

Patient-Centered Outcomes Research Institute Methodology Committee (MC) Report

March 5, 2012



- 1. Finalizing the Methodology Report**
- 2. Board- Methodology Committee Engagement**
- 3. Beyond the Methodology Report**
- 4. PCOR Definition**

Finalizing the Methodology Report

CHAPTER 1. **Introduction**

- **What is PCOR? (Based on our definition)**
- **What is the pressing need for a report on methods for conducting PCOR?**
- **Who is this report for?**
- **Goals of the First MC Report**
- **Types of Research Addressed in this Report**

CHAPTER 2. **How we Developed Standards**

- **What are standards?**
- **Categories for Rating Potential Standards**
- **Selecting Standards**

CHAPTER 3. **What is Patient – Centeredness?**

- **How does patient centeredness apply in research prioritization, identification of research questions, design of studies (PICOTS*), and dissemination/implementation?**
- **What methods can make research more patient-centered?**
- **How is patient-centeredness balanced with feasibility and other stakeholders' concerns?**

CHAPTERS 4-? **Standards for Selecting, Designing, and Conducting Research**

- **Formulating Research Questions (PICOTS*)**
- **Choosing a Data Source, Study Design, & Analysis Plan**
- **Methods for Conducting Research Studies**

CHAPTER N. **Future Plans & Direction**

- **Public Review**
- **Dissemination and Implementation**
- **Plans for Updating**

CHAPTER 1.
Introduction

CHAPTER 2.
**How we Developed
Standards**

CHAPTER 3.
**What is Patient –
Centeredness?**

CHAPTERS 4-?
**Standards for Selecting,
Designing, and Conducting
Research**

CHAPTER N.
Future Plans & Direction

Example Section:

***ENDORSED STANDARDS AND ACTIONS
RELATED TO MISSING DATA***

I. Background

“Missing data is not only inevitable in human health studies and trials, it is more likely....”

The committee reviewed standards for methods including Last Observation Carried Forward (LOCF), [*insert other methods here*].

II. Recommended Standards

1. Adopted standard #1
2. Adopted standard #2

II. Rationale for Standards

“The committee believes these standards...”

II. Recommended Actions to support the Standards

1. “PCORI shall encourage training in the...”
2. “PCORI shall disseminate software to conduct...”

Report Writing Process



The four phases below illustrate the key milestones which will take place during the report writing process



Key Board Engagement

Report Writing Process

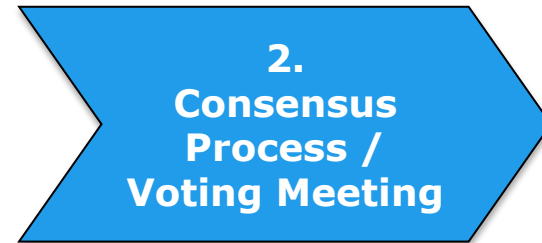


The next two phases demonstrate the process by which the Committee determines which Standards and Recommendations will be adopted for inclusion in the Report



March 1-15, 2012

- Two workshops will be held to discuss the findings of research groups contracted by the MC in order to facilitate writing of first Methodology Report
- 15 Reports will be delivered in March outlining findings and recommendations of each research team



April 3, 2012

- The Committee has defined an approach to select standards and recommendations for inclusion in the May Report
- During the April 3 Meeting, the Committee will come to consensus on standards to be included in the first Methodology Report

Report Writing Process



During the last two phases, the Committee will finalize the Report in preparation for delivery to the Board and Public Comment



April 2012

- The Report Writing Team and workgroups will collaborate to finalize the report
- Four experienced report writers have been brought on board to develop the Report



May 10, 2012

- Leading up to May 10, the Committee will prepare the Report for delivery to the Board
- Upon Board Approval, the Methodology Report will be posted for Public Comment Period

