PCORI Board of Governors Meeting Minutes
September 19, 2011
Seattle, WA

Public Session B: 1:00 pm - 4:00 pm

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I. Call to Order

Washington called the meeting to order at 1:01p.m. He welcomed those in attendance and reminded all that the meeting was being webcast live.

II. In Attendance

PCORI Board

Eugene Washington (Chair), Steve Lipstein (Vice Chair), Kerry Barnett, Lawrence Becker, Arnold Epstein, Christine Goertz, Leah Hole-Curry, Gail Hunt, Robert Jesse, Harlan Krumholz, Richard Kuntz, Freda Lewis-Hall, Ellen Sigal, Harlan Weisman, Robert Zwolak.

Methodology Committee

Sherine Gabriel (Chair), Sharon-Lise Normand (Vice Chair), Naomi Aronson, Ethan Basch, Alfred Berg, David Flum, Steve Goodman, Mark Helfand, David Meltzer, Brian Mittman, Robin Newhouse, Sebastian Schneeweiss, Jean Slutsky

Staff

Joe Selby (Executive Director), Mark Freeman (Executive Assistant)

Guests

Kathy Hudson (NIH), Pat Nichols (TMC), Shar'on Barclay (TMC), Richard Schmitz (GolinHarris), Erica Fischer (GolinHarris), Chandan Karnik (Deloitte Consulting), Jessica Nadler (Deloitte Consulting), Anna Cottone (Deloitte Consulting), Rayneisha Watson (Deloitte Consulting)

a) Attended via Phone

Carolyn Clancy and Ellen Sigal

b) Absent

Francis Collins (represented by Kathy Hudson) and Freda Lewis-Hall

III. Opening Comments from Executive Director

Selby reported that PCORI has accomplished a lot in the past two months. He highlighted the achievements over the past two months and talked about future plans. PCORI has been working to establish policies and procedures for HR, purchasing and RFPs, conflict of interests, and research. The website has been revamped with lots of new material. He noted his outreach in Washington D.C. Additionally, there has been development in the IT infrastructure and planning for future staff. The new long-term home will be on the corner of 19th and L Street.

At the July 2011 board meeting, a number of urgent issues were raised. Those were to clarify decision-making roles among staff, board, and the Methodology Committee. There was a Sunday afternoon session, prior to the meeting, to discuss how to partner more effectively. In July 2011, the board expressed itself clearly on patient engagement and the need to hire dedicated staff and have an advisory panel. PCORI must get started on the national priorities and research agenda so funding can begin in 2012. There is support to the Program Development Committee in preparing an RFP for pilot projects. Additionally, there is work being done to get support and staff for the Methodology Committee so they can move forward quickly on their work.

There are three directors positions developed which include patient engagement, communications and stakeholder engagement. These are open and PCORI is actively seeking applicants.

We have a working group on establishing the national priorities and research agenda, co-chaired by Clancy, Epstein, Krumholz and Hole-Curry, respectively. The work is underway. The goal is to have the national priorities finalized in March 2012 and a research agenda finalized in April 2012. Some of the steps to accomplish that will happen concurrently. The timeline is conservative.

Goertz and Hunt are co-chairing the pilot project initiative. Public input was reviewed and incorporated into revised areas of interest for the funding announcement set for September 28, 2011. NIH will be reviewing the applications.

Facilitation of the hiring of interim staff for the Methodology Committee is being developed so that their report is completed by May 2012.

One RFP has closed for qualitative research on the definition of PCOR. Once the Methodology Committee revises the definition based on the chosen firms analysis, the firm will then do further focus group testing.

The staff is growing and the plan is to have a Chief Operating Officer in place by November 2011. The hiring of a director of staff, finance, the first scientists and engagement directors before the end of the year is underway.

Before November 2011, stakeholder input on national priorities and research agenda will be collected. By the end of the year, the first draft of the national priorities will be published and ready for public comment. By February 2012, the first draft of the research agenda will be published and ready for public comment, specifically on what will be funded or not funded.

IV. Approval of Minutes

a) Action

There was a motion and second to approve the July 2011 public session minutes with the correction of Barksdale and Clancy in attendance.

b) Patient Engagement Working Group

Lipstein reported that a working group was convened to look at patient engagement. He noted that Hunt and Becker would lead the discussion.

Hunt reported that the working group identified criteria of future advisory panels around four areas:

- Subject matter
- Charter duration
- Membership
- Experience base

Each panel will have a clearly defined charter and will provide advice and counsel to the board. Meetings may or may not be open to the board. Panels can help provide input on the research agenda and priorities. The duration and variety of subject matters may vary among panels.

