July 11, 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 Diet and Physical Activity to Prevent Cardiovascular Disease in Adults With Risk Factors: Counseling.*

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 Comment:
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 "diet and physical activity" and "dietary counseling" to describe counseling interventions whereas other USPSTF guidelines use terms such as: lifestyle modification, 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.

Draft: Preface
In the Preface of the Draft Evidence Review, it states that "a concurrent systematic review on screening for abnormal blood glucose and type 2 diabetes mellitus will examine the effectiveness of counseling on diet and physical activity to prevent progression to diabetes and CVD among adults with prediabetes." The DAA seeks clarification about how USPSTF intends to link the two reviews since there is significant overlap in the population of patients at risk for CVD and diabetes. Is the intent of USPSTF to merge the two reviews into one recommendation? Nothing in this Draft Research Plan or the *Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus* Draft Research Plan mentions how the two will be combined or linked thus the DAA requests additional information from USPSTF about their concurrent review process and plan.

Finally, the DAA notes that this Draft Research Plan uses the term "counseling" in the title, while the Draft Research Plan on diabetes released on July 5th, 2018 uses the term "screening". It is our understanding from conversations with USPSTF that the *Abnormal Blood Glucose and Type 2 Diabetes Mellitus* guideline pertains to both screening and interventions/counseling for diabetes prevention and thus should be reflected in the Draft Research Plan title. Further, if these two guidelines are ultimately linked or combined, DAA urges USPSTF to clearly state the guidelines address both screening and counseling.

Draft: Proposed Analytic Framework
The DAA is concerned that prediabetes, also referred to as "abnormal blood glucose" and "impaired fasting glucose/impaired glucose tolerance" in the Draft Research Plan, and diabetes mellitus are not included as known CVD risk factors in the framework. The American Heart Association considers diabetes to be 1 of the 7 major controllable

risk factors for CVD.[1] Adults with diabetes are twice as likely to die from heart disease compared to adults without diabetes, and vascular disease is the leading cause of death among people with diabetes. The *Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening* guideline published in October 2015 states "modifiable cardiovascular risk factors include abnormal blood glucose…"[2] which is further evidence for including prediabetes and diabetes as risk factors. DAA strongly encourages USPSTF to add prediabetes and diabetes as known CVD risk factors in the Final Research Plan. In addition, the DAA recommends that blood glucose be added as an intermediate outcome in the analytic framework.

Draft: Proposed Key Questions to Be Systematically Reviewed

The DAA would like to call out inconsistencies in several of the Proposed Key Questions when compared to the criteria outlined in the Analytic Framework. As previously mentioned the Analytic Framework does not include prediabetes and diabetes as known CVD risk factors but several of the Proposed Key Questions mention "fasting glucose" or "impaired fasting glucose" as CVD intermediate outcomes or known CVD risk factors. As recommended above, the DAA urges USPSTF to include prediabetes and diabetes as known CVD risk factors and to include blood glucose as an intermediate outcome. We further recommend USPSTF fully align the Analytic
Framework and Proposed Key Questions as it pertains to these criteria.

Draft: Proposed Research Approach

Populations

As previously mentioned, diabetes is a known risk factor for CVD, as such, the DAA is concerned that the draft research plan excludes persons with impaired fasting glucose/impaired glucose tolerance as well as persons with known diabetes mellitus when defining the study characteristics and criteria related to populations. We recommend that USPSTF include persons with impaired fasting glucose/impaired glucose tolerance as well as persons with known diabetes in the study criteria. The USPSTF *Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening* guideline recommends "screening for abnormal blood glucose as part of cardiovascular risk assessment." The abnormal blood glucose screening guideline clearly connects abnormal blood glucose and type 2 diabetes to cardiovascular risk and thus DAA recommends USPSTF clearly link prediabetes and diabetes in the Final Research Plan.

Settings

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. 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 *Diet and Physical Activity to Prevent Cardiovascular Disease in Adults With Risk Factors: Counseling.*

[1] American Heart Association. Cardiovascular Disease & Diabetes. Updated Jan 29, 2018. Online: http://www.heart.org/HEARTORG/Conditions/More/Diabetes/WhyDiabetesMatters/Cardiovascular-Disease-Diabetes_UCM_313865_Article.jsp#.WzulztJKgdU

[2] Sui AL, on behalf of the U.S. Preventive Services Task Force. Screening for abnormal blood glucose and type 2 diabetes mellitus: U.S. preventive services task force recommendation statement. Ann Intern Med 2015; 163(11):861-868.

Interventions
The Interventions criteria exclude studies aimed at diabetes prevention and counseling interventions that are primarily community-based. The Centers for Disease Control and Prevention's (CDC) National Diabetes Prevention Program (National DPP) is a proven, community-based lifestyle intervention aimed at preventing type 2 diabetes in individuals with prediabetes. The National DPP is based on the Diabetes Prevention Program clinical trial which found that the lifestyle intervention had favorable effects on reducing cardiovascular risk factors.[3] More than 90 million Americans are living with some form of cardiovascular disease[4] and more than 30 million Americans have diabetes. Community-based programs, delivered in non-clinical settings, are essential if we seek to make an impact on the millions of people living with or at risk of developing CVD and diabetes. The DAA strongly urges USPSTF to include community-based programs in their study criteria.

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	Karin Gillespie	Meghan Riley
Endocrine Society	Novo Nordisk Inc.	American Diabetes Association
DAA Co-Chair	DAA Co-Chair	DAA Co-Chair

[3] Diabetes Prevention Program Research Group. Impact of intensive lifestyle and metformin therapy on cardiovascular disease risk factors in the Diabetes Prevention Program. Diabetes Care. 2005;28:888–894.

[4] Benjamin EJ, Virani SS, Callaway CW, Chang AR, Cheng S, Chiuve SE, Cushman M, Delling FN, Deo R, de Ferranti SD, Ferguson JF, Fornage M, Gillespie C, Isasi CR, Jimenez MC, Jordan LC, Judd SE, Lackland D, Lichtman JH, Lisabeth L, Liu S, Longenecker CT, Lutsey PL, Matchar DB, Matsushita K, Mussolino ME, Nasir K, O'Flaherty M, Palaniappan LP, Pandey DK, Reeves MJ, Ritchey MD, Rodriguez CJ, Roth GA, Rosamond WD, Sampson UKA, Satou GM, Shah SH, Spartano NL, Tirschwell DL, Tsao CW, Voeks JH, Willey JZ, Wilkins JT, Wu JHY, Alger HM, Wong SS, Muntner P; on behalf of the American Heart Association Council on Epidemiology and Prevention Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2018 update: a report from the American Heart Association [published online ahead of print January 31, 2018]. Circulation. DOI: 10.1161/CIR.0000000000000558.