Methodology Committee – Board Engagement

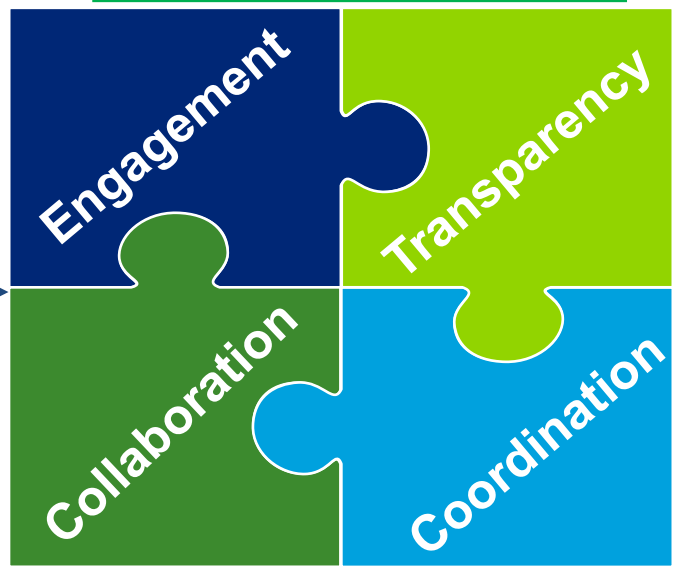
Board of Governors Engagement



The Methodology Committee has engaged with the Board in a number of ways in order to accomplish the following objectives:

Two Methodology Committee members will participate as members of the PCORI Pilot Project Selection Subcommittee

Methodology Committee members to attend the Closed Board Session at March Board Meeting



Orchestrated three teleconference calls to engage the Board in discussion of the report outline and translation tool

Established Liaisons to the Patient Centeredness Working Group: Ellen Sigal & Gray Norquist

Gained support of two Committee Members with framing the PCORI Funding Announcement (PFA)

Submitted approximately 12 Briefings since Sept. 2011

Participates in at least five bi-monthly Board Meetings with a total of approx. 25 hours of direct interaction

Collaborated with Board Members to develop a joint Dissemination Plan

Provided input regarding methodologic research on the Research Agenda and Pilot Projects

Shared highlights of the electronic data task & solicited approximately 6 candidates for interview referred by Harlan Weisman, Richard Kuntz, Steve Lipstein, & Harlan Krumholz

Invited Board Members to participate in reviews of contractor proposals: Leah-Hole Curry, Harlan Weisman, Debra Barksdale, Rick Kuntz, Steve Lipstein

