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About ICER

The Institute for Clinical and Economic Review (ICER) is an independent non-profit research organization that evaluates medical evidence and convenes public deliberative bodies to help stakeholders interpret and apply evidence to improve patient outcomes and control costs. ICER receives funding from government grants, non-profit foundations, health plans, provider groups, and health industry manufacturers. For a complete list of funders, visit http://www.icer-review.org/about/support/. Through all its work, ICER seeks to help create a future in which collaborative efforts to move evidence into action provide the foundation for a more effective, efficient, and just health care system. More information about ICER is available at http://www.icer-review.org

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The California Technology Assessment Forum (CTAF) – a core program of ICER – provides a public venue in which the evidence on the effectiveness and value of health care services can be discussed with the input of all stakeholders. CTAF seeks to help patients, clinicians, insurers, and policymakers interpret and use evidence to improve the quality and value of health care.

The CTAF Panel is an independent committee of medical evidence experts from across California, with a mix of practicing clinicians, methodologists, and leaders in patient engagement and advocacy. All Panel members meet strict conflict of interest guidelines and are convened to discuss the evidence summarized in ICER reports and vote on the comparative clinical effectiveness and value of medical interventions. More information about CTAF is available at http://www.ctaf.org
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<th>Full Form</th>
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<tbody>
<tr>
<td>ACA</td>
<td>Affordable Care Act</td>
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<tr>
<td>ACO</td>
<td>Accountable care organization</td>
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<tr>
<td>ADA</td>
<td>American Diabetes Association</td>
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<tr>
<td>AE</td>
<td>Adverse event</td>
</tr>
<tr>
<td>AHIP</td>
<td>America’s Health Insurance Plans</td>
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<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
</tr>
<tr>
<td>AMA</td>
<td>American Medical Association</td>
</tr>
<tr>
<td>BI</td>
<td>Budget impact</td>
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<tr>
<td>BMI</td>
<td>Body mass index</td>
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<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>CDPH</td>
<td>California Department of Public Health</td>
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<tr>
<td>CEA</td>
<td>Cost-effectiveness analysis</td>
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<tr>
<td>CI</td>
<td>Confidence interval</td>
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<tr>
<td>CMMI</td>
<td>Center for Medicare and Medicaid Innovation</td>
</tr>
<tr>
<td>CMS</td>
<td>Centers for Medicare &amp; Medicaid Services</td>
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<tr>
<td>CVD</td>
<td>Cardiovascular disease</td>
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<tr>
<td>DHCS</td>
<td>Department of Health Care Services</td>
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<tr>
<td>DM</td>
<td>Diabetes mellitus</td>
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<tr>
<td>DPP</td>
<td>Diabetes prevention program</td>
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<tr>
<td>DPPOS</td>
<td>Diabetes Prevention Program Outcomes Study</td>
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<tr>
<td>DPRP</td>
<td>Diabetes Prevention Recognition Program</td>
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<tr>
<td>EHR</td>
<td>Electronic health record</td>
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<tr>
<td>FPG</td>
<td>Fasting plasma glucose</td>
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<tr>
<td>GDM</td>
<td>Gestational diabetes mellitus</td>
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<tr>
<td>HbA1c</td>
<td>Hemoglobin A1c</td>
</tr>
<tr>
<td>HRQOL</td>
<td>Health-related quality of life</td>
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<tr>
<td>HHS</td>
<td>Health &amp; Human Services</td>
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<tr>
<td>ICSI</td>
<td>Institute for Clinical Systems Improvement</td>
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<tr>
<td>IFG</td>
<td>Impaired fasting glucose</td>
</tr>
<tr>
<td>IGT</td>
<td>Impaired glucose tolerance</td>
</tr>
<tr>
<td>NDEP</td>
<td>National Diabetes Education Program</td>
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<td>NDPP</td>
<td>National Diabetes Prevention Program</td>
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<tr>
<td>NHANES</td>
<td>National Health and Nutrition Examination Survey</td>
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<tr>
<td>NIH</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>OGTT</td>
<td>Oral glucose tolerance test</td>
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<tr>
<td>P4P</td>
<td>Pay for performance</td>
</tr>
<tr>
<td>PICOTS</td>
<td>Population, Intervention, Comparators, Outcomes, Timing, and Settings</td>
</tr>
<tr>
<td>PRISMA</td>
<td>Preferred Reporting Items for Systematic Reviews and Meta-Analyses</td>
</tr>
<tr>
<td>PSA</td>
<td>Public service advertisement</td>
</tr>
<tr>
<td>QALY</td>
<td>Quality-adjusted life-year</td>
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<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>ROI</td>
<td>Return on investment</td>
</tr>
<tr>
<td>RR</td>
<td>Risk ratio</td>
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<tr>
<td>RRR</td>
<td>Relative risk reduction</td>
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<tr>
<td>SF-36</td>
<td>36-Item Short-Form Health Survey</td>
</tr>
<tr>
<td>STAT</td>
<td>Screen, Test, Act Today</td>
</tr>
<tr>
<td>UCLA</td>
<td>University of California, Los Angeles</td>
</tr>
<tr>
<td>USPSTF</td>
<td>United States Preventive Services Task Force</td>
</tr>
<tr>
<td>VLM</td>
<td>Virtual Lifestyle Management</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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</table>
Executive Summary