Becker reported that membership on the panels depends on the subject matter. The working group would seek nominations for panels from a wide variety of sources, including self-nomination. The goal is to ensure diversity – in demographics, as well as role in relation PCORI and health care. The panels will have nine to eleven members.

Lipstein stated that statute encourages the board to make use of advisory panels. These guidelines will help do that effectively.

Washington noted that the guidelines would not be posted for official public comments but comments are welcome.

c) Dissemination Working Group

Washington noted that Levine and Clancy are co-chairing the working group on dissemination.

Levine reported that the dissemination working group convened for the first time last week. Dissemination is the responsibility of AHRQ; PCORI's responsibility is to make information available about the research.

Clancy pointed out that there are things AHRQ cannot do as a government agency that PCORI can do. A more in-depth briefing will be scheduled on what AHRQ does do in relation to dissemination.

d) Public Comments

Washington opened the floor to the public for comment.

- Eric Nealson of Washington Biomedical Biotechnology Association
- Barack Gastion of Consortium of Academic Health Centers for Integrative Medicine; University of Washington
- Robert Chiack; retired physician
- Heather Evans of the University of Washington
- Diana Busse of Group Health Research Institute

e) Communication, Outreach and Engagement Committee

Levine reported that at some point, the board may want to revisit this charter but for now the committee is charged with assisting the board with communications and branding work, stakeholder engagement and dissemination processes.

The first real public input opportunity was the working definition of "patient-centered outcomes research." There were nearly 600 responses received between July 20, 2011 and September 2, 2011. All responses will be posted on the website. A vendor has been solicited, through a RFP, to analyze and summarize the input received so that there is movement forward to the second phase – patient focus groups. A report will be given to the board at the January 2012 meeting. More than 150 responses were received in response to the request for initial pilot projects. Promotion of PCORI's RFPs is through email lists and supplemental lists of research centers, academic institutions as well as provider and advocacy organizations. Postings will not be in the Federal Register because PCORI is not a government agency.

Levine noted that the website has been redesigned at www.pcori.org.

The pilot project funding announcement will be posted September 28, 2011. A press release will be issued and PCORI will reach out via direct email lists and speaker presentations.

There are eight upcoming speaking opportunities at conferences and industry events. PCORI has made a commitment to engage stakeholders in the board meeting locales. Norquist is taking the lead on coordinating site visits to clinical care facilities in Louisiana for the November 2011 board meeting.

f) Methodology Committee Report

Gabriel reported that we are structured around three work groups and one assimilation group. The chairs of these work groups will present on the activities. Based on the timeline, there is a lot of work moving forward simultaneously among the four subgroups to reach the May 2012 deadline.

Basch reported that the Patient Centeredness Work Group is charged with identifying standards for incorporating the patient perspective into three key areas:

- Development and prioritization of research questions
- Design of study components including selection of interventions, comparators, and outcomes
- Processes of clinical decision-making/care delivery

Two RFPs have been released. Proposals are due October 6, 2011. Selection of vendors is October 13, 2011. The vendors' reports are due March 1, 2012. There is a thought to issue an open RFI and conduct a workshop.

Meltzer reported on the Research Prioritization Work Group. The group is trying to provide advice that is useful so PCORI can make the best research decisions, not to set the methods themselves. The scope of work is to prepare a section of the report due in May 2012 on the methods to inform the establishment of research prioritization approaches. White papers will be commissioned. Paper topics will include: suggesting strategies to identify future priority areas; suggest standards for how PCORI systematic reviews should be performed and used to generate research topics; provide board and applicants with tools to quantify expected benefits; provide data to inform how PCORI might design, evaluate and continually improve its peer review process. A workshop will be held in January 2012 to synthesize the papers. To date, the working group has identified methodological areas of interest, hired an interim researcher and released the RFA for the white papers. White paper proposals are due by September 30, 2011. Awardees will be announced within two weeks.

Goodman reported that the Research Methods Work Group is tasked with directly responding to the statute that requires development of a translation tool to help guide researchers. The working group job is to review and issue statements on methods standards best practices and look at the entire electronic records system as a platform for PCORI. To date, the working group has established initial specs for the translation tool. Additionally, a prototype for standards documents is being developed that combines expert statements, published examples and PCORI input. Leading researchers are being interviewed. The translation tool dimensions include:

- Intrinsic factors of internal validity and external validity
- Precision, personalized evidence and ethical dimensions
- Extrinsic factors of timeliness, logistical burden and constraints

The framework for methods standards/recommendations:

1. Method
2. Key sources
3. Major recommendations
4. PCORI Methodology Committee commentary
5. Published examples
6. Tools for researchers

Helfand reported that the Assimilation Work Group's job is to resolve overlaps between the other groups and knit the pieces together. There has been a lot of success already in these areas that has just happened naturally. The work group's real obligation is to produce a report in May 2012 that includes the translation tool with recommended actions and standards. The report will outline the rationale for PCOR, as well as the standards.

