Orientation to the Nutrition Evidence Library

2015 DGAC: Meeting #1

Joanne Spahn
Director
Evidence Analysis Library Division, CNPP, USDA

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Orientation Objectives

- Background of the NEL
- Overview of NEL's systematic review process
  - Highlight the interaction between the DGAC and NEL staff
  - Provide details on systematic review question development

Nutrition Evidence Library (NEL)

- Specializes in conducting systematic reviews to inform Federal nutrition policy and programs
  - Methodology added transparency and credibility to the 2010 DGA process
- Meets Federal mandates requiring that all agencies ensure the quality, objectivity, utility, and integrity of information used to form Federal guidance

NEL Process Improvements since 2010

- After-actions: DGAC, NEL, DGMT
- IOM – "Standards for SRs"
- Evolution in systematic review methodology

USDA Nutrition Evidence Library: Six-Step Process

1. Step 1: Systematic review question development
2. Step 2: Literature search, screening, and selection
3. Step 3: Data extraction and quality assessment
4. Step 4: Describing the evidence and evidence synthesis
5. Step 5: Conclusion statements and grading the evidence
6. Step 6: Research recommendations and technical abstracts

Step 1: Systematic review question development

- Goal: Develop, refine and prioritize systematic review questions which reflect important decisional dilemmas in public health nutrition guidance
- Information provided by the DGAC during topic identification is used to draft systematic review questions, PICOs, and analytic frameworks

Step 1: Systematic review question development

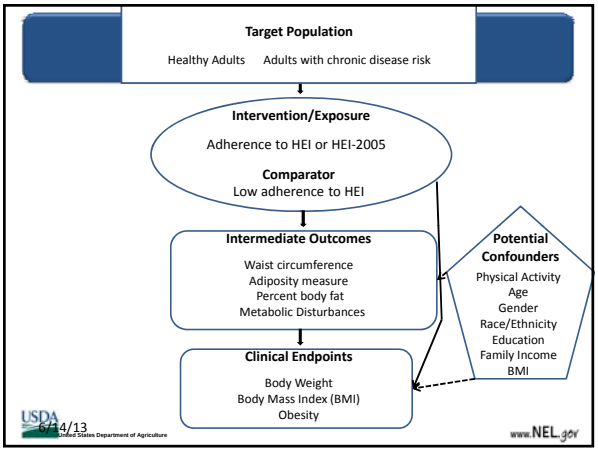
- SR questions should reflect important decisional dilemmas in public health nutrition guidance and reflect what decision makers need to know to make evidence-based decisions to enhance public health
- Must be researchable using NEL methodology (i.e., not too broad, but not too specific)
  - Too broad: What is the relationship between nuts and health?
  - Too specific: What is the relationship between intake of 2 oz/day of nuts over a one month period on cholesterol?
  - What is the relationship between nuts and risk of cardiovascular disease?

Step 1: Systematic review question development

- Defining the PICO ensures that key aspects of the systematic review question have been defined and is used to develop the analytic framework
  - Population: Target population of interest, and any relevant subpopulations
  - Intervention: Intervention and/or exposure
  - Comparator: Main comparison (e.g., main alternative to compare with the intervention or exposure)
  - Outcomes: Public health outcomes (e.g., health or diet-related)

Step 1: Systematic review question development

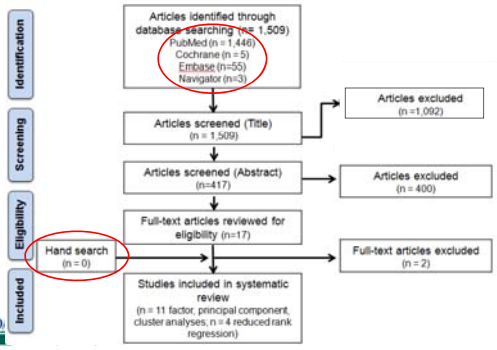
- An analytical framework is developed for each SR question (or family of questions) using the information from the PICO
- Analytic frameworks are a type of evidence model that links and defines clinical concepts, evidence, and populations as they relate to outcomes
  - Alternative and related concepts are:
    - Causal pathway
    - Conceptual framework
    - Influence diagrams
    - Theoretical frameworks
    - Logic models



