

The 2015 Dietary Guidelines Advisory Committee's Scientific Process: An Overview of the Methodology Used to Create the 2015 Scientific Advisory Reportⁱ

A brief from the Johns Hopkins Center for a Livable Future

There has been a great deal of discussion about the process used by the 2015 Dietary Guidelines Advisory Committee (DGAC). With this briefing, the Johns Hopkins Center for a Livable Future provides an overview of the rigorous methodology employed by the 2015 DGAC to develop dietary recommendations for the U.S. population.

Every 5 years, the Departments of Agriculture (USDA) and Health and Human Services (HHS) establish a DGAC to analyze the current *Dietary Guidelines for Americans* and review new scientific evidence that may be incorporated into updated guidelines. The USDA's Nutrition Evidence Library (NEL) assists each DGAC in scientific reviews and the development of the DGAC's Advisory Report, which is then submitted to USDA and HHS. USDA and HHS jointly develop the final *Dietary Guidelines for Americans* document using information in the DGAC's Advisory Report and comments from the public and federal agencies.

The NEL's methodology in reviewing, evaluating, and synthesizing peer-reviewed food and nutrition research is informed by the Agency for Healthcare Research and Quality, the Cochrane Collaboration, the Academy of Nutrition and Dietetics, and the 2011 Institute of Medicine systematic review standards:

- Agency for Healthcare Research and Quality (AHRQ): The NEL uses the AHRQ's Methods Guide for Effectiveness and Comparative Effectiveness Reviews, which "presents issues key to the development of Comparative Effectiveness Reviews and describes recommended approaches for addressing difficult, frequently encountered methodological issues."ⁱⁱ
- The Cochrane Collaboration: The NEL uses The Cochrane Handbook for Systematic Reviews of Interventions, which contains methodological guidance to help reviewers make well-informed decisions about the review methods they use.^{III}
- The Academy of Nutrition and Dietetics: The NEL employs the Academy's Evidence Analysis Manual, which helps "expert workgroup members and evidence analysts understand and carry out the process of evidence analysis."^{iv}
- 2011 Institute of Medicine Systematic Review Standards: The NEL uses the standards developed by the Institute of Medicine's Committee on Standards for

Systematic Reviews of Comparative Effective Research, which were developed "to assess potential methodological standards that would assure objective, transparent, and scientifically valid systemic reviews of comparative effective research and to recommend a set of methodological standards for developing and reporting such systematic reviews."

Once a DGAC is formed, it begins by identifying research questions to be addressed through systematic reviews. DGACs then work directly with NEL staff to conduct multiple systematic reviews. NEL staff provide oversight and assistance to ensure that the DGAC's process is efficiently and accurately implemented in accordance with the NEL methodology, as summarized above, though the DGAC makes all substantive decisions involved with the process. The DGAC's employment of NEL's methodology allows USDA and HHS to comply with the Data Quality Act, which states that Federal agencies must ensure the quality, objectivity, utility, and integrity of the information disseminated by Federal agencies.^{vi}

In advising the 2015 DGAC, the NEL employed a six-step systematic review process (the following language is adapted from the description of methodology in the 2015 Scientific Report):

Step 1: Develop questions for systematic review and analytic frameworks

The DGAC identified, refined, and prioritized the most relevant topics and then developed systematic review questions that were appropriate in scope, reflected the state of the science, and targeted important policy relevant to public health issues. Once topics and specific questions to be answered by systematic review were generated, the DGAC developed an analytical framework for each topic in accordance with NEL methodology. These frameworks clearly identified the core elements of the systematic review question/s, key definitions, and potential confounders to inform development of the systematic review protocol.

Step 2: Search, screen, and select studies to review

The NEL librarians created search strategies that used appropriate databases and search terms to identify literature to answer each systematic review question. The NEL librarians and staff screened the results of the literature search to determine which articles met the criteria for inclusion in the review. NEL staff and the DGAC also conducted a duplication assessment to determine whether high-quality systematic reviews or meta-analyses were available to augment or replace a NEL systematic review.

Step 3: Extract data and assess the risk of bias of the research

NEL staff performed a risk of bias assessment using key information from each study included in systematic reviews. The risk of bias for each study was assessed using the NEL Bias Assessment Tool, which helped determine whether any systematic error existed to either over- or under-estimate the study results. This tool was developed in collaboration with a panel of international systematic review experts. NEL staff reviewed the work of abstractors, resolved inconsistencies, and generated a draft of a descriptive summary of the body of evidence. The DGAC reviewed this work and used it to inform their synthesis of the evidence. Step 4: Describe and synthesize the evidence

The DGAC compared, contrasted, and combined evidence from multiple studies to develop key findings and a graded conclusion statement to answer each systematic review question. This qualitative synthesis of the body of evidence involved identifying overarching themes or key concepts from the findings, identifying and explaining similarities and differences between studies, and determining whether certain factors affected the relationships being examined.