Background

According to the Centers for Disease Control and Prevention (CDC), approximately 86 million Americans age 20 and older (37%) have prediabetes (i.e., blood glucose levels higher\(^a\) than normal but not high enough to be diagnosed with diabetes) and 90% of those with prediabetes do not know they have it.\(^1\) In California, a recent study found that 13 million adults in the state have prediabetes or undiagnosed diabetes (about 46%).\(^2\)

Interventions to prevent diabetes have the potential both to improve individual health and quality of life through disease avoidance (e.g., eye, kidney, and nerve damage; strokes; heart attacks) and to save the health care system substantial medical costs by reducing the incidence of diabetes and its associated complications. Without such interventions, it is estimated that 15-30% of individuals with prediabetes will develop type 2 diabetes mellitus (DM) within five years.\(^1\) The Diabetes Prevention Program Trial (DPP Trial) demonstrated that the incidence of diabetes could be reduced using intensive diet and lifestyle counseling for individuals at high risk for developing diabetes.\(^3\) Since publication of the trial results in 2002, many commercial programs have been developed to implement a less expensive, scalable version of the DPP Trial intervention.

Topic in Context

This report addresses several key issues related to diabetes prevention programs (DPPs) for patients, provider organizations, payers, and other policymakers and includes: 1) a landscape analysis of available DPP approaches and relevant policy considerations; 2) a comparative effectiveness evaluation of DPPs participating in the CDC Diabetes Prevention Recognition Program (DPRP); and 3) an assessment of the costs, cost-effectiveness, and potential budget impact of DPPs.

Studies have shown that 5-7% weight loss can prevent the development of diabetes in individuals with elevated levels of blood sugar consistent with prediabetes, and many clinicians and researchers use weight loss as a surrogate measure for effective prevention of diabetes.\(^4,5\) Participants in the DPP Trial lowered their body weight by approximately 7% after one year (decreasing to weight loss of about 4% after four years), which led to a 58% reduction in the risk of

---

\(^a\) Hemoglobin A1c (HbA1c) between 5.7 and 6.5%, fasting plasma glucose (FPG) between 100-125, and oral glucose tolerance test (OGTT) between 140 and 199. As explained in section 6.3 of the full report, use of a FPG threshold for prediabetes of 110 mg/dL rather than 100 mg/dL decreases the number of people estimated to have prediabetes by about two-thirds.
progressing to diabetes over three years compared with standard lifestyle recommendations plus a placebo.\textsuperscript{3,6} The lifestyle intervention was also more effective than drug therapy with metformin.

Because the initial DPP Trial involved individual counseling and the one-year program cost was about $1,400 per participant, subsequent research and practice have focused on replicating the results with programs that could be distributed more widely at a lower cost. Several published studies have examined the effectiveness of DPPs delivered in community settings, and more recently, in digital/online formats, both of which have reported significant weight loss.\textsuperscript{7-9}

The CDC developed the National Diabetes Prevention Program (NDPP), a public/private partnership working to offer evidence-based, cost-effective interventions across the US with the goals of reducing the growing problem of prediabetes and type 2 DM as well as to build on the DPP Trial results with a focus on scalability. Organizations delivering a DPP with three key components – a CDC-approved curriculum\textsuperscript{b} that promotes 5-7% weight loss and increased physical activity, a lifestyle coach, and a peer support group of program participants – can apply for CDC recognition through the DPRP. To achieve recognition, programs must submit data annually to assess program impact on preventing or delaying the onset of type 2 DM.