Step 2: Literature search, screening, and selection

- Librarians from USDA and HHS
- Select inclusion/exclusion criteria
- Literature search
  - Electronic databases and hand search
- Literature screening and selection
  - Dual process using web-based tool
- All searches are documented

Step 2: Literature search, screening, and selection



Step 3: Data extraction and quality assessment

- Data Extraction:
  - Extract the key information needed to answer the systematic review question into the NEL "Grid"
    - Information about the study sample
    - Details about the methods used
    - Results
    - Strengths, limitations

Step 3: Data extraction and quality assessment

Step 3: Data extraction and quality assessment

- Quality Assessment:
  - The quality of each article used in a NEL systematic review is assessed:
    - Primary articles: NEL Quality Assessment Tool (QAT) *(currently being validated)*
    - Systematic reviews/meta-analyses: AMSTAR

Step 4: Describing the evidence and evidence synthesis

- NEL staff prepares a description of the evidence

SECTION 1: (provided mostly as bullets)
- # OF STUDIES:
- STUDY DESIGN:
- QUALITY RATING
- COUNTRY/LOCATION OF STUDIES:
- SAMPLE SIZE
- SUBJECT GENDER
- SUBJECT AGE:
- OTHER SUBJECT CHARACTERISTICS: Note any other important subject characteristics.
  - SUBJECT RACE
  - SUBJECT SES

SECTION 2: (provide as bullets, as appropriate)
Describe the interventions tested and methodology used
- How were the studies designed?
- What outcomes were considered and how were they measured?

SECTION 3: (provide as bullets, as appropriate)
Describe the results of the studies.
- How many studies found similar results?
- What studies had conflicting results?
- Did results vary depending on subject characteristics (ex. Age, gender, weight status)?
- Provide comparisons in table format, as possible

Step 4: Describing the evidence and evidence synthesis

- The description of the evidence is sent to the DGAC, along with a series of questions to solicit input on key trends, themes
  - Patterns of agreement/ disagreement?
  - Similarities/differences between the studies that explain any agreement/disagreement?
  - Factors (e.g., sex, race/ethnicity, age) that should be discussed?
  - Limitations, generalizability, magnitude of effect?
- NEL staff compiles the DGAC input and drafts the evidence synthesis, which is reviewed and revised by the DGAC

Step 4: Evidence synthesis

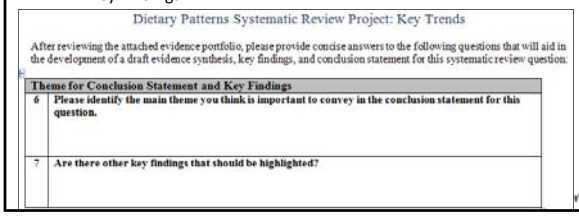
Dietary Patterns Systematic Review Project: Key Trends

After reviewing the attached evidence portfolio, please provide concise answers to the following questions that will aid in the development of a draft evidence synthesis, key findings, and conclusion statement for this systematic review question:

	Major Trends and Key Observations from this Body of Evidence
1	What are the patterns of agreement related to the intermediate and/or clinical outcomes among the articles (if any)?
2	a. What are the patterns of disagreement related to the intermediate and/or clinical outcomes among the articles (if any)?
	b. Are there differences between the studies (e.g., populations studied, methodology used, outcomes measured, or confounding variables considered) that may help explain the disagreement among the articles?
3	Are there certain dietary patterns that are consistently related (or not related) to weight status?
4	Are there certain components of the various dietary patterns examined in this body of evidence that are consistently related (or not related) to weight status?
5	Which of the factors (e.g., sex, race/ethnicity, age) identified in this body of evidence merit discussion when describing the relationship between dietary patterns and weight status?
	Evaluating the Body of Evidence
8	What methodological problems or limitations of the studies included in this review warrant discussion in the evidence synthesis?
9	Were results observed clinically meaningful from a public health perspective? (Magnitude of effect)
10	Are the participants included in this body of evidence representative of the general US population, including key subpopulations? (Generalizability)

