

Diabetes Prevention Programs: Effectiveness and Value

Summary of Public Comments Received on Draft Evidence Report and ICER Response

The Institute for Clinical and Economic Review (ICER) values the opportunity to receive and respond to public comment on its work products by interested stakeholders. There were nine sets of stakeholder comments submitted in response to the Draft Evidence Report on diabetes prevention programs (DPPs) that was posted on May 9, 2016. Below is a summary of the major comments received, organized by report component, along with responses from the ICER team and its research collaborators, including any major changes made to the report. We also received a number of comments asking for language clarification and/or other minor corrections in our draft report. While not summarized in detail here, we have adjudicated each stated concern and revised our report when appropriate.

Overarching Concerns

- We received two comments suggesting that bariatric surgery should be included as an intervention to prevent or treat diabetes. As noted in the scoping document, our goal was to assess the value of lifestyle-based interventions that are certified by the CDC for the prevention of diabetes. While we appreciate the value of bariatric surgery for specific patient populations, this was beyond the scope of this assessment. ICER and CTAF previously reviewed the evidence on various approaches to obesity management, including bariatric surgery for individuals with a BMI of 30 to 35 kg/m² and type 2 diabetes, at its July 2015 meeting. Additional information can be found here: <http://icer-review.org/topic/obesity-management/>.
- Two commenters suggested the addition of language describing the heterogeneity of DPPs, particularly with respect to the in-person programs. We fully concur that the programs are heterogeneous and that the professional background of the individuals performing the coaching for in-person DPPs may impact the effectiveness of such programs. We have added additional emphasis to this effect in the assessment.
- One reviewer noted that it may be more accurate to describe the effect of DPP interventions as delaying rather than truly preventing the diagnosis of diabetes. We concur and have added language about the length of the delay observed in the DPP Trial and used the language “prevent or delay” rather than “prevent” throughout the assessment.
- We received the suggestion to include a person with diabetes and/or prediabetes as a participant at the public meeting. We appreciate the suggestion and have been actively working with patient and provider organizations to identify an appropriate participant. ICER is committed to including patient representatives at every level of our review process and including patients with the disease of interest to the extent possible in our public meetings.

- We received criticism for describing prediabetes as a "risk factor for a risk factor" in our discussion of controversies about prediabetes. It was not our intent to imply that this is the position of ICER or the review; rather, this description was intended to summarize a widely-cited critique of the use of prediabetes as a diagnosis in medicine. We have clarified the section by including the direct quote from the critique.
- The report was criticized for downplaying the seriousness of diabetes and the increasing incidence of diabetes in the population based on our reporting of controversies in the literature. We believe that the overall tenor of the report reflects our recognition of the health impact of diabetes and the potential for diabetes prevention programs to improve health.
- Commenters noted that we highlighted the association between weight change and decreased risk of diabetes in the randomized trials, but not the epidemiological association between weight and both prediabetes and diabetes in the US. We have added that contextual information to the background section of the report.
- There were several comments related to the scalability of different DPP implementations. We have added more emphasis to scalability considerations of programs with established centers across the country and online programs that do not require physical centers to deliver a DPP.

Comparative Clinical Effectiveness

- We received comments highlighting the option for team-based support for the digital automated DPP. There were no group sessions, but virtual teams were established. The published clinical trial used teams of 10 participants.¹ The software allows for variable team sizes, although no data were offered in the comments as to optimal team size. The Evidence Report has been updated to reflect this information.
- Unpublished data on the one-year incidence of diabetes for the digital automated DPP were included in the comments even though the published trial states that the primary outcomes were changes in fasting glucose and HbA1c at six months and that the control group received the intervention at six months. The one-year incidence of diabetes was 6.45% in the intervention group and 12.21% in the control group. These results were not included in the report since any interpretation of these findings would be challenging due to the crossover study design.
- Commenters highlighted the uncertainty due to the lack of data on the impact of the interventions on the incidence of diabetes. We agree that this is an important limitation of the current evidence base and that it adds considerable uncertainty to estimates of the value of all of the translational DPPs that were evaluated. We have further noted this uncertainty in the revised report.

Comparative Value

- The ICER report was criticized as not consistent with prior ICER reports because we summarized the literature on the cost-effectiveness of DPPs rather than developing our own model. In fact, our current approach was consistent the approach employed in our assessment of other health-system or programmatic interventions (see reports on Integrating Behavioral Health into Primary Care [<http://icer-review.org/topic/bhi/>] and Palliative Care [<http://icer-review.org/topic/palliative-care/>] for recent examples). Such topics often have accumulated a robust level of published economic evaluation, lessening the need for developing de novo models. In addition, creation of any new model would be problematic at the current time due to concerns we have raised regarding the paucity of clinical evidence for some DPP interventions and the lack of head-to-head data comparing different types of DPPs.
- There was also a request to add a direct question about cost-effectiveness to the voting questions. It is not our practice to vote directly on cost-effectiveness for a number of reasons. First, there is no agreed upon single threshold to determine what makes an intervention cost-effective in California or in the US. Second, there is always uncertainty about the inputs to any model and the assumptions implicit in the model structure, so a range of outputs from any model should be considered. That said, cost-effectiveness is one of the essential inputs into the decision about the "care value" of a DPP. As described in the voting questions "**Care value** is determined by looking at four elements: comparative clinical effectiveness, incremental costs per outcomes achieved, other benefits or disadvantages, and contextual considerations. Care value represents the long-term perspective, at the individual patient level, on patient benefits and the incremental costs to achieve those benefits."
- The primary cost analysis for the digital automated DPP was based on unpublished HbA1c changes from only one program, which was later supplemented by unpublished fasting plasma glucose results from the same program. We therefore report the potential budget impact results for the digital automated DPP in a separate scenario analysis. We also added results based on the change in fasting blood glucose to those for HbA1c, in response to comments received. The additional scenario analysis is included in the potential budget impact analyses, but both analyses are characterized separately from those of other DPP program types because they have not been published or presented publicly.
- One comment suggested including a study on the cost-effectiveness of intensive, individual coaching, which was published in the *Journal of the Academy of Nutrition and Dietetics* in 2012. The study was not included because it focused on outcomes of "cases averted to achieve cost-savings" and "cases averted to achieve cost-effectiveness" using data from published DPP trials, but did not actually attempt to measure cost-effectiveness ratios or include any original cost data.

References

1. Block G: Public comments received on "Diabetes Prevention Programs: Effectiveness and Value" by May 23, 2016, 2016, pp 16-18