**Barriers and Opportunities**

**Scalability**

To attain the NDPP goal of scalability, the format of DPPs has evolved from individual in-person counseling in the DPP Trial to in-person group sessions, and more recently to digital programs delivered via computer, tablet, or phone (see Table ES1). Among the digital programs currently available, some are delivered to virtual groups that are assigned a human coach while another delivers coaching messages through a fully-automated system based on algorithms.

\textsuperscript{b} In addition to the DPP curriculum publicly available from the CDC, organizations offering DPPs can submit their curricula to the CDC for review. If approved, organizations can then seek recognition.
### Table ES1. Key Features of DPPs

<table>
<thead>
<tr>
<th>Format</th>
<th>Scalability</th>
<th>Cost*</th>
<th>Typical Group Size</th>
<th>Key Resources</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-person, individual coaching</td>
<td>Lowest</td>
<td>Highest</td>
<td>1</td>
<td>Humans, facilities</td>
<td>DPP Trial</td>
</tr>
<tr>
<td>In-person, group coaching</td>
<td>Medium</td>
<td>Medium</td>
<td>8-15</td>
<td>Humans, facilities</td>
<td>Weight Watchers for Prediabetes</td>
</tr>
<tr>
<td>Digital, human coaching (virtual interaction)</td>
<td>High</td>
<td>Medium</td>
<td>1-24</td>
<td>Humans, technology</td>
<td>Virtual Lifestyle Management (VLM™, Canary Health, Inc.) Prevent® (Omada Health, Inc.)</td>
</tr>
<tr>
<td>Digital, fully-automated coaching (based on algorithms)</td>
<td>Highest</td>
<td>Lowest</td>
<td>1</td>
<td>Technology</td>
<td>Alive-PD™ (Turnaround Health)</td>
</tr>
</tbody>
</table>

*Average costs and cost-offsets by program type are available in Appendix Table I1

**Coverage of DPPs by Health Plans and Purchasers**

One of the major goals of the CDC and its NDPP partners is to increase access to DPPs by promoting health insurance coverage in both public and private settings. Medicare does not currently cover DPPs, and only one state Medicaid program (Montana) does. There is wide variation among private health plans in their coverage of DPPs, but at least 30 private plans currently cover DPPs for some of their enrollees. Some private and public purchasers are incorporating DPPs into their health plans or wellness programs, or offering them as standalone benefits, but it is challenging to assess how extensive these practices are. Increased payer coverage of DPPs may be forthcoming based on 1) a proposal by Medicare to expand coverage of DPPs to all Medicare beneficiaries (using the 110 mg/dL FPG threshold), 2) a CDC initiative to partner with two to three states to expand Medicaid coverage for DPPs, and 3) two US Preventive Services Task Force (USPSTF) recommendations related to DPPs with a grade of B (i.e., services that must be covered by private plans without patient cost sharing to be compliant with the Affordable Care Act [ACA]).

**Additional DPP Implementation Considerations**

Despite several national and state efforts to increase awareness of prediabetes and the use of DPPs, the expansion of DPPs is challenged by several factors that are discussed in greater detail in the full report and include:

1) A steep learning curve in terms of data collection and analysis requirements for DPPs seeking CDC recognition, as well as limitations on data sharing among providers, patients, DPP vendors, and plans;
2) A need for better, culturally-appropriate methods to reach underserved communities with populations at high risk of diabetes based on race/ethnicity, literacy, and income; and a need for innovative approaches to retain such participants in the year-long program;

3) A need for greater provider awareness of prediabetes and increased referral by providers of patients to DPPs, as well as more linkages between clinicians and DPPs;

4) The extensive efforts required to screen, identify, train, and retain skilled lifestyle program coaches who can connect to the community targeted by the DPP; and

5) A lack of awareness of prediabetes by many individuals who are at risk of developing diabetes and who must be willing to make a commitment to a year-long program of behavior change.

