



August 1, 2018

Dear Members of the USPSTF

The Diabetes Advocacy Alliance (DAA) appreciates the opportunity to comment on the U.S. Preventive Services Task Force (USPSTF) *Draft Research Plan for Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening*.

The DAA is a coalition of 24 diverse member organizations, representing patient, professional and trade associations, other non-profit organizations, and corporations, all united in the desire to change the way diabetes is viewed and treated in America. Since 2010, the DAA has worked to increase awareness of, and action on, the diabetes epidemic among legislators and policymakers. The organizations that comprise the DAA share a common goal of elevating diabetes on the national agenda so we may ultimately defeat diabetes and its complications.

Overarching Comments:

As DAA commented on the Draft Research Plan for *Diet and Physical Activity to Prevent Cardiovascular Disease in Adults With Risk Factors: Counseling*, we seek clarification and additional information about how USPSTF intends to link the two guidelines that are under concurrent review. Is the intent of USPSTF to merge the two reviews into one recommendation? The two Draft Research Plans do not mention how the two will be combined or linked thus DAA requests additional information from USPSTF about their concurrent review process and plan.

The DAA would like to call attention to the terminology used in this Draft Evidence Review compared to terminology used in other USPSTF guidelines. This Draft Evidence Review uses the terms “interventions for glycemic control” and “lifestyle modifications” to describe counseling interventions whereas the USPSTF guideline under concurrent review and other USPSTF guidelines use terms such as: diet and physical activity, dietary counseling, behavioral counseling for healthy lifestyle, multicomponent intensive behavioral therapy for obesity, etc. The DAA strongly urges USPSTF to use a consistent set of terminology across similar/overlapping guidelines since inconsistent use of terms causes confusion for payers, physicians and other healthcare stakeholders.

Finally, the DAA notes that this Draft Research Plan uses the term “screening” in the title while the guideline under concurrent review uses the term “counseling.” It is our understanding from conversations with USPSTF that the *Abnormal Blood Glucose and Type 2 Diabetes Mellitus* guideline pertains to both screening and counseling for diabetes prevention and thus “counseling” should be reflected in the Draft Research Plan title. Screening and referral to counseling interventions go hand-in-hand and must be directly connected in this guideline which is in accordance with commonly accepted public health principles. DAA urges USPSTF to clearly state the guideline(s) address both screening and counseling.

Draft: Proposed Key Questions to Be Systematically Reviewed

In general, the DAA supports the proposed key questions to be systematically reviewed but we seek clarification on the difference between “screen-detected type 2 diabetes” and “recently diagnosed type 2 diabetes” referenced in question #6 since the purpose of screening is to diagnose patients if they are found to have the disease being screened for.

Draft: Proposed Contextual Questions

In general, the DAA supports the proposed contextual questions and commends USPSTF for including a range of screening tests, including hemoglobin A1c, fasting plasma glucose, and the oral glucose tolerance test, in its review. The

hemoglobin A1c test is often cited by health care professionals as their preferred screening test since it is simple to administer and cost-effective. The DAA strongly believes greater utilization of the hemoglobin A1c test for the purposes of prediabetes and diabetes screening has the potential to increase screening rates in the U.S. With that said, in response to question #1, DAA would like to call to USPSTF's attention that the Centers for Disease Control and Prevention (CDC) Prediabetes Screening Test is a widely used and accepted risk assessment tool that is feasible for use in primary care settings and accurately predicts the risk of type 2 diabetes. The CDC has validated its use and allows National DPP suppliers to screen for program eligibility using the tool. In the CDC's Diabetes Prevention Recognition Program standards, they allow up to 65% of a program's participants to meet the eligibility standard through the risk test; the remaining 35% must have a valid blood test or have a history of gestational diabetes.

Draft: Proposed Research Approach

Screening

As previously stated, the DAA supports inclusion of the hemoglobin A1c, fasting plasma glucose, and the oral glucose tolerance test in the screening section. As previously mentioned, we'd again like to recommend that USPSTF include the CDC Prediabetes Screening Test as an eligible screening test in the research criteria since it is accepted by the CDC for determining eligibility and recognition of National DPPs.

Interventions

The DAA supports including interventions for glycemic control and lifestyle modifications in the criteria. However, the DAA is very concerned USPSTF excludes counseling interventions that are primarily community-based. The CDC National DPP is a community-based lifestyle intervention aimed at people with prediabetes and it is hugely effective in helping people with prediabetes prevent or delay onset of type 2 diabetes. Approximately 84 million Americans have prediabetes. Community-based programs, delivered in non-clinical settings, are essential if we seek to make an impact on the millions at risk of developing diabetes. The DAA strongly urges USPSTF to include community-based programs in their study criteria. Primary care providers and primary care organizations have expressed their preference for referring patients to interventions offered outside their offices due to resource constraints and/or inadequate expertise. The current *Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening* guideline which was finalized in October 2015 is based on strong evidence about community-based diabetes prevention programs.

In addition, the DAA recommends USPSTF include interventions for diabetes self-management education and support (DSMES) and diabetes self-management training (DSMT) in the research criteria. For people with diagnosed diabetes, DSMES/DSMT is an effective intervention to help the patient lower their A1c, weight, and improve their disease management and quality of life.

The Draft Research Plan does not specify whether USPSTF will only review counseling interventions that are offered in-person or whether other modalities, such as distance learning, telehealth, or digital health, will be included. As of July 2018, more than 220,000 adults have received counseling interventions through these modalities as part of the National DPP, which are delivered outside the physician's office. The DAA recommends that interventions delivered through any of the above mentioned modalities be included since they are all primary care relevant. While in-person interventions are familiar and widely utilized, the evidence base for interventions delivered via digital or other non-traditional modalities has grown substantially over the last several years and achieves similar health outcomes. In the Final Research Plan on *Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Behavioral Interventions*, the USPSTF included "technology interventions" in the Settings section and further specified they would review interventions "delivered via face-to-face contact, telephone, print materials, or technology (e.g., computer-based, text messages)." DAA recommends USPSTF include similar language to address technology-enabled interventions in the Final Research Plan for *Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening*.

Study Designs

The DAA is concerned USPSTF excludes systematic reviews from the research criteria. We understand that randomized clinical trials (RCTs) are the gold standard to demonstrate the impact of diabetes screening and lifestyle modification programs but these trials are exceedingly challenging to design and conduct. As the DAA commented in 2013 when the diabetes screening guideline was last under review, in lieu of direct evidence from RCTs comparing screening to no-screening, an indirect chain of evidence establishing the effect of screening on health outcomes can be deduced through relationships between intermediate outcomes and final outcomes. Further, we recommend USPSTF consider additional study design types, such as modeling, when conducting this review. Modeling studies have the potential to contribute important information to help better understand the impact of diabetes screening on long-term health outcomes.

Settings

The DAA is concerned USPSTF excludes studies conducted in community-based settings from the research criteria. The evidence base for the *Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening* guideline published in 2015 relied on community-based diabetes prevention programs which have grown rapidly in number over the last several years. The research criteria should include studies conducted in community-based settings and also studies looking at technology interventions like virtual diabetes prevention programs.

Thank you for your consideration of our comments. If you have any questions or need additional information, please free to contact Amy Wotring at awot@novonordisk.com.

Sincerely,

Meredith Dyer
Endocrine Society
DAA Co-Chair

Karin Gillespie
Novo Nordisk Inc.
DAA Co-Chair

Meghan Riley
American Diabetes Association
DAA Co-Chair