PCORI Board of Governors Meeting Minutes

January 18, 2012

Jacksonville, Florida

Public Session A: 1:00 am - 4:00 pm

Contents

I. Call to Order

Washington called to order the **open session** of the Board of Governors on January 18, 2012, in Jacksonville, Florida.

II. Roll Call

a) In Attendance

Dr. Eugene Washington (Chair), Steve Lipstein (Vice Chair), Kerry Barnett, Dr. Sharon Levine, Dr. Richard Kuntz, Dr. Sherine Gabriel (Methodology Committee), Lawrence Becker, Dr. Debra Barksdale, Dr. Carolyn Clancy, Dr. Arnold Epstein, Dr. Christine Goertz, Leah Hole-Curry, Gail Hunt, Dr. Robert Jesse, Dr. Harlan Krumholz, Dr. Freda Lewis-Hall, Dr. Grayson Norquist, Dr. Harlan Weisman, Dr. Robert Zwolak, Dr. Sharon-Lise Normand (Methodology Committee)

Staff and Others

Dr. Joe Selby (PCORI), Dr. Anne Beal (PCORI), Shar'on Barclay (TMC), Mark Freeman (PCORI), Richard Schmitz (GolinHarris), Jessica Nadler (Deloitte), Gail Shearer (TMC), Josh Weisz (GolinHarris), Heather Meyer (PCORI), Judy Glanz (PCORI), Bill Silberg (PCORI), Melissa Stern (PCORI), Lori Frank (PCORI), Denise Earlington (PCORI), Jean Slutsky (MC), Robin Newhouse (MC), Mark Helfand (MC)

b) Attending via Conference Call

Dr. Francis Collins, Dr. Allen Douma, Dave Flum (MC)

c) Absent

Ellen Sigal

III. Agenda Items

a) Executive Director's Report

Staffing

Selby introduced four new staff members:

- Lori Frank, PCORI's first scientist, who will begin by supporting the Methodology Committee

- Judy Glanz, director of patient engagement, who will be responsible for all stakeholder group outreach
- Bill Silberg, communications director, who will be working closely with Glanz and the future director of patient engagement
- Melissa Stern, director of strategic initiatives, who will be tying together research and engagement activities.

Selby also noted that offers for the positions of director of patient engagement and chief science officer had been made, while an offer had been accepted for director of finance. He noted that PCORI is recruiting for a scientific review officer, a grants manager, scientists, associates and support staff.

b) Program Development Committee Report

Kuntz stated that the National Priorities and Research Agenda will be sent out for review on Monday.

National Priorities

Clancy spoke on the process of how the initial version of the National Priorities came to be, stating that PCORI's purpose is defined in the statute, which also requires that National Priorities and a Research Agenda be set. She referred to a diagram, noting that input that helped form the initial version came from environmental scans, the statute, stakeholder input, pilot project applications, the board and the Methodology Committee. She noted that the initial version would be revised and refined over time. She stated that the public comment period will begin January 23, 2012.

Clancy noted that frequently cited priority areas were meshed with those defined by the statute to develop drafts for five National Priorities:

- Comparative assessment of options for prevention, diagnosis and treatment
- Improvement of healthcare systems
- Communication and dissemination research
- Mitigation of disparities
- Acceleration of PCOR and methodological research

Clancy recognized that, by design, this was a very broad set of priorities, built over a five-month period and incorporating stakeholder input from the beginning. She stated that, as an additional draft, the National Priorities were ready for public comment.

Weisman questioned whether all priority areas that were frequently cited were covered by the draft National Priorities. Clancy responded yes, but that those involved were looking forward to more board and stakeholder input. She also acknowledged some overlapping features. Levine pointed out that it is fair to say that "comparative assessment" can be applied to the other four priorities, and suggested that including that phrase in each definition would help people understand better.

Norquist questioned whether the priorities are appropriate for patient-centered outcomes research, and whether each should be weighted equally. Selby noted that the initial draft proposes "weight," but the board is looking for public input as well.

Research Agenda

Krumholz started by emphasizing return on investment, and stated that, to make an impact, it will be necessary to really listen to the stakeholders. He stated that the agenda has been aligned to the statute, and that some pilot programs have already been undertaken. He noted that environmental scans are being commissioned, and that the intent is for the research agenda to have an outward perspective.

