

Comment on FR Doc # 2019-12806

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Comment

RE: Questions regarding the application of NESR methodology as reflected in updated protocols

The Beef Checkoff appreciates the opportunity to share the attached for consideration on the new and updated protocols presented at the 3rd Dietary Guidelines Advisory Committee Meeting, as the Committee continues to examine the topics and supporting scientific questions identified by USDA and HHS.

Attachments (1)

Beef Checkoff Mtg3 Updated Protocol Comments





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Submitter Information

Submitter Name:

Shalene McNeill, PhD, RD

City:

Centennial

Country:

United States

State or Province:

Organization Name:

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

Checkoff

Category: Food industry



November 6, 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, Deputy Undersecretary for Food and Nutrition Consumer Services

RE: Questions regarding the application of NESR methodology as reflected in updated protocols

Dear Members of the Dietary Guidelines Advisory Committee (DGAC):

Revised systematic review (SR) protocols posted in advance of Meeting 3 of the 2020 Dietary Guidelines Advisory Committee (DGAC) partially address observations outlined in a prior evidence overview submitted by National Cattlemen's Beef Association (NCBA) on behalf of the Beef Checkoff. Newly posted protocols, and discussions among the DGAC during Meeting 3, have also added new insights into the systematic approach taken by the Nutrition Evidence Systematic Review (NESR) team and the 2020 DGAC. The following questions regarding the application of NESR methodology are discussed in detail in the attached document

- 1. How does the use of the AMDR as a cut-point for specific macronutrient proportion diets affect conclusions and evidence recommendations?
- 2. During title first screening, how will studies of diets examining specific macronutrient proportions be consistently recognized?
- 3. Why is external evidence (i.e. SR evidence from external organizations) being considered in the protocol regarding dietary patterns and cardiovascular disease (CVD) risk?
- 4. Will the next revision of SR protocols establish numeric cut-points for acceptable distribution of study participant health status (i.e. with or without outcome of interest) and risk factor thresholds (e.g. define "high cholesterol")?
- 5. How will study design exceptions, i.e. use of case-control evidence for some, but not all, DGAC research questions be recognized in DGAC conclusions and recommendations?
- 6. Regarding evidence gaps created by search strategy and related publication date criteria, how will studies of specific macronutrient proportion diet studies published prior to 2000 be identified in the re-screening of existing NESR SR evidence?

9110 E. Nichols Ave. Suite 300 Centennial, CO 80112 303.694.0305 www.beef.org



We look forward to the next set of revised protocols and continued efforts by NESR and the 2020 DGAC to make evidence-based public health recommendations that are objective, transparent, and scientifically valid.

Shalene McNeill, PhD, RD

Executive Director, Human Nutrition Research National Cattlemen's Beef Association smcneill@beef.org 830-569-0046

Shalene McNeill

RE: Questions regarding the application of NESR methodology as reflected in updated protocols

Revised systematic review (SR) protocols posted in advance of Meeting 3 of the 2020 Dietary Guidelines Advisory Committee (DGAC) [1] partially address observations outlined in a prior evidence overview submitted by National Cattlemen's Beef Association (NCBA) on behalf of the Beef Checkoff [2]. Newly posted protocols, and discussions among the DGAC during Meeting 3, have also added new insights into the systematic approach taken by the Nutrition Evidence Systematic Review (NESR) team and the 2020 DGAC. The following discussion provides a list of questions and a related scenarios grid (Table 1) regarding application of NESR methodology.

