2010 Dietary Guidelines Advisory Committee (DGAC) Nutrition Evidence Library Methodology

USDA's Nutrition Evidence Library supported the 2010 Dietary Guidelines Advisory Committee as it conducted systematic reviews on diet and health. This document includes archives from www.NEL.gov describing the systematic review methodology used by the 2010 Dietary Guidelines Advisory Committee. The NEL systematic review methodology is also outlined in *Part C: Methodology* of the *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010*.

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OVERVIEW

Government staff assisted the 2010 Dietary Guidelines Advisory Committee members in the execution of the systematic review using the methodology outlined in *Part C: Methodology* of the *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010*. Below is a summary of the NEL evidence-based systematic review process and the division of duties between government staff and the Dietary Guidelines Advisory Committee.

For additional information on 2010 Dietary Guidelines Advisory Committee NEL methodology, see the following published article:

Spahn JM, Lyon JM, Altman JM, Blum-Kemelor DM, Essery EV, Fungwe TV, Macneil PC, McGrane MM, Obbagy JE, Wong YP. The systematic review methodology used to support the 2010 Dietary Guidelines Advisory Committee. J Am Diet Assoc. 2011 Apr;111(4):520-3. doi: 10.1016/j.jada.2011.01.005. PubMed PMID: 21443982.

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SUMMARY OF THE NEL SYSTEMATIC REVIEW PROCESS USED TO SUPPORT THE 2010 DGAC

NEL Process Steps	Brief Description	Government Staff Responsibilities	DGAC Responsibilities
Formulate the Question	Specify a question. Define the **P**opulation, **I**ntervention/cause, **C**omparator and **O**utcome of interest (PICO chart development); define criteria for study selection.	- Facilitate meetings - Facilitate PICO chart development - Conduct preliminary searches - Recommend search strategies - Populate sort list tool (e.g., search terms, inclusion & exclusion criteria)	- Define topic areas - Draft questions to research - Develop an analytical framework - Define scope of question (PICO) - Define inclusion and exclusion criteria for literature search and sort plan
Gather/classify evidence	Conduct and document a systematic search of the literature to find evidence related to the question; list systematic reviews and primary studies separately.	- Facilitate meetings - Conduct and document a systematic search of the literature - List included systematic reviews and primary studies separately - List excluded studies with rationale - Hand search manuscripts for additional citations	- Review/approve the sort list e.g., review inclusion/ exclusion criteria, databases and search terms used, included and excluded studies - Describe critical components and table column headings to guide data extraction
Critically appraise each included study	Review studies for relevance to the question and critique for scientific validity. Abstract key information to an evidence worksheet and determine the study quality rating (positive, negative, or neutral) based upon the Research Design and Implementation Checklist (see below).	- Facilitate meetings - Build portal infrastructure - Assign included articles to abstractors to draft evidence worksheets - Perform quality review and finalize evidence worksheets	- Review the evidence summary paragraph for each study for accuracy and clarity - Review overview tables for completeness and clarity

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Summarize the evidence	Write a brief paragraph that summarizes the key data from each included study. Develop an overview table that displays key information from each study to answer the question.	- Facilitate meetings - Draft a brief, easy-to-read evidence summary paragraph for each included study to report relevant, scientifically valid data - Create an overview table based upon DGAC specifications - Facilitate review of the evidence summary by all subcommittee members - Update text in portal as instructed by DGAC members	- Create an evidence summary which synthesizes the available evidence. This may include: - A brief overall summary statement describing number and type of studies reviewed - Findings including agreement and disagreement among studies - Comparison factor statements e.g., differences in findings by gender, age, disease stage - Methodological statements - Impact of outcome - Definitions - if needed can be added as glossary terms - Bring to full DGAC for review/approval
Develop a conclusion statement and grade the strength of evidence supporting the conclusion	Develop a concise conclusion statement to answer the question based on a synthesis of all relevant studies and deliberation with subcommittee members. Grade the strength of the evidence informing the conclusion statement using the 2010 DGAC Conclusion Grading Chart (see below).	- Facilitate meetings - Update text in portal as instructed by DGAC members	- Develop a conclusion statement, based upon a synthesis of the findings of all relevant studies - Assign a grade to indicate the overall strength or weakness of evidence informing the conclusion statement - Bring to DGAC for review/approval
Develop research recommendations	Develop research recommendations.	- Facilitate meetings and input research recommendations in the computer	- Develop research recommendations based on the review of literature

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RESEARCH DESIGN AND IMPLEMENTATION (RDI) CHECKLISTS

Each study the 2010 Dietary Guidelines Advisory Committee reviewed received a quality rating of positive, neutral, or negative, based upon a predefined scoring system. The appraisal of study quality is a critical component of the systematic review methodology because in a highly transparent manner, it indicates the Committee's judgment regarding the relevance (external validity/generalizability) and validity of each study's results. Ratings were assessed using two versions of the Research Design and Implementation Checklists.

