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Systematic Reviews and Dietary Supplements: Omega-3 Fatty Acids

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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

Context

- 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

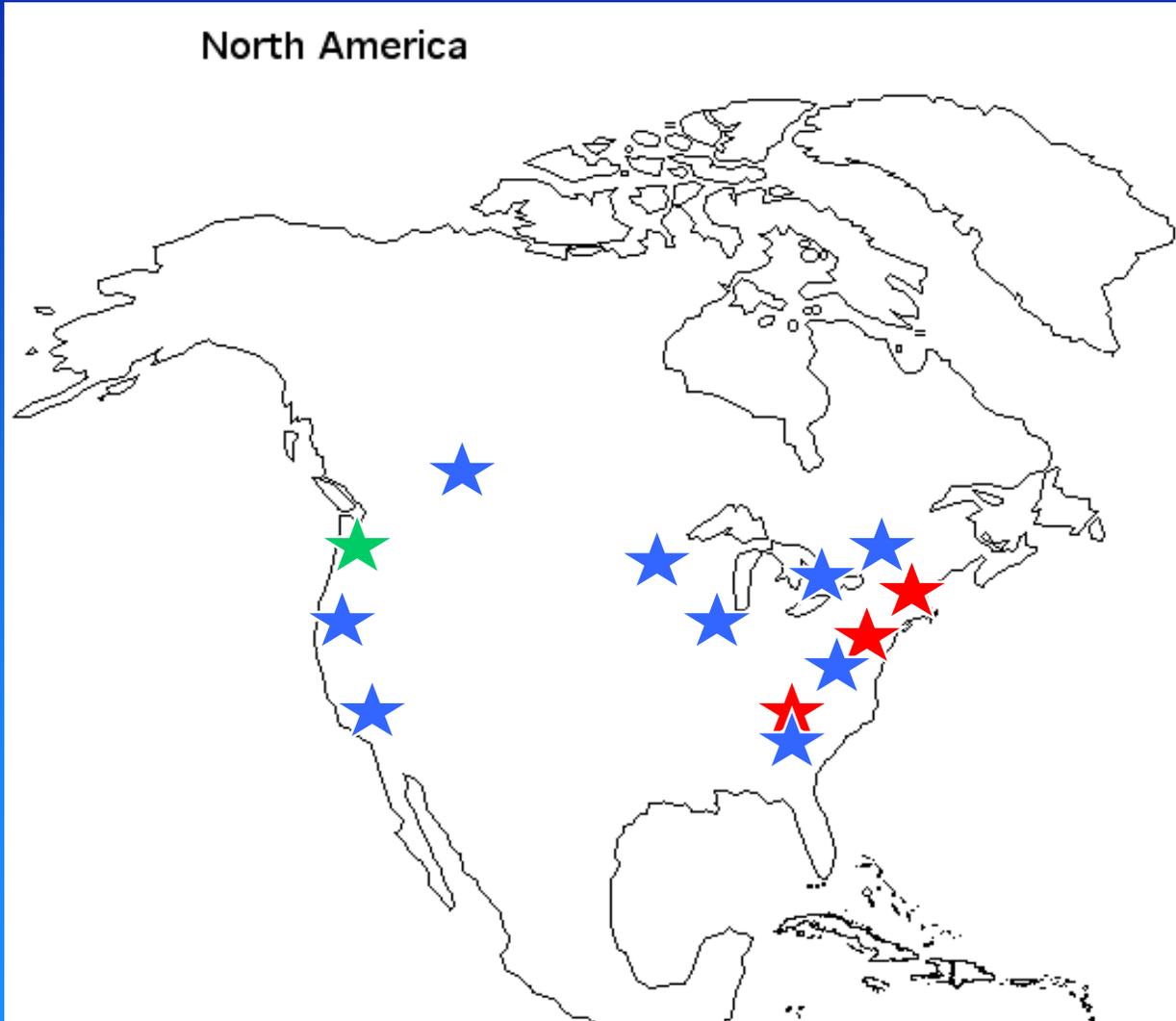
- Clarify key questions
 - Populations, interventions, comparisons, outcomes
- Determine strategy to obtain evidence
 - Language, databases, inclusion/exclusion criteria
- Evaluate the quality of evidence
 - Individual studies and the body of evidence
- Synthesize the evidence
 - Effectively and efficiently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

