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Comment on FR Doc # 2019-12806

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Comment

RE: Questions regarding "new" protocols as presented at January 2020 DGAC meeting

This edition of the Dietary Guidelines for Americans (DGA) is the first to specifically address the nutrient needs of pregnant and lactating women, and infants and young children from birth to 24 months (B-24), as well as the first to explore the association between dietary patterns and risk of sarcopenia, unique to older Americans. The protocols for most of the Pregnancy/B-24 research questions rely on use of existing NESR systematic reviews (SR). According to criteria previously outlined in Meeting 1, 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." This relevancy criterion is not met by any of the existing NESR pregnancy SR, as these SR relied exclusively on a dietary pattern approach such that macronutrient proportion diets (i.e. low-carbohydrate and high-fat diets) were not considered, and these diets are part of the 2020 DGAC's current research agenda.

Also explained during Meeting 4, in the interest of prioritization and refinement, evidence outcomes for sarcopenia have been reduced to the disease endpoints of sarcopenia and severe sarcopenia exclusively. This shift from review of both intermediate and endpoint outcomes, to endpoint outcomes only, will reduce the amount and nature of the evidence used to answer this question, and has been introduced as a time saving measure.

The attached overview outlines evidence regarding the use of existing NESR SR and endpoint only approaches to answer these questions as it regards timeliness and relevancy, and preferential reliance on observational evidence.

Attachments (1)

[BeefCheckoffCommentsOnMeeting4Protocols](#)

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

Category:

Food industry

February 7, 2020

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 “new” protocols as presented at January 2020 DGAC meeting

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

This edition of the Dietary Guidelines for Americans (DGA) is the first to specifically address the nutrient needs of pregnant and lactating women, and infants and young children from birth to 24 months (B-24), as well as the first to explore the association between dietary patterns and risk of sarcopenia, unique to older Americans. The protocols for most of the Pregnancy/B-24 research questions rely on use of existing NESR systematic reviews (SR). According to criteria previously outlined in Meeting 1, 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.” This relevancy criterion is not met by any of the existing NESR pregnancy SR, as these SR relied exclusively on a dietary pattern approach such that macronutrient proportion diets (i.e. low-carbohydrate and high-fat diets) were not considered, and these diets are part of the 2020 DGAC’s current research agenda.

Also explained during Meeting 4, in the interest of prioritization and refinement, evidence outcomes for sarcopenia have been reduced to the disease endpoints of sarcopenia and severe sarcopenia exclusively. This shift from review of both intermediate and endpoint outcomes, to endpoint outcomes only, will reduce the amount and nature of the evidence used to answer this question, and has been introduced as a time saving measure.

The following overview outlines evidence (see attached) regarding the use of existing NESR SR and endpoint only approaches to answer these questions as it regards timeliness and relevancy, and preferential reliance on observational evidence.



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RE: Questions regarding “new” protocols as presented at January 2020 DGAC meeting Evidence Overview and Supporting Citations

This edition of the Dietary Guidelines for Americans (DGA) is the first to specifically address the nutrient needs of pregnant and lactating women, and infants and young children from birth to 24 months (B-24).¹ This edition of the DGA is also the first to explore a research topic unique to older Americans, i.e. the association between dietary patterns and risk of sarcopenia.² As detailed below, the protocols for most of the Pregnancy/B-24 research questions rely on use of existing NESR systematic reviews (SR).^{3,4} Also explained during Meeting 4 (January 23-24, 2020), in the interest of prioritization and refinement, evidence outcomes for sarcopenia have been reduced to the disease endpoints of sarcopenia and severe sarcopenia exclusively.⁵ This shift from review of both intermediate and endpoint outcomes, to endpoint outcomes only, will reduce the amount and nature of the evidence used to answer this question, and has been introduced as a time saving measure.⁶ The following overview outlines evidence regarding the use of existing NESR SR and endpoint only approaches to answer these questions as it regards timeliness and relevancy, and preferential reliance on observational evidence.

