. To obtain the most current information about the National DPP, visit www.cdc.gov/diabetes/prevention.

#### **Tiered Approach to Prevention**

Debates about optimal prevention strategies for chronic diseases often center around the merits of "high-risk" versus "population-wide" approaches.<sup>19,20</sup> Approaches directed to those at high risk typically include a process of screening and identification of people with a high probability of developing a condition. This identification of high risk allows preventive services to be reserved for and directed to people most likely to benefit.

A population approach aims to shift the entire distribution of a risk factor in a healthy direction, even if just by a small degree, to have a large effect on the proportion who develop disease. Several aspects of the etiology and evidence base for type 2 diabetes prevention suggest that both high-risk and population approaches are necessary to make a major impact on trends in the diabetes epidemic. Further, these combined strategies will have an optimal effect if they are implemented as part of a multi-tiered approach that links the type and intensity of the intervention to the appropriate level of risk while at the same time altering the hazardous cultural, environmental, and economic conditions that underlie risk factors for type 2 diabetes.

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The most-appropriate tiers, risk indicators, and corresponding interventions remain a rapidly evolving area of science.<sup>21</sup> However, epidemiologic and intervention studies point to four natural tiers (Table 1). At the first tier, adults with fasting plasma glucose (FPG) >110 mg/dL; HbA1c levels >5.7%; 2-hour glucose >140 mg/dL; a history of gestational diabetes; or a predicted 10-year diabetes incidence of 30% or more are particularly good candidates for structured lifestyle interventions in community settings as described in the National DPP, owing to their very high risk and potential to benefit. People who do not meet criteria for "very high risk," yet have FPG >100 or a predicted risk of at least 20% over 10 years, are also reasonable candidates for community-based lifestyle interventions, although the cost effectiveness of selecting them for intervention may not be as high as it is for the group that is at very high risk.<sup>22</sup>

These top two risk tiers for people who receive particular prioritization of structured lifestyle programs are warranted by several observations. First, the majority of cases of type 2 diabetes over a 5–10-year period occur among those with hyperglycemia or a clustering of several major risk factors, such as obesity, hypertension, increased age, and history of gestational diabetes.<sup>21,23</sup> Second, the strongest and clearest evidence for diabetes prevention comes from RCTs conducted among people with impaired glucose tolerance. By contrast, no major RCTs have examined and demonstrated the impact of diabetes prevention among those with normal glucose tolerance.

Third, there is a consistent dose–response relationship between the amount of lifestyle intervention support one is given and the magnitude of risk reduction, and results are best when long-term maintenance is provided.<sup>17</sup> Even though effective lifestyle interventions can be delivered at relatively low costs, particularly in community settings, this dose–response relationship means that optimal impact still requires enough resources in terms of personnel, time, and facilities, and that provision of such services to anyone regardless of risk level makes poor economic sense. This point is portrayed in recent analyses showing that structured lifestyle intervention programs are more cost effective when applied to high-risk adults than when applied to those of moderate or low risk.<sup>22</sup> This is mainly because using overly inclusive screening criteria for diabetes prevention programs leads to the use of services on many people who would not go on to develop diabetes even in the absence of the intervention.

A large segment of the population is likely to have a "moderate," or higher than average, future risk of diabetes based on the presence of two or more risk factors, such as a family history of diabetes, being aged 45 years, having hypertension, or central or overall obesity, which makes up a third tier. Although these individuals may present no evidence of hyperglycemia, better awareness and brief education or counseling about how they can influence their risk may help to reduce progression to higher levels of risk.<sup>23,24</sup> A fourth tier of people at below-average risk can be defined as a 10-year risk of less than 10%. Population-targeted approaches, including innovative approaches to change the food, social, built environment, or economic factors underlying diabetes risk or factors underlying obesity in the population, may benefit all four tiers regardless of risk.

