MOVING THE NEEDLE: CHALLENGES AND OPPORTUNITIES IN COMMUNICATING PATIENT-CENTERED OUTCOMES RESEARCH

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The views and opinions expressed in this presentation are mine and not necessarily those of the Patient-Centered Outcomes Research Institute.

I have no conflicts of interest to disclose.

I have received no compensation for my talk today, including travel support.
About PCORI

- An independent non-profit research organization authorized by Congress as part of the 2010 Patient Protection and Affordable Care Act (ACA).
- Committed to continuously seeking input from patients and a broad range of stakeholders to guide its work.
- Requires the “end users” of the research -- patients and those who care for them -- to be a meaningful part of the research team.
- “Research Done Differently”
Learning Objectives

- Describe the vision, scope and mission of the Patient-Centered Outcomes Research Institute (PCORI)

- Review PCORI’s criteria for assessing research proposals and its particular focus on patient engagement in research

- Outline PCORI’s approach to dissemination of research results, including those required by PCORI’s authorizing legislation, in light of the well-understood challenges to dissemination and implementation of new research
Subtitle D—Patient-Centered Outcomes Research

SEC. 6301. PATIENT-CENTERED OUTCOMES RESEARCH.

(a) IN GENERAL.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part:

“(c) PURPOSE.—The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and research.

“(h) ENSURING TRANSPARENCY, CREDIBILITY, AND ACCESS.—The Institute shall establish procedures to ensure that the following requirements for ensuring transparency, credibility, and access are met:
Our Mission and Vision

Mission
The Patient-Centered Outcomes Research Institute (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.

Vision
Patients and the public have the information they need to make decisions that reflect their desired health outcomes.
A Multi-Stakeholder Board of Governors

Appointed by the Comptroller General, our 21-member Board of Governors represents patients/consumers, caregivers, clinicians, researchers, payers, policymakers and industry. By law, it includes:

- Three patient/health care consumer representatives.
- Five clinician/provider representatives.
- Three private payer representatives.
- Three pharmaceutical, device and diagnostic industry representatives.
- One representative of the quality improvement/independent health service research field.
- Two federal or state government representatives, at least one of a federal health program.
- The directors of the NIH and AHRQ (or their designees).
Our Core Duties

- Establish national research priorities
- Establish and carry out a research agenda
- Develop and update methodological standards
- Disseminate research findings
Some of Our Key Accomplishments

- Defined Patient-Centered Outcomes Research (PCOR)
- Established First National Priorities for Research and Research Agenda
- Awarded 50 Pilot Projects
- Approved Revised Methodology Standards
- Awarded 25 Primary Research Projects
- Built a Robust Patient and Stakeholder Engagement Program
National Priorities for Research and Research Agenda

Assessment of Prevention, Diagnosis, and Treatment Options
- Comparisons of alternative clinical options to support personalized decision-making and self-care
- Identifying patient differences in response to therapy
- Studies of patient preferences for various outcomes

Improving Healthcare Systems
- Improving support of patient self-management
- Focusing on coordination of care for complex conditions and improving access to care
- Comparing alternative strategies for workforce deployment

Communication & Dissemination Research
- Understanding and enhancing shared decision-making
- Alternative strategies for dissemination of evidence
- Exploring opportunities to improve patient health literacy

Addressing Disparities
- Understanding differences in effectiveness across groups
- Understanding differences in preferences across groups
- Reducing disparities through use of findings from PCOR

Accelerating PCOR and Methodological Research
- Improving study designs and analytic methods of PCOR
- Building and improving clinical data networks
- Methods for training researchers, patients to participate in PCOR
- Establishing methodology for the study of rare diseases
## Our Review Criteria

1. **Impact of the Condition on the Health of Individuals and Populations**
2. **Potential for Improving Care and Outcomes**
3. **Effects on Health Care Delivery**
4. **Patient-Centeredness**
5. **Rigorous Research Methods**
6. **Inclusiveness of Different Populations**
7. **Research Team – Engagement**
8. **Efficient Use of Research Resources**
Our Research Portfolio: 50 Pilot Projects

- Approved April 25, 2012
- 50 projects
- 24 states
- $31 million

- Advance the field of patient-centered outcomes research
- Support the identification of methodologies
- Identify gaps where methodological research needs further development
Our Research Portfolio: 25 Cycle I Projects

