



MINUTES OF THE
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE
DENVER, COLORADO
MAY 20-21, 2012

MEMBERS PRESENT: Eugene Washington, MD, MSc; Steven Lipstein, MHA; Debra Barksdale, PhD, RN; Kerry Barnett, JD; Lawrence Becker, Carolyn Clancy, MD; Francis Collins, MD, PhD; Leah Hole-Curry, JD; Allen Douma, MD; Arnold Epstein, MD; Christine Goertz, DC, PhD; Gail Hunt, Richard Kuntz, MD, MSc; Sharon Levine, MD; Grayson Norquist, MD; Ellen Sigal, PhD; Harlan Weisman, MD; Robert Zwolak, MD, PhD.

STAFF PRESENT: Joe Selby, MD, MPH; Anne Beal, MD, MPH; Judith Glanz, Bill Silberg, Melissa Stern, Martin Duenas, Susan Hildebrandt, Mark Freeman, Gail Shearer, Lori Frank, Denise Earlington, Rachael Fleurence, Pam Goodnow, Susan Sheridan, Peter Brooks

METHODOLOGY MEMBERS PRESENT: Jean Slutsky, Robin Newhouse, Mark Helfand, David Flum, Sherine Gabriel, Sharon-Lise Normand, Steven Goodman, Brian Mittman, Sebastian Schneeweiss

GUESTS: Richard Schmitz, Josh Weisz, Jessica Nadler, Kim Myers, Nancy Miller, Bill Holtsnider, Andrew Holtz

Participating by Conference Call: Harlan Krumholz, MD

Board Members Absent: Robert Jesse, MD, PhD; Freda Lewis-Hall, MD

WELCOME AND APPROVAL OF BOARD MEETING MINUTES

Chair Washington called to order the **open session** of the Board of Governors on May 20, 2012.

Jacksonville, FL, January 18-19, 2012
Baltimore, MD, March 5-6, 2012

A motion was made and seconded to approve the minutes of the March 5, 2012 meeting in Baltimore, MD. The Board approved the minutes unanimously.

There were inconsistencies regarding dates in the Jacksonville, FL meeting's minutes. A motion to table consideration of these minutes was made, seconded and approved.

Welcome PCORI's New Scientist

Welcome to the newest PCORI scientist Rachel Fleurence. She will be very involved in the ongoing discussions about research prioritization.

Celebrate Funding

PCORI has funded \$31 million in pilot projects. 50 projects have been approved and the awardees will be posted on the PCORI website within the week. This research is not comparative effectiveness research, because the statute specified that no comparative effectiveness research could be funded until a Research Agenda was adopted and posted. Rather, the purpose of the pilot projects was to explore methods for engaging patients in aspects of the research process. . Areas of interest funded by one or more projects include:

- 3 projects dedicated to engaging patients and stakeholders in the process of forming PCORI's national priorities
- 2 projects on engaging patients and stakeholders in the entire research process
- 19 projects on engaging patients in research to build support tools that account for patient preferences
- 12 projects on engagement of patients in developing patient-centered outcome instruments for a wide range of conditions
- 4 projects on involving patients in researching behaviors, life styles, and choices that patients make
- 6 projects studying patient care team interaction in situations where multiple options are being deliberated
- 7 projects devoted to analytic methods of comparative effectiveness or patient-centered outcomes research

There were 850 applications. We plan to evaluate further:

- The geographic distribution of applicants and awardees
- How patient engagement scores affected final overall merit review scores

- The effects of including patient and stakeholder reviewers on the review process

Congratulations to Board Member Sharon Levine for being awarded:

- BF Bay Area Woman of the Year Award
- Industry Leader Award from the Professional Women of California

A change in the format of PCORI Board meetings agenda was highlighted. The agenda will be organized by strategic imperatives derived from the preliminary strategic plan (see below). The agenda is increasingly organized and driven by staff rather than by board committee's.

Methodology Report and Plans for Public Comment

Chair Sherine Gabriel gave the Methodology Committee Report. Gabriel referred to quotes from two Board members, Harlan Krumholz (“...this will be research done differently”) and Larry Becker (“the MC is writing the source code”) and said the report addresses just how research will be done differently. She discussed how the report was developed: Working groups identified and prioritized major research methods questions to be addressed; researchers were contracted to address selected topics; these contractors developed research materials (e.g., reports, summary templates for proposed standard); MC solicited external feedback on the translation table (through an RFI); workshops were held to discuss contractor findings in the areas of patient engagement and research prioritization, with invited experts in attendance; MC conducted in-depth internal review of materials developed by contractors, and support staff; MC independently submitted preliminary votes on proposed standards; MC deliberated to reach consensus on recommendations to be endorsed in the report, and finally refined recommendations and report content per committee evaluations and discussions.

The MC sought to address selected topics in 4 broad phases of activities in the first Methodology Report:

1. What should we study? (research prioritization)
2. What study designs should we use? (analytic methods and translation table)
3. How do we carry out and govern the study? (patient and stakeholder engagement)

4. How do we enable people to apply the study results? (dissemination)

Gabriel discussed the methods selection, information gathering, internal review, and ultimate recommendation of sixty methodological standards across ten domains. She then introduced Bill Silberg to discuss next steps including initial posting of this report, a public comment period that would begin in mid-July; elements of the initial communications plan once the report is revised, and the dissemination plan.

Silberg started by saying that the ultimate goal of the next steps should be a phased approach where the resource would be one that the community can own.

Gabriel then ended her presentation with a three-minute thank you video clip to her fellow members of the Methodology Committee.

