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USDA Nutrition Evidence Library Systematic Reviews: Using food and nutrition research to inform nutrition programs and policies

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Introduction

The U.S. Department of Agriculture's Nutrition Evidence Library (NEL) is housed within the Center for Nutrition Policy and Promotion, and specializes in conducting systematic reviews (SRs) to inform Federal food- and nutrition-related policies and programs. NEL SRs provide government policymakers and program leaders with the scientific foundation that allows decisions to be made based on the strongest available evidence. For example, NEL SRs, conducted in conjunction with the 2010 Dietary Guidelines Advisory Committee (DGAC) and currently underway with the 2015 DGAC, provide evidence to support development of the *Dietary Guidelines for Americans*. Use of the NEL helps ensure compliance with mandates that Federal agencies ensure the quality, objectivity, utility, and integrity of the information used to form federal guidance as are outlined in the Consolidated Appropriations Act of 2001, the *Data Quality Act*.

Historically, SRs have been used to guide clinical decision-making in the healthcare arena. However, in recent years, the use of SRs has expanded to many other disciplines, including clinical and public health nutrition, as well as other areas of public health, education, and the social sciences. In response to this expansion, SR methods have been adapted and developed to address the diverse types of evidence that exist in these fields. Groups such as the Cochrane Collaboration Public Health Group (http://ph.cochrane.org), the Campbell Collaboration (http://www.campbellcollaboration.org), and the Agency for Healthcare Research and Quality (http://www.ahrq.gov) are leaders in the development of SR methodology, and the research conducted by these organizations can be leveraged by a variety of disciplines as they seek to ensure that SRs are being conducted using the most up-to-date methods and tools.

The field of public health nutrition, and in particular, the work of the NEL, has benefitted from this evolution in SR methodology. NEL has worked to ensure that its process meets current standards for conducting SRs,[1] and utilizes the most up-to-date methods and tools available.[2-4] The purpose of this paper is to describe the NEL methodology for conducting SRs, and highlight parts of this process that may be of particular interest to researchers.

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Nutrition Evidence Library Systematic Review Methodology

NEL's methods are designed to promote objective and transparent review, evaluation, and synthesis of peer-reviewed research to answer important food- and nutrition-related questions. Each step of the SR process is guided by a group of scientific experts with expertise in the topic being addressed (e.g., the DGAC or a Technical Expert Collaborative [TEC]). The TEC/DGAC makes the substantive decisions required throughout the process of conducting a SR, while NEL staff provides facilitation and support to ensure that the process is consistently implemented in accordance with NEL systematic review methodology. All NEL SRs are publically available at www.NEL.gov. Each step of the NEL SR methodology is described below.

Topic identification and systematic review question development

The primary aim of topic identification and SR question development is to obtain input from a broad group of experts to identify SR topics and key SR questions relevant to federal food and nutrition policy and programs.[5] As systematic reviews are labor intensive, this process is designed to ensure that the most relevant topics are selected for SRs, and questions are clearly focused and appropriate in scope. In general, a topic is considered to be within scope, and therefore appropriate for a NEL SR, if it addresses a food or nutrition issue that will inform public health action to: 1) promote population health or well-being, and/or 2) reduce the significant burden of avoidable disease in the U.S. population as a whole or in specific population subgroups. A topic is considered to be important when the results of a SR stimulated by the topic are likely to inform decisions about federal public health food and nutrition policies and programs, in particular, those areas of major public health concern for which there is uncertainty and/or a knowledge gap that is critical to improving public health. The SR questions developed to address these topics should reflect important decisional dilemmas in public health nutrition and reflect what decision makers need in order to make evidence-based policy and program decisions. SR questions must be specific enough to be researchable using NEL methodology, but broad enough to not overly limit the scope of the literature search. As part of the process, core elements of a SR question, Population, Intervention or Exposure, Comparator and Outcomes (PICO) are identified. The PICO represents key aspects of the topic that need to be considered in developing a SR framework. Once SR questions have been drafted, an analytic framework is created to help further refine and define elements of the SR question(s) and lay the foundation for the rest of the SR process. An analytic framework is a type of evidence model that defines and links populations, interventions or exposures and the comparators, intermediate outcomes, and clinical health outcomes, as well as key confounders to consider.