9 Assessment of Prevention, Diagnosis, and Treatment Options

6 Improving Healthcare Systems

6 Communication and Dissemination Research

4 Addressing Disparities

25 Total

Inaugural PFA Funding Cycle Totals (Cycle I)
Slate of Awards Selected December 18, 2012

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<th>Average</th>
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<td>Improving Healthcare Systems</td>
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<tr>
<td><strong>Grand Total</strong></td>
<td>1,628,635</td>
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Our First Targeted Research Topics

- Identified several high-priority, stakeholder-vetted topics for targeted PFAs
- Jumpstarts PCORI’s long-term topic generation and research prioritization effort
- Leverages stakeholder input from before PCORI’s existence
- Allows us to build on our engagement work

Research Topics:

- Treatment options for uterine fibroids
- Treatment of severe asthma in African-Americans and Hispanics/Latinos
- Preventing injuries from falls in the elderly
- Treatment options for back pain
- Obesity treatment options in diverse populations
Communications Challenges

- We serve multiple audiences (per the ACA)
- We have specific communication requirements
  - Time: Within 90 days “after conduct or receipt”
  - Audience: Comprehensible and useful to patients and providers in making health care decisions”
- CER/PCOR are not necessarily the easiest topics to communicate broadly
- We have no study results to talk about as yet
So What Do We Do?

- Build visibility and “brand”
- Focus on “results” we have (methods standards)
- Focus on what we’re learning
- Find good “stories” about everything else
- Set the stage for the work to come
- Start planning for the dissemination of our research results by building a “communications community”
Case Study: Methodology Standards

Overall goal

- Improve researcher adherence to PCORI methods standards by influencing their knowledge, attitudes, beliefs and behaviors as researchers and peer reviewers.

General strategy

- Short-term: Identify and seek to change key determinants of research practices, including those involved in designing, funding, conducting, reporting and disseminating research.

- Long-term: Influence the overall culture of research and the capacity, ability and tendency of researchers/stakeholders to follow standards (in lieu of “professional autonomy” and judgment) in research practices.
Case Study: Methodology Standards

- Standards for Formulating Research Questions
- Standards Associated with Patient-Centeredness
- Standards for Systematic Reviews
- General and Crosscutting Methods For All PCOR
- Causal Inference Standards
- Standards for Heterogeneity of Treatment Effect (HTE)
- Standards for Preventing and Handling Missing Data
- Standards for Data Networks
- Standards for Adaptive and Bayesian Trial Designs
- Standards for Data Registries
- Standards for Studies of Diagnostic Tests
It Will Be a Challenge to Move the Needle

- Requires a significant change in researcher culture, norms, attitudes, knowledge and skill, incentives, policies and procedures.
- Must deal with multiple influences and constraints acting simultaneously on researchers and research stakeholders.
- Changes in individual influences and elements of practice are usually necessary but not sufficient.
It Will Be a Challenge to Move the Needle

- We have limited control and influence over many of the key factors affecting research practices.
- We can’t do it alone – we must identify key stakeholders and plan collaborative activities needed to effect change.
- Change will occur slowly and requires a long-term, multi-phase/multi-component plan.
- We must prioritize activities based on resources and competing demands.
What To Focus On

- Facilitate awareness.
- Promote education and training.
- Facilitate professional acceptance and legitimacy via endorsements, editorials, opinion leader strategies.
- Facilitate feasibility and ease of use through dissemination of tools and identification and removal of other barriers.
- Establish comprehensive range of incentives/rewards.
- Design and implement monitoring and feedback mechanisms; use resulting data to continuously refine dissemination/ implementation strategy.
Key Stakeholders and Modes of Influence

- Funding agencies. Funding announcements/proposal requirements, peer review, monitoring and reporting, agency-conducted dissemination.

- Professional and trade associations. Training and professional development activities influencing professional norms and standards of practice, incentive and reward activities.

- Regulatory agencies. Requirements for research conducted to meet regulatory or approval standards.

- Journals/professional media. Manuscript content and related submission requirements, peer review.

- Academic leaders and institutions. Training programs, institutional review and reward processes.