Evidence-based Practice Centers (EPC) Program



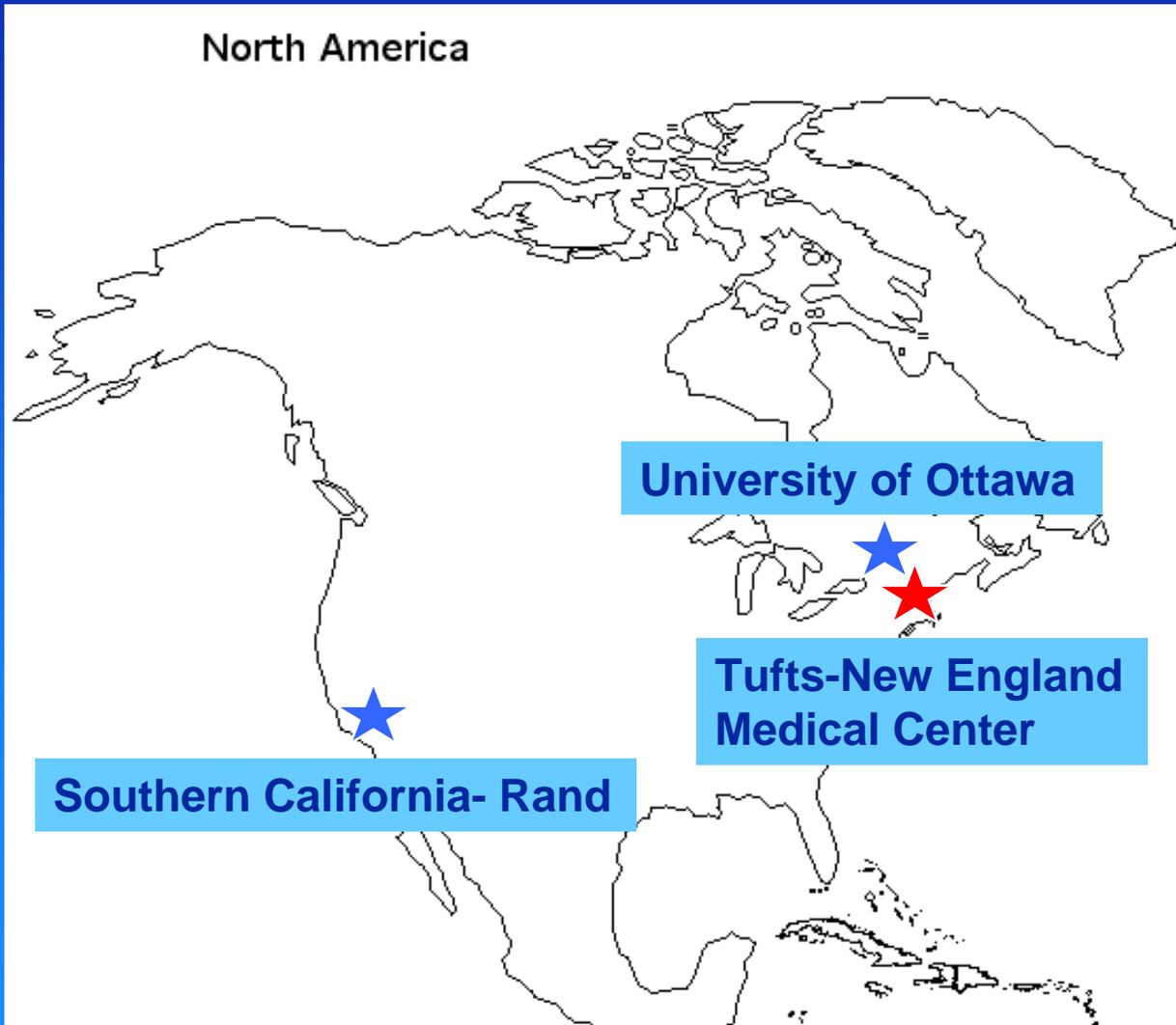
- Sponsor and disseminate state-of-the-art systematic reviews
- Provide the evidence base to support decision making
 - User driven
- Advance methodology for systematic reviews

