The Patient-Centered Outcomes Research Institute: Research Foundations and Priorities
6th Annual Nursing Quality Conference
January 25 - 27, 2012
Objectives

1. Explain history, mission and vision of the Patient Centered Outcomes Research Institute (PCORI) to include the foundational work to date and national research priorities.

2. Identify resources available through the Patient Centered Outcomes Research Institute (PCORI) to include networking and funding.
Who is PCORI?

- Patient representatives
- Caregivers
- Physicians, nurses and providers
- Health services researchers
- State and federal health officials
- Pharmaceutical, device, and diagnostic manufacturers
- Private payers
- Employers
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.
The Promise of PCORI

Understanding the choices patients face

Aligning methods and data with patient needs

Providing patients and clinicians information for better decisions
PCORI’s Core Duties

- Establish national research priorities
- Establish and carry out a research project agenda
- Develop and update methodological standards
- Provide a peer-review process for primary research
- Disseminate research findings
Methodology Committee

Co-Chairs: Sherine Gabriel, MD & Sharon-Lise Normand, MD

- Patient-Centeredness
  - Methods to incorporate the patient perspective into all phases of PCOR

- Research Prioritization
  - Methods to inform prioritization of new research studies

- Research Methods
  - Methods for using data, design, and statistical analyses to conduct PCOR
Working Definition of Patient-Centered Outcomes Research

Patient-Centered Outcomes Research 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?”
To what extent will PCOR be CER?

• Incorporating a stronger patient focus will help ensure that:
  – Research questions are practical, and usually comparative
  – The variety of outcomes important to patients are not overlooked
  – Patients studied come from relevant settings and are representative
  – Possibilities of heterogeneity in effectiveness are examined
PCORI Timeline

- **PCORI’s Establishment**
  September 2010 – January 2011
- **Organizational Development**
  January 2011 – December 2011
- **Setting Initial National Research Priorities**
  July 2011 – June 2012
- **Establishing PCOR Agenda, Generating Knowledge, Disseminating Findings, and Updating Priorities**
  July 2012 -
PCORI’s Establishment

Sep. 2010 - Jan. 2011

- Mar. 2010 – Created by Patient Protection and Affordable Care Act (Subtitle D, Sec. 6301)
- Sep. 2010 – GAO Appoints PCORI Board of Governors
- Nov. 2010 – PCORI Incorporated as Independent Not-For-Profit Entity
- Jan. 2011 – GAO Appoints Methodology Committee
Organizational Development

- Mission Defined
- Governance and Financial Systems Established
- Standing Committees Created
- Public Board Meetings
- Stakeholder Engagement
- Annual Operating Plan and Budget Approved
- Methodology Workgroups Created
- Executive Director and COO Hired
- Website expanded: www.pcori.org
Setting Initial National Research Priorities


- Priorities informed by:
  - Stakeholder Engagement
  - Landscape Reviews
  - Pilot Projects
  - Conference Grants
  - Methodology Committee Report

- Extensive public comment

- To be approved by Board of Governors
Research Agenda, Generating Knowledge, Disseminating Findings, and Updating Priorities

Jul. 2012 –

- Full research arsenal
- Informed by national priorities
- Methodological standards defined and updated
- Collaboration with AHRQ, NIH, and others
- Close gap between availability of information and uptake
- Stakeholder engagement throughout
- Extensive public comment
- To be approved by Board of Governors
PCORI Pilot Projects Grants Program

Purpose:

• **National Priorities** – provide information to PCORI that informs future iterations of national research priorities for patient-centered outcomes research.

• **Research Agenda** – support the collection of preliminary data to advance the field of patient-centered outcomes research, providing the platform for an evolving PCORI research agenda.

• **Methodologies** – support identification of research methodologies that advance patient-centered outcomes research.
Pilot Projects Process

- Expect to commit approximately $13 million in FY 2012 to support up to 40 projects.
- Applicants can propose project periods of up to two years. Second year funding is subject to noncompetitive review by PCORI staff.
- Direct costs are limited to $250,000/year with an additional 40% of salary and fringe allowable as indirect costs.
- NIH will conduct review process, all other aspects of grant awards and management handled by PCORI. Award notification and funding will occur in May 2012.