Step 5: Conclusion statements and grading the evidence

- Development of CSs
  - NEL obtains DGAC input and uses it to facilitate the drafting of a conclusion statement with the DGAC
  - Brief overall summary statement worded as an answer to the systematic review question; additional information provided in "Key Findings"



Dietary Patterns Systematic Review Project: Key Trends

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	Theme for Conclusion Statement and Key Findings
6	**Please identify the main theme you think is important to convey in the conclusion statement for this question.**
7	**Are there other key findings that should be highlighted?**

Step 5: Conclusion statements and grading the evidence

- Grading the evidence
  - Request DGAC members complete a grading rubric, which includes elements related to:
    - Quality
    - Quantity
    - Consistency
    - Impact
    - Generalizability
  - NEL compiles the input and facilitates a grading decision by the DGAC

Step 5: Conclusion statements and grading the evidence

Elements	Grade I: Strong	Grade II: Moderate	Grade III: Limited	Grade IV: Grade Not Assignable
Quality (as determined using the NEL QAT) • Scientific rigor and validity • Consider 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	Serious design flaws, bias, or execution problems across the body of evidence
Quantity • Number of studies • Number of subjects in studies	Several good quality studies Large number of subjects studied Studies 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	Available studies do not directly answer the question OR no studies available
Consistency of findings across studies	Findings generally consistent in direction and size of effect or degree of association, and statistical significance with very minor exceptions	Some inconsistency in results across studies in direction and size of effect, degree of association, or statistical significance	Unexplained inconsistency among results from different studies	Independent variables and/or outcomes are too disparate to synthesize OR single small study unconfirmed by other studies
Impact • Directness of studied outcomes • Magnitude of effect	Studied outcome relates directly to the question Size of effect is clinically meaningful	Some study outcomes relate to the question indirectly Some doubt about the clinical significance of the effect	Most studied outcomes relate to the question indirectly Size of effect is small or lacks clinical significance	Studied outcomes relate to the question indirectly Size of effect cannot be determined
Generalizability to the U.S. 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	Highly unlikely that the studied population, intervention AND/OR outcomes are generalizable to the population of interest

Step 5: Conclusion statements and grading the evidence

- Conclusion statement and grade are paired together
- Final conclusion statement leads with a descriptor of the quality of the evidence
  - Grade I: Strong
  - Grade II: Moderate
  - Grade III: Limited
  - Grade IV: Insufficient evidence

Examples

Strong and consistent evidence indicates that children and adults who eat fast food are at increased risk of weight gain, overweight and obesity. The strongest documented relationship between fast food and obesity is when one or more fast food meals are consumed per week. There is not enough evidence at this time to similarly evaluate eating out at other types of restaurants and risk of weight gain, overweight and obesity.

Moderate evidence shows that consumption of two servings of seafood per week (4oz per serving), which provide an average of 250mg per day of long-chain n-3 fatty acids, is associated with reduced cardiac mortality from coronary heart disease (CHD) or sudden death in persons with cardiovascular disease (CVD).

Step 6: Research recommendations and technical abstracts

- Research recommendations
  - NEL solicits DGAC input and uses it to draft a conclusion statement
- Technical abstract
  - Summary of a NEL systematic review, designed to describe the overall scope, process and findings of a review

NEL Team

- Donna Blum Kemelor
- Patricia MacNeil
- Joanne Spahn
- Jean Altman
- Thomas Fungwe
- Julie Obbagy
- Molly McGrane
- Yat Ping Wong
- Nancy Terry (HHS) (not in photo)