Comparative Effectiveness: Effective Health Care (EHC) Program

- Created in 2005, authorized by Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003

- To improve the quality, effectiveness, and efficiency of health care delivered through Medicare, Medicaid, and Children’s programs by focusing on
  - What is known *now*
  - What research *gaps* are critical to fill
  - *Clinical effectiveness*
Definition: HHS

Comparative effectiveness research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in “real world” settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.
The Role of Clinical Decision Makers in CER

CER

Researcher looking through lens of decision maker to do research

EBM

Decision maker looking through lens of research to make decisions
Provides current, unbiased evidence on health care interventions

Helps consumers, providers, and policy-makers make informed choices among alternatives

Long-term Goal: Improve quality of care and health outcomes through informed decision making
An Unprecedented Investment in CER

The American Recovery and Reinvestment Act of 2009 includes $1.1 billion for comparative effectiveness research:

- AHRQ: $300 million
- NIH: $400 million
- Office of the Secretary: $400 million
AHRQ FY 2008 – 2010
(including ARRA) Investments

- Stakeholder Input & Involvement: 3%
- Horizon Scanning: 3%
- Research Training: 6%
- Evidence Synthesis: 13%
- Evidence Need Identification: 6%
- Evidence Generation: 57%
- Career Development: 6%
- Dissemination & Translation: 12%
Seven Steps to CER

1. Identify new and emerging clinical interventions
2. Review and synthesize current medical research
3. Identify gaps between existing medical research and the needs of clinical practice
4. Promote and generate new scientific evidence and analytic tools
5. Train and develop clinical researchers
6. Translate and disseminate research findings to diverse audiences
7. Research out to stakeholders and communities
A Framework for CER

- Horizon Scanning
- Evidence Identification
- Evidence Synthesis
- Evidence Generation
  - Strategies
  - Interventions
  - Conditions
  - Populations
- Dissemination
- Translation
- Improvements in Health Care

Research Platform
Infrastructure – Methods Development – Training
Horizon Scanning for CER

- Horizon Scanning methodology for identifying and monitoring cutting edge health system and clinical interventions that are likely to have a high clinical, system, and cost impact in the US
- Reports on findings from HS activities to be made public
- Provide framework of pertinent issues and identify significant or controversial questions of effectiveness that may be addressed by undertaking new CER
Evidence Synthesis

- Systematic review and synthesis of current medical research, to provide rigorous evaluation of what is known on the basis of existing research about the comparative effectiveness of different health care interventions.
- Conducted by Evidence-based Practice Centers (EPCs).
- Advance the scientific methods of systematic review.
Evidence Gap Identification

- Identification of areas where new research conducted would contribute to bridging the gap between existing medical research and clinical practice
- Produces recommendations that consider the timing, value, and feasibility of research that would fill these gaps
- Transparent, systematic, strategic, and methodologically rigorous process
Investments in Evidence Generation

- Conduct of new research that compares the effectiveness of different health care interventions

- Examples:
  - Non-experimental/observational studies, both retrospective and prospective
  - Sponsorship of pragmatic clinical trials addressing key foci of comparative effectiveness
  - Distributed data networks and related infrastructure development
  - Methods development
Evidence Generation Activities
Under ARRA

- Patient Registries (PROSPECT): creation or enhancement of national patient registries ($48M)
- DEcIDE Consortium Support: Expansion of multi-center research system and funding for distributed data network models that use clinically rich data from electronic health records ($24M)
- Clinical and Health Outcomes Initiative in Comparative Effectiveness (CHOICE): Coordinated national effort to establish a series of pragmatic clinical comparative effectiveness studies ($100M)
- iADAPT: Innovative dissemination and implementation grants for CER ($29.5M)
Sonography vs. Tomography for Nephrolithiasis Evaluation

Randomized controlled trial with ten large urban emergency departments of patients presenting with suspected renal colic to compare effectiveness, safety, accuracy, and cost:

1. Ultrasound in the emergency department
2. Ultrasound in Radiology
3. Computed Tomography in Radiology

Rebecca Smith-Bindman, MD

- Professor of Radiology and Biomedical Imaging, Epidemiology and Biostatistics, Obstetrics, Gynecology and Reproductive Medicine, UCSF
Randomized Evaluation of Patients with Stable Angina Comparing Utilization of Noninvasive Examinations (RESCUE)

- Multi-center (40) non-inferiority RCT of CCTA vs. SPECT-MPI with subsequent medical interventions of OMT or revascularization
- CE analyses of the outcomes: MACE (cardiac-related death, MI) and revascularization; cost effectiveness; angina symptoms; self-reported health status at 6, 12 (major outcomes), 18, 24 months
- Funded amount: $9,009,912 direct and $656,814 indirect costs
- Arthur Stillman – American College of Radiology
Training and Career Development

