

PCORI FUNDamentals

Submitting Proposals to PCORI

November 7, 2012

Intermountain Healthcare

Institute for Health Care Delivery Research

CCTS Community Engagement Core, University of Utah

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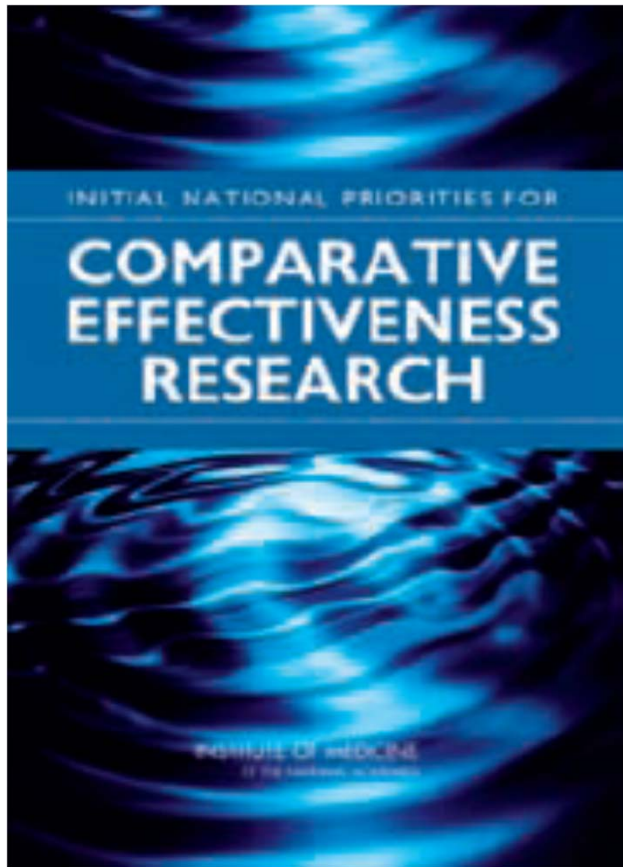
University of Utah, School of Medicine

Setting the Stage



- First, some context so we have a world view in considering CER.

Institute of Medicine (IOM) Report Released June 30, 2009



The purpose of CER is to assist
consumers,
clinicians,
purchasers, and
policy makers
to make informed decisions that
will improve health care at both
the individual and population
levels.

Comparative Effectiveness Research (CER)

IOM's CER Definition

- **CER is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care.**

Patient Protection & Affordable Care Act

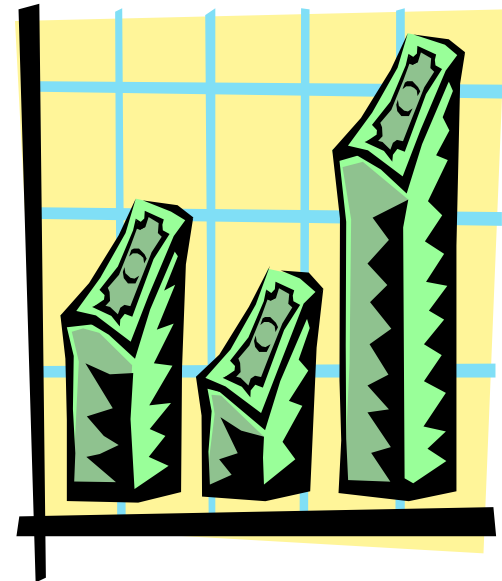
- Provides important insurance reform
- Offers care delivery models that align financial incentives to be explored
- Designates an investment in care delivery innovation through
 - **Patient Centered Outcomes Research Institute (PCORI)**
 - Center for Medicare and Medicaid Innovation (CMMI)

Why Track/Why Care About PCORI?

- Primary source of funding for research that has high operational utility in achieving our mission of performance excellence.

Further CER Investment via PCORI

- 2010-2012, \$210 Million, general revenues
- 2013, \$150 Million
 - + \$1 fee/Medicare Beneficiary
 - + \$1 fee/privately insured individual
- 2014-2019, \$150 Million
 - + \$2 fee/Medicare Beneficiary
 - + \$2 fee/privately insured individual
- Total of \$500 Million by 2015
- Annually, 20% of PCORI funding transferred to AHRQ to fulfill Pt. Safety & QI Act of 2005 → OCKT responsibilities



PCORI

- PCORI will spearhead efforts to prioritize and fund CER using a largely stakeholder-driven process.
- Builds on foundation laid in 2009 by the \$1.1 billion in funding for CER in the ARRA
- Will establish & execute a national CER agenda.