13 EPCs Across North America



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

EPCs Working on Omega-3 Fatty Acids



- ★ 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

- Defining Exposure
 - Dietary sources or supplements
 - Doses
- Defining Outcomes
 - Intermediate or clinical
 - Antioxidant level → lipid oxidation → atherosclerosis → MI
- 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



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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

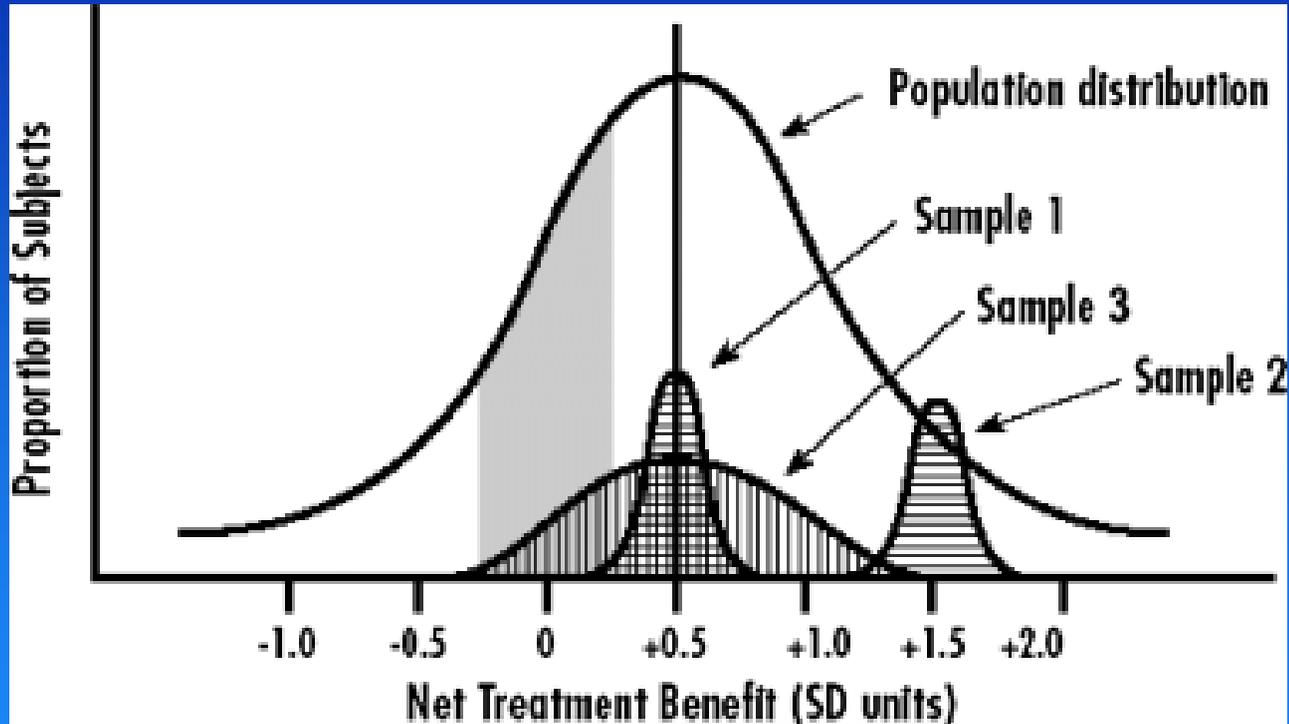
Synthesis and Reporting

- 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



Kravitz et al. Millbank Quarterly 2004.

Generalist EPC Program

- 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

Analytic Framework

- In healthy adults, does folic acid supplementation compared to usual dietary intake reduce the risk of cardiovascular events?