Literature search, screening, and selection

Searching, screening and selection of scientific literature is an objective process used to identify the body of evidence available to answer a systematic review question. This process is guided by inclusion/exclusion criteria that are determined a *priori*. Because NEL reviews are used to inform U.S. policies and programs, these criteria are often designed to ensure that the literature collected offers the strongest evidence for a causal relationship, and is most representative of the U.S. population. The NEL uses a standard set of criteria that are tailored based on the SR question, addressing various aspects of study design and implementation (e.g., study design, type of study subjects, study setting and location, sample size, dropout rate).

The NEL librarian creates and implements a search strategy that includes a list of appropriate databases and search terms to use in identifying literature. The results of the literature search are screened by the NEL staff in a dual, step-wise manner, beginning with titles, followed by abstracts, and then full text articles, to determine which articles meet the criteria for inclusion in the review. All articles that meet the inclusion criteria and related SRs are hand searched in an effort to find additional pertinent articles not identified through the electronic search. In addition, as part of this process, a duplication assessment is conducted to determine whether there are existing high-quality SRs or meta-analyses (MAs) that can be used to augment or replace a NEL SR.

The TEC/DGAC provides input throughout this process, to ensure that the inclusion and exclusion criteria are applied appropriately and the final list of included articles is complete and captures the most

relevant research to answer a SR question. In addition, each step of the process is meticulously documented to ensure transparency and reproducibility.

Data extraction and risk of bias assessment

Key data relevant to the SR question are extracted by NEL abstractors (i.e., trained volunteers with advanced degrees in nutrition or a related field) based on a data extraction template developed by NEL and the TEC/DGAC, and an Evidence Grid is developed that includes the data extracted for all studies included in the review. In addition, the risk of bias (i.e., internal validity) for each study is assessed by NEL abstractors using the NEL Bias Assessment Tool (BAT). These materials are then used by the TEC/DGAC in their review and synthesis of the body of evidence.

The data extraction from each article included in a systematic review should provide an overview of the methodology and key findings of an individual study as it relates to the SR question being addressed. Standard types of data extracted include:

- Sample size
- Location
- Subject characteristics: age, gender, race/ethnicity, socio-economic status, health status
- A description of the study
- Study duration
- Dietary assessment method
- Description of the independent variables
- Description of the outcomes measures and methods of outcome assessment
- Statistical adjustments/models
- Results
- Risk of Bias rating and limitations
- Funding source

Table 1: The types of bias that are addressed by the Nutrition Evidence Library Bias Assessment Tool

Selection Bias	Systematic differences between baseline characteristics of the groups that are compared; error in choosing the individuals or groups taking part in a study
Performance Bias	Systematic differences between groups in the intervention/exposure received, or in experience with factors other than the interventions/exposures of interest
Detection Bias	Systematic differences between groups in how outcomes are determined; outcomes are more likely to be observed or reported in certain subjects
Attrition Bias	Systematic differences between groups in withdrawals from a study, particularly if those who drop out of the study are systematically different from those who remain in the study

Adapted from: Cochrane Bias Methods Group: http://bmg.cochrane.org/assessing-risk-bias-included-studies

The NEL BAT is used to assess the risk of bias (i.e., internal validity) of each individual study included in a SR to determine whether any systematic error exists to either over- or under-estimate the study results. The types of bias that are addressed in the NEL BAT are described in Table 1.

The NEL BAT is tailored by study design, with different sets of questions applying to randomized controlled trials (14 questions), non-randomized controlled trials (14 questions), and observational studies (13 questions). NEL Abstractors complete the NEL BAT after data extraction for the article is complete, answering the questions based on the SR question being addressed. There are four response options:

- **Yes:** Information provided in the article is adequate to answer "yes".
- **No:** Information provided in the article clearly indicates an answer of "no".
- **Cannot Determine:** No information or insufficient information is provided in the article, so an answer of "yes" or "no" is not possible.
- **N/A:** The question is not applicable to the article.

