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Meetings: 2020 Dietary Guidelines Advisory Committee

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Comment

RE: Protocols for the conduct of new and the update of existing systematic reviews for the 2020 Dietary Guidelines Advisory Committee

The Beef Checkoff appreciates the opportunity to share the attached for consideration on the first 40 protocols to be used by the 2020 Dietary Guidelines Advisory Committee as they examine specific topics and supporting scientific questions identified by USDA and HHS.

Attachments (1)

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National Cattlemen's Beef Association
a contractor to the Beef Checkoff

July 24, 2019

Barbara Schneeman, PhD
Chair, 2020-2025 Dietary Guidelines Advisory Committee

Ron Kleinman, MD
Vice-Chair, 2020-2025 Dietary Guidelines Advisory Committee

CC: 2020-2025 Dietary Guidelines Advisory Committee Members
U.S. Department of Agriculture
U.S. Department of Health and Human Services
Brandon Lipps, Acting Deputy Undersecretary for Food and Nutrition Consumer Services

RE: Protocols for the conduct of new and the update of existing systematic reviews for the 2020 Dietary Guidelines Advisory Committee

Dear Members of the Dietary Guidelines Advisory Committee:

The Beef Checkoff appreciates the opportunity to share the attached for consideration on the first 40 protocols to be used by the 2020 Dietary Guidelines Advisory Committee as they examine specific topics and supporting scientific questions identified by USDA and HHS.

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RE: Protocols for the conduct of new and the update of existing systematic reviews for the 2020 Dietary Guidelines Advisory Committee

Systematic reviews (SR) are foundational for dietary guidance and provide the opportunity to make evidence-based public health recommendations that are objective, transparent, and scientifically robust (1, 2). Best practices for SR methodology aim to ensure that reviews are comprehensive and free from bias (1). Well-designed search strategies and study selection criteria are necessary to identify the totality of evidence relevant to research questions (3). The following evidence overview will focus on the protocols for the conduct of new SR for use by the 2020 Dietary Guidelines Advisory Committee (DGAC) by the Nutrition Evidence Systematic Review (NESR) and the update of existing NESR SR, in particular, the proposed search terms, search dates, use of existing NESR SR, and study selection criteria.

Importance of Search Terms to Evidence Identification

Best practice in SR requires the presentation of the full electronic search strategy for at least one of the literature databases to be searched, including any limits used, such that it could be repeated (3). **The currently posted 40 SR protocols to be utilized by the DGAC to answer key research questions do not provide key search strategy details,** in particular, search/indexing terms (4). As noted in the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) standards, "high quality searches are essential components in the efforts toward accuracy and completeness of the evidence base" (3). **Providing search strategy details is crucial for appraisement of SR protocols (3) and to producing research syntheses that are more transparent and easy to replicate (5). Without the transparency offered by a complete search strategy, the public is unable to comment on the complete search strategy.**

While not made available in the SR protocols, during brief discussion on day 1 of DGAC Meeting 2 (D1M2), DGAC support staff member, Dr. Laural English, indicated that comprehensive search strategies have been developed, peer reviewed, and implemented for some research questions (6). As further indicated by Dr. English, these strategies rely, at least in part, on the use of Medical Subject Headings (MeSH) terms (6). MeSH terms/descriptors are used by the U.S. National Library of Medicine as a tool to aid searchers in the discovery of publications relevant to their topic of interest (7). During the discussions of D1M2, DGAC member, Dr. Heather Leidy, pointed out that it is unclear what search terms will be used to identify dietary patterns related to carbohydrate restriction (6). According to the Manual of Methodological Expectations of Cochrane Intervention Reviews, inappropriate or inadequate search strategies may fail to identify relevant publications (see C32) (8). While low-carbohydrate (low CHO) and high-fat diets are listed as distinct diet scenarios in the DGAC research questions (9), low CHO diets emphasize a change in recommended macronutrient distribution with CHO restriction implemented by elimination or reduction of specific foods and food groups, and replacement of these with high-fat and/or high-protein foods (10). The Cochrane Handbook for Systematic Reviews of Interventions states that it is necessary to include a wide range of search terms for each of the concepts to be evaluated (11). Identification of all studies relevant to low CHO diets, including those identified as high-protein,

provides the totality of evidence regarding low-CHO dietary patterns and health outcomes. Missing relevant search terms in a search strategy is estimated to be the most common error affecting retrieval of evidence (12).

Specifically, when using MeSH descriptors to search, PubMed automatically searches on narrower descriptors indented under it in the MeSH tree structures, but it does not search at the upper levels of the tree structure/hierarchy (13). The MeSH descriptor relevant to high protein diets [diet, high protein], is not encompassed in the MeSH tree structure for low CHO diets [diet, carbohydrate restricted] or high fat diets [diet, high fat] (14). Therefore, using the descriptors "diet, carbohydrate-restricted" and "diet, high fat" will capture studies relevant to these macronutrient distributions, along with any more narrow descriptors included in their tree, e.g. "diet, ketogenic", but will not, based on the design of the MESH tree, identify publications indexed in Pub Med as high in protein (13, 14). Only the search descriptor "Diet therapy", which is highest in the MeSH tree for the diets of interest, is designed to capture all of the relevant macronutrient descriptions that may represent a low CHO diet (14). **Thus, in order to also capture publications indexed as "diet, high protein" that provided a low CHO dietary pattern, the search strategy will need to include the MESH term "diet therapy".** Furthermore, in the systematic review and meta-analysis conducted by Naude et al. (2014), the MeSH descriptor "fat restricted diet" was also included to capture high protein, low carbohydrate diets (10). **The MeSH term "fat restricted diet" is not part of the "diet therapy" MeSH tree and would be an additional descriptor to the search strategies for low-CHO diets (10, 15).**