Questions include:

- 1. How does the use of the AMDR as a cut-point for specific macronutrient proportion diets affect conclusions and evidence recommendations?
- 2. During title first screening, how will studies of diets examining specific macronutrient proportions be consistently recognized?
- 3. Why is external evidence (i.e. SR evidence from external organizations) being considered in the protocol regarding dietary patterns and cardiovascular disease (CVD) risk?
- 4. Will the next revision of SR protocols establish numeric cut-points for acceptable distribution of study participant health status (i.e. with or without outcome of interest) and risk factor thresholds (e.g. define "high cholesterol")?
- 5. How will study design exceptions, i.e. use of case-control evidence for some, but not all, DGAC research questions be recognized in DGAC conclusions and recommendations?
- 6. Regarding evidence gaps created by search strategy and related publication date criteria, how will studies of specific macronutrient proportion diet studies published prior to 2000 be identified in the re-screening of existing NESR SR evidence?

Evidence gaps created by search strategy and publication date criteria

As noted previously by the Beef Checkoff [2], SR best practice aims to examine the totality of evidence, and typically examines data regardless of the year published [3, see C35]. The revision of protocols designed to update existing NESR team SRs to begin in the year 2000, rather than from the end date of the existing review as noted by protocols posted in July, narrows the evidence gap for dietary patterns not considered by the 2015 DGAC, i.e. specific macronutrient proportion diets. Further updating of inclusion criteria for dietary pattern research questions to note that efforts will be made to "...include literature that examines macronutrient proportion diets in articles published prior to 2014 that were not included in the existing review" adds additional assurance that relevant evidence will be identified [4,5]. These revisions do, however, result in evidence for specific macronutrient proportion diets being gathered using a variety of approaches, i.e. evidence published between 1980 and 2000 will be gleaned from existing search results produced using search strategies not designed to address these particular diets, and evidence for the period from 2000-present will be searched using targeted macronutrient-specific search terms [6]. How will this approach influence the resulting evidence base? In other words, will review of evidence

published prior to 2000, but found only via a search designed to find certain dietary patterns and/or dietary pattern methods, identify the full scope of available evidence for specific macronutrient proportion diets, and will previously excluded studies be considered relevant if their titles and abstracts are lacking the targeted terminology used in post-2000 searches? Table 1 provides an example of a study published prior to 2000 that was excluded from the existing 2015 NESR SR regarding dietary patterns and measures of body weight or obesity. The final disposition of this study of "glycemic load", despite being related to a carbohydrate-modified diet, in the re-screening of 2015 results for the 2020 DGAC is unclear. The rationale for curtailing the literature searches for new NESR SRs from 2000 to the present has not been provided by the posted protocols, and the consequence of not using a targeted search strategy for identifying and screening evidence related to specific macronutrient proportion diets published prior to 2000 remains to be seen.

Study design exceptions

Updated protocols also provide an explanation for the use of case-control studies as part of the evidence base designed to answer research questions related to dietary patterns and risk of sarcopenia and neurocognitive function [5,7]. Case-control studies are considered a weaker level of evidence [8,9], but updated protocols indicate that case-control evidence will be "considered" due to the low incidence of certain outcomes related to these topics [5,7]. This is contrary to the "Standard NESR Inclusion and Exclusion Criteria" as presented by Dr. Barbara Schneeman [10]. The allowance of lower quality evidence for the sarcopenia and neurocognitive protocols, but not all the SR protocols, introduces an element of inconsistency in the evidence base for DGAC conclusions and recommendations. Will DGAC conclusions and recommendations recognize evidence limitations and downgrade the strength of evidence for risk of bias introduced by weak study designs [11,12]?

Evidence cut-points for populations and biomarker values

Posted protocols [1] continue to lack an objective definition for the term, "some," as it refers to the allowance for participants with a particular disease/outcome in studies designed to measure a particular disease or outcome. "Some" is a subjective term and leaves room for inconsistency in the screening process for the inclusion or exclusion of studies based on population demographics. During subcommittee (SC) discussions during meeting 3, reference was made to the exclusion of studies "exclusively" conducted in a particular population, but allowance for "some" subjects with a particular disease or condition [13]. Without further clarification, this approach suggests that studies with any percentage of participants with a particular condition/outcome less than 100% would be eligible for inclusion. If this is the case, we request that this clarification be stated in the next revision of protocols.

