

Commentary

The Systematic Review Methodology Used to Support the 2010 Dietary Guidelines Advisory Committee

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The Dietary Guidelines for Americans (DGA) are jointly issued and updated every 5 years by the US Department of Agriculture (USDA) and the US Department of Health and Human Services (HHS). They provide authoritative nutrition advice for people age 2 years and older to promote health and reduce risk for major chronic diseases. To update the 2005 DGA (1), the USDA and HHS appointed a 13-member Dietary Guidelines Advisory Committee (DGAC) to provide independent, science-based advice and recommendations that would inform the development of the 2010 DGA. The Committee was charged to focus their review on scientific evidence published since the 2005 DGAC report and place primary emphasis on the development of food-based recommendations (2).

The purpose of this paper is to describe the systematic review methodology used by the 2010 DGAC to support the development of its evidence-based conclusions and recommendations. Strengths and opportunities for enhancing the process are also presented. The USDA Nutrition Evidence Library (NEL) was created to conduct systematic reviews to inform federal nutrition policy and programs. The NEL methodology was developed with assistance from the Agency for Healthcare Research and Quality and the American Dietetic Association and was

informed by the US Cochrane Collaboration process. The Committee worked with the NEL, along with other USDA and HHS staff, to conduct an extensive, rigorous, and transparent review of the scientific literature to form the foundation for the *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010* (3). This report focuses on the role of food and food groups, nutrients, and dietary habits on health promotion and disease prevention.

COMMITTEE FRAMEWORK

The DGAC was divided into the following seven subcommittees: Energy Balance and Weight Management; Nutrient Adequacy; Fatty Acids and Cholesterol; Carbohydrates and Protein; Sodium, Potassium, and Water; Alcohol; and Food Safety and Technology. In addition, a Science Review subcommittee was formed to provide oversight. Over a 2-year period, the subcommittees met regularly via conference calls, webinars, e-mail, and in face-to-face meetings. In addition, there were six public meetings in which the full DGAC met to deliberate the science and formulate their conclusions and recommendations. The public had opportunities throughout the process to provide oral and written comments to the DGAC. The 2010 DGAC Report and materials from each of the public meetings, including archived recordings, meeting minutes, and public comment summary reports, are available at www.dietaryguidelines.gov.

OVERVIEW

The DGAC led the evidence analysis project with technical assistance from NEL staff and support from the Dietary Guidelines Management Team and other USDA and HHS staff.

The NEL six-step systematic review process provided the structure for the review. The steps include: 1) develop research questions, 2) create and implement literature search and sort plans, 3) develop evidence portfolios, 4) synthesize the bodies of evidence, 5) develop conclusion statements and grade the evidence, and 6) describe research recommendations (Figure 1). The process is iterative, such that every step of the process may be revised or refined to ensure that the final body of evidence appropriately answers the research question.

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- 1. Develop research questions**
 - PICO (Population, Intervention, Comparator, and Outcome[s]) framework used
- 2. Create and implement literature search and sort plans**
 - Establish inclusion and exclusion criteria for study selection
 - Define search strategy
 - Conduct literature search
 - Determine included and excluded studies
- 3. Develop evidence portfolios**
 - Extract relevant evidence from studies in worksheets
 - Evaluate the methodological rigor of each study
 - Draft an evidence paragraph and table entry for each study
- 4. Synthesize the bodies of evidence**
 - Develop evidence summary overviews
- 5. Develop conclusion statements and grade the evidence**
 - Come to consensus across the full committee
- 6. Describe research recommendations**

Figure 1. Overview of the Nutrition Evidence Library (NEL) systematic evidence-based review methodology.

DEVELOP RESEARCH QUESTIONS

The first step of the evidence analysis process was the development of research questions. To identify which research questions would be addressed, each DGAC subcommittee first identified topic areas of interest by reviewing the 2005 DGAC report, determining areas of rapidly developing science, focusing on those with the greatest public health impact, and taking into consideration the oral and written public comments. In addition, NEL staff conducted exploratory literature searches and developed analytical frameworks to guide the subcommittees' work. Because the topic areas identified were numerous and broad, the subcommittees then prioritized the topics and made critical decisions related to the comprehensiveness of the reviews. In some cases, there were existing systematic reviews that addressed key topic areas and questions, and to reduce redundancy the DGAC chose to use these existing reviews rather than conduct their own systematic reviews on the topic. For example, the 2007 World Cancer Research Fund/American Institute for Cancer Research report *Food, Nutrition, Physical Activity, and the Prevention of Cancer: A Global Perspective* (4) was used as the basis for many recommendations related to cancer outcomes. The 2008 *Physical Activity Guidelines for Americans* (5) formed the basis of physical activity recommendations, and the *Seafood Choices: Balancing Benefits and Risks*, 2007 report (6) from the Institute of Medicine provided evidence to support recommendations regarding the benefits and risks of fish consumption.