- Grants provide institutional and individual support
- Enhance the research and methodological capacity for conducting CER
- AHRQ is leader in growing the pipeline of researchers in patient-centered health research
Emerging Methods in Comparative Effectiveness, EBM & Safety

- Variation in methods among systematic reviews undercuts transparency
- Poorly done new research can be misleading
- Methods must continue to evolve and not remain stagnant
- AHRQ has and will continue to make investments in improving methods, esp. in understanding clinical heterogeneity.
New Resource on Comparative Effectiveness Research Methods

- June 2010 supplement to *Medical Care* on CER Methods
- 22 original articles, special focus on:
  - Ways to enhance the inclusion of clinically heterogeneous populations in clinical and comparative effectiveness studies
  - Methods for implementing longitudinal investigations that capture longer term health outcomes, including patient-reported outcomes
- Printed copies available free of charge through the AHRQ Publications Clearinghouse

[www.effectivehealthcare.ahrq.gov](http://www.effectivehealthcare.ahrq.gov)  
AHRQ publication number: OM10-0067
Just Released

Second Edition
Published White Paper Series Provides Groundwork for Methods Guide To Compare Medical Tests

A set of white papers published in the September 22, 2009, issue of Medical Decision Making will serve as the groundwork for an Agency for Healthcare Research and Quality (AHRQ) Work Group charged with creating a new methods guide to focus on comparisons of diagnostic and prognostic tests for the Effective Health Care (EHC) Program. The new methods guide is scheduled to be released in draft form during the first part of 2010.

The white papers were originally commissioned by AHRQ and presented to researchers from the various Evidence-based Practice Centers by international leaders in the field of systematic reviews. The goal of the papers was to provide EHC Program researchers with state-of-the-art methods for conducting assessments of evidence surrounding medical test technologies and procedures. A planning committee of AHRQ staff and the directors of the 14 Evidence-based Practice Centers coordinated the conference, held in May 2008, to help the Work Group begin addressing the specific methodological needs for this type of comparative effectiveness research.
Ensure knowledge synthesized or generated within the EHC program is available to decision makers to inform health care decisions.

Products include summary guides and other tools for clinicians, consumers, and policymakers.

Focus on developing and implementing innovative approaches to integrating patient-centered health research findings into clinical practice and health care decision making.

### Fast Facts
- ACEIs and ARBs are two of the many kinds of blood pressure pills.
- Both kinds of pills (ACEIs and ARBs) do a good job of lowering blood pressure.
- ACEIs and ARBs rarely cause serious problems. The main difference in side effects is that ACEIs are more likely than ARBs to cause a dry cough.
- ACEIs and ARBs do not affect cholesterol levels or blood sugar levels.
- Some ACEIs are available as generics, which cost less.
CME/CE activities are available for the following health conditions and methods areas:

- Diabetes
- Heart and Blood Vessel Conditions
- Muscle Bone and Joint Conditions
- AHRQ Training Modules for the Systematic Reviews Methods Guide
- Other Topics
AHRQ Community Forum on Comparative Effectiveness Research initiative to develop new mechanisms and refine existing approaches to eliciting public input.

- Expand and systematize public and stakeholder engagement in AHRQ’s Effective Healthcare Program.
  - Members of the general public identified without regard to medical background or experience.
  - Persons or groups who have a vested interest in a clinical, research or health policy decision.
Underlying Principles

Attentive to subgroups

- Under-represented in clinical trials (elderly, children, racial and ethnic minorities)
- Inclusive of comorbidities
- Explore heterogeneity of treatment effects
Public Engagement

- Topic nominations for research
- Comment period for key research questions
- Comment period for draft reviews
- Focus testing translation products

www.effectivehealthcare.ahrq.gov
Submit a Suggestion for Research

Before you get started

When you submit a suggestion for research, you are nominating a potential topic for future studies. You can read more about how to suggest a topic for research or learn about how suggestions for research are chosen. You can also read topics for research that were suggested by others or view an example of a completed topic nomination form.

To nominate a topic for research in the Program

Please fill in the form below as completely as possible and click on "submit" at the end. If you prefer, you may fill out the rich text format (rtf) version of the form, which can be edited in any text–editing program (e.g., MS Word, Wordpad), and e-mail the completed form to effectivehealthcare@ahrq.hhs.gov, or you may print out the completed form and mail it to:

Michelle Eder
AHRQ Effective Health Care Program
c/o Scientific Resource Center at Oregon EPC
Center for Health Research
3800 N Interstate Avenue
Portland, OR 97227-1110
Read Suggested Topics for Research

Browse through these suggestions to see what others have submitted. To read the full submission, click on the text of the suggestion. Suggestions are presented as they were submitted and are not edited.