The Research Design and Implementation Checklist: Primary Research includes ten validity questions based on the Agency for Healthcare Research and Quality (AHRQ) domains for research studies. Sub-questions are listed under each validity question that identify important aspects of sound study design and execution relevant to each domain. Some sub-questions also identify how the domain applies in specific research designs.

RESEARCH DESIGN AND IMPLEMENTATION CHECKLIST: PRIMARY RESEARCH

RELEVANCE QUESTIONS
1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some epidemiological studies)
2. Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?
3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?
4. Is the intervention or procedure feasible? (NA for some epidemiological studies)
VALIDITY QUESTIONS
1. Was the research question clearly stated? 1.1 Was the specific intervention(s) or procedure (independent variable(s)) identified? 1.2 Was the outcome(s) (dependent variable(s)) clearly indicated? 1.3 Were the target population and setting specified?
2. Was the selection of study subjects/patients free from bias? 2.1 Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria

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critical to the study?

2.2 Were criteria applied equally to all study groups?

2.3 Were health, demographics, and other characteristics of subjects described?

2.4 Were the subjects/patients a representative sample of the relevant population?

3. Were study groups comparable?

3.1 Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if randomized controlled trial (RCT))

3.2 Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?

3.3 Were concurrent controls used? (Concurrent preferred over historical controls.)

3.4 If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?

3.5 If case control study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)

3.6 If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., “gold standard”)?

4. Was method of handling withdrawals described?

4.1 Were follow up methods described and the same for all groups?

4.2 Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)

4.3 Were all enrolled subjects/patients (in the original sample) accounted for?

4.4 Were reasons for withdrawals similar across groups?

4.5 If diagnostic test, was decision to perform reference test not dependent on results of test under study?

5. Was blinding used to prevent introduction of bias?

5.1 In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?

5.2 Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)

5.3 In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?

5.4 In case control study, was case definition explicit and case ascertainment not influenced by exposure status?

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5.5 In diagnostic study, were test results blinded to patient history and other test results?

6. Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?

6.1 In RCT or other intervention trial, were protocols described for all regimens studied?

6.2 In observational study, were interventions, study settings, and clinicians/provider described?

6.3 Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?

6.4 Was the amount of exposure and, if relevant, subject/patient compliance measured?

6.5 Were co-interventions (e.g., ancillary treatments, other therapies) described?

6.6 Were extra or unplanned treatments described?

6.7 Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?

6.8 In diagnostic study, were details of test administration and replication sufficient?

7. Were outcomes clearly defined and the measurements valid and reliable?

7.1 Were primary and secondary endpoints described and relevant to the question?

7.2 Were nutrition measures appropriate to question and outcomes of concern?

7.3 Was the period of follow-up long enough for important outcome(s) to occur?

7.4 Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?

7.5 Was the measurement of effect at an appropriate level of precision?

7.6 Were other factors accounted for (measured) that could affect outcomes?

7.7 Were the measurements conducted consistently across groups?

8. Was the statistical analysis appropriate for the study design and type of outcome indicators?

8.1 Were statistical analyses adequately described the results reported appropriately?

8.2 Were correct statistical tests used and assumptions of test not violated?

8.3 Were statistics reported with levels of significance and/or confidence intervals?

8.4 Was “intent to treat” analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?

8.5 Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?

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8.6 Was clinical significance as well as statistical significance reported? 8.7 If negative findings, was a power calculation reported to address type 2 error?
9. Are conclusions supported by results with biases and limitations taken into consideration? 9.1 Is there a discussion of findings? 9.2 Are biases and study limitations identified and discussed?
10. Is bias due to study's funding or sponsorship unlikely? 10.1 Were sources of funding and investigators' affiliations described? 10.2 Was there no apparent conflict of interest?

RESEARCH DESIGN AND IMPLEMENTATION CHECKLIST: REVIEW ARTICLES

The Research Design and Implementation Checklist: Review Articles has ten validity questions that incorporate the AHRQ domains for systematic reviews. These questions identify the systematic process for drawing valid inferences from a body of literature.

RELEVANCE QUESTIONS
1. Will the answer if true, have a direct bearing on the health of patients?
2. Is the outcome or topic something that patients/clients/population groups would care about?
3. Is the problem addressed in the review one that is relevant to dietetics practice?
4. Will the information, if true, require a change in practice?
VALIDITY QUESTIONS
1. Was the question for the review clearly focused and appropriate?
2. Was the search strategy used to locate relevant studies comprehensive? Were the databases searched and the search terms used described?
3. Were explicit methods used to select studies to include in the review? Were inclusion/exclusion criteria specified and appropriate? Were selection methods unbiased?

