Systematic Reviews and Dietary Supplements: Omega-3 Fatty Acids

Kenneth Fink, MD, MGA, MPH
Director, Evidence-based Practice Centers Program
Agency for Healthcare Research and Quality
Overview

- Evidence-based practice and systematic reviews
- Process for performing a systematic review
- The AHRQ Evidence-based Practice Centers (EPC) Program
- EPC work on omega-3 fatty acids
Decision-makers try to make the most informed decisions possible.

A formal or systematic review provides a synthesis of the best available evidence.

Systematic reviews can be used for many purposes:
- Guidelines
- Coverage decisions
- Quality measures
- Educational material
- Research agendas
Levels of Evidence

- Systematic review
- Randomized controlled trial
- Cohort study
- Ecological study
- Case-control study
- Expert opinion
Why use systematic reviews?

- Comprehensive
- Credible
- Reproducible
- Transparent
- Facilitate decision making
Approach to a Systematic Process

- Clarify key questions
  - Populations, interventions, comparisons, outcomes
- Determine strategy to obtain evidence
  - Language, databases, inclusion/exclusion criteria
- Evaluate the quality of evidence
  - Individual studies and the body of evidence
- Synthesize the evidence
  - Effectively and efficiently communicate findings
Evidence-based Practice Centers (EPC) Program

- Sponsor and disseminate state-of-the-art systematic reviews
- Provide the evidence base to support decision making
  - User driven
- Advance methodology for systematic reviews
13 EPCs Across North America

- US Preventive Services Task Force (1)
- Technology Assessment (3)
- Generalist (9)
EPCs Working on Omega-3 Fatty Acids

North America

- Tufts-New England Medical Center
- University of Ottawa
- Southern California-Rand

US Preventive Services Task Force (1)
Technology Assessment (3)
Generalist (9)
Methodology

- Technical Expert Panel
- Topic Assessment and Refinement
- Literature Review
- Data Extraction
- Assessment of Study Quality
- Statistical Analyses
- Synthesis and Reporting
- Peer Review
Evidence Reports on Vitamins, Minerals, or Supplements

- Antioxidant Supplements
- B Vitamins and other constituents of berries
- Ephedra
- Melatonin
- Milk Thistle
- S-Adenosyl-L-Methionine (SAMe)
- Soy
- Vitamin D
- Multivitamin/mineral
Evidence Reports on Omega-3 Fatty Acids

- Arrhythmogenic Mechanisms in Culture Studies
- Asthma
- Cardiovascular Disease
- Cardiovascular Risk Factors
- Type II Diabetes, Rheumatoid Arthritis, and Other Diseases
More Evidence Reports on Omega-3 Fatty Acids

- Cancer
- Cognitive Functions
- Organ Transplantation
- Maternal and Child Health*
- Mental Health*
- Ocular Health*

* In progress
Challenges of Systematic Reviews

- Resource consuming
- Requires up-front work
- Need to monitor that initial decisions appropriate
- Generalizability dependent upon included studies
Challenges of Dietary Supplement Systematic Reviews

1. Defining Exposure
   - Dietary sources or supplements
   - Doses

2. Defining Outcomes
   - Intermediate or clinical
   - Antioxidant level → lipid oxidation → atherosclerosis → MI

3. Study Design Inclusion
   - Adequacy of data from RCTs
   - Limitations of observational studies
   - Role of animal studies
Summary

- AHRQ’s EPC program completes systematic reviews to inform decision makers
- Office of Dietary Supplements has been a consistent and valuable partner
- Systematic reviews can contribute to the field of dietary supplements

EPC web page:  http://www.ahrq.gov/clinic/epcix.htm
Questions

Kenny Fink
kfink@ahrq.gov
301-427-1617
Value of Review to Updating

- Clarifies areas of stronger and weaker evidence
- Identifies specific gaps in evidence
  - Missing outcomes, populations or study designs
- Survey literature for new evidence that addresses a critical gap
  - Ignore areas where evidence and recommendations are strong
Evidence-based Policy Making

The judicious application of the best available evidence within the context of the affected population’s interests and the political climate

- **Best available evidence** means a systematic comprehensive approach using high quality research
- **Population’s interests** means factors affecting policy acceptance such as the range of values, preferences, and perceived net benefit
- **Political climate** means factors affecting policy implementation such as experience, resources, and competing interests
Synthesis and Reporting

- Summarize evidence for each key question
- Summarize *strength* of evidence
  - Study designs
  - Quality of individual studies
  - Size of effect/ strength of association
  - Number of studies/ consistency across studies
  - External validity ("applicability")
  - "Directness" – intermediate endpoint or health outcome
- Quantitative or qualitative synthesis as appropriate
Assessing Quality

“Extent to which one can be confident that an estimate of effect is correct” - GRADE 2004

- Focuses on internal validity
- Incorporates quality rating systems
  - Different elements for different designs
- Increases confidence in findings
- Increases rigor, transparency, and validity of synthesis
- Translates into credible recommendation
AHRQ funds about 9 evidence reports per year

Topics nominated by non-Federal partners
- Organizations for providers, purchasers, insurers

Selection criteria
- Key questions
- Burden of condition
- Controversy, uncertainty, or variability
- Cost
- Potential for impact
- Partner’s plan for use
In healthy adults, does folic acid supplementation compared to usual dietary intake reduce the risk of cardiovascular events?

- Healthy adults
- Usual Intake
- Folic acid Supplement
- Decreased homocysteine levels
- Decreased rate of heart attacks
- Harms