Evidence Gaps Created by Use of Existing NESR SR

The DGAC discussions and protocols indicate that existing NESR SR will be utilized to answer many of the 2020 DGAC questions. In DGAC Meeting 1, Dr. Julie Obaggy provided a definition of "relevancy" to guide in the decision of when to use an existing NESR SR to answer a current DGAC research question. Specifically, an existing NESR SR would be considered relevant if "the existing NESR review addressed the same population, intervention and/or exposure, comparator, and outcomes; used the same definitions for key terms and exclusion criteria" (Slide 22) (16). **This relevancy criteria is not met for any of the existing NESR SR research questions because the intervention and/or exposures differ for each current research question designed to assess dietary patterns; and the existing 2014 and 2015 NESR reviews did not include low CHO or high-fat diets as interventions/exposures of interest (17).**

Based on review of the individual NESR SR update protocols, NESR reviews searching for new publications will begin from the last search date of the existing review (2013/2014/2015), rather than reconsidering the entire search (1980 to the present) to include the totality of evidence for new interventions of interest (4). For example, the update protocol for overweight and obesity and dietary patterns notes the date inclusion criteria as August 2013 – June 2019, further noting, "…this date range is in addition to the original systematic review, which included articles published from January 1980-July 2013"(18). It is unclear from this wording, if the entire search will be updated from 1980 to 2019, or if the update will only be accomplished from 2013-2019. Regarding best practice in SR updates, experts on a National Academies committee note, "Updating a systematic review may require collecting additional

data or performing new analyses. As a result, newly published studies may be added or previously included studies may be excluded based on refined methods (2)." The research questions from 2013/2014/2015 have now been refined to include low CHO and high fat diets. **As currently proposed, evidence for DGAC recommendations related to health outcomes and low CHO or high fat diets will be based on the last 5 years of evidence, eliminating older relevant research.** *When grading strength of evidence (SOE), an evidence base with a low number of studies is typically assigned a weaker SOE for precision, while an evidence base with an abundance of studies, assuming consistency, is assigned a strong SOE.* (Slide 19,20) (16).

Evidence Gaps Created by Proposed Search Dates for New NESR SR

Best practice in SR indicates that "searches for studies should be as extensive as possible in order to reduce the risk of publication bias and to identify as much relevant evidence as possible (See C24) (8). Protocols indicate that for new NESR SR, such as those supporting the research questions related to dietary patterns and sarcopenia and all-cause mortality, searches will begin in January 2000 (19, 20). *The rationale for curtailing the literature searches for new NESR SRs from 2000 to the present, versus existing NESR SR which include studies from 1980, has not been provided by the posted protocols.* **Best practices in SR examine the totality of evidence, and typically examine data regardless of the year published (see C35) (8).** In fact, the Cochrane Methodology Handbook indicates that date restrictions "…should be applied only if it is known that relevant studies could only have been reported during a specific time period, for example if the intervention was only available after a certain time point" (See C35) (8). Further, in a review of 6,743 SR performed by 54 Cochrane Collaboration review groups only 21 of 45,587 excluded publications were excluded for being published outside a pre-specified publication range (21). Proposed search dates, 1980 to present vs 2000 to the present, are not consistent among the posted protocols (4). Several DGAC members recognized the importance of consistency and harmonization in the approach to the DGAC research questions during D1M2. Applying search limits in a search strategy, such as limiting results by date, limits the number of studies returned by the literature search (22). **Thus, limiting search strategies by date limits the amount of evidence available for DGAC recommendations.**

Additional Clarity for Study Selection Criteria

As discussed during D1M2, the analytic framework of most DGAC research protocols indicates allowance for the inclusion of studies that enrolled "some" participants at risk for chronic disease, however, specific criteria for how chronic disease risk will be assessed has not been provided, nor is a definition of "some" proposed. The protocol for the research question regarding dietary patterns and cardiovascular disease allows for the inclusion of studies that enrolled "some" participants with high cholesterol, but a definition of high cholesterol has not been provided (23). In 2014, randomized controlled trial evidence regarding beef in a DASH-style dietary pattern (the BOLD study) was excluded from the NESR (then NEL) SR regarding dietary patterns and cardiovascular disease risk, in part, because participants were identified as hypercholesterolemic (24). However, as noted in an earlier submission to the docket, the BOLD subjects represent an un-medicated population with "near/above optimal" to

"borderline high" LDL levels (24). Without a definition of "high cholesterol", the current SR protocol for dietary patterns and cardiovascular disease provides no clarity on how a study like BOLD will be considered in the updated NESR SR. Best practice in SR protocol reporting requires "Listing all outcomes for which data will be sought in a review and providing sufficient details and definitions…" PRISMA-P guidelines indicate that the importance of outcomes is such that specific attention to this protocol element "greatly" facilitates "complete and transparent reporting" (3).

Also discussed during D1M2 is the application of standard NESR inclusion exclusion criteria to the various DGAC SR, with allowance for tailoring by each Subcommittee. The inclusion exclusion criteria for research questions related to dietary patterns and risk of sarcopenia and neurocognitive function have been tailored to include case control studies (19, 25). **Case-control studies are considered a weaker level of evidence (26). An explanation for this deviation has not been provided.**

In conclusion, well-designed search strategies and study selection criteria are necessary to identify the totality of evidence relevant to research questions (3). Inappropriate or inadequate search strategies may fail to identify relevant publications (8). A comprehensive and complete literature search increases the accuracy and completeness of the evidence base (3). Outcome definitions and criteria in SR protocols enhances complete and transparent reporting (3). As recognized by the NASEM Committee for the Redesign of the Dietary Guidelines, "Conduct of original systematic reviews will need to be transparent and follow state-of-the-art methods… (2)".

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