June 8, 2020

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 Recommendation Statement: **Healthy Diet and Physical Activity to Prevent Cardiovascular Disease in Adults with Risk Factors: Behavioral Counseling Interventions.**

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.

We have a number of observations, suggestions, and questions for the USPSTF as it moves toward a final recommendation statement.

Overall Comments

1. Compared to the earlier recommendation, this recommendation statement provides better clarity on the population to which it applies and how it overlaps with the healthy lifestyle behavioral counseling recommendations for abnormal blood glucose, obesity, and CVD risk reduction for those with lower risk. Also, by using the terms "behavioral counseling" and "behavioral counseling interventions," the USPSTF is moving toward terminology more consistent with that used in other similar recommendation statements. In addition, this draft recommendation statement makes it clearer that evidence supports delivery of the service by lifestyle coaches and trained leaders.

Also, the DAA believes it is vital that USPSTF highlight and repeatedly note both the efficacy of behavioral counseling for healthy lifestyle AND that it is widely accessible, available and affordable, because, as the draft evidence review noted, clinicians are providing or referring this recommended preventive service very, very infrequently. We must increase referral and provision rates of behavioral counseling for healthy lifestyle to increase the health status of our nation.

Comments Related to Specific Sections of the Draft Recommendation Statement

2. **The boxed recommendation summary at the beginning of the Draft Recommendation Statement** is stated: "The USPSTF recommends offering or referring adults with CVD risk factors to behavioral counseling interventions to promote a healthy diet and physical activity." The

DAA suggests a re-wording of this sentence for the following reasons. While a portion of the studies reviewed showed efficacy for clinician offered multi-component behavioral interventions for healthy lifestyle (e.g., interventions provided by clinicians in a medical setting), the preponderance of the studies reviewed were of programs and interventions not directly provided by the primary care professional, but instead were community based multi-component behavioral interventions for healthy lifestyle. The currently-worded summary statement does not reflect the preponderance of the evidence and recommends clinicians “offer” the service, implying preference for primary care clinician delivery of the service in the medical setting. We urge USPSTF to align the recommendation statement with the evidence by modifying the recommendation sentence to reflect the evidence that was reviewed and found effective and by removing the term “offer.” **We suggest this wording instead**: “For adults with CVD risk factors, the USPSTF recommends behavioral counseling interventions to promote a healthy diet and physical activity through referral to widely accessible healthy lifestyle counseling programs or provided directly by clinicians.”

3. **In the “Importance” section at the top of the Draft Recommendation Statement**, this sentence appears: “Known modifiable risk factors for CVD include smoking, overweight and obesity, diabetes, elevated blood pressure or hypertension, dyslipidemia, lack of physical activity, and unhealthy diet.” The DAA believes that USPSTF should add prediabetes (what USPSTF refers to as abnormal blood glucose) to this list. We direct you to a meta-analysis in The BMJ entitled “Association between prediabetes and risk of cardiovascular disease and all-cause mortality: systematic review and meta-analysis,” from 2016. (https://doi.org/10.1136/bmj.i5953*)* This study concluded that “Prediabetes, defined as impaired glucose tolerance, impaired fasting glucose, or raised HbA_{1c}, was associated with an increased risk of cardiovascular disease. The health risk might be increased in people with a fasting glucose concentration as low as 5.6 mmol/L or HbA_{1c} of 39 mmol/mol.”

4. **In the “Importance” section at the top of the Draft Recommendation Statement**, this sentence appears: “All persons, regardless of their CVD risk status, can gain health benefits from healthy eating behaviors and appropriate physical activity.” We recommend editing this sentence as follows: “All persons, regardless of their CVD risk status **or socioeconomic status**, can gain health benefits from healthy eating behaviors and appropriate physical activity.” The evidence review found that behavioral counseling is effective for people with CVD risk in all socio-economic levels and we believe it is vital to highlight this finding for providers. As health care providers grapple with social determinants of health and health disparities, this evidence review finding is important to highlight for clinicians and those implementing preventive health strategies.