Normand stated that the Methodology Committee is working on the review process for the contract proposals which include four steps:

- Administrative review by staff to identify any conflict of interests
- Content review by the specific working group
- Programmatic review by the full Methodology Committee
- Executive decision

The anticipation is that the review will be very timely with a transparent process. Awardees will be announced within two weeks after submission.

V. Adjournment

The meeting adjourned at 5:15p.m.

PCORI Board of Governors Meeting Minutes
September 20, 2011
Seattle, WA

Public Session A: 8:00 am - 11:00 am

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IV. Adjournment 7

I. Call to Order

Washington called the meeting to order at 8:03a.m. He welcomed the public attendees. He reminded all that the meeting was being webcast live.

II. Roll Call

a) In Attendance

PCORI Board

Eugene Washington (Chair), Steve Lipstein (Vice Chair), Kerry Barnett, Lawrence Becker, Arnold Epstein, Christine Goertz, Leah Hole-Curry, Gail Hunt, Robert Jesse, Harlan Krumholz, Richard Kuntz, Freda Lewis-Hall, Ellen Sigal, Harlan Weisman, Robert Zwolak

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b) Attended via Phone

Carolyn Clancy and Ellen Sigal

c) Absent

Francis Collins (represented by Kathy Hudson) and Freda Lewis-Hall

III. Agenda Items

a) Program Development Committee Report

Kuntz reported that the committee is working on four projects now: pilot projects, national priorities, research agenda, and the landscape review program.

Goertz reported that the purpose of the pilot project is to inform on national priorities, to support the research agenda, and to identify methodologies. Stakeholder involvement is required. Applicants must address one of eight areas of interest. It is expected that PCORI will fund about $13 million for approximately 40 projects. Direct costs are limited to $250,000 per year with an indirect cost rate set at 40 percent. The letters of intent are due on November 1, 2011. Applications are due December 1, 2011. NIH will conduct the actual merit review. The areas of interest were put out for public input. Approximately 150 people responded. The areas of interest are as follows:

1. New or existing methods and approaches that can inform the process of establishing and updating national priorities for the conduct of patient-centered outcomes research
2. Refining existing methods for bringing together patients, caregivers, clinicians and other stakeholders
3. Patient-centered approaches for translating evidence-based care into health care practice in ways that account for individual patient preferences for various outcomes
4. Identifying gaps in CE knowledge
5. Patient-centered outcomes instruments
6. Assessing the patient perspective
7. Patient care team interaction in situations where multiple options for wellness, prevention, diagnosis or treatment exist
8. Advancing analytical methods for CER

The letters of intent will be reviewed by PCORI, then forward to NIH. PCORI will be signing off on the final slate of reviewers. A public call will be posted to solicit scientific and stakeholder reviewers. Applications will be received by PCORI and reviewed for adherence to application guidelines. There will be very strict deadlines and technical requirements. Each application will be assigned to three reviewers. The anticipation is that about half of the reviewed applications will move to the next stage of a review meeting. A summary statement from this meeting, with a compilation of the three reviewers' scores and any discussion will be provided. Our chairman will appoint a PCORI review committee. This committee will then review the summary statements to make recommendations

for funding to the entire board. NIH will work with PCORI to train novice reviewers. An analysis of the recommended awardees will be prepared highlighting the range of areas of interest, dollar amounts and geographic locations. The standard merit review criterion from NIH has been modified to better reflect PCORI, including the addition of patient and stakeholder engagement and innovation, particularly in methodology. The application is based on the NIH PHS 398 form with some modifications and simplifications with the novice grant writer/researcher in mind. Applicants will have to self-report/categorize their applications according to the eight areas of interest and specific populations. There will be a webinar for potential applicants on October 12, 2011. FAQs will be available as well as time during the webinar for additional questions. The funding announcement goes out next week. The letters of intent due November 1, 2011 and applications are due December 1, 2011. The merit reviews by NIH will occur in February 2012. The final decisions by the board will take place at the March 2012 meeting. There is a request to approve on this plan with permission to finalize it before it goes out next week.

Action

There was a motion and second to approve the plan for the pilot projects.