The completed NEL BAT is used to rate the overall risk of bias for the article by tallying the responses to each question. Each "Yes" response receives 0 points, each "Cannot Determine" response receives 1 point, each "No" response receives 2 points, and each "N/A" response receives 0 points. Since 14 questions are answered for randomized controlled trials and non-randomized controlled trials, they will be assigned a risk of bias rating out of a maximum of 28 points; while observational studies will be out of 26 points. The lower the number of points received, the lower the risk of bias. Table 2 lists each question in the NEL BAT, the response options, and the applicable study design(s) for each question.

Evidence synthesis, conclusion statements and grading the strength of the evidence

Evidence synthesis is the process by which evidence from multiple studies is compared, contrasted, and analyzed to develop a graded conclusion statement that answers the SR question. This qualitative synthesis of the body of evidence

Table 2: NEL Bias Assessment Tool Questions, response options, and applicable study designs

	Risk of Bias Questions	Response Options	Randomized Controlled Trials	Controlled Trials	Observational Studies
1.	Were the inclusion/exclusion criteria similar across study groups?	• Yes • No • Cannot Determine • N/A		X	X
2.	Was the strategy for recruiting or allocating participants similar across study groups?	• Yes • No • Cannot determine • N/A		X	X
3.	Was the allocation sequence randomly generated?	• Yes • No • Cannot determine • N/A	X		
4.	Was the group allocation concealed (so that assignments could not be predicted)?	• Yes • No • Cannot determine • N/A	X		
5.	Was there an attempt to balance the allocation between the study groups or match the study groups (e.g., through stratification, matching, propensity scores)?	• Yes • No • Cannot determine • N/A			X
6.	Was distribution of health status, demographics, and other critical confounding factors similar across study groups at baseline? If not, does the analysis control for baseline differences between groups?	• Yes • No • Cannot determine • N/A	X	X	X
7.	Did the investigators account for important variations in the execution of the study from the proposed protocol or research plan?	• Yes • No • Cannot determine • N/A	X	X	X
8.	Was adherence to the study protocols similar across study groups?	• Yes • No • Cannot determine • N/A	X	X	X
9.	Did the investigators account for the impact of unintended/unplanned concurrent interventions or exposures that were differentially experienced by study groups and might bias results?	• Yes • No • Cannot determine • N/A	X	X	X
10.	Were participants blinded to their intervention or exposure status?	• Yes • No • Cannot determine • N/A	X	X	
11.	Were investigators blinded to the intervention or exposure status of participants?	• Yes • No • Cannot determine • N/A	X	X	
12.	Were outcome assessors blinded to the intervention or exposure status of participants?	• Yes • No • Cannot determine • N/A	X	X	X
13.	Were valid and reliable measures used consistently across all study groups to assess inclusion/exclusion criteria, interventions/exposures, outcomes, participant health benefits and harms, and confounding?	• Yes • No • Cannot determine • N/A	X	X	X
14.	Was the length of follow-up similar across study groups?	• Yes • No • Cannot determine • N/A	X	X	X

Table 2: Contunued on page 5

Table 2: Continued

15. In cases of high or differential loss to follow-up, was the impact assessed (e.g., through sensitivity analysis or other adjustment method)?	• Yes • No • Cannot determine • N/A	X	X	X
16. Were other sources of bias taken into account in the design and/or analysis of the study (e.g., through matching, stratification, interaction terms, multivariate analysis, or other statistical adjustment such as instrumental variables)?	• Yes • No • Cannot determine • N/A	X	X	X
17. Were the statistical methods used to assess the primary outcomes adequate?	• Yes • No • Cannot determine • N/A	X	X	X