Timeliness and Relevancy

During Meeting 4, the Birth to 24 Months subcommittee (SC) chair, Dr. Kay Dewey announced that conclusions from existing NESR SR, completed independent of the DGA process, regarding the association between complementary feeding and infant health outcomes would be carried forward as 2020 Dietary Guidelines Advisory Committee (DGAC) draft conclusions.⁷ Likewise, Pregnancy and Lactation SC chair, Dr. Sharon Donovan indicated that conclusions from existing NESR SR regarding dietary patterns and risk of gestational diabetes (GDM), hypertension (HTN), and others would be carried forward as 2020 DGAC conclusions.⁸ According to criteria outlined in Meeting 1, 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.”⁹ **This relevancy criterion is not met by any of the existing NESR pregnancy SR, as these SR relied exclusively on a dietary pattern approach such that macronutrient proportion diets (i.e. low-carbohydrate and high-fat diets) were not considered, and these diets are part of the 2020 DGAC’s current research agenda.**^{10,11}

¹ Stoody E, et al. The Pregnancy and Birth to 24 Months Project: a series of systematic reviews on diet and health. *Am J Clin Nutr* 2019;109(Suppl):685S–697S.

² <https://www.dietaryguidelines.gov/work-under-way/review-science/topics-and-questions-under-review#DietaryPatterns> Accessed February 1, 2020

³ <https://www.dietaryguidelines.gov/work-under-way/review-science/topics-and-questions-under-review#PregnancyAndLactation> Accessed February 1, 2020

⁴ <https://www.dietaryguidelines.gov/work-under-way/review-science/topics-and-questions-under-review#BirthTo24Months> Access February 1, 2020

⁵ <https://www.youtube.com/watch?v=2RnX37Xoz18&feature=youtu.be> 18:35; 36:18 Accessed February 1, 2020

⁶ <https://www.youtube.com/watch?v=2RnX37Xoz18&feature=youtu.be> 36:05 Accessed February 1, 2020

⁷ <https://www.youtube.com/watch?v=LRHw6gtwLL8&feature=youtu.be> 45:43; 56:00 Accessed February 1, 2020

⁸ <https://www.youtube.com/watch?v=LRHw6gtwLL8&feature=youtu.be> 1:53:42 Access February 1, 2020

⁹ Obbagy J. Nutrition Evidence Systematic Review. resented at 2020 Dietary Guidelines Advisory Committee - First meeting, March 28-29, 2019. Available at: <https://www.dietaryguidelines.gov/sites/default/files/2019-05/Day%201%20Nutrition%20Evidence%20Systematic%20Review.pdf> Slide 22

¹⁰ Raghavan R, et al. Dietary patterns before and during pregnancy and maternal outcomes: a systematic review. *Am J Clin Nutr* 2019;109(Suppl):705S–728S.

¹¹ <https://www.dietaryguidelines.gov/work-under-way/topics-and-questions-review-organized-topic> Accessed February 1, 2020

Regarding timeliness, criteria described in Meeting 1 indicates that an existing NESR SR would be considered “timely” if the “existing NESR review considered articles published within, or close to, the same date range selected for the systematic review question’s inclusion and exclusion criteria.”⁹ Best practices in systematic review recommend SR updates every two years and, at the very latest after 5.5 years, to maintain timeliness.¹² The pregnancy SR are at the best practice threshold for timeliness of two years, with evidence from articles published through 2017.¹⁰ The B-24 systematic reviews on the other hand, have exceeded the best practice recommendation of two years, and will be nearing the upper limit of the best practice range by the time the DGAC completes their deliberations, as included evidence will be 4 years out of date with include articles published through July 2016.¹³ According to the existing NESR SR conclusion statements, in numerous instances, evidence published through July 2016 proved insufficient to answer the proposed research questions.^{13,14} It was noted, however, in Meeting 1, that “If the review is not timely, and an update is needed, NESR will conduct a literature search to identify articles published since the end of the date range used in the existing NESR review.”⁹ Dr. Kay Dewey noted during Meeting 4 that an “informal” search of the literature published since the completion of the existing NESR SR was conducted, but no evidence was found that would change the existing conclusions.⁷ **A protocol for this “informal” search has not been provided to aid the public in providing evidence that may be relevant. Furthermore, without documentation of the results of this “informal” search, it is not clear how the public will be able to meet the requirement indicated by Dr. Dewey, i.e. that the public should only submit evidence that the DGAC would consider sufficient to change the existing NESR conclusions.**⁷

