

The Patient-Centered Outcomes Research Institute (PCORI)

Carolyn M. Clancy, MD Director

Agency for Healthcare Research and Quality

Shaping Convergent Strategies in

Comparative Effectiveness Research (CER)

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The Patient-Centered Outcomes Research Institute (PCORI)



- Building a Research Agenda
- Comparative Effectiveness Research/Effective Health Care Program
- Transparency and Stakeholders
 - Where To From Here?



Patient Protection and Affordable Care Act Creates PCORI

- Independent, nonprofit Institute with public- and private-sector funding
- Sets priorities and coordinates with existing agencies that support CER
- 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 researchers on CER and build capacity for research



PCORI Board of Governors

- Members of the board collectively must represent a broad range of perspectives
- AHRQ and NIH Directors will serve on the Institute's 21-member board and it's methodology committee
- At least three board members must represent patients and consumers, with seven representing providers – all stakeholders are encouraged to "cultivate" nominees
- The Comptroller General must appoint board members by September 23, 2010

Notice published in the Federal Register on May 7th calls for nominations to be submitted by June 30th PCORI@gao.gov



AHRQ and Comparative Effectiveness Research

- AHRQ's Effective Health Care Program created by Medicare Modernization Act of 2003
 From 2005-2009, received \$129 million from
 - Congress for CER
- The American Recovery and Reinvestment Act of 2009 included \$1.1 billion for comparative effectiveness research, including \$300 million to AHRQ
- The President's FY 2011 budget proposal for AHRQ includes \$286 million for patient-centered health research, up \$261 million over the FY 2010 budget



Effective Health Care Program

Has published more than 45 products, including guides for clinicians, consumers and policymakers

- Research Reviews
- Summary Guides
- New Research Reports



Reducing the Risk of Breast Cancer With Medicine

A Guide for Women





Observations

- Framing the Research Questions
 - Findings should be revisited frequently to incorporate new evidence
- Balancing Benefits and Harms
 - Variation that results from informed decision making offers future opportunities to evaluate the outcomes of different decisions
- Comparative Effectiveness Research and Health Services Research
 - Assuring timely and effective use of CER cannot be done in isolation of HSR

Benefits

Harms

- Trust as a process, not a structure
 - Transparency is vital



Stakeholder Engagement



Priorities should be informed by a transparent process that includes *all* stakeholders

Research is a means, not an end, and ongoing input is a necessity

Different types of input:

- Strategic
- Operational



Effective Health Care Program Governance Evaluation

- Phase 1: Collect information to identify strengths and weaknesses in current EHC program's governance structure, methods for engaging stakeholders, and approaches to setting priorities for research conducted by the program (complete)
- Phase 2: Contrast the governance structure of the EHC program with international programs with similar aims (in-progress)

Phase 3: Develop a roadmap for the EHC program that provides alternative governance options for engaging stakeholders and setting priorities, a contrast of the options with similar international programs, and recommendations for the EHC program governance (October, 2010)



Where to From Here?

- Identify synergies methods and infrastructure – between CER and post-marketing surveillance: identification of signals and investigations of causes
- Make sure all activities enhance quality, safety, efficiency and effectiveness at the <u>front line</u>
- Operationalize the expanded definition of CER (i.e. the 'care delivery interventions' piece)
- Ensure that more informed means better informed





- We are MUCH better at measuring than improving
- Growing list of successful 'prototypes' but only one clear home run
- Government has multiple roles
 - Pay for care / provide incentives
 - Support research
 - Regulate; provide; monitor



- Transition from setting-specific approach to <u>patient focused</u>, taking advantage of health IT
- Transparency and financial levers are important but NOT the only levers for change
- At the end of the day, only those who provide care can improve that care"
- Incredible opportunity to leverage ARRA and other investments



Thank You



AHRQ Mission

To improve the quality, safety, efficiency, and effectiveness of health care for all Americans

AHRQ Vision

As a result of AHRQ's efforts, American health care will provide services of the highest quality, with the best possible outcomes, at the lowest cost

www.ahrcj.gov