involves identifying overarching themes or key concepts from the findings, identifying and explaining similarities and differences between studies, and determining whether certain factors impact the relationships being examined. A series of probing questions designed to facilitate the TEC's/DGAC's review and analysis of the evidence are developed and provided to the TEC/DGAC. The TEC/DGAC uses the description of the evidence, along with the full data extraction grid, the NEL BAT summary information, and full-text manuscripts, to critically examine the evidence and respond to the probing questions. Feedback from the TEC/DGAC is compiled and used to draft the qualitative evidence synthesis and the conclusion statement. The conclusion statement is then graded (Table 3), taking into consideration the following characteristics of the body of evidence used to develop the conclusion statement:

- **Quality (Risk of Bias)** assessment for studies included in a NEL SR is done using the NEL BAT. The NEL BAT assesses the internal validity of each study, or the scientific soundness of study design and execution to avoid potential bias in the findings.
- **Quantity** involves an assessment of the number of available studies, the number of subjects studied and adequacy of statistical power to detect type I and type II errors.
- **Consistency** refers to the degree of similarity in the direction and size of effect, degree of association and statistical significance across the studies available to answer the question.
- **Impact** assessment evaluates the directness of the study outcomes and magnitude of effect. Directness refers to the extent to which the body of evidence was designed to address the SR question, specifically, the link between the intervention or exposure of interest and a defined health outcome. Studies are considered indirect if the outcome measured is a surrogate outcome versus a health outcome. An evaluation of the size of the effect and judgment regarding clinical significance is also involved.
- **Generalizability**, or external validity to the U.S. population, is also assessed. NEL SRs are conducted to inform development of US Federal food and nutrition policy and guidance, therefore this assessment is important to decision makers. Experts must evaluate exposures and/or interventions, the comparators and outcomes measured for applicability to the US population as a whole or segments of the US population specified in the conclusion statement.

Research recommendations

Finally, NEL staff draft research recommendations based on input received from the TEC/DGAC throughout the process of reviewing and synthesizing the evidence. These research recommendations often reflect gaps in the literature, or the need to improve upon limitations in study methodology commonly found in the body of evidence examined. Some example research recommendations that were developed during the course of NEL systematic reviews examining the evidence around effective nutrition education for children and adolescents, and dietary patterns and health (full reviews are available at www.NEL.gov), are outlined in Table 4.

Table 3: Description of Grades Used by the USDA Nutrition Evidence Library

Strong	The conclusion statement is substantiated by a strong body of evidence and is unlikely to change if new evidence emerges.
Moderate	There are some methodological concerns related to the body of evidence, and new data might arise which would modify the conclusion statement.
Limited	The quality and/or quantity of evidence available to support the conclusion statement are weak, and are not strong enough to support policy recommendations.
Grade not assignable	The body of evidence is too small or has serious design flaws and a valid conclusion statement is not possible.

Table 4: Sample research recommendations from Nutrition Evidence Library systematic reviews.