Further, 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 numeric cut point for "high cholesterol" has not been provided [4]. 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 [14]. However, as noted in an earlier submission to the docket, the BOLD study participants represent an un-medicated population with "near/above optimal" to "borderline high" LDL levels [14]. Without a definition of "high cholesterol", the current SR protocol for dietary patterns and cardiovascular disease provides no clarity on how a study like the BOLD study 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"[15].

Revised dietary fat and cardiovascular disease protocol introduces evidence from external systematic reviews

During her opening remarks for Meeting 3, DGAC chair, Barbara Schneeman reiterated information from Meeting 1, specifically, that SRs conducted by organizations other than NESR will not be used by the 2020 DGAC to answer their questions [16]. All protocols designed to produce new NESR SRs related to dietary fat [17] have been aligned to the same search start date, beginning in the year 2000, with the exception of the protocol designed to address the relationship between dietary fat and CVD risk [18]. This protocol indicates that the literature search will begin in 2010 because the protocol has been designed to "builds upon the 2015 DGAC report which considered evidence in adults preceding January 2010."[18] The 2015 DGAC report in and of itself is not a SR and the 2015 DGAC did not base their recommendations solely on NESR SR, as is the stated intention of the 2020 **DGAC.** In fact, the 2015 DGAC "chose to conduct a focused review of published systematic reviews and meta-analyses on saturated fat intake and CVD" [19], and the report notes that in the case of questions related to cardiovascular health, "The DGAC examined research compiled in the NEL Dietary Patterns Systematic Review Project, which included 55 articles summarizing evidence from 52 prospective cohort studies and 7 randomized controlled trials (RCTs), and the 2013 AHA/ACC Lifestyle Guideline on Lifestyle Management to Reduce Cardiovascular Risk and associated National Heart, Lung, and Blood Institute (NHLBI) Lifestyle Report, which included primarily RCTs. The Committee drew additional evidence and effect size from six published systematic reviews/meta-analyses..."[20]. Thus, proceeding as proposed with the use of the 2015 DGAC report as the foundation to answer the research question related to CVD and dietary fat, will result in the introduction of systematic reviews by an outside organization for this question, and is inconsistent with every other protocol outlined for the 2020 DGAC to date.

How does the use of the AMDR as a cut-point for macronutrient proportion specific diets affect conclusions and evidence recommendations?

SR protocols for dietary pattern questions have been revised to specify that specific macronutrient proportion diets must fall outside the AMDR to be considered as evidence to answer related research questions [21]. This specification makes clear that studies of low carbohydrate diets must investigate dietary patterns with less than 45% of energy as carbohydrate and, in the case of high-fat diets, greater than 35% of energy as fat. What remains unclear, however, is if any requirements will be imposed on the remaining macronutrients in a particular macronutrient specific proportion diet. In other words, because

"...the AMDR is expressed as a percentage of total energy intake because its requirement, in a classical sense, is not independent of other energy fuel sources or of the total energy requirement of the individual" requiring each macronutrient be expressed in terms relative to each other [22], will other macronutrients also be required to fall outside the AMDR to be considered acceptable evidence? Diets low in carbohydrate are typically accompanied by either higher protein or higher fat intakes but, in the case of higher protein diets, typically remain within the AMDR for protein [23]. It would add additional clarity regarding the process of evidence identification if the SR protocols would note if any inclusion/exclusion criteria will be applied to other macronutrients in a macronutrient specific proportion diet and, if so, provide the rationale.