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<tr>
<th>Pilot Projects by the Numbers</th>
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<tr>
<td>850</td>
<td>People who registered for webinars</td>
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<td>1375</td>
<td>Letters of Intent received</td>
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<tr>
<td>350</td>
<td>Patient/Stakeholder reviewer applications received</td>
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<tr>
<td>498</td>
<td>Scientific reviewer applications received</td>
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<tr>
<td>800</td>
<td>Number of applicant questions answered</td>
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Proposed Timeline for Setting National Priorities

Underway
Develop Candidate Framework & Engage Stakeholders

January-March 2012
Receive Public Comments

April 2012
Finalize National Priorities Research Agenda 1.0

May - June 2012
Issue PCORI Funding Announcement

Increasing Specificity
Framework for Refining PCORI National Priorities and Developing Research Agenda

Priority Themes

- Clinical Effectiveness
- Improving Healthcare Systems
- Communication & Dissemination
- Fairness / Addressing Disparities
- Accelerating Patient-Centered Research

PCORI Criteria

- Impact on Health of Individuals and Populations
- Probability of Improvability via Research
- Inclusiveness of Different Sub-populations
- Addresses Current Gaps in Knowledge / Variation in Care / Disparities
- Improved Health Care System Performance
- Potential to Influence Decision Making
- Efficient Use of Research Resources

PCORI Research Agenda

In Statute
Developing PCORI’s Research Agenda

Priority Themes

- Comparative Clinical Effectiveness
- Accelerating Patient-Centered Research
- Communication & Dissemination
- Improving Healthcare Systems
- Fairness / Addressing Disparities

Priority Themes + Proposed PCORI Criteria = PCORI Research Agenda
Developing PCORI’s Research Agenda

PCORI Criteria

- Potential to Influence Decision Making
- Improved Health Care System Performance
- Probability of Improvability via Research
- Current Health Disparities
- Address Current Gaps in Knowledge
- Address Variation in Care
- Impact on Health of Individuals and Populations

Priority Themes + Proposed PCORI Criteria = PCORI Research Agenda

In Statute

Efficient Use of Research Resources

From Board
# PCORI Research Agenda

**April 2012 release**

<table>
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<th>Agenda Will...</th>
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<tr>
<td>Be tied to the National Priorities and filtered through the criteria</td>
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<tr>
<td>Demonstrate a commitment to a diverse research portfolio with respect to patients, geography, health care professionals, investigators, and organizations</td>
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<td>Promote patients as partners, with a role in the design, governance, review, and dissemination of research</td>
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<td>Be a living document that is updated and revised according to stakeholder input</td>
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Guiding Principles for Engaging Stakeholders

Balanced Representation
- Obtain feedback from a diverse and representative range of patients, health care stakeholders and the general public

Transparency
- Enable an open engagement process that makes clear how participants can get involved and how their input will be incorporated

Facilitate Participation
- Provide easy, accessible forums for participants to provide feedback equitably
Work in progress...

- Analysis of Input Received on Working Definition of “Patient-Centered Outcomes Research (PCOR)”
- Review and Synthesis of Evidence for Eliciting the Patient’s Perspective in PCOR
- Expert Stakeholder Interviews to Identify Evidence for Eliciting the Patient’s Perspective in PCOR
- Methods for Setting Priorities in Research
- Review of Guidance Documents for Selected Methods in PCOR
Request for Information

Draft Translation Table Framework

Available at:

http://www.pcori.org/provide-input/translation-table/

Due: February 17, 2012 at 5:00 PM ET
Translation Tool Structure

http://www.pcori.org/provide-input/translation-table/
PCORI National Priorities

1. Comparative Assessments of Prevention, Diagnosis, and Treatment Options
2. Improving Healthcare Systems
3. Communication and Dissemination
4. Addressing Disparities
5. Accelerating Patient-Centered and Methodological Research

Public comment period will remain open until 11:59 p.m. EST on March 15.
Connect with PCORI

Website: pcori.org
Email: info@pcori.org

- Provide feedback
- Submit inquiries
- Subscribe to PCORI’s mailing list

Live webcast and teleconference provided for all Board meetings.