PCORI Mission

PCORI helps people make informed health care decisions and improves health care delivery and outcomes by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader health care community.

PCOR Working Definition

- Patient Centered Outcomes Research (PCOR) helps people make informed health care decisions and allows their voice to be heard in assessing the value of health care options. This research answers patient-focused questions:
 1. “Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”
 2. “What are my options and what are the benefits and harms of those options?”
 3. “What can I do to improve the outcomes that are most important to me?”
 4. “How can the health care system improve my chances of achieving the outcomes I prefer?”

Working Definition: PCOR

(continued, operationalized characteristics)

To answer these questions, PCOR:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, or health delivery system interventions to inform decision making, highlighting comparisons and outcomes that matter to people;
- Is inclusive of an individual's preferences, autonomy and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health-related quality of life
- Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination; and
- Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, resources, and other stakeholder perspectives.

The CER Hypothesis

- Gaps in evidence will be reduced with greater engagement of end users (patients, clinicians, payers) in
 - Selecting research questions
 - Developing study protocols/methods
 - Implementing research

Stakeholder Engagement in CER



- Successful engagement will lead to more useful research because it deliberately attempts to answer the questions of most relevance to end users, *rather than primarily investigators or funders.*

Research Process Steps

Developing Research Questions
Designing Study
Patient Recruitment
Data Collection
Data Analysis /Interpretation of results
Dissemination

Stakeholder Insight

- October 26-27 Stakeholder Meeting
- Listen to the plenary session at <http://www.onlinevideoservice.com/clients/p/cori/1012/index.html>

DRAFT National Priorities for Research & Research Agenda

Released 1/23/12; public comment period closes 3/15/12

- Describes CER prioritization efforts
- Identifies 10 CER priority areas from existing literature.
- Lays out 5 priorities given statutory requirements.
- Describes the research agenda and process.
- Provides a proposed funding model.

5 Priorities Driving Research Agenda, PFAs

Proposed Funds Allocation in Parentheses

1. Comparative assessment of options for prevention, diagnosis and treatment (40%).
2. Improving healthcare systems (20%).
3. Communications and dissemination research (10%).
4. Addressing disparities (10%).
5. Accelerating patient-centered outcomes research and methodological research (20%) → to be released on November 15, 2012

Funding Cycle

Action	Cycle 1	Cycle 2	Cycle 3
PFA Release Date	May 22, 2012		
System Opening	May 15, 2012	Sept. 17, 2012	Jan. 15, 2013
LOI Due Date	June 15, 2012	Oct. 15, 2012	Feb. 15, 2013
Info Webinars	July & August	Oct & November	Feb & March
App Deadlines	August 15, 2012	December 17, 2012	April 15, 2013
Merit Review	Sept - Nov	Jan-March	May-July
Awards Made	Dec-Jan, 2013	April-May, 2013	Aug-Sept, 2013
Start Dates	Jan 2013	May 2013	Sept, 2013

Funding Projections

PFA	Cycle 1	Cycle 2	Cycle 3
Prevention/Treatment	\$48 mill 54 awards	\$48 mill 54 awards	TBD
Healthcare Systems	\$24 mill 27 awards	\$24 mill 27 awards	TBD
Comm/Dissem	\$12 mill 14 awards	\$12 mill 14 awards	TBD
Disparities	\$12 mill 14 awards	\$12 mill 14 awards	TBD

Patient Centeredness Requirement

- Must be authentically patient centric
 - Not research for patients
 - Research with patients
 - Focus groups are not considered full engagement
- Patients/stakeholders as peers with researchers (if not included, provide rationale)
- Participatory research is not limited to community-based participatory research (CBPR)

PCOR Methods

- Lays out acceptable approaches/methods in this 191 page report (6,500 page views & 1,600 report downloads as of 8/12)
- Public comment period 7/23-9/14/12
- November, 2012 revised draft standards are due to the PCORI Board of Governors
- For a copy go to <http://www.pcori.org/2012/methodology-report/>