Prepared weekly Status Reports on Committee progress to PCORI Leadership

Engagement Next Steps



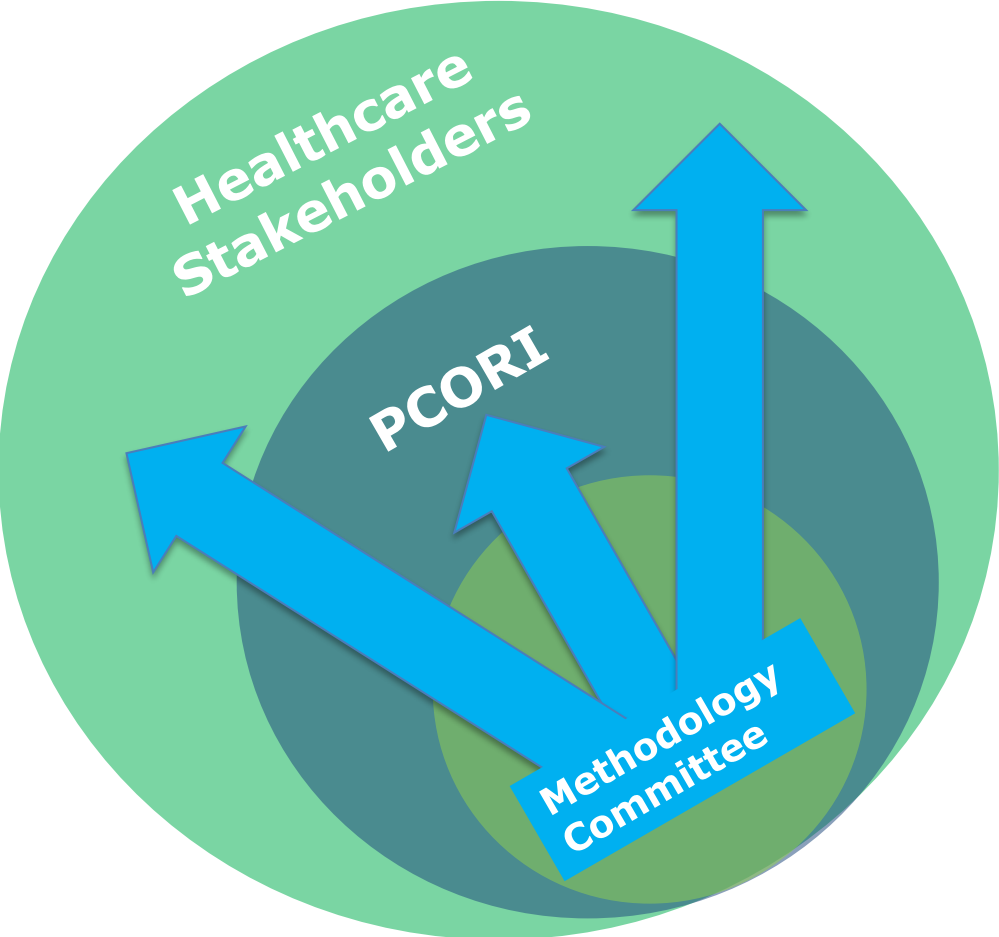
The below steps outline the opportunities for the Board to engage with the Methodology Committee during the development of the May Report

February 2012	'Case Study' Teleconference Call with Board	Review & Revise Outlines	Provide proposed recommendations	Draft sections of the report
March 2012	Synthesize contractor reports, research, and workshop results	Share Workshop Executive Summary & Contractor Reports	Prepare for meeting to vote on proposed standards	
April 2012	Voting Standards Meeting– <u>April 3rd</u>	Submit final drafts, Review, & Finalize Report Sections	Share Report & Receive input from Board of Governors	
May 2012	Submit Report to the Board	Post for Public Comment	Discuss and Approve Dissemination Plan	

Key: Board Engagement

Beyond the Methodology Report

Maximizing the impact of the Report



Following the release of the first Methodology Report, the MC intends to enhance adoption of the recommended standards and best practices within the broader research and health care communities by acting as a convener, communicator, and catalyst

In the months following the release of the May Report, the Committee plans to engage in the following activities:

- Committee Member Feedback Sessions
- Dissemination/Implementation of Standards
- June 2012 Retreat Strategic Planning
- Professional societies and stakeholders (Advisory Groups)
 - Electronic Data Systems
 - Implementation
 - Novel Delivery Tools
 - Systems Engineering
- 1st Annual PCOR conference

Patient-Centered Outcomes Research Definition



Workgroup Members:

Dave Flum
Mary Tinetti
Jean Slutsky

Mark Helfand
Sebastian
Schneeweiss

Board Members:

Debra Barksdale
Bob Jesse
Harlan Weisman
Gray Norquist
Rick Kuntz

Sharon Levine
Allen Douma
Gail Hunt
Harlan Krumholz

Working Group Accomplishments

- Reached consensus on changes to PCOR definition in response to public input
 - Added reference to improving communication and including caregivers
 - Modified question four so that mention of healthcare system emphasizes role of the system in getting better decisions
- Prepared revised document that explains proposed response to public input

Patient Centered Outcomes Research (PCOR) helps people and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options. This research answers patient-centered questions such as:

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 potential benefits and harms of those options?"
3. "What can I do to improve the outcomes that are most important to me?"
4. "How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?"

To answer these questions, PCOR:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, 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, resource availability, and other stakeholder perspectives.

Thank You!