5. **In the “Practice Considerations” section, “Patient Population Under Consideration**,” this sentence appears: “This recommendation applies to adults age 18 years or older with known hypertension or elevated blood pressure, with dyslipidemia, or who have mixed or multiple risk factors such as metabolic syndrome or an estimated 10-year CVD risk of 7.5% or greater.” Why was “metabolic syndrome” included in this description? In the Conclusions section of the Evidence Review’s abstract, metabolic syndrome is not mentioned. Metabolic syndrome is an

inexact term, that some physicians also call insulin resistance syndrome or Syndrome X. The components and various definitions of metabolic syndrome are not always the same or described with the same language. However, in four examples we reviewed, all of them include impaired glucose (either impaired fasting glucose or impaired glucose tolerance) and abdominal obesity as two of the 5 or 6 elements of the metabolic syndrome.[1,2,3,4] Since USPSTF has stated that this Draft Recommendation does not apply to patients with prediabetes/abnormal glucose or obesity, why, then, is metabolic syndrome included in the patient population under consideration?

Also, nothing is mentioned in the "Practice Considerations" section, "Patient Population Under Consideration," nor elsewhere in the Draft Recommendation Statement, about special populations. The DAA notes that sub-questions that were in the draft research plan were removed from the final version of the research plan. Could the USPSTF add subpopulation characteristics back into the recommendation? We also request that there be consistency between the evidence review and the recommendation statement.

6. **In the "Practice Considerations" section, "Behavioral Counseling Interventions**" sub-section, the DAA recommends that USPSTF add pharmacists to the listing of specially trained professionals that can deliver these interventions. Additionally, while we appreciate the clear identification of the wide range of individuals that can and do provide evidence based behavioral counseling effectively, we feel this section does not adequately reflect the plethora of evidence that has demonstrated that affordable, scalable translation of behavioral counseling using "non-clinician interventionists" (such as trained coaches) is equally effective. We urge adding information in this section that notes that **over 75% of the studies reviewed engaged non-clinician interventionists**. Also, the evidence that USPSTF has reviewed for other healthy lifestyle behavioral counseling recommendations relies heavily on community-based programs with trained lifestyle coaches. Indeed, in Table 2 of the Draft Recommendation Statement, in the section entitled "Person Delivering Intervention," this is said: "Most were nonphysicians, including registered dieticians, health educators, nurses, lifestyle coaches, psychologists or psychology graduate students, and exercise physiologists."

7. **In the "Practice Considerations" section, "Implementation" sub-section**, USPSTF uses these vague terms: "other settings" and "media-based interventions." We urge USPSTF to instead use language that appears in Table 2, where implementation is described as "Face-to-face sessions with or without additional telephone or web-based or other technology enhanced components." The draft evidence review is more aligned with the description in Table 2, as it noted behavioral counseling was delivered in integrated health system settings, community settings, or through telephonic counseling, all of which might be supplemented with online resources. Further confusing this section is that healthy lifestyle behavioral counseling for diabetes prevention, which is evidence based, uses terms like "virtual" (online sessions and tracking plus telephonic coaching) and "distance classroom" type programs (group sessions conducted via video conference) and in-person group or individual sessions. Please ensure the language used in the implementation section matches Table 2 and is aligned with the

extensively researched and developed diabetes prevention program language on implementation.

Questions for USPSTF

Were subgroup analyses conducted on the effects of behavioral counseling intervention conducted by different interventionists, such as registered dietitian nutritionists, on health outcomes? We note that such work has been done for healthy lifestyle behavioral counseling for weight management and diabetes prevention. (For examples, see **Interventions to Promote Physical Activity and Dietary Lifestyle Changes for Cardiovascular Risk Factor Reduction in Adults: A Scientific Statement from the American Heart Association** cited in this USPSTF evidence review and recommendation statement.) We also note that such subgroup analyses are reflected in the implementation of the National Diabetes Prevention Program.

Did the findings differ among different behavior change goals, behavior change techniques, or intervention modality?

References

1 https://www.nhlbi.nih.gov/health-topics/metabolic-syndrome

2 https://www.mayoclinic.org/diseases-conditions/metabolic-syndrome/symptoms-causes/syc-20351916

3 https://www.ahajournals.org/doi/10.1161/01.CIR.0000111245.75752.C6

4 https://www.heart.org/en/health-topics/metabolic-syndrome/about-metabolic-syndrome