



Methodology Report:

-Submission to Board

-Dissemination and Implementation Plan

Robin Newhouse, Chair of the Methodology Committee

David Hickam, Director of Clinical Effectiveness Research

PCORI Board of Governors Meeting

Atlanta, GA

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Patient-Centered Outcomes Research Institute

Session Topics and Objectives

What are we going to cover today?

Methodology Report

- Review and accept revised Methodology Report
- Adopt minor revisions to Methodology Standards

Dissemination and Implementation

- Discuss the plan for disseminating and implementing the standards and report

Timeline & Next Steps

- Timeline for key dissemination and implementation strategies

Methodology Report

- The Methodology Committee is submitting the revised Methodology Report to the Board of Governors for acceptance
- Overview of Timeline:
 - May – June 2012: **Draft report accepted by the Board** and released to the public
 - July – September 2012: **Open public comment period** on the report and Methodology Standards
 - November 2012: **Methodology Standards adopted by the Board**
 - December 2012: **Methodology Standards published**
 - January – September 2013: Report revised by the Methodology Committee and PCORI staff
 - Under the oversight of the Methodology Committee, minor editorial changes were made to the Methodology Standards based on editing of the final report
 - September 2013: **Methodology Committee approved revised report**
 - November 2013: Revised report is ready for submission to the Board and public release after Board acceptance

Highlights of the Revised Report

Response to Public Comments

- Public comments led to substantive revisions
 - Comments pertained to the Methodology Standards and the general Report
- Total of 1,487 unique comments from 124 stakeholder groups:
 - Researchers (28%); Representatives of industry (27%); Patients, caregivers, patient advocates (9%); Others, including clinicians, organizational providers, policymakers (23%); Unspecified (13%)
- Comments fell into three broad categories:
 - Suggestions for PCORI unrelated to the Report
 - General comments about the Report
 - Including suggestions for the Translation Table
 - Comments related to specific Methodology Standards
- Appendix C of the Report contains a full explanation of the response to public comments

Highlights of the Revised Report

Stories and Examples

- Inclusion of stories and examples based on public comments about accessibility and utility of the report
- Four types of stories and examples illustrate the importance of the methodology issues addressed in the report:
 - **CER WINS:** CER studies that led to important changes in clinical practice and patient care
 - **Research in Practice:** Interviews and insight on the value, and challenges, of implementing CER
 - **Patient Voices:** Stories from patients sharing their own experiences in navigating choices and weighing options
 - **Research Stories:** Examples of published research studies that capture the impact good methodology has on research

Dissemination and Implementation Plan

Overview

 **Goals:** Increase awareness of and adherence to the standards

 Key Phases

- PHASE 1: Operationalize the Methodology Standards in the PCORI **merit review process** (*Q1 FY2014*)
- PHASE 2: Develop and implement **training programs** for the Methodology Standards (*Q1-Q2 FY2014*)
- PHASE 3: **Increase awareness** of the Methodology Standards (*Q1-Q4 FY2014*)
- PHASE 4: **Implementation tools** development (*Q4 FY2014*)
- PHASE 5: Ongoing **monitoring and evaluation** (*Q1-Q4 FY2014*)

Discussion Question for the Board

Discuss

- What other dissemination or implementation strategies or mechanisms should PCORI consider?

Board Vote: Methodology Report

Call for a Motion to:

- **Accept the revised Methodology Report and Adopt editorial revisions to Methodology Standards** as endorsed by the Methodology Committee

Call for the Motion to Be Seconded:

- **Second** the Motion
 - If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Vote:

- Vote to **Approve** the **Final** Motion
 - Ask for votes in favor
 - Ask for votes opposed
 - Ask for abstentions

PUBLIC COMMENT



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WRAP-UP & ADJOURN



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