Although the clearest evidence for how to prevent type 2 diabetes comes from studies conducted specifically in high-risk adults, type 2 diabetes is often thought of as a common-source epidemic that has been rooted in culture and society as much as in individual behaviors.<sup>25</sup> This is evident in many of the secular trends in risk factors in the U.S. population, including increased portion sizes, increased caloric intake of sweetened beverages and refined carbohydrates, and a calorie-to-cost mismatch that has made healthy

foods such as fruits and vegetables increase in cost more than unhealthy, energy-dense foods.<sup>26,27</sup> Considerable national variation exists in the options available around the U.S., as many communities, both rural and urban, have poor food choices and limited options for physical activity.

These macro-level determinants and obesity point to opportunities to influence population risk by targeting the food environment, the planning of communities, as well as social and economic factors.<sup>25,28–31</sup> Promising targets of the food environment that have been associated with diabetes risk in observational studies include approaches to increase fruit, vegetable, and whole-grain intake, and to reduce portion sizes and sweetened beverages.<sup>27,30</sup> Several strategies have been proposed for the food environment, including better food and menu labeling, and incentives for communities to support diverse healthy foods through farmers' markets and other diverse groceries.<sup>32</sup> Employers and schools may be key partners in their efforts because of their ability to alter procurement and availability of healthy foods and pass those options on to large segments of the population.

Although interventions that can reduce obesity in youth are unlikely to have a short-term payoff in diabetes incidence, they may have an important long-term impact. School-based nutrition and physical education policies, support of strong community-based recreation programs, and interventions to change advertising to youth are all promising approaches for youth.<sup>32</sup> Finally, public policy approaches that are able to change the educational and economic status of populations should be evaluated for their potential impact on diabetes and other chronic diseases. As an example, a recent social experiment in which low-income families were randomized to receive vouchers that moved them to healthier neighborhoods found reduced prevalence of obesity and diabetes after 5 years.<sup>33</sup> Such studies are rare, however, and are a reminder of the difficulty of demonstrating impact of policy approaches and the need for a broader spectrum of research to guide policies.<sup>34</sup>

# Conclusion

The existing and projected burden of diabetes requires that efforts to treat diabetes continue to improve and that effective strategies to prevent type 2 diabetes be implemented on a large scale. The strongest and clearest evidence for the prevention of type 2 diabetes is from RCTs in which people at high risk for type 2 diabetes are exposed to a structured lifestyle intervention that addresses nutrition, physical activity, and behavior change strategies that result in modest weight loss. Several translation studies have demonstrated that the lifestyle intervention can be delivered more cost effectively and achieve similar weight loss.

In response to the growing incidence of type 2 diabetes and the body of evidence for type 2 diabetes prevention in high-risk adults, Congress authorized the CDC to establish and lead

the National DPP. By serving as the backbone for bringing the effective lifestyle intervention across the country, the National DPP puts in place the necessary components of workforce training, quality assurance through program recognition, an effective program delivery and payment model, and health marketing to increase program uptake necessary for reducing the incidence of type 2 diabetes. Several aspects of the etiology of type 2 diabetes suggest that both high-risk and whole-population approaches are necessary to make a major impact on trends in the diabetes epidemic. These combined strategies will be more effective if they are implemented as a multi-tiered approach that links type and intensity of the intervention to the appropriate level of risk, as well as altering unhealthy cultural, environmental, and economic conditions that produce risk factors for type 2 diabetes.

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#### Figure 1.

Summary of the four core components of the National Diabetes Prevention Program *Note:* Provided by the CDC, Division of Diabetes Translation

#### Table 1

#### Risk stratification for diabetes prevention interventions

Risk level	10-year diabetes risk, %	Risk indicators	Intervention
Very high	30-40	HbA1c 5.7% and <6.5%; FPG >110	Structured lifestyle intervention in community setting
High	20–30	FPG 100 mg/dL and <126 mg/dL	
Moderate	10–20	2+ risk factors	Risk counseling
Low	0–10	0–1 risk factor	Whole-population strategies

*Note:* Relevant risk factors include being overweight; having a parent or sibling with diabetes; having a family background that is African-American, Hispanic/Latino, American Indian, Asian American or Pacific Islander; a history of gestational diabetes; diagnosed hypertension; and sedentary lifestyle.

FPG, fasting plasma glucose; HbA1c, hemoglobin A1c