



SOCIETY OF ACTUARIES

**Health Spring Meeting
June 2009**

**Session # 45 PD: Quality and Efficiency II -
Government Sponsored Research and Initiatives**

Steve E. Phurrough, MD, MPA
Indra Pulcins, MD

Moderator
Jim Toole, FSA, MAAA



Agency for Healthcare Research and Quality

Advancing Excellence in Health Care www.ahrq.gov

Comparative Effectiveness Research in the US

Society of Actuaries
2009 Health Spring Meeting
Toronto
June 9, 2009



Current Challenges

- Growing concerns about health spending – about \$2.3 trillion per year in the U.S. and the causes of increased spending
- Large variations in clinical care
- A lot of uncertainty about best practices involving treatments, procedures, and technologies
- Pervasive problems with the quality of care that people receive



What Healthcare Decision Makers Need To Know

- Can it work?
- Will it work?
 - For this patient?
 - In this setting?
- Is it worth it?
 - Do benefits outweigh harms?
 - Do benefits justify costs?
 - Does it offer important advantages over existing alternatives?



Adapted from Brian Haynes
ACP Journal Club



What Policy Makers Need to Know

- What is the outcome I care most about?
- How good is the evidence that the interventions can improve those outcomes?
- How sure am I that it will work in “real world”?
- How do the potential benefits compare to possible harms and costs?
- What constitutes “good enough” evidence?
- What other considerations are relevant?



Donald Schön, 1983

- “In the varied topography of professional practice, there is a high, hard ground, where practitioners can make effective use of research-based theory and techniques, and there is a swampy lowland where the situations are confusing ‘messes’ incapable of technical solution. **The difficulty is that the problems of the high ground, however great their technical interest, are often relatively unimportant to clients or the larger society while in the swamp are the problems of greatest human concern.**”



Evidence-Based Medicine



What Evidence-Based Medicine Is

“Evidence-based medicine is the integration of **best research evidence** with **clinical expertise** and **patient values**”

Sackett, *et al* 2001



Misperceptions About Evidence-Based Medicine

- Restricted to Randomized Controlled Trials
 - sets unattainable standard for evidence
- Excludes role of clinical judgment
- Does not take into account the individual patient
- Aims only to limit health services
- Ignores realities of practice
 - reimbursement, liability concerns, patient expectations
- Useless when evidence is uncertain



EBM Scope

EBM can be applied to both the quality of care and the cost of care.



Comparative Effectiveness



Comparative Effectiveness

“...a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients.”

CBO, 2007

CONGRESS OF THE UNITED STATES
CONGRESSIONAL BUDGET OFFICE
**A
CBO
PAPER**

DECEMBER 2007
Research on the
Comparative
Effectiveness of
Medical Treatments



Comparative Effectiveness and Improved Health Outcomes



- A Public Good
- Gives health care decision makers – patients, clinicians, purchasers and policy makers – access to the latest open and unbiased evidence-based information about treatment options
- Informs choices and, where possible, is closely aligned with the sequence of decisions patients and clinicians face

The Right Treatment for the Right Patient at the Right Time



Comparative Effectiveness Research Cannot:

- Solve controversies due to values, costs, etc.
- Solve barriers due to misaligned incentives, patient factors, and system failures
- Ensure appropriate application to policy



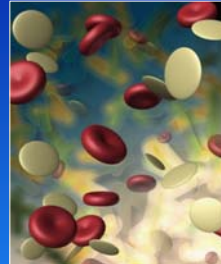
But Can...

- Reduce the chance of getting it wrong
- Help make decisions more consistent, transparent and rational
- Clarify nature of disputes over practice and policy
- Persuade skeptical parties(?)



Improving Evidence about Benefits and Risks

- Comparative effectiveness research addresses issues including:
 - Relevancy
 - Timeliness
 - Impact on priority populations
 - Disproportionate impact on subpopulations
 - The ability to enhance treatment decisions



What types of studies are CER?

- Product A versus Product B
- Condition X versus Condition Y
- Population segmentation (age, gender, geographic location (rural vs. urban, high/low altitude), income, race/ethnicity, genetic or other risk profiles)
- Short-term vs. long-term
- Research setting vs. community (“real world”)
- Inpatient vs. outpatient
- Hospital vs. SNF vs. home health vs. other
- Cost of option A versus option B



Agency for Healthcare Research and Quality



AHRQ's Role in Comparative Effectiveness

- Lead USA national agency for comparative effectiveness research
- HTA at the request of CMS
- Analyze data/options for CED and post CED data collection
- Provide translation of comparative effectiveness findings
- Promote and fund comparative effectiveness methods research
- Fund training grants focused on comparative effectiveness



Comparative Effectiveness Research at AHRQ

- Created in 2005, authorized by Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003
- New federal initiative to compare the effectiveness of different health care interventions
- Goal: to provide patients, clinicians and policy makers with reliable, evidence-based healthcare information



