



To The Institute for Clinical and Economic Review:

The Diabetes Advocacy Alliance (DAA), a coalition of 21 diverse members, appreciates the opportunity to provide comments related to the **Lifestyle Interventions for the Prevention of Diabetes: Effectiveness and Value** Scoping Document.

We urge ICER to be flexible in its assessment of diabetes prevention programs to allow and encourage evidence-based innovation. Please consider the following suggestions.

Background

ICER refers to controversy around the American Diabetes Association's (ADA) definition of prediabetes. The DAA encourages ICER to accept the ADA's definition which is widely accepted. Furthermore, the CDC's National Diabetes Prevention Program classifies an individual as eligible if they had gestational diabetes (GDM) or if they screened positive based on the CDC Prediabetes Screening Test which is based on ADA's definition of prediabetes.¹

Report Aim

DAA members, including the American Association of Diabetes Educators, American Diabetes Association, American Medical Association, Omada Health, Weight Watchers, and the YMCA are involved with the National DPP and could engage directly with ICER throughout the assessment process.

Scope of the Assessment

The DAA urges ICER to use an expanded evidence base instead of limiting its scope to only certain types of studies. The evidence base for DPPs is growing, and rests on NIH's Diabetes Prevention Program randomized controlled trial and its 10-year follow up study. Not all of the published research on "real-world" DPPs meets the scoping document's rigorous standards since most programs are new. We recommend ICER review the USPSTF final guideline on screening for abnormal blood glucose and type 2 diabetes² and research examined by the Community Preventive Services Task Force in their 2014 recommendation.³

Analytic Framework

Outcomes

The CDC doesn't require recognized DPPs to report pre- and post-impact on glycemic control since they adhere to program standards based on the NIH RCT or have conducted their own research.⁴ Therefore, the DAA

¹ Available online: <http://www.cdc.gov/widgets/Prediabetes/Prediabetes.swf>

² United States Preventive Services Task Force. Screening for abnormal blood glucose and type 2 diabetes mellitus: u.s. preventive services task force recommendation statement. *Annals of Internal Medicine*. 2015;163(11):861-869.

³ Guide to Community Preventive Services. Diabetes prevention and control: combined diet and physical activity promotion programs to prevent type 2 diabetes among people at increased risk. July 2014. www.thecommunityguide.org/diabetes/combineddietandpa.html.

⁴ 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.

recommends that ICER accept studies generated by DPPs that document impact on other outcomes described in the framework, even when glycemic control is not reported.

Settings

The DAA recommends that digital/virtual settings be included in “all relevant settings will be considered.” The CDC’s Diabetes Prevention Recognition Program Standards and Operating Procedures provide rigorous criteria to determine how face-face and online programs should be “recognized.” We encourage ICER to incorporate this framework into their assessment.

Economic Evaluation

The DAA recommends ICER review: [Avalere Health’s analysis](#)⁵ which found coverage of the DPP lifestyle intervention would significantly reduce federal spending; Dall et al, which found the economic benefits far outweighed intervention costs over a 10-year period;⁶ the microsimulation model used by IHS Life Sciences Consulting; and the Center for Medicare and Medicaid Innovation (CMMI) evaluation of a Health Care Innovation Award that provides Medicare coverage for the YMCA’s DPP. ICER should contact Darshak Sanghavi, Director, Preventive and Population Health Care Models Group at CMMI.

Thank you for considering our suggestions. We look forward to the draft report. Please feel free to contact Amy Wotring at awot@novonordisk.com with any questions.

Sincerely,

Karin Gillespie
Mary Pat Raimondi, MS, RDN
Henry Rodriguez, MD
DAA Co-chairs

⁵ Avalere Health. Estimated Federal Impact of H.R. 962/S. 452 “The Medicare Diabetes Prevention Act.” 2014. Available online: <http://www.diabetes.org/assets/pdfs/advocacy/estimated-federal-impact-of.pdf>

⁶ Dall TM, Storm MV, Semilla AP, Wintfeld N, et al. Value of lifestyle intervention to prevent diabetes and sequelae. *American Journal of Preventive Medicine*. 2015;48(3):271-280.