In addition, clarification regarding the interpretation of this evidence is currently lacking in the protocols. Specially, the AMDR is defined as "...a range of intakes for a particular energy source that is associated with reduced risk of chronic diseases while providing adequate intakes of essential nutrients" [22]. Based on this definition, if the DGAC finds sufficient favorable evidence for low carbohydrate diets (i.e. outside the AMDR for carbohydrate), would their recommendations endorse a level of intake that by definition may increase risk of disease or nutrient inadequacy? The AMDR for carbohydrate ranges from 45-65% of total calories. Reducing carbohydrate intake by 20%, i.e. from the upper to the lower level of the range, represents a lower carbohydrate diet that remains within the AMDR but evidence regarding this level of carbohydrate intake will be excluded by the current criteria despite the potential for positive health outcomes. In other words, do the current criteria establish a scenario where, for example, evidence regarding balanced, lower carbohydrate diets will be dismissed, and only evidence for diets that are outside the AMDR will be considered (See Table 1)? It is unclear how favorable evidence from specific macronutrient proportion diets within and outside the AMDR will be interpreted and used to model related dietary patterns.

Title Only Screening is Expedited Methodology

In the discussion of results reviewed by the Dietary Fats and Seafood SC, Dr. Snetselaar presented a slide outlining the flow of search results through the various stages of screening [24]. From this slide, and similar flow charts from other SC discussions during Meeting 3, it is apparent that NESR has implemented a two-step process for the screening of titles and abstracts. Specifically, rather than reviewing these titles and abstracts simultaneously, titles are being screened first, independent of abstracts. This practice in the context of the NESR SR reviewed during Meeting 3, has resulted in the majority of exclusions occurring at the title only screening level [24]. The implementation of title-first screening has been previously proposed as a useful method for scoping searches and rapid reviews, the generalizability of this expedited methodology to datasets designed for other applications, i.e. for an evidence-based review designed to inform public policy, is unknown [25], but precision has been found to be higher using the traditional title and abstract combined screening versus a title-first approach [26]. Attempts to validate a title-first screening approach have found that the method consistently results in reduced workload but requires "...a thorough workup of the potential synonyms and alternative terms." [25]. Search terms, search strategies/search

strings, could provide insight regarding potential synonyms used by NESR in the screening of titles but, despite requests for the public posting of this information [27-29] currently posted protocols do not provide search term information. Table 1 provides two examples studies that would likely be screened out based on the title but otherwise meets current inclusion criteria based on review of the abstract or full text.

As detailed above, updates to the NESR/DGAC SR protocols will narrow evidence gaps by expanding search date criteria but introduce inconsistency in the process of gathering evidence by utilizing targeted search strategies from the year 2000 forward but not for the identification of evidence published prior to 2000 [6]; allowing study designs of lower quality of evidence to be evaluated by the DGAC for some but not all topics [8-10]; and introduce external systematic reviews through the use of the 2015 DGAC report as the foundation for the CVD and dietary fats research question [18-20]. Further, confirmation that title-first screening methodology will identify all relevant evidence and that use of AMDR cut-points will not exclude evidence related to diets that test the full-range of the AMDR has not been provided. Science-based dietary guidance relies on systematically reviewing the totality of evidence for the nutrition questions at hand, using best practice methods [11]. We look forward to the next set of revised protocols and continued efforts by NESR and the 2020 DGAC to make evidence-based public health recommendations that are objective, transparent, and scientifically valid.

References:

- 1. Topics and Questions Under Review by the Committee https://www.dietaryguidelines.gov/work-under-way/review-science/topics-and-questions-under-review Accessed November 5, 2019
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- What is the relationship between dietary patterns consumed and neurocognitive health?: Systematic Review Protocol https://www.dietaryguidelines.gov/sites/default/files/2019-09/DP-NeurocognitiveHealthProtocol-09-19-19.pdf Accessed November 5, 2019
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- 16. 2020 Dietary Guidelines Advisory Committee Third Meeting October 24, 2019 Morning Session https://www.youtube.com/watch?v=x4SF4rcgYX4&feature=youtu.be Dr. Barbara Schneeman at 23:15.
- 17. Topics and Questions Under Review by the Dietary Fats and Seafood Subcommittee https://www.dietaryguidelines.gov/work-under-way/review-science/topics-and-questions-under-review#DietaryFatsAndSeafood Accessed November 5, 2019
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Table 1. Sample Questions Regarding the Application of NESR Inclusion Exclusion Criteria During Screening of Evidence Related to Dietary Pattern Questions¹