Implications for research design

- RCTs
 - Pragmatic - real-world settings; large N's to assess subgroups
 - Focus on effect size, not just superiority
 - Bayesian and adaptive approaches to design, accounting for prior probabilities
- Observational studies
 - Causal inference modeling
 - Tension for studies using pure administrative data – powerful and low-cost; lack high-quality patient-centric data
- Cost and cost-effectiveness
 - PCORI not allowed to evaluate cost as a primary outcome in making coverage recommendations, won't fund "pure" CEA
 - Cost can be studied as it relates to out-of-pocket costs and as a secondary outcome



Research Plan

- Specific Aims (1 page)
 - Research Strategy (10 pages)
 - References Cited
 - Protection of Human Subjects
 - Consortium/Contractual
 - **Letters of Support**
-
- No appendices are allowed and will be removed by PCORI before sending to reviewers

IOM Recommendation 6

- The CER Program should fully involve consumers, patients, and caregivers in key aspects of CER, including strategic planning, priority setting, research proposal development, peer review, and dissemination.

Review Process

- Initial assignments & screening → triaging cost effectiveness OR cost/benefit analyses
- Initial review process (individual with at approximately 6 reviewers per proposal)
- Secondary panel review (instructed to focus review/decision making to comments from initial reviewer comments vs. reading full proposals)



Scoring

9-point score scale is used to provide:

- Criterion Scores for each of the core review criteria
- Overall Impact/Priority Score based on but not an average of the core criterion scores plus additional criteria

All applications receive scores:

- Not discussed applications (bottom half by pre-meeting scores) will receive only initial criterion scores from the 3 assigned reviewers.
- Discussed applications also receive an averaged overall impact score from eligible panel members (i.e., those without conflicts of interest).
- These scores will be averaged to one decimal place, and multiplied by 10. The 81 possible priority scores will thus range from 10-90.



9-Point Score Scale Descriptors

Impact	Score	Descriptor	Additional Guidance
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

Review Criteria

- 1: Impact of the condition on the health of individuals and populations
- 2: Innovation and potential for improvement through research
- 3: Impact on health care performance
- 4: Patient-centeredness (relevance to patients)
- 5: Rigorous research methods
- 6: Inclusiveness of different populations

Review Criteria (continued)

- 7: Research team environment
 - 8: Efficient use of research resources (budget)
 - Protection of human subjects (acceptable risks and/or adequate protections)
 - Overall score
-
- Scientific reviewer focus: 1, 3, 5, 6, 8
 - Stakeholder reviewer focus: 2, 4, 7

Challenges to Collaboration

- Inherent tension with current PI-driven model
- Few well-documented models to copy
- Language differences, clinical and methodological complexity
- Limited stakeholder supply; and fatigue
- Time and resource intensive
- Rarely evaluated, so difficult to measure impact

Local Resources/Shared Learning

- Learn how CER/PCOR can effectively engage patients, physicians, and other stakeholders
 - New Certificate Program in PCOR/CER
 - Patient Centered Outcomes & Participatory Research Course (first offering was Summer, 2012)
 - CCTS Community Engagement Core → Patient Centered Research Methods Core and Community Collaborative Core
- 8th Annual HSR Conference, February 25, 2012

Additional Resources

Academy Health PCORI Training

<http://www.academyhealth.org/Training/ResourceDetail.cfm?ItemNumber=9112>

Academy Health Webinar: Making the Most of Participatory Research, 11/8/12 2-3pm ET, register on-line

Institute for Patient and Family-Centered Care resources to support active and meaningful engagement (see <http://www.ipfcc.org/tools/downloads-tools.html>)

For Support/More Information

- CCTS Community Engagement Core
amyanne.wuthrich@hsc.utah.edu
- Intermountain Institute for Health Care
Delivery Research
<http://intermountainhealthcare.org/qualityandresearch/institute/Pages/home.aspx>
- PCORI Application pcori.org/apply
 - Application guidelines & templates
 - Apply on-line
 - Frequently asked questions
 - Glossary



**Intermountain
Healthcare**

*Healing for life*SM