Research recommendations from a series of systematic reviews on the effects of nutrition education on children's and adolescents' dietary intake
The systematic reviews highlighted a number of overarching limitations in the research on nutrition education, and research recommendations which apply globally to the field of nutrition education were identified. The following limitations were identified in the literature reviewed: • Many studies were conducted in single school districts or individual schools, limiting the generalizability of the study findings. • A number of studies were not designed or adequately powered to determine whether certain children are more responsive to nutrition education. • In much of the existing nutrition education research, the dose, frequency, and intensity of the interventions tested were not well characterized. More research is recommended to investigate: • Whether subject characteristics, such as age, gender, ethnicity, or socioeconomic status, affect the outcomes of nutrition education, and how nutrition education can effectively be delivered to diverse populations • Which dose of nutrition education is optimal in terms of changing children's and adolescents' dietary intake behavior • If there are long-term impacts of these types of interventions on children's and adolescents' dietary intake behavior, as well as body weight and other health outcomes.
Research recommendations from a series of systematic reviews on the relationship between dietary patterns and health outcomes
These systematic reviews highlighted a number of overarching limitations in the research on dietary patterns. The following limitations and research recommendations were identified: • Many studies only assessed dietary intake once at baseline. Dietary patterns are likely to change over time, due to a myriad of factors, including trends in the food supply, population and individual-level changes in food choices, and individual circumstances and physical needs, future studies which examine diet patterns over time in relation to the life course would be beneficial to understand the relationship between dietary patterns, critical periods of exposure, and health. • There was variability in how studies grouped foods and assessed the types and amounts of foods consumed; therefore, it was difficult to compare food and beverage intakes across studies. Additional research is needed to better quantitate the components of dietary patterns. • A number of studies, particularly studies examining vegetarian diets, were excluded from the reviews because they did not provide sufficient description of the dietary pattern consumed. Complete description of the foods and beverages consumed is essential for comparing studies and understanding the characteristics of the dietary patterns. • Many of the studies were conducted in predominantly Caucasian populations or presumed predominantly Caucasian for those conducted in Europe. Additional research should be conducted to examine if and how sex and ethnicity might influence the relationship between dietary patterns and health outcomes. Additionally, more research is recommended to: • Advance dietary pattern methodologies to better elucidate the indispensable aspects of dietary patterns which are key to promoting health and preventing disease. • Investigate other aspects of dietary patterns, including where and when foods and beverages are consumed • Test the effectiveness of dietary patterns identified in observational studies in randomized controlled trials. • Regarding *a priori* scores, examine the effects of different methods by which components are chosen, grouped, and scored and the effect those different methods have on the resulting relationships with health outcomes. • Strengthen the analysis of food components and their association with health outcomes, within the context of dietary patterns, to determine "drivers" of dietary patterns. For example, further investigation into the multivariate patterns within the range of overall scores is needed in index analyses. Scores that are neither very high nor very low can represent tremendous variation in patterns of dietary components. • Regarding *a posteriori* approaches, evaluate and standardize methods used to assess, organize, aggregate, and adjust food variables to facilitate interpretation of findings across studies.

Roles for nutrition researchers in the systematic review process

Systematic reviews that address public health nutrition questions are an important resource for the development of Federal policies and programs designed to improve the health of all Americans. Nutrition researchers play an essential role in building the scientific foundation supporting Federal food and nutrition policy and programs. The strength of a SR depends upon the availability of well designed, implemented, analyzed and reported research studies.

Nutrition researchers also support the NEL process by participating in a TEC/DGAC, serving as NEL abstractors, and by using SR tools and products, including the NEL BAT and research recommendations, to inform decisions they make when developing and implementing new

research. Additionally, nutrition researchers can contribute to the continuing evolution and refinement of SR methodology by collaborating with systematic review methodologists to understand how best to address the complexities of public health nutrition. Strategic use of SR products may support development of evidence in areas of high nutrition policy importance.

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Volunteers Needed…

Get involved! The RDPG needs volunteers for the following positions.

Student Editor for The Digest:
We are looking for a PhD student with experience publishing in peer-reviewed journals and strong editorial skills to serve as the student editor for *The Digest*. Email by 5/10/14 for details.
Contact: Ashley Vargas
AshleyVargasRDN@gmail.com

Student Writer for The Digest:
Are you a student? Consider writing a review or short research article for *The Digest*.
Contact: Ashley Vargas
AshleyVargasRDN@gmail.com

LinkedIn Coordinator:
We are looking for someone who is experienced with LinkedIn, has been actively involved in the RDPG, and has a presence on LinkedIn. Assistance is needed in monitoring our private community site and assisting in content contributions as needed.
Contact: Lauri Byerly
lbyerly@msn.com

Student Reps:
Participate with the practice group as a student volunteer. We need three volunteers: one to represent the eastern part of the US, one to represent the western part of the US, one to represent the middle part of the US. Student representatives would be responsible for representing student interests within the RDPG, organizing a meet-and-greet at FNCE for students interested in research, and other student-related opportunities.
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