A total of 130 research questions were approved by the full Committee. The PICO (Population, Intervention, Comparator, and Outcomes) method was used to focus each of the research questions. The general population was the focus of the majority of questions, including healthy children and adults, as well as those who were overweight, obese, or at increased risk of chronic disease. A few questions targeted pregnant or breastfeeding

women or older adults as the population of interest. The interventions and comparators that most questions focused on were foods and food group intake, micro- and macronutrient intake, dietary behaviors, and environment, whereas outcomes included both health-related outcomes and diet-related behaviors. In addition, a family of questions assessed consumer use of generally accepted food safety practices.

CREATE AND IMPLEMENT LITERATURE SEARCH AND SORT PLANS

After the research questions were approved by the full DGAC, subcommittees developed a literature search and sort plan that would guide the identification of scientific articles used to answer each research question. The search and sort plan includes databases and search terms, as well as inclusion and exclusion criteria. A wide variety of search terms and key words were used, including subject headings such as Medline Subject Headings (MeSH) and thesaurus terms. DGAC members reviewed, refined, and approved each search and sort plan, and provided related articles to guide the search strategy when appropriate. The primary databases searched for all of the research questions were PubMed/Medline and the Cochrane Database of Systematic Reviews. These were supplemented by other databases such as Bioscience Information Service of Biological Abstracts (BIOSIS), Centre for Agricultural Bioscience Abstracts, Embase, ScienceDirect, Scopus, and other subject-specific databases as appropriate, depending on the specific research question. The DGAC only included studies published in English in peer-reviewed journals that focused on human subjects and were conducted in developed countries as defined by the Human Development Index. Subcommittees established additional inclusion and exclusion criteria by question or family of questions, including date range and study design.

For questions that were addressed by the 2005 DGAC, the date range for the updated search was 2004 through 2009. In some cases, previously published systematic reviews were selected as a starting point for a review if the seminal research on a question was considered to be "settled science" or if inclusion of a broader collection of studies was desired. For questions not addressed by the 2005 DGAC, the date range was often extended based on expert opinion and exploratory literature searches.

The DGAC also considered which study designs to include and exclude for each research question. Randomized and nonrandomized controlled trials, observational studies (cohort and cross-sectional studies), ecological studies, systematic reviews, and meta-analyses were all considered for inclusion based on the nature of the question. In many cases, cross-sectional studies were excluded if studies of stronger design were available. If the subcommittees decided to include systematic reviews or meta-analyses in the review, the primary studies included in the review or meta-analyses were excluded. If multiple systematic reviews or meta-analyses were included, with an overlapping body of primary studies, this was noted in the evidence summary.

The NEL librarian conducted all database searches and did initial title sorts to exclude articles that clearly did not address the question. NEL project managers sorted

abstracts and full-text articles based on approved criteria and developed a list of included and excluded articles (citing rationale for exclusion). Reference lists from review and primary articles were hand-searched. Subcommittee members reviewed the sort lists. If members identified relevant articles that were not on the sort list, or if results were too expansive or too limited, the subcommittee refined the search strategy and the search was rerun. Once the search and sort was complete, the DGAC subcommittee members approved the sort list for evidence portfolio development. The NEL staff continued to monitor the literature for new articles until a defined end date.

DEVELOP EVIDENCE PORTFOLIOS FOR EACH QUESTION

Relevant information from all included articles in the review was assembled into evidence portfolios. In addition to the full text of each article, the DGAC was provided with an evidence worksheet, evidence paragraph, and overview table that summarized the information from each study in the review.

Each article on the included list was assigned to an evidence abstractor to analyze and extract key data into an evidence worksheet template. Evidence abstractors had advanced degrees in nutrition or a related field and completed a comprehensive training program on reviewing and extracting relevant data from research articles and evaluating the methodological rigor of studies based on predefined criteria. The quality of each article was assessed using the Research Design and Implementation (RDI) Checklist, developed and validated by the American Dietetic Association. The RDI checklist is based on criteria outlined in the Agency for Healthcare Research and Quality report, *Systems to Rate the Strength of Scientific Evidence* (7). Two RDI checklists (for primary and review studies) were used, and both include four relevancy questions and 10 scientific validity questions (8). NEL project managers reviewed the accuracy and quality of each evidence worksheet and RDI checklist, and the DGAC was provided the worksheets as a component of the evidence portfolio.

The NEL staff worked with the DGAC to define the content of evidence paragraphs and overview tables for a question or family of questions. Using the evidence worksheets, RDI checklists, and full-text articles, NEL staff drafted evidence paragraphs and overview tables. The evidence paragraphs briefly summarized each included study and reported relevant data, including: authors, year, rating, population, location, subject number, sex, age, intervention and comparison/control condition, assessment of food intake and intervention methodology, intermediate markers and health outcomes, and authors' conclusions. The overview tables paralleled the evidence paragraphs and provided concise information on each included study.