Clarification Question	Current Inclusion Criteria	Current Exclusion Criteria	Rationale for Clarification Request
Will diets designed to examine specific macronutrient within the AMDR be considered as dietary pattern evidence?	"•Studies that examine consumption of and/or adherence to a specific macronutrient proportion diet (i.e., studies that examine a diet where the level of the macronutrient is outside of the AMDR such as low-carbohydrate diet <45% of energy from carbohydrate or a high-fat diet of >35% of energy from fat)	•Studies that do not provide a description of or examine a specific % of energy from macronutrients (i.e., low-carbohydrate diet <45% of energy from carbohydrate or a high-fat diet >35% of energy from fat) •Studies that do not describe all of the macronutrients in the diet (i.e., carbohydrate, fat, and protein)"	During discussion on Day 1 Meeting 3 Dr. Rick Mattes asked Dr. Carol Boushey about how a heavily plant-based diet would be treated if it was within the AMDR since inclusion criteria had been updated to require that specific macronutrient proportion diets must fall outside the AMDR. Dr. Boushey indicated that these diets would be captured in the "top definition" and that she "went through the same thing" even though she'd worked on it. ² Given that the DGAC members continue to question how these criteria will be applied, we respectfully request clarification on the grouping of specific macronutrient proportion diets <i>within and outside</i> the AMDR.
During title first screening, how will studies of diets examining specific macronutrient proportions be consistently recognized?	See above	See above	The following title reflects results from a study designed to determine the benefits of high protein on weight loss: "Equivalent reductions in body weight during the Beef WISE Study: beef's role in weight improvement, satisfaction and energy." However, the description of the study as high protein is not noted until the first line of the abstract "The objective of this randomized equivalence trial was to determine the impact of consuming lean beef as part of a high protein (HP) weight-reducing diet on changes in body weight, body composition and cardiometabolic health." Is there a mechanism to prevent eligible studies from being incorrectly excluded with title-first screening methodology?

During re-screening of studies published prior to 2000 in existing NESR SR, how will macronutrient specific proportion diets be recognized?	The inclusion and exclusion criteria for the date of publication were edited to include literature that examines macronutrient proportion diets in articles published prior to 2014 that were not included in the existing review.	Articles published prior to January 1980 or after September 2019	The following title reflects results from a study originally excluded from the existing NESR SR used to inform 2015 DGAC recommendations ⁴ - "Long-term effects of 2 energy-restricted diets differing in glycemic load on dietary adherence, body composition, and metabolism in CALERIE: a 1-y randomized controlled trial." Neither the title, nor the abstract, directly describe a specific macronutrient proportion diet in terms currently outlined in NESR SR protocols i.e. low-carbohydrate or high-fat but the full text of the paper provides the distribution of all 3 macronutrients of interest and indicates that this study was designed to test a diet with 40% of energy as carbohydrate.
			Is there a mechanism to prevent eligible studies from being incorrectly excluded

Examples taken from https://www.dietaryguidelines.gov/sites/default/files/2019-09/DP-ObesityProtocol-09-19-19.pdf

² 2020 Dietary Guidelines Advisory Committee Third Meeting October 24, 2019 Morning Session https://www.youtube.com/watch?v=x4SF4rcgYX4&feature=youtu.be
Begin 1:19:31

³Sayer RD, et al. Equivalent reductions in body weight during the Beef WISE Study: beef's role in weight improvement, satisfaction and energy. Obes Sci Pract 2017;3:298–310.

⁴ A Series of Systematic Reviews on the Relationship Between Dietary Patterns and Health Outcomes. https://www.semanticscholar.org/paper/A-Series-of-Systematic-Reviews-on-the-Relationship/9dc0ebed6c942f2be042fe359c12a801f1dbc690 Accessed November 5, 2019

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