**Comparative Clinical Effectiveness of DPPs**

Since publication of the initial results of the DPP Trial, there have been more than 50 studies translating the lifestyle intervention to real world settings. Several systematic reviews found that these programs decrease body weight, decrease fasting plasma glucose, improve blood pressure and cholesterol levels, and prevent the onset of type 2 DM.\textsuperscript{11-16} The CDC and the Community Preventive Services Task Force recently commissioned a review of programs that promote dietary changes and physical activity to prevent diabetes.\textsuperscript{14} This high-quality systematic review and meta-analysis summarized 53 studies describing 66 diet and activity programs published through February 2015. They found that diet and exercise programs reduced diabetes incidence by 41% (95% confidence interval [CI]: 34% to 48%) compared with usual care. The programs also reduced body weight by 2.2% (95% CI: 1.4% to 2.9%) and FPG by 2.2 mg/dL (95% CI: 0.9 to 3.6 mg/dL). The more intensive programs, like the DPP Trial intervention, were more effective.\textsuperscript{14}

This evidence review summarizes the published literature for lifestyle interventions in the US that have full or pending recognition through the DPRP. The literature search identified 10 studies that met our inclusion criteria (five randomized controlled trials [RCTs], five case-series using a pre-post design).\textsuperscript{7-9,17-31} The studies are grouped by degree of human contact ranging from in-person individual counseling performed on a weekly, one-on-one basis with a trained health care professional (DPP Trial) to digital with fully-automated counseling (Alive-PD). Studies using in-person group counseling were the most common, and included four studies in the Y system (formerly referred to as the YMCA), one supported by the Montana Department of Public Health and Human Services, one at Weight Watchers, and one at Wake Forest University.

**Quality of the Studies**

The original DPP Trial was a large, good-quality trial with long enough follow-up (15 years) to assess the impact of the intervention on diabetes incidence.\textsuperscript{3} Three of the implementation trials were randomized trials of good quality (RAPID, Alive-PD, HELP-PD), though the Alive-PD trial has only published six-month outcomes.\textsuperscript{18,21,27} The lifestyle changes necessary to prevent or delay the
development of diabetes need to be sustained for decades, so outcomes beyond the initial intensive intervention period are preferred. The two other randomized trials (DEPLOY, Weight Watchers) were judged to be of fair quality because of baseline differences between the groups and significant loss to follow-up.\textsuperscript{7,8}

Among the pre-post case series, one (Prevent) was judged to be of fair quality because although case series provide weaker evidence than RCTs, the study included a careful description of the participants, and featured adequate length and completeness of follow-up, objective outcome measures, and appropriate analysis methods.\textsuperscript{9,30} The other four were judged to be of poor quality because of the small number of participants with prediabetes, the use of self-reported outcomes, and significant loss to follow-up.\textsuperscript{23,24,29,31}

**Weight Loss**

In the DPP Trial, weight loss was the primary predictor of the reduction in diabetes incidence,\textsuperscript{4,5} ranging from a 35% reduction among participants with 0-3% weight loss to 85% reduction for participants with >10% weight (see figure ES1).\textsuperscript{5} Participants in the lifestyle intervention also had reductions in blood pressure and improvements in cholesterol measurements that should translate into additional benefits in the long term prevention of cardiovascular disease.\textsuperscript{32}

**Figure ES1. Correlation of Percentage Weight Loss with Reduction in the Risk of Diabetes for Patients in the Intensive Lifestyle Intervention Arm of the DPP Trial**

With one exception, weight loss at one year was consistently in the 5-7% range across the studies of in-person counseling (individual or group), with the DPP Trial and the HELP-PD studies at the upper end of the range (see Figure ES2). The weight loss results for the two programs using a digital with a
human coach design were somewhat lower (4-5%). The VLM study did not report percentage weight loss overall but was estimated to be about 4.5% (from data and figures in the published results). In the Prevent trial, the average weight loss at 12 months was 4.8%. The study results of a digital DPP with fully-automated counseling design (Alive-PD) showed a 3.6% weight loss at six months, which is only about half the weight loss reported in the DPP Trial at six months; this may reflect the lack of a primary weight loss goal in their program.

**Figure ES2. Percentage Weight Loss at Six and 12 Months for Translational DPPs compared with the DPP Trial**

![Graph showing percentage weight loss at six and 12 months for various programs](image)

* Estimated from results in publication

**Glycemic Control**

Half of the available studies reported some measure of change in glycemic control during follow-up. In the original DPP Trial, there was only a small reduction in HbA1c (-0.1%) and in FPG (-5 mg/dL) at one year in the lifestyle group. Among the in-person group counseling programs, the DEPLOY study had a similar reduction in HbA1c at six and 12 months (-0.1%); the Weight Watchers study reported a greater reduction in HbA1c at 12 months (-0.26%) but a smaller reduction in FPG (-2.8 mg/dL); and the HELP-PD study only reported changes in FPG (-4.5 mg/dL) at 12 months.

