

## **Diabetes Prevention Programs: Effectiveness and Value**

*Final Background and Scope*  
**April 1, 2016**

### **Background:**

The Centers for Disease Control and Prevention (CDC) estimates that 29.1 million Americans have diabetes and 1.7 million adults are newly diagnosed with diabetes mellitus each year.<sup>1</sup> The direct medical costs of diabetes were estimated to be \$176 billion in 2012.<sup>1</sup> Interventions to prevent diabetes have the potential to save the healthcare system substantial medical costs by reducing the incidence of diabetes and its associated complications. The Diabetes Prevention Program Trial (DPPT) demonstrated that the incidence of diabetes could be reduced using intensive diet and lifestyle counseling for individuals at very high risk for diabetes.<sup>2</sup> Since publication of the trial results, many commercial programs have been developed to implement a scalable version of the DPPT intervention using fewer resources. The CDC National Center for Chronic Disease Prevention and Health Promotion estimates that approximately 86 million Americans age 20 and older have prediabetes and are potentially eligible for such programs.<sup>1</sup> The definition of prediabetes used in the NHANES study comes from the American Diabetes Association (ADA),<sup>3</sup> and is broader than that used for participation in the DPPT. There has been controversy around the ADA definition of prediabetes, with proponents of a narrower definition arguing that too broad a definition will result in overdiagnosis and stigmatization.<sup>4</sup>

### **Report Aim:**

This project will evaluate the health and economic outcomes of archetypal programs with full or pending recognition from the CDC Diabetes Prevention Recognition Program (DPRP) to change behaviors (such as diet, exercise) in order to prevent diabetes. In addition, the report will provide context and a summary of information gathered from interviews with key stakeholders involved in the design and delivery of interventions seeking to prevent diabetes. Vendor perspectives, as well as those of payers, purchasers, and patient advocacy organizations will be sought. The report will not evaluate drugs or surgical procedures that may prevent diabetes, or lifestyle programs that are not specifically targeted to prevent diabetes.

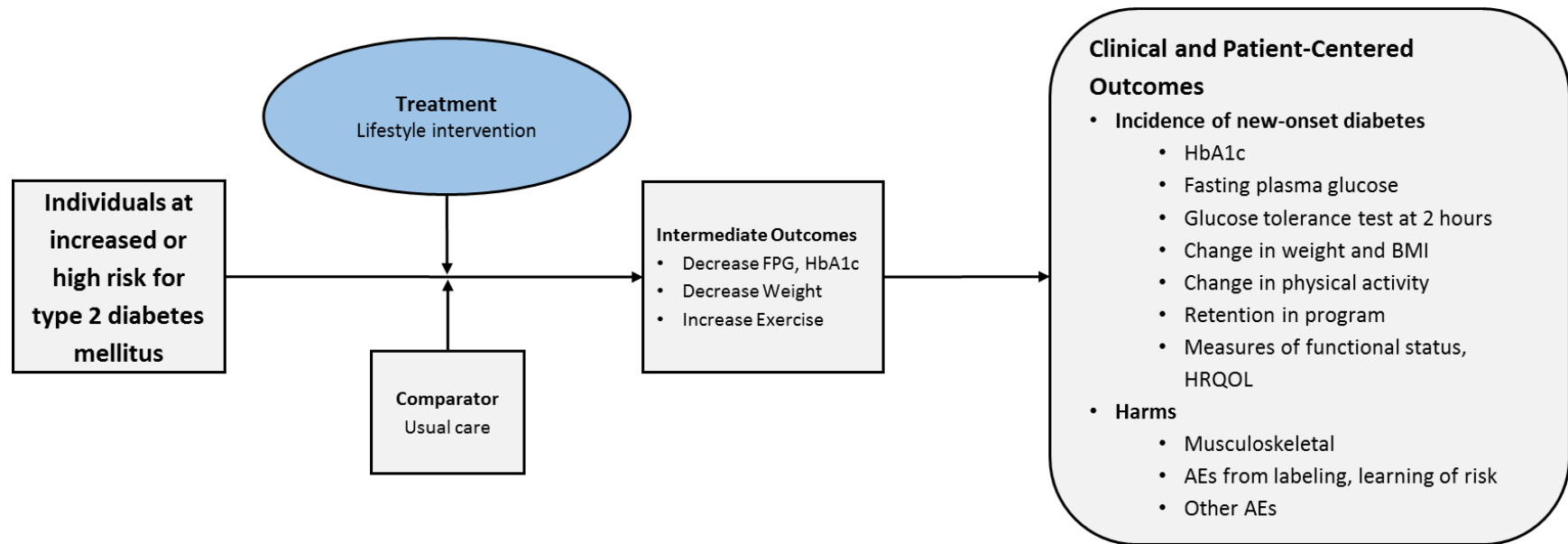
### **Scope of the Assessment:**

The proposed scope for this assessment is described below using the PICOTS (Population, Intervention, Comparators, Outcomes, Timing, and Settings) framework. Evidence will be culled from randomized controlled trials and comparative cohort studies as well as high-quality systematic reviews where available. We will also include case series that meet certain quality criteria (e.g., sample retention, consecutive patients, clearly-defined entry criteria, sample size thresholds, follow-up of 2+ years), and will describe data from these studies separately. We will supplement our review of published studies with data from regulatory documents, information submitted by vendors, and other grey literature when the evidence meets ICER standards (for more information, see <http://www.icer-review.org/policy-on-inclusion-of-grey-literature-in-evidence-reviews/>).