If it is indeed the DGAC’s intention to not systematically review evidence published later than mid-2016 for B-24, or later than 2017 for pregnancy-related research questions, and not consider evidence regarding the role of low-carbohydrate and high-fat diets when making recommendations for pregnant and lactating women, then it is within best practices in SR for the DGAC to qualify their recommendations with acknowledgment of these limitations.¹⁵ In other words, the DGAC’s strength of evidence assessment would indicate that their conclusions for these questions are based on dated evidence and lack evidence regarding certain dietary patterns.¹⁵

Preferential reliance on observational evidence

The Dietary Patterns SC has “refined” the sarcopenia protocol to include only studies that report disease endpoints (i.e. sarcopenia or severe sarcopenia), rather than intermediate endpoints.⁵ **This approach creates an observational-only evidence base, as disease endpoints are not typically randomized control trial (RCT) outcomes.**¹⁶ The originally posted DGAC protocol included “skeletal muscle mass (e.g., sum of skeletal muscle mass in both arms and legs); muscle strength (e.g., handgrip); muscle performance (e.g., gait speed)” as functional, intermediate outcomes.¹⁷ **A significant evidence base regarding the role of high quality protein intake in supporting these intermediate outcomes in older**

¹² IOM (Institute of Medicine). 2011. Finding What Works in Health Care: Standards for Systematic Reviews. Washington, DC: The National Academies Press.

¹³ Obbagy, JE et al. Complementary feeding and micronutrient status: a systematic review. *Am J Clin Nutr* 2019;109(Suppl):852S–871S

¹⁴ Obbagy, JE et al. Complementary feeding and bone health: a systematic review. *Am J Clin Nutr* 2019;109(Suppl):872S–878S

¹⁵ National Academies of Sciences, Engineering, and Medicine. Redesigning the Process for Establishing the Dietary Guidelines for Americans. Washington, DC: The National Academies Press, 2017.

¹⁶ Schulze, MB, et al. Food based dietary patterns and chronic disease Prevention. *BMJ* 2018;361:k2396 | doi: 10.1136/bmj.k2396

¹⁷ <https://www.dietaryguidelines.gov/sites/default/files/2019-09/DP-SarcopeniaProtocol-09-19-19.pdf>

adults is available,¹⁸ but with this protocol change, such evidence will be eliminated from the DGAC’s deliberations and will be unavailable to support their recommendations. It is recognized that, “...randomized controlled trials can support or refute observations using surrogate markers of disease” and that “surrogate (intermediate) markers... can be important mediating factors between food intake, food pattern, and disease risk.”¹⁶ Use of intermediate markers or outcomes also supports determination of biological causality and testing within RCTs provides evidence for dietary patterns where relationships for chronic disease prevention are still emerging.¹⁶ **By eliminating intermediate markers of sarcopenia from consideration, there will be less evidence for use by the DGAC to make strong recommendations despite an abundance of literature that supports a role of key dietary patterns in intermediate markers of this disease.¹⁸ In other words, use of intermediate markers provides more evidence to help formulate recommendations for healthful dietary patterns in this vulnerable American sub-population.**

Science-based dietary guidance relies on systematically reviewing the totality of evidence for the nutrition questions at hand, using best practice methods that are thorough, transparent, objective, relevant, and timely.^{9,12,15} In closing, as outlined above, **reliance on existing NESR SR (without systematic updates) and abbreviation of the sarcopenia protocol to eliminate intermediate endpoints, prohibits consideration of the totality of evidence for these topics, and is inconsistent with best practices in systematic review and nutrition science.^{12,15}**

¹⁸ Lio CD, et al. Effects of protein supplementation combined with resistance exercise on body composition and physical function in older adults: a systematic review and meta-analysis. *Am J Clin Nutr* 2017;106:1078–91.