Epstein reported on the national priorities. He stated that the process will be dynamic with increasing specificity, starting from priorities, moving to the agenda and then to individual PFAs. Currently underway is the development of a candidate framework. We want to have this finalized by next March 2012. Prior CER frameworks have been reviewed so the wheel is not reinvented. The previous efforts in relation to frameworks are varied in levels of granularity. There are ten priorities that have been identified that are consistent with other frameworks which include: prevention, acute care, chronic disease care, palliative care, care coordination, patient engagement, safety, appropriate use, health IT to improve patient experience and impact of new technology. The first four seem very salient to people. Care coordination is fifth, which brings to mind lots of silos. The proposed criteria include eight items defined in the statute with two added: advancing CER methods and fitting the definition of PCOR. Guiding principles for stakeholder engagement are balanced representation, transparency and facilitated participation. The plan is to deliver version 1 in March 2012 followed at some point, by version 2. It will be dynamic and evolving.

b) Public Comments

Washington opened the floor to public comment.

- Sherry Reynolds of AHH; patient
- Farrell Adrian of NAMI Washington
- Joseph Knapp of IHI Montana; cardiologist
- Steven Lipstein; PCORI vice-chair
- Jennifer Graff of Healthcare Pharmaceutical Association

Kuntz reported that a few landscape reviews have already been completed, including an overview of the CER inventory project (by Lewin) and CER organizations. RFPs are out for literature reviews on patient perspectives in PCOR and stakeholder interviews for PCOR. The Methodology Committee is developing a landscape review of existing methodology standards and the COEC is considering a landscape review of patient engagement.

c) Finance and Administration Committee

Barnett reported that there are no action items in the report. The GAO is currently reviewing the revisions made to the bylaws. The only other change to be proposed in the final version is a name change of this committee to the "Finance, Administration, and Audit" committee. The final action on the bylaws will be at the November 2011 board meeting. Douma has been helpful in the audit project. The accounting firm helped draft the RFP that will go out this week to about twelve large firms. The audit will not be that difficult because 2011 was our first year. Proposals are due by end of October 2011; the committee will make a recommendation to the board. Fieldwork will begin in November 2011 and must be completed by March 2012 in time for the GAO report to Congress in April 2012. This is both a performance audit as well as our fulfilling our requirements to the GAO. PCORI's financial position has not changed significantly since the July 2011 board meeting. There is about $5 million cash on hand; we increased this to cover our growing number of outstanding obligations. The total assets were $46.3 million as of August 31, 2011. Expenditures are at $3.7 million year to date, less than the budgeted amount. The year will be ended under budget. The pilot project grants won't be funded until early 2012.

The last item to cover is the conflicts of interest policies. There is a working group focused on the COI policies. This group is chaired by Larry Becker.

Becker reported that a particular question is that of the methodology committee members being eligible to receive PCORI funding for research projects. Once there is a recommendation, the working group will consult with an ethicist for an external opinion. The goal is to have this completed by the November 2011 board meeting.

Barnett continued with report that the Finance & Administration Committee will be focused on the audit launch and closure on the bylaws between now and November 2011. The committee will be supporting the working group as well as working with Selby on developing a broader compensation policy. Where we need the board's help is on the 2012 budget. A template will be created for the committee chairs to guide the thinking.

Selby closed the meeting by saying that from this meeting the urgent action items are:

1. Specify review process for Methodology Committee's RFPs
2. Work with AHRQ, NIH, and wide variety of sources to identify potential reviewers for Pilot Project Study Sections
3. Develop a list of characteristics on what PCORI seeks in a reviewer then consider public solicitation for interested reviewers
4. Work with AHRQ on processing the calls from interested applicants for Pilot Projects
5. Strongly consider a contract for evaluation of review process, review results, experience of applicants and reviewers
6. Refine National Priorities Framework and develop an approach for discussing with stakeholders
7. Identify and outreach to stakeholder communities: patients, providers; plans and employers, researchers, government, industry – thoroughly and in representative fashion
8. Launch Research Agenda Working Group with view toward major discussion in New Orleans
9. Recruit staff, both scientific and programmatic to:
    i. Support Methodology Committee to manage Pilot Project Grants, both programmatically and fiscally
    ii. To work with the Program Development Committee on Priorities, Research Agenda, and for developing PFAs
10. Summarize and synthesize the discussion from the board – Methodology Committee offsite and continue to develop plans for closer engagement
11. Look for ways to integrate board into work of the Methodology Committee subcommittees
12. Look for ways to integrate Methodology Committee members into National Priorities and Research Agenda planning
13. Consider another off-site prior to New Orleans meeting, or a lengthy phone call meeting before New Orleans

IV. Adjournment

The meeting adjourned at 10:32a.m