Among the digital with human coach programs, only the Prevent study reported results, but the change in HbA1c (-0.4% at 12 months) was the largest reported of any program including the
original DPP Trial. Interestingly, even though the Alive-PD program (digital with fully automated counseling) reported a relatively low percentage weight loss at 6 months (3.6%), the reductions in HbA1c (-0.3%) and FPG (-7.4 mg/dL) were greater than those observed in most other studies. This may reflect the greater focus on diabetes prevention and control as the primary goal of their dietary intervention rather than weight loss.

**Diabetes Incidence**

Most of the studies were of too short a duration to assess incident diabetes. The HELP-PD study (in-person group counseling) reported that the diabetes incidence at two years was non-significantly lower in the lifestyle group than in the usual care group (3.0% versus 8.7%, p=0.10).

**Other Cardiovascular Risk Factors**

The DPP Trial reported reductions in blood pressure and improvements in total and HDL-cholesterol levels (Appendix Table H10). These improvements, though small, could contribute to an overall reduction in cardiovascular disease independent of the reduction in diabetes incidence. Among the in-person group counseling programs, the DEPLOY study reported greater improvements in cholesterol than those reported in the DPP Trial. The Weight Watchers study reported similar reductions in blood pressure compared with the DPP Trial and a greater increase in HDL-cholesterol, but also a small increase in total cholesterol. Finally, the VLM study (digital with a human coach) reported twice the reduction in systolic blood pressure compared with the DPP Trial, but a slight increase in diastolic blood pressure. None of the other digital programs reported changes in blood pressure or cholesterol levels.

**Harms**

There was no excess of adverse events or serious adverse events in patients randomized to the lifestyle intervention in any of the randomized trials. The DPP Trial and other RCTs specifically assessed myalgias, arthralgias, fractures and other musculoskeletal complaints and no significant increases were observed for participants in the lifestyle group.

**Controversies and Uncertainties**

The degree of weight loss observed in translational DPP studies is somewhat less than that attained by participants in the DPP Trial, and the long-term sustainability of this weight loss has not yet been demonstrated. The primary uncertainty is whether the one-year weight loss observed in these studies will lead to a significant reduction in the incidence of diabetes in these patients and whether the reduction (or delay) in the diagnosis of diabetes will result in meaningful reductions in the complications of diabetes for patients with prediabetes. At 15 years of follow-up, there was no reduction in either microvascular disease or cardiovascular disease in the DPP Trial.
Additional controversy arises from the definition of prediabetes. In clinical practice, patients with prediabetes are usually diagnosed by measurement of FPG. In the US, the American Diabetes Association (ADA) defines a FPG of 100-125 mg/dL as prediabetes, but the World Health Organization (WHO) definition requires a FPG of 110-125. Patients with a FPG of 100-109 mg/dL are at lower risk for progression to diabetes and may receive less benefit from intensive lifestyle interventions. Furthermore, critics of the term “prediabetes” have raised concerns about the adverse effects of labeling patients given that prediabetes is simply a group at high risk for diabetes, which in itself is primarily a risk factor for conditions that matter to patients: strokes, heart attacks, blindness, kidney failure, and death.\(^{33}\)

**Comparative Clinical Effectiveness: Summary and Comment**

We judge the evidence for the CDC-recognized intensive lifestyle programs using an in-person group coaching design to provide an incremental or better (B+) net health benefit when compared to usual care for patients with prediabetes. There is no question that these programs yield modest weight loss in the short term compared with usual care. However, there is moderate certainty of a net benefit because of the uncertainties about the long-term durability of weight loss and the long-term improvements in health from the modest weight reductions demonstrated after one to two years of follow-up in the published studies.

We also judge the evidence for the CDC-recognized intensive lifestyle programs using a digital with human coach design to provide an incremental or better (B+) net health benefit when compared to usual care for patients with prediabetes. There is more uncertainty in this judgement than that for in-person group coaching because the number of studies is smaller (two) and because there are no good-quality trials. However, there is clearly modest weight loss with these programs through two years compared with usual care that is similar in magnitude to that observed with the in-person group coaching programs. There is uncertainty about the long-term durability of weight loss and subsequent long-term health improvements similar to that described for the in-person group counseling programs.