AHRQ Comparative Effectiveness Research

The screenshot displays the Effective Health Care website interface. At the top, it features the AHRQ logo and the text 'U.S. Department of Health & Human Services' and 'www.hhs.gov'. Below this is the AHRQ logo and 'Agency for Healthcare Research and Quality'. A search bar is visible on the right. The main content area is titled 'Effective Health Care Home' and includes a navigation menu on the left with options like 'Home', 'Reports', 'Get Involved', 'News', 'About Us', 'Contact Us', 'Questions?', 'Search', 'Site Map', 'Submit Data', and 'Information on Español'. The main content area is divided into several sections: 'Reports' (with sub-sections for Summary Guides, Research Reviews, New Research, and Search Reports), 'Spotlight' (featuring reports like 'Caution para la diabetes tipo 2. Guía para adultos', 'Osteoporosis Treatments that Help Prevent Broken Bones. A Guide for Women After Menopause', 'Exactos Prevention Treatments for Postmenopausal Women with Osteoporosis', 'A Case Control Study to Assess Association of Variations in DCC Genes with 1-Ethylene of Metabolic in Diabetic Patients', 'Methods for Studying Bone Treatment and Outcomes in Observational Databases', and 'Comparative Effects of Classes of Antidepressants on the Risk of Adiposity Parameters in the Aged'), and 'Get Involved' (with options for Suggest Research, Read Suggestions, and Provide Comments). On the right side, there are several smaller panels, including one titled 'Comparing Oral Medications for Adults With Type 2 Diabetes' and another titled 'Summer 2009 Update'.

<http://effectivehealthcare.ahrq.gov>



Comparative Effectiveness: AHRQ Effective Health Care Program

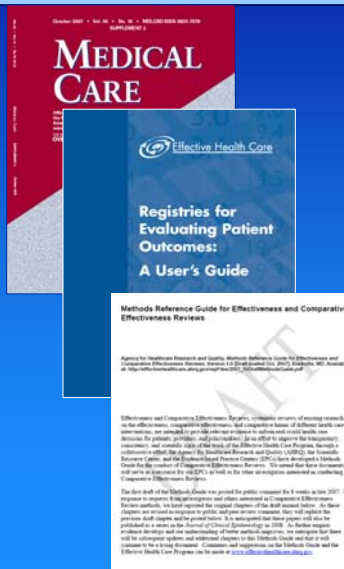
- Uses current, unbiased evidence in making comparisons to show which health interventions:
 - Add Value
 - Offer minimal benefit above current choices
 - Fail to reach their potential
 - Work for some patients, but not others



Goal: to develop and disseminate better evidence about benefits and risks of alternative choices



Emerging Methods in Comparative Effectiveness & Safety



- Variation in methods among systematic reviews undercuts transparency
- Methods reduce the likelihood of scientific impartiality
- Methods help minimize misclassification of data
- 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.



American Recovery and Reinvestment Act



American Recovery and Reinvestment Act and CER

\$1.1 B for comparative effectiveness research:

- AHRQ: \$300M
- NIH : \$400M (appropriated to AHRQ and transferred to NIH)
- Office of the Secretary : \$400M (allocated at the Secretary's discretion)
- Funds are available through September 30, 2010



AHRQ's CER Role under ARRA

- AHRQ to continue its CER work under the auspices of section 1013 of MMA
- AHRQ will continue to have a collaborative, open, and transparent process for comparative effectiveness that allows for input from all perspectives.
- AHRQ will continue to involve all stakeholders in the research process.
- Currently, developing spending plan



Challenges with Using Comparative Effectiveness Research



Users of CER

- Physicians
- Patients
- Payers
- Policy Makers



Physicians/Patients

Better decision on
diagnostics & therapeutics



Payers/ Policy Makers

Options



Clinical Effectiveness





Comparative Clinical Effectiveness



Comparative Cost Effectiveness





What do the outcomes of CER mean?

- If a difference is found, the “better” treatment has a greater probability of improving outcomes in the relevant population
- It does not mean that all patients will have better outcomes with the “winner”
- Some patients are likely to only improve with the “loser”
- Introduce costs and options are even more difficult



Payers & Policy Makers

Options

- Don't cover the less effective technology
- Reimburse at a higher level for more effective technology
- Increase co-payments for the less effective technology
- Bundle payments
- Reimburse at the “cost-effective” price




The Future

- Public-private funding and participation likely a necessity
- More effort to get better conditional reimbursement study designs/protocols
- Need to tackle important issues
 - Ethical
 - When to know when the evidence is sufficient
 - Transparency
 - Setting priorities



Future Challenges

- Downstream effects of policy applications
 - Payment Issues
 - Diffusion of technology
 - Effects on innovation
 - Unintended consequences
 - International collaboration
 - Understanding the role of costs in the U.S.
 - Determining where comparative effectiveness should reside
- 



Trust

- To achieve widespread use and influence, trust must be established among:
 - Patients, who will benefit from informed decisions and understanding the importance of participating in studies
 - Industry, so they understand they will not be inappropriately dealt with
 - Physicians, who need comparative effectiveness information to treat
 - Providers/plans and policymakers, must make tough decisions



According to Yogi Berra

- If you don't know where you are going, you might wind up someplace else.





Steve Phurrough, MD
Agency for Healthcare Research & Quality
steve.phurrough@ahrq.hhs.gov
301-427-1617