Step 5: Develop conclusion statements and grade the evidence

The conclusion statement—worded as an answer to the systematic review question must be tightly associated with the evidence, focused on general agreement among the studies around the independent variable(s) and outcome(s), and may acknowledge areas of disagreement or limitations, where they exist. The conclusion statement reflects the evidence reviewed and does not include information that is not addressed in the studies.

The DGAC used predefined criteria to evaluate and grade the strength of available evidence supporting each conclusion statement. The grade communicates the strength of the evidence supporting a specific conclusion statement. The grade for the body of evidence and conclusion statement was based on five elements outlined in the NEL grading rubric: quality, quantity, consistency, impact and generalizability.

Step 6: Identify research recommendations

Based on the existing body of evidence, research gaps, and limitations, the DGAC formulated research recommendations in order to advance knowledge and inform future Federal food and nutrition guidance as well as other policies and programs.

In order to prevent duplication of effort and promote efficiency in time and resource management, the DGAC chose to review existing high-quality sources of evidence such as reports from leading scientific organizations or Federal agencies, systematic reviews, and/ or meta-analyses. When systematic reviews or meta-analyses that addressed the DGAC's questions were identified, NEL staff conducted a quality assessment using the Assessment of Multiple Systematic Reviews (AMSTAR) tool. This tool includes 11 questions, each of which is given a score of one if the criterion is met or a score of zero if the criterion is not met, is unclear, or is not applicable. Articles rated 0-3 were considered to be of low quality, 4-7 of medium quality, and 8-11 of high quality. Unless otherwise noted, only high quality systematic reviews and meta-analyses were considered by the DGAC.

The 2015 DGAC established a Data Analysis Team (DAT) to streamline the data acquisition process and support data requests. Upon request from the DGAC, the DAT either conducted data analyses or compiled data from their agencies' publications for the DGAC to use for specific research questions. The DGAC took the strengths and limitations of data analyses into account in drawing conclusions. All data used by the DGAC were made publically available through www.DietaryGuidelines.gov. Upon publication, the data also became available via the report's references and appendices.

Given that the primary charge of the DGAC is to provide food-based recommendations with the potential to inform the next edition of the Dietary Guidelines for Americans, it is imperative that the DGAC also advise the government on how to articulate the evidence on the relationships between diet and health through food patterns. This is a critical task because the Dietary Guidelines are the basis for all Federal nutrition assistance and educational initiatives. For this reason, as with the 2005 and 2010 DGACs, the 2015 Committee developed a number of questions to be answered through a food pattern modeling approach, using the USDA Food Patterns.

The 2015 DGAC followed a rigorous process outlined in the legislative and agency guidance^{vii} and developed recommendations that are based in sound science.

For more information about the DGAC's or NEL's scientific processes or methodology, see the full Methodology section of the 2015 DGAC's Scientific Report or visit the guides and standards employed by the NEL (linked in references below).

For more information or additional resources from the Center for a Livable Future on the Dietary Guidelines for Americans, please <u>visit our website</u> or <u>contact us</u>.

(Endnotes)

ⁱ Scientific Report of the 2015 Dietary Guidelines Advisory Committee—Part C. Methodology. Office of Disease Prevention and Health Promotion website. Accessed on July 31, 2015. Available at: <u>http://www.health.</u> gov/dietaryguidelines/2015-scientific-report/05-methodology.asp#footnote_link-2

ⁱⁱ Methods Guide for Effectiveness and Comparative Effectiveness Reviews. Agency for Healthcare Research and Quality. U.S. Department of Health Human Services Website. Updated January 2014. Accessed on July 31, 2015. Available at: <u>http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-re-</u> <u>ports/?productid=318&pageaction=displayproduct</u>

Higgins J, Green S. Cochrane Handbook for Systematic Reviews of Interventions. The Cochrane Collaboration. Version 5.1.0 Accessed on October 5, 2015. Available at: <u>http://handbook.cochrane.org/</u>

^{iv} Evidence Analysis Manual: Steps in the Academy Evidence Analysis Process. Academy of Nutrition and Dietetics website. Published January 2012. Accessed on July 31, 2015. Available at: <u>http://www.andeal.org/files/Docs/2012_Jan_EA_Manual.pdf</u>

^v Institute of Medicine. Finding What Works in Health Care: Standards for Systematic Reviews. Washington, DC: The National Academies Press; 2011. Accessed on July 31, 2015. Available at: <u>http://books.nap.edu/</u> <u>openbook.php?record_id=13059</u>

^{vi} Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies. Office of Management and Budget. The White House website. Published September 2001. Accessed on July 31, 2015. Available at: <u>https://www.whitehouse.gov/omb/fedreg_final_infor-</u> <u>mation_quality_guidelines/</u>

^{vii} Charter—2015 Dietary Guidelines Advisory Committee. The Secretary of Health and Human Services. January 9, 2013. Available at: <u>http://health.gov/dietaryguidelines/dgac2015-charter-final.pdf</u>