We judge the evidence for the CDC-recognized intensive lifestyle programs using a digital with fully automated coaching design to provide comparable or better (C+) net health benefit when compared to usual care for patients with prediabetes. There is greater uncertainty of a net benefit for the fully automated approach because there is only one trial, it only reported six month outcomes, and the weight loss was qualitatively less than that observed in the original DPP Trial and the majority of the other translational programs. However, it was a high-quality randomized trial that showed statistically significant improvements in body weight and glycemic control compared with usual care.

We judge that there is Insufficient Evidence (I) to distinguish the efficacy of any one approach (in-person group counseling; digital with a human coach; digital with fully-automated counseling) from
the others. There are no randomized trials or cohort studies that directly compare any two of the approaches, and the evidence base is too sparse to perform a network meta-analysis.

**Other Benefits or Disadvantages**

The primary additional benefit would be the public health benefits that may result from decreasing weight and increasing physical activity of a large segment of the population. In addition to the likely reductions in diabetes and cardiovascular disease described above, there may be reductions in some of the many complications of obesity including arthritis, sleep apnea, and esophageal reflux disease. Further, exercise has been proposed to improve mental health and quality of life, and to decrease long-term disability.

**Comparative Value of DPPs**

We reviewed the published literature for analyses that have examined the economics of DPPs in the US with full or pending recognition from the CDC DPRP. We also explored the potential health system budget impact of DPPs 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.

**Cost-Effectiveness Analyses**

Li et al. conducted a systematic review of economic analyses of “diet and physical activity promotion programs with at least two sessions over at least three months delivered to persons at increased risk for type 2 DM.” Overall, the median cost per quality-adjusted life-year (QALY) for the eight US-based analyses was $9,824, with an interquartile range of $1,930 to $41,982 per QALY gained. However, the authors noted that few studies included information on recruitment costs, or on the cost to scale up these programs.

**In-person, Individual Coaching**

**DPP Trial**

The DPP Research Group has conducted multiple analyses based on the DPP Trial. From a health system perspective, the cost per QALY for the intensive lifestyle intervention decreased as the time horizon increased, from $32,000/QALY at three years, to $13,000/QALY at 10 years, and $1,100/QALY using a lifetime time horizon.

In contrast to the above analyses, Eddy et al. conducted a cost-effectiveness analysis (CEA) of the DPP lifestyle intervention using the Archimedes model, which simulates detailed anatomic and physiologic components of several diseases. Over a 30-year time horizon, they found that the DPP
Trial intervention would cost approximately $143,000 per QALY gained from a health system perspective. The primary differences from the DPP Research Group models were that Eddy et al. assumed that the clinical benefits of the DPP would diminish over time, that there would be a lower rate of glycemic progression (i.e., slower progression from prediabetes to diabetes, and from diabetes diagnosis to complications). Their health system perspective analysis also assumed a rate of participant turnover, which would lead to higher estimated cost-effectiveness ratios than in the DPP Trial evaluations.

**In-person, Group Coaching**

**DPP Trial**

As part of the DPP Research Group’s within-trial CEA of the DPP Trial, they evaluated the DPP as a group intervention rather than an individual one, assuming lower costs but equal effectiveness. The group DPP was estimated to cost $4,500 per diabetes case prevented and $9,000 per QALY gained from a health system perspective at three years. In their evaluation of the lifetime cost-effectiveness of the DPP Trial intervention, Herman and colleagues also estimated the impact if costs could be reduced by implementing the lifestyle intervention in groups of 10 participants rather than one-to-one coaching, assuming equal clinical effectiveness. They estimated that the program would be cost-saving over a lifetime, even if effectiveness were reduced by 50%. Finally, Eddy et al. evaluated a scenario where the DPP was provided as a group intervention costing $217 per year, and they estimated a cost per QALY of $27,000 from a health system perspective.