### **Analytic Framework:**

The analytic framework for this assessment is depicted in Figure 1 on the following page.

Figure: Analytic Framework: Diabetes Prevention with Lifestyle Interventions



FPG: fasting plasma glucose, HbA1c: hemoglobin A1c, BMI: body mass index, HRQOL: health-related quality of life; AE: adverse event

## Populations

The population of focus for the review is adults ages 18 and older with prediabetes. We will examine the impact of different definitions of prediabetes on the outcomes of interest.

## Interventions

The interventions of interest will include lifestyle interventions to prevent type 2 diabetes that have full or pending recognition from the CDC DPRP, including programs incorporating smart phone and web-assisted programs. Medical and surgical therapies will not be considered.

## Comparators

Wherever possible, we will seek out head-to-head studies of these interventions. In the absence of head-to-head studies, the primary comparator will be usual care, which may take multiple forms. If feasible, we will also make use of validated techniques for indirect comparisons (e.g. network meta-analysis) to compare the clinical effects of different lifestyle interventions.

## Outcomes

This review will examine clinical and health care utilization outcomes related to lifestyle interventions to prevent diabetes that have full or pending recognition from the CDC DPRP. To be included, studies must report the impact of the intervention on at least one measure of glycemic control or weight loss. Listed below are the outcomes of interest:

- Incidence of type 2 diabetes mellitus
- Hemoglobin A1c as a measure of glycemic control
- Fasting plasma glucose as a measure of glycemic control
- Glucose tolerance test at 2 hours as a measure of glycemic control
- Change in body weight and body mass index (BMI)
- Change in physical activity
- Retention in program
- Measures of functional status, and/or health-related quality of life
- Costs and cost-effectiveness of diabetes prevention programs

## Timing

Evidence on intervention effectiveness and harms will be derived from studies of at least one year's duration.

## Settings

All relevant settings will be considered, including telephonic, online, clinic, employer-based, community-based, and hybrid settings in the United States.

## **Economic Evaluation:**

We will review the published literature for analyses that have examined the economics of archetypal diabetes prevention programs with full or pending recognition from the CDC DPRP. This may include studies of the cost to initiate and operate diabetes prevention programs and/or specific components of

such programs, analyses of the costs that are potentially offset through the use of such programs (e.g., reduced downstream medical costs), and cost-effectiveness analyses. Our report will summarize what is currently known in the literature about the economic impact of diabetes prevention programs and specific components of those programs, the strength and validity of that evidence, and where gaps in knowledge still exist. If possible, we will also highlight those programs or program components best correlated with cost-offsets or favorable cost-effectiveness.

Data permitting, we will also model the estimated cost-effectiveness of diabetes prevention programs. Data needed for this evaluation will include the cost of initiating and operating such programs, their effectiveness in delaying or preventing incident diabetes cases as well as other intermediate outcomes that would lend themselves to assessing diabetes risk (e.g., changes in weight, measures of glycemic control, lipids, etc.), and the cost offsets associated with such delays. If sufficient data are available for multiple programs or their components, we will compare the cost-effectiveness of different types of diabetes prevention programs.

We will also explore the potential health system budgetary impact of diabetes prevention programs over a near-term time horizon, utilizing published or otherwise publicly-available information on program planning, implementation, and ongoing treatment costs, any cost offsets, and the potential population eligible for such services. These budgetary impact analyses will assume a specific program “uptake” rate over a 5-year period for specific populations of interest, given the availability of relevant data. This analysis will indicate the potential budgetary impact of widespread implementation of diabetes prevention programs, and allow assessment of any need for managing the cost of such interventions. More information on ICER’s methods for estimating product uptake and calculating potential budget impacts can be found at: <http://www.icer-review.org/wp-content/uploads/2014/01/Slides-on-value-framework-for-national-webinar1.pdf>.

#### References:

1. Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014. 2014.
2. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *The New England journal of medicine*. 2002;346(6):393-403.
3. American Diabetes Association. Diagnosis and classification of diabetes mellitus. *Diabetes care*. 2010;33 Suppl 1:S62-69.
4. Yudkin JS, Montori VM. The epidemic of pre-diabetes: the medicine and the politics. *BMJ (Clinical research ed.)*. 2014;349:g4485.