Suggestions that have completed the Program's selection process are identified by a topic suggestion disposition (PDF). **Suggestions submitted prior to 2008 were reviewed under a different process and disposition reports may not be available.**

See [Search for Guides, Reviews, and Reports](#) for research in progress and final reports.

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**Dec. 14, 2008**
As a practicing community psychiatrist working in public service, one of the primary concerns I have, which I hear from others is the utility of the 15 minute med check. This is now the primary e...

[View Topic Suggestion Disposition](#) (PDF) 99 kB

**Nov. 23, 2008**
My nomination is about comparing outcomes of different glaucoma treatments, particularly canaloplasty and trabeculectomy and to medical therapy alone.

[View Topic Suggestion Disposition](#) (PDF) 110 kB

**Nov. 13, 2008**
Comment on Key Questions

Please fill out the form below to provide comments on the key questions associated with this topic.

Before you get started

1. PLEASE NOTE: Most text-entry areas on this form have an 8,000-character limit.
2. If you prefer, you can print the form and mail it in. Before attempting to print the paper form, you will need to have the Adobe Acrobat Reader installed (download Acrobat Reader®). The free Adobe Acrobat reader will allow you to view and print PDF files.

Proposed Research Title for the Topic:
Comparative Effectiveness of Bariatric Surgery and Non-Surgical Therapy in Adults with Metabolic Conditions and Body Mass Index of 30 to 34.9
Open for comment until Sept. 27, 2010.

Supporting material:
View Background
Commenting on Reports

The Draft Reports and White Papers available for comment are:

- **Comparative Effectiveness of Case Management for Adults with Medical Illness and Complex Care Needs**
  Sept. 13–Oct. 11, 2010

- **Progestogens for the Prevention of Preterm Birth**
  Sept. 15–Oct. 13, 2010

- **Future Research Needs: Comparative Effectiveness of Percutaneous Coronary Interventions and Coronary Artery Bypass Grafting for Patients with Coronary Artery Disease**
  Sept. 24–Oct. 22, 2010

Privacy Policy

The Agency for Healthcare Research and Quality’s (AHRQ) Effective Health Care Program supports and is committed to the transparency of its review processes. All comments and the report authors’ responses to the comments (the ‘disposition of comments’) will be publicly posted on this Web site within 3 months after the final report is posted. Each comment will be listed with the associated name and affiliation, if such information is provided. Those providing public comment are not required to provide their names or affiliations in order to submit suggestions or comments. We will use your contact information only to get in touch with you if we have questions about your submitted comments.

Related Content

- What Is a White Paper?
- What Is a Draft Report?
- What Are Key Questions?
Comments to Research Review

The Effective Health Care Program encourages input on its projects. Comments and input may be submitted through several modes, including this website, letter and e-mail. Comments to draft reports and the response to the comments will be posted publicly without distribution on this website 3 months after the reports are published. Comments are not edited for spelling, grammar or other content errors.

Comparative Effectiveness, Safety, and Indications of Insulin Analogues in Premixed Formulations for Adults with Type 2 Diabetes


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<thead>
<tr>
<th>Comment, by Section</th>
<th>Response</th>
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<tbody>
<tr>
<td><strong>Executive Summary</strong></td>
<td>Thank you very much for this suggestion. We captured this article when we conducted an update of our literature search.</td>
</tr>
<tr>
<td>Comment: A statement under Gaps in Evidence and Future Directions for Research (page ES-4) states, Probably the most important comparative study that needs to be performed should compare premixed insulin analogues and a combination of bolus insulin injections with rapid-acting insulin analogues plus a basal insulin injection with long-acting insulin analogues? [Identifying information redacted] agrees and have completed a Phase III randomized controlled clinical trial ([Identifying information redacted]). The results were published in 2008. The citation is: [Identifying information redacted]</td>
<td></td>
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<tr>
<td>Under Conclusion (pages ES-3 through ES-7), several inconsistent conclusions were observed between text and table. For example, when weight gain was compared between premixed insulin analogues and long-acting insulin analogues, text on page ES-3 states, Premixed insulin analogues appear to have? an increased risk of weight</td>
<td>We have corrected this inconsistency.</td>
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Patient-Centered Outcomes Research Institute (PCORI)

- Independent, nonprofit Institute with public- and private-sector funding
- Sets priorities and coordinates with existing agencies that support comparative effectiveness research
- Prohibits findings to be construed as mandates on practice guidelines or coverage decisions and contains patient safeguards
- Provides funding for AHRQ to disseminate research findings of the Institute and other Government-funded research and to train research on CER and build capacity for research
- Board of Governors appointed September 23; collectively represents a broad range of perspectives; AHRQ and NIH Directors serve on the board and methodology committee