**Diabetes Education & Prevention with a Lifestyle Intervention Offered at the Y (DEPLOY)**

RTI International conducted an evaluation of the Y DPP using claims analysis based on the Center for Medicare & Medicaid Services’ (CMS) Chronic Conditions Data Warehouse through 2014. The authors compared 1,679 participants to propensity score-matched Medicare beneficiaries diagnosed with prediabetes, and found statistically significant reductions in spending for the treatment group in the first five calendar quarters of the program with no significant differences in subsequent quarters. The overall weighted average quarterly spending differential was calculated as $455 per member per quarter.

The CMS Office of the Actuary developed a model to project net costs per beneficiary over a lifetime horizon, as detailed in a Certification of Medicare DPP memorandum. The model estimated net costs or savings per year from lowering the probability of progression to diabetes and thus delaying diabetes-related costs, and it assumed that the Medicare DPP expansion would be somewhat less effective than the DPP Trial because it was less intensive. Their analysis estimated that near-term savings would be offset by higher Medicare spending due to lower mortality, making it unclear whether the DPP expansion would break even over a lifetime horizon. If the mortality
reduction is ignored (as required in the certification process), the model suggested that the DPP would reduce Medicare expenditures.

**Digital, Human Coaching**

*Prevent (Omada Health)*

A recent analysis examined the return on investment (ROI) of the Prevent digital DPP. A Markov-based model with a 10-year time horizon was used to compare Prevent DPP participants with propensity score-matched community controls with prediabetes. Their simulation found a break-even point at three years, with a positive ROI of $1,565 at five years. One limitation of this study is that it relied on only 26 weeks of weight loss data from Prevent participants, which required assumptions about longer-term weight loss.

*VLM (Canary Health)*

Smith et al. assessed the cost-effectiveness of the VLM DPP using a Markov model with a 10-year time horizon. Costs and changes in weight came from a pre-post study of the VLM intervention, which estimated an incremental cost of $458 and incremental gain of approximately 0.06 QALYs compared to usual care in a hypothetical cohort without diabetes. They estimated that the intervention would cost approximately $7,800 per QALY gained from a health system perspective. Using a $100,000 per QALY threshold, the intervention was found to be cost-effective in over 95% of model iterations in a probabilistic sensitivity analysis. However, it should be noted that these results are based on data from one study using a one-year before/after design in 50 patients, 14 of whom already had diabetes.

**Digital, Fully-automated Coaching**

We were unable to locate any publicly-available CEAs of digital DPPs with fully-automated coaching.

**Potential Budget Impact**

We also estimated the potential budget impact of different types of DPPs among candidate populations for such treatment in the US. Our estimates are based on those found in the published and grey literature, as well as communications with individual DPP vendors. We combined estimates of the mean cost per participant with estimates of the prediabetes population potentially eligible for DPPs, as well as different assumed levels of uptake of such programs.

Potential budget impact was defined as the total incremental cost of DPPs for the enrolled population, calculated as the incremental health care costs of DPPs minus any health care costs that were offset in enrolled participants. All costs were undiscounted and estimated over one- and five-year time horizons. The five-year timeframe was of primary interest, given the potential for cost
offsets to accrue over time. The candidate population size is approximately 93.7 million individuals in the US using FPG of 100-125 mg/dL as the definition of prediabetes and approximately 31.2 million individuals using 110-125 mg/dL. We assumed that 2% of the eligible population would enroll in each year.

Over the entire five-year time horizon, 10% uptake for individuals meeting the ADA definition (i.e., including individuals with FPG of 100-109 mg/dL) would lead to approximately 9.4 million individuals enrolled in a DPP for one or more years. Across this timeframe, the weighted potential budget impact (i.e., adjusted for differing periods of utilization and associated cost-offsets) for in-person individual programs is approximately $2,800 per participant, leading to an average annual potential budget impact of approximately $5.2 billion. Estimated savings from enrollment in in-person group and digital automated programs, which are cost-saving after one year, continue to accrue over five years, resulting in estimated potential savings of $2.2 billion and $130 million per year, respectively. Digital programs with human coaches increase costs by $220 million over a one-year time horizon, but generate potential cost savings of approximately $1.2 billion over a five-year time horizon. Results of the potential budget impact analysis using the broader definition of prediabetes are presented in Table ES2, while results using the narrower definition can be found in section 6.3 of the full report.

