





### Tufts-New England Medical Center Evidence-based Practice Center Boston, MA

Joseph Lau, MD, Director Ethan Balk, MD, MPH, Associate Director

Thomas Trikalinos, MD, PhD, Assistant Director Stanley Ip, MD, Assistant Director Gowri Raman, MD, Research Associate Mei Chung, MPH, Research Associate Soledad Cepedad, MD, PhD, Research Associate Deirdre Devine, Research Administrator Audrey Mahoney, Research Assistant







## **Organization & Purpose**

#### > 1 of 14 EPCs in US & Canada

- Organized and funded via AHRQ
- Program beginning its 3<sup>rd</sup> 5-year cycle
- Produce
  - General topic systematic reviews
  - Technology assessments for CMS and other agencies
  - Comparative Effectiveness Reviews (MMA Section 1013)

#### Purpose

- Synthesize literature on clinical, behavioral, organizational, and financing topics
- Promote improvements in health and healthcare
- Provide data for others to
  - make coverage decisions
  - develop quality measures, educational materials, and guidelines
  - set research agendas







## **Selection of Topics**

### > AHRQ solicits topics from

- Public: professional organizations, industry, payers, etc.
- Gov't agencies: NIH, CMS, FDA, etc.
- AHRQ vets and chooses topics based on agency and other government priorities, impact of disease and/or intervention, unanswered questions
- EPCs compete based on interest, experience, local expertise, equitable distribution





# **Selection of Team Members**

- Teams of ~3-7 EPC core members
  - 6 MD methodologists, 1 PhD candidate methodologist
    - Internal medicine, pediatrics, anesthesia, nutrition
  - No conflicts of interest
  - Organize, perform and write systematic reviews
- > 1-2 local (Tufts) clinical domain experts
  - Provide advice, guidance, background material
    - No conflicts of interest
- Technical Expert Panels: ~4-8 clinical and other experts
  - Assist with question refinement, provide advice etc.
    - Disclose potential conflicts of interest
- AHRQ Task Order Officers
  - Assist with question/topic refinement
  - Organizational support





# Systematic Review Methodology

- Refine Topics and Questions with PICO criteria
  - With clinical experts, AHRQ, Agency representatives
  - +/- Analytic framework
- Perform structured systematic review
  - Include grading of study quality: Good / Fair / Poor (A/B/C)
  - +/- Applicability: High / Moderate / Low
  - Summarize evidence
    - Every study summarized in tables, but not necessarily described
  - +/- Meta-analysis and other statistical approaches
- Evaluate future research needs
- Draft reports reviewed by experts and users
- AHRQ and EPCs working toward standard approaches to systematic review steps and presentation





# **Other Projects, Caveats, and Examples**

#### Other Projects

- Methodological research
- Disseminate evidence-based methodology
  - eg, Expanding EBM to EBN (nutrition)
- Occasional systematic reviews of basic research (animals, in vitro)

#### Caveats

- Do not produce guidelines
  - Do not provide guidance/opinion on what <u>should</u> be done (clinical recommendations)
- Defer to clinical/research experts and others on how to implement findings or interpret conclusions
  - Generally do not evaluate (or come to final conclusions about) different perspectives (society vs provider vs patient, cross-cultural, etc.
- Generally EPC not asked to consider costs (esp. for Technology Assessments-CMS), though occasionally produce cost-effectiveness analyses

#### Examples

- Small, focused topics: routine Swan-Ganz catheter use
- Horizon scans: chronic wounds, PAD interventions
- Broad topics: Soy and health, n-3 and CVD





# Methodology (Additional Grading)

- Comparative Effectiveness Reviews (MMA)
  - Grade strength of evidence / Confidence in evidence
  - Specifics still evolving
    - High OOO "There are consistent results from good quality studies"
    - Medium OOO "Findings are supported, but further research could change the conclusions"
    - Low OOO "There are very few studies, or existing studies are flawed"
    - Insufficient evidence
  - Low and Insufficient evidence is not presented in guides
  - Levels not presented in consumer guides
  - Language continually being tested in focus groups of "consumers" and clinicians
  - Not guidelines or recommendations, but evaluation of evidence







### **Dissemination**

- Reports made available at www.ahrq.gov
- AHRQ press releases (esp for CERs)
- Technology assessments presented to CMS Evidence Forum and at Medicare Evidence Development and Coverage Advisory Committee (MedCAC) panel meetings
- Journal publications
- Presentations at scientific meetings
- Presentations to and participation in advisory panels (on recommendations for future research)
- Not Guidelines





## **Strengths and Challenges**

- Well-established methodology for systematic review
  Positive impacts on CMS, NIH (ODS), and other agencies' approach toward and use of evidence
- Unclear impact on clinical practice or ongoing/future research
- Resource intensive processes
  - Article screening, Data extraction
- Implementing and understanding assessment of study quality and applicability – still evolving





# **Compared to KDIGO ERT Process**

- Different goal: evidence synthesis vs clinical guidance >- "No evidence" that meet criteria is an acceptable final synthesis Applicability usually related to US population and health care Generally more focused & fewer topics & questions Specific initial questions determined by AHRQ prior to award Broader range of topics, not all aimed at providing answers to  $\succ$ clinical management questions eg, B vitamin animal studies, range of tests being investigated  $\succ$  Shorter timeframe (~6-12 mo) Less intensive involvement of clinical experts and users of systematic reviews. EPC controls more decisions. Question formulation, draft review
- Fewer a priori eligibility restrictions based on "strength of evidence"; evaluation of strength of evidence uncommon
- Only occasional involvement of trainees (fellows)







### Future

- Beginning 3<sup>rd</sup> 5-year cycle
- Continuing great interest from CMS, FDA, NIH, Congress, Professional societies, Insurers, etc.
- Shift to more translation of evidence into improved patient care and health
  - Including development of consumer and clinician guides
  - Not guideline development
- Increasing focus on improving and guiding future research
- Methodology
  - Improving consistency across reports and EPCs
  - Methods manual
  - Improve efficiency of process