- Select consumer media. Accessible, real-world examples of and stories about why our work – and methods -- matter.
“Research Done Differently”

We want patients and other stakeholders to:

- Participate in formulating research questions
- Define essential characteristics of study participants, comparators, and outcomes
- Monitor of study conduct and progress
- Help disseminate research results
Setting the Stage/Telling Stories

- What is CER/PCOR and why should anyone care?
- What do you mean by “research done differently”?
- What is “patient-centeredness?”
- Why are you studying what you’re studying?
- How will your approach help me?
PCORI Challenge

Competition to create a system for connecting healthcare researchers and patient partners to advance patient-centered comparative effectiveness research

Prizes:
- Conceptual Model - $10,000
- Prototype - $40,000

Key Dates:
- December 14, 2012 - Submission period begins
- April 15, 2013 - Submission period ends
- May 15, 2013 - Winners notified
- Spring 2013 - Winners announced at a national health conference
Engaging Stakeholders to Improve Depression Management in a Tribal Health System (Pilot Project)

- **Primary Investigator and Institution:** Renee F. Robinson, PharmD, MPH, Southcentral Foundation
- **Award Amount:** $604,301
- **Description:** Project will develop, test, and refine a tool to support decision making within a tribally-owned health care organization, using depression as example condition. There are three specific aims:
  - Identify stakeholder preferences and needs that influence depression treatment decisions in Alaska Native and American Indian people.
  - Develop a tool to help translate and integrate evidence-based guidelines, and stakeholder preferences and needs into depression management decisions.
  - Determine impact of the stakeholder-centered tool on health, service utilization, and outcomes.

**Featured Project Strengths:**
- Studies an issue with high prevalence in an underserved community.
- The results will be applicable to other chronic health concerns, and other racially and ethnically diverse populations with persistent health disparities.
Reducing Health Disparities in Appalachians with Multiple Cardiovascular Disease Risk Factors

**Primary Investigator and Institution:** Debra Moser, DNSc, RN, FAAN, University of Kentucky

**Award Amount:** $2,092,473.60

**Description:** Compares the effects of two approaches in reducing risk of cardiovascular disease. Comparison is between the current standard of care and the standard of care supplemented by culturally appropriate self-care tools.

- Examines four-month and one year impact of various measures, including tobacco use, blood pressure, BMI, and the number of recruited people who stay with the program.
- Study involves 300 individuals from Appalachian Kentucky who do not have a primary care provider, and otherwise are not able to receive the standard of care without intercession, and are at risk by having two or more modifiable risk factors.

**Featured Project Strengths:**

- This study will have a substantial impact on cardiovascular health because it will provide needed patient-centered risk reduction to a major at-risk population living in an environment where risk reduction is difficult.
- The potential for application to other environments and high-risk populations is high.
Innovative Methods for Parents and Clinics to Create Tools (IMPACCT) for Kids Care

Primary Investigator and Institution: Jennifer DeVoe, MD, Dphil, Oregon Community Health Information Network

Award Amount: $1,830,297

Description: Focus is on innovative methods for parents and clinics to create tools for kids’ care.

- Aims to partner with stakeholders to develop IT tools that community health clinics use in communicating about children’s public health insurance options.
- Compares results in two community clinics using the tools vs. two clinics who are not using the tools.
- Ultimate goal is improve health insurance coverage and health care for children.

Featured Project Strengths:

- This addresses a known gap in continuous care due to changes in insurance status that has significant impact on the health of children with chronic disease.
- Empowers parents of children with chronic disease to manage access to care.
How We’ll Know We’ve Moved the Needle

Surveys to:
- Measure our reputation and understanding of/support of CER and PCOR.
- Measure quality and effectiveness of events’ supporting communications.

Media monitoring, including “pull-through.”

Measurements of stakeholder participation in our work.

Uptake and application of our methods standards.

How quickly and widely our research changes practice.

Reauthorization (the ACA has evaluation metrics).
Connect with PCORI

www.pcori.org

More News From PCORI

PCORI Adopts Revised Methodology Standards
Board adopts 47 revised Methodology Standards to guide the conduct of patient-centered outcomes research more →

PCORI Issues RFP for Comprehensive Inventory of Research Networks
Contract will help PCORI understand platforms conducive to patient-centered outcomes research more →

Director Named for Improving Healthcare Systems Program
PCORI Names Chad Boult, MD, MPH, MBA, Johns Hopkins Professor and CMS Advisor to Head Program more →
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