Table ES2. Total Potential Budget Impact (BI) of DPPs Based on 10% Uptake at One and Five Years Using FPG of 100-125 mg/dL (n=9,366,203)

<table>
<thead>
<tr>
<th>DPP Type</th>
<th>Analytic Horizon = 1 Year</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number Enrolled (millions)</td>
<td>Annual BI per Participant ($)</td>
<td>Total BI (billions)</td>
<td>Number Enrolled (millions)</td>
<td>Weighted BI per Participant ($)</td>
<td>Average BI per year (billions)</td>
<td></td>
</tr>
<tr>
<td>In-person, Individual Coaching</td>
<td>1.87</td>
<td>$1,902</td>
<td>$3.56</td>
<td>9.37</td>
<td>$2,793</td>
<td>$5.23</td>
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<tr>
<td>In-person, Group Coaching</td>
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<td>-$455</td>
<td>-$0.85</td>
<td>9.37</td>
<td>-$1,146</td>
<td>-$2.15</td>
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<tr>
<td>Digital, Human Coaching</td>
<td>1.87</td>
<td>$117</td>
<td>$0.22</td>
<td>9.37</td>
<td>-$618</td>
<td>-$1.16</td>
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</tr>
<tr>
<td>Digital, Fully-automated Coaching</td>
<td>1.87</td>
<td>-$24</td>
<td>-$0.04</td>
<td>9.37</td>
<td>-$72</td>
<td>-$0.13</td>
<td></td>
</tr>
</tbody>
</table>

*Weighted budget impact calculated by subtracting cost offsets from DPP costs for one-year horizon. For five-year horizon, DPP costs and cost offsets apportioned assuming 20% of patients in uptake target initiate therapy each year.

Figure ES3 demonstrates the variation in potential budget impact levels associated with different uptake assumptions when using the 100-125 mg/dL definition. Varying rates of uptake using the 110-125 mg/dL definition would result in a similar pattern (see Appendix Figure I1), but with smaller annualized costs for individual in-person programs and smaller annualized savings for in-person group, digital human-coached, and digital automated programs.
Figure ES3. Potential Budget Impact Graph for DPPs Provided to Varying Proportions of the US Population with FPG 100-125 mg/dL

Note: Colored lines represent the annualized potential budget impact of different uptake patterns (percent of eligible population enrolled) for each type of DPP.

Comparative Value: Summary and Comment

With one exception, the consensus in the literature is that the cost-effectiveness of an in-person DPP at the individual level is well below commonly-accepted thresholds. Providing the program in a group setting appears to be cost-saving over time, with little or no apparent loss in effectiveness relative to individual coaching. Delivering the DPP via digital adaptations with human coaches also appears to be cost-effective or cost-saving, although these findings are based on fewer studies with only short-term effectiveness data available to date. We were unable to find any published evaluations of the cost-effectiveness of digital fully-automated programs for delivery of a DPP. While online adaptations are less costly than in-person DPPs, longer-term studies are needed to determine whether online versions of the DPP will provide comparable effectiveness over time. In addition, it should be noted that analyses sometimes differed in how they defined program participation (e.g., enrollment vs. completion) and in how that relates to program costs; more standardized definitions would make comparisons across program types more comparable.

Our estimates of the short-term potential budget impact of these programs were more variable and depended on using averages across relatively sparse data, especially for the digital programs. Using averages of the available data within program type and the assumptions in our analysis, in-person individual DPPs had positive annual budget impacts over five years, while in-person group and
Digital coached programs appear to be cost-saving in the short-term. We estimated that a digital fully-automated program was relatively budget neutral or slightly cost-saving, but available data was most limited for this category of programs. It should also be noted that this analysis was based on annual program costs that did not include development or start-up costs for these programs, which may be substantial. One area where further research would be helpful is the tabulation of such costs, as well as detailed cost and cost offset data from implementations of DPPs in different settings.

Furthermore, our estimates of levels of DPP uptake in the health care system by five years were based on arbitrary assumptions, so actual uptake may not reach these levels this quickly. In addition, the costs used in our analysis came from a specific set of programs, and so may not be representative of the costs for such programs in other settings in the US.

Finally, further data on the long-term effectiveness of these programs in maintaining weight loss and diabetes risk reductions would confirm whether these programs will actually be cost-effective or cost-saving over time. This would be especially useful for the newer, digital adaptations of the DPP. There is also a need for data on the costs and effectiveness of these programs in different populations and settings, evaluation of the efficacy of maintenance modules of the digital programs, and a need to measure the efficiency of extending these programs to lower-risk groups.