Strategic Planning

Melissa Stern introduced the preliminary strategic plan and the Board discussed the Vision and Mission statements and the Strategic Imperatives which include: Engaging Patients and Stakeholders

- Advancing Rigorous PCOR Methods

- Conducting PCOR

- Communicating and Disseminating PCOR Findings

- Developing Infrastructure

The plan is a preliminary strategic plan. The board will return to this plan within the following six months to develop it further. No vote was taken on the preliminary plan.

Conducting PCOR:-NP/RA

Leah Hole-Curry presented the National Priorities and Research Agenda Version 1.0.

Hole-Curry discussed the timeline for establishing PCORI's first National Priorities for Research and Initial Research Agenda and the development of the draft National Priorities and Research Agenda. She discussed the commitment to public comment, the 53-day public comment period, the need for additional forums, and the rigorous, systematic review and analysis of these comments. She also covered an overview of themes heard during the comment period and options for response to them.

Lipstein then asked Hole-Curry if she would make a motion for the Board to approve the National Priorities and Research Agenda Version 1.0. Selby clarified that the Board was required to

“adopt” not “accept” the Priorities and Agenda. A motion to adopt the National Priorities and Research Agenda Version 1.0. was made and seconded.

Vote: The Board voted (unanimously) to adopt the National Priorities and Research Agenda Version 1.0.

Chair Washington called a recess for lunch.

Chair Washington reconvened the meeting.

Conducting PCOR: PFA Release and PFA Review Process

Selby presented on the release of the Public Funding Announcements (PFAs), discussing the history of the development of the first funding announcements and the relationship of the four PFAS to the first four National Priorities, the Research Agenda and the Methodology Report; unique features of PCORI research; a brief description of each PFA; review plans for review process. In his presentation he also described the areas of interest in all four of the funding announcements.

Martin Duenas reviewed the two-staged merit review process. His topics included:

- **Goals & Key Facts**
Duenas said that the goal is to establish a rigorous peer review process that assures all PCORI funded projects are of the highest scientific quality and provide patients/stakeholders a clear and valued voice in the decision making process to support PCORI’s mission
- **PCORI’s Two-Stage Merit Review**
Two-stage process requires a Phase I technical review and a Phase II impact review of the applications. Phase II involves technical and patient/stakeholders reviewers recommendation (review and score) for funding of the top applications that have the greatest impact for PCORI’s mission.
- **PCORI’s Administration**
The roles and responsibilities include the assignment of a PCORI Project Manager for the overall management of PFA review process; an NIH Project Manager to support the PCORI Project Manager and the overall process; Scientific Review Officers (SROs) to recruit reviewers, conduct applications quality control, lead applications assignments, manage panel II in-person review, write the summary statement, develop and conduct trainings, provide customer services, establish a timeline, and maintain the integrity of the process

Patient and Stakeholder Engagement

Chief Operating Officer, Anne Beal, presented with Susan Hildebrandt, Director, Stakeholder Engagement, and Judith Glanz, Director, Patient Engagement.

Beal presented on the “whys” of engagement and discussed the guiding principles for stakeholder engagement: asking and prioritizing meaningful research questions, reviewing proposals and conduct research, getting feedback on PCORI impact, accelerating dissemination.

Glanz gave an outline of her presentation which included how PCORI engages patients and caregivers in PCORI’s research enterprise.

Hildebrandt started off with a definition of “stakeholder” and included how PCORI engages stakeholders.

Public Comment

Kerri Diamant, AlterMed Research

Tami Ellison, N/A

Lauren Frey, Epilepsy Foundation of Colorado

Finance Report

Kerry Barnett and Pam Goodnow gave the FA&AC report and discussed the findings of the independent audit. The firm McGladrey & Pullen, LLP issued an unqualified opinion on the PCORI financial statements from Year 1: November 10 (Inception) through December 31, 2010 and Year 2: calendar year ending December 31, 2011.

They also reported on PCORI’s cash flow projections

Conflict of Interest (COI) Policy and the Standing Committee on Conflict of Interest

Lawrence Becker reported on the SCCOI and discussed the context of PCORI and COI:

- The mission of PCORI transcends any individual or group of individuals
- The integrity and trust of the resulting research is of utmost importance
- Competing for grants in health and health care research is a very competitive field
- The pool of researchers who can successfully compete and produce meaningful results in PCORI’s domain is relatively small

He also discussed the risks to the PCORI mission:

- There is risk involved in allowing MC, close relatives of Board or MC, and contractors to compete for PCORI funding
- There are risks associated with restricting eligibility
- Risks stem from the perception of an advantage and from obtaining access to information in advance of others
- There are also the issues of real conflicts involving financial benefit

Becker discussed the conclusions of the ad hoc committee on conflict that resulted in the formation of the SCCOI. He introduced a slide presentation and introduced the members of the committee. Becker also reported on the SCCOI's first meeting in April, where recommendations were made to the group from its members, stressing that the integrity of the resulting research is the most important thing. He mentioned that competing for grants in health and health care is very competitive. Researchers who can compete and produce meaningful results are a pool of scientific talent and expertise is limited. The discussion of proposed policy on COI and the Board and Methodology Committee members followed.

The issue of spouses and partners was addressed. Spouses and partners of Board members are not eligible to apply for PCORI funding. MC members will not be eligible to apply for the first round of PFAs to be issued this week. However, the Board did not reach agreement on eligibility for subsequent PFA's. Consideration and revision of the proposed policy on conflict of interest as it pertains to MC members will continue. The revised policy will be brought to the Board for discussion and approval at a future open meeting of the Board.

Adjournment

Chair Washington adjourned the meeting at 5:35 p.m.