SYNTHESIS OF THE BODY OF EVIDENCE

Subcommittee members reviewed the portfolio of evidence, clarified definitions and inclusion criteria, and defined an approach to analyzing the body of evidence based on: study design (eg, systematic reviews, randomized con-

The criteria for grading the strength of the evidence included the following elements:

Quality

- Scientific rigor and validity
- Study design and execution

Quantity

- Number of studies
- Number of subjects in studies

Consistency of findings across studies

Impact

- Importance of studied outcomes
- Magnitude of effect

Generalizability to the population of interest

The 2010 DGAC Conclusion Statement Chart can be accessed at: <http://www.nutritionevidencelibrary.gov/topic.cfm?cat=3210>

Figure 2. The Dietary Guidelines Advisory Committee's predetermined criteria for grading the strength of the evidence supporting each conclusion statement developed.

trolled trials, and cohort studies), population characteristics (eg, data from healthy subjects were analyzed separately from data from subjects with type 2 diabetes), and/or intervention characteristics (eg, intervention diets substituting saturated fat with carbohydrate vs polyunsaturated fat were analyzed separately).

Subcommittee members and NEL staff worked together to develop evidence summary overviews that enumerated the number, type, and quality of included studies, key definitions, statements about methodology and strengths and limitations of the body of evidence, key findings or trends, potential rationale for variations observed, and a discussion of findings.

DEVELOP AND GRADE THE CONCLUSION STATEMENT

Subcommittee members reviewed and deliberated on the body of evidence as they developed a conclusion statement to answer each research question. Committee members focused on areas of general agreement among the studies and when evidence addressed only one sex, age group, ethnicity, or level of health risk, this was reflected in the conclusion statement.

Subcommittees evaluated the strength of the body of evidence supporting each conclusion using criteria approved by the DGAC. This criteria was adapted and validated by the American Dietetic Association based on the original work by Greer and colleagues (9). Grading criteria included: quality of design, the quantity of studies and subjects, the consistency of findings across studies, the generalizability to the population of interest, and the magnitude of the effect or public health impact. **Figure 2** provides more detail on the grading criteria. The Committee selected the following qualitative words to describe the strength of the evidence supporting their conclusion statements: *strong*, *moderate*, *limited*, *expert opinion*, and *grade not assignable*. The full DGAC-approved grading chart is available on the NEL Web site (www.nutritionevidencelibrary.gov/topic.cfm?cat=3210).

Once a subcommittee reached agreement on a conclusion statement and grade, the conclusion and portfolio of evidence was presented at a Science Review Subcommittee meeting for further deliberation. Finally, each graded conclusion statement was presented to the DGAC at a public meeting and, when necessary, additional revisions were made to conclusion statements and grades until consensus was reached. Development and grading of conclusion statements was a time-consuming process that benefited from group interaction.

DEFINE RESEARCH RECOMMENDATIONS

After subcommittees developed a conclusion for a research question, they identified research recommendations related to the question or topic area. These recommendations are included in the 2010 DGAC report (www.dietaryguidelines.gov) and are available on the NEL Web site (www.nutritionevidencelibrary.gov).

STRENGTHS, LIMITATIONS, AND FUTURE IMPROVEMENTS

The involvement and leadership provided by the 13 eminent scientists who served on the 2010 DGAC was a fundamental strength of the evidence-based, systematic review process. The Committee conducted an exhaustive review of topics, developed structured research questions, and followed a rigorous, unbiased, and transparent process to examine and analyze the evidence. Based on this extensive review and synthesis, the DGAC drew conclusions and reached consensus regarding the strength of the evidence supporting each conclusion. Further research is needed to clarify the optimal hierarchy of study designs to use to answer various types of research questions and to guide grading of portfolios of evidence consisting of both experimental and observational data. The NEL will continue to monitor and update the systematic review methodology used, based on the evolution of the science in this area.

CONCLUSIONS

The 2010 DGAC, with support from USDA and HHS staff, invested an enormous amount of time and talent in developing, for the first time, a broad range of evidence portfolios that fully documented the review of science supporting the 2010 DGAC Report. All systematic re-

views completed as a part of the Report can be accessed by the public at: www.nutritionevidencelibrary.gov. This work will serve as a strong foundation for subsequent DGACs. The USDA and HHS are currently assessing methodology to monitor and update these portfolios in the interim. DGAC members stated that the NEL process provided a much-needed structure for the evidence-based review that led to a transparent and rigorous process, which minimized bias and increased the credibility of the report.

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