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4. Was there an appraisal of the quality and validity of studies included in the review? Were appraisal methods specified, appropriate, and reproducible?
5. Were specific treatments/interventions/exposures described? Were treatments similar enough to be combined?
6. Was the outcome of interest clearly indicated? Were other potential harms and benefits considered?
7. Were processes for data abstraction, synthesis, and analysis described? Were they applied consistently across studies and groups? Was there appropriate use of qualitative and/or quantitative synthesis? Was variation in findings among studies analyzed? Were heterogeneity issued considered? If data from studies were aggregated for meta-analysis, was the procedure described?
8. Are the results clearly presented in narrative and/or quantitative terms? If summary statistics are used, are levels of significance and/or confidence intervals included?
9. Are conclusions supported by results with biases and limitations taken into consideration? Are limitations of the review identified and discussed?
10. Was bias due to the review's funding or sponsorship unlikely?

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CLASS OF RESEARCH

Classifying studies and reports gives an initial picture of the type of studies and level of evidence available. It also helps organize the reports for critical appraisal. Once the study design is identified and classified, this classification was then recorded on the article's worksheet template.

CLASSIFICATION OF REPORTS

Classification	Primary Reports
A	Randomized controlled trial (RCT)
B	Cohort study
C	Nonrandomized trial with concurrent or historical controls Case-control study Study of sensitivity and specificity of a diagnostic test Time series
D	Cross-sectional study Trend Study Case series Case report Before and after study
Classification	**Secondary Reports**
M	Meta-analysis or Systematic review Decision analysis Cost-benefit analysis Cost-effectiveness study
R	Narrative review (Review article) Consensus statement Consensus report
X	Medical opinion

Adapted by the American Dietetic Association from ©Joint Commission Resources: "A Practical Approach to Evidence Grading." Joint Commission Journal on Quality Improvement 2000:Volume 26(12):707

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CONCLUSION GRADING CHART

The 2010 Dietary Guideline Advisory Committee approved the use of the following predefined criteria to grade the strength of the evidence supporting each conclusion statement. These criteria guided members to carefully evaluate the following characteristics of the body of literature supporting each conclusion:

- quality of studies (both strength of design and execution),
- quantity of studies and subjects,
- consistency of findings across studies,
- the magnitude of effect, and
- generalizability of findings.

The chart below was used by the 2010 Dietary Guidelines Advisory Committee and defines the criteria used to determine each grade.

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GRADING CHART USED BY THE 2010 DGAC TO EVALUATE THE STRENGTH OF THE BODY OF EVIDENCE SUPPORTING CONCLUSION STATEMENTS

Elements	Strong	Moderate	Limited	Expert Opinion Only	Grade Not Assignable
Quality - Scientific rigor and validity - Study design and execution	Studies of strong design Free from design flaws, bias, and execution problems	Studies of strong design with minor methodological concerns OR only studies of weaker study design for question	Studies of weak design for answering the question OR inconclusive findings due to design flaws, bias, or execution problems	No studies available Conclusion based on usual practice, expert consensus, clinical experience, opinion, or extrapolation from basic research	No evidence that pertains to question being addressed
Consistency - Consistency of findings across studies	Findings generally consistent in direction and size of effect or degree of association, and statistical significance with minor very exceptions	Inconsistency among results of studies with strong design, OR consistency with minor exceptions across studies of weaker design	Unexplained inconsistency among results from different studies, OR single study unconfirmed by other studies	Conclusion supported solely by statements of informed nutrition or medical commentators	NA
Quantity - Number of studies - Number of study participants	One large study with a diverse population or several good quality studies Large number of subjects studied Studies with negative results have sufficiently large sample size for adequate statistical power	Several studies by independent investigators Doubts about adequacy of sample size to avoid Type I and Type II error	Limited number of studies Low number of subjects studied and/or inadequate sample size within studies	Unsubstantiated by published research studies	Relevant studies have not been done

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Impact - Importance of studied outcomes - Magnitude of effect	Studied outcome relates directly to the question Size of effect is clinically meaningful Significant (statistical) difference is large	Some doubt about the statistical or clinical significance of the effect	Studied outcome is an intermediate outcome or surrogate for the true outcome of interest OR size of effect is small or lacks statistical and/or clinical significance	Objective data unavailable	Indicates area for future research
Generalizability - Generalizability to population of interest	Studied population, intervention and outcomes are free from serious doubts about generalizability	Minor doubts about generalizability	Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied	Generalizability limited to scope of experience	NA

Criteria adapted from the American Dietetic Association Evidence Analysis Library® and based upon: Greer N, Mosser G, Logan G, Wagstrom Halaas G. A practical approach to evidence grading. The Joint Commission Journal on Quality Improvement. 2000;26:700-712. Explanation of Grades and Grading Chart

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