He stated that, while significant progress has been made, the process is just beginning and is iterative, so every step is helping to refine the longer-term priorities and agenda, increasing specificity around the questions. He noted that a sense of urgency has led to the National Priorities and Research Agenda being developed simultaneously, thereby expediting program announcements.

Lipstein questioned whether the board was comfortable with this process. Washington stated that he envisioned the National Priorities as being of higher importance, and acknowledged the process as iterative, but noted that the real focus over the shorter term is on refining the Research Agenda.

Selby noted that 2012 will be a year of engagement for PCORI, and that from Monday, January 23, through mid-March public comments will be accepted in addition to the staging of a national meeting event in late February, at which people will be invited to express themselves publicly. The engagement will help to hone in on both broad and specific funding announcements.

Gabriel added that the Methodology Report will add to specificity when it offers guidelines on research.

Krumholz noted select items on the PCORI Research Agenda, including:

- Promoting patients and caregivers—and stakeholders—as partners in care
- Understanding questions from the patient perspective
- Emphasizing open and transparent science that involves participants
- Committing to a diverse research portfolio
- Emphasizing knowledge that is likely to make a positive difference
- Emphasizing knowledge that emerges from the healthcare "community"

He noted that it had taken four months to get the draft Research Agenda ready for public comment and stated that it would be modified and refined.

Norquist suggested the need to be careful of the term "rigorous research," as it may sound daunting to some stakeholders and potential applicants. Goertz responded that PCORI's responsibility is to create opportunities that ensure rigor and community involvement. Selby noted that steps have been taken in the review criteria for the pilot projects to be collaborative, which is, he suggested, strong evidence that PCORI wants a different kind of research.

Selby stated that the Research Agenda will be posted on the Web site and that those commenting can answer structured questions and provide free text responses and information. Washington noted that the first draft will officially be posted and distributed on Monday, January 23, 2012.

c) Public Comment Period

Speakers:

- Andrew Spurling – National Alliance on Mental Illness, Partnership to Improve Patient Care
- Malcolm Foster – Florida Chapter, American College of Physicians
- Jennifer Graff – National Pharmaceutical Council
- Winnie Hayes – Hayes Incorporated

d) Program Development Committee Report (continued)

Pilot Projects

Goertz stated that the first funding announcement was issued in September, and elicited 842 applications. She stated that a four-step process for review had begun, and that a review committee meeting will be held in February to recommend a slate for funding. She stated that the board will make final selection in early April, with award notification in May.

Selby noted that PCORI's aim is to be transparent, and questioned whether it would be possible to include stakeholders in determining the balance criteria. He asked if those could be presented at the March meeting, to which Goertz replied yes on both accounts. Normand questioned how to ensure that there is no conflict related to defining the balance criteria, stating that, in a perfect world, it should have been done beforehand. She also asked how many projects would be funded. Goertz replied that her points about conflict and timing were valid, and provided an example of how PCORI is learning as it goes along. She stated that approximately 40 projects were likely to be funded. Normand pointed out her concern over soliciting comments from people who may have applied for the grants, and Hole-Curry suggested that people identify themselves so a cross-reference can be conducted to ensure that they are not applicants.

Washington invited formal public comment on the process and questioned whether there would be learning opportunities for those not funded. Goertz replied that every applicant would receive summary statements as feedback.

Clancy expressed concern about soliciting public input on decisions that will be made in real time, and Normand agreed. Washington replied that it is okay to ask for public input, especially on something not related to scientific merit. Lipstein suggested that stakeholder input could be made more neutral by stipulating that no more than 10 percent of grants would go to any specific disorder or state. Goertz stated that some basic characteristics that are likely to be considered have already been announced, and noted that this important issue merits more deliberation in a broader context.

e) Methodology Committee Report

Gabriel advised the group to refer to the briefing materials for detailed information on timelines and current work, and noted that the NORC report and summary are also included in the briefing materials.

Gabriel stated that there is a need to define a better approach to the Methodology Committee Report keeping patients in mind, and suggested the NORC report as a prototype for how it could be accomplished.

Gabriel stated that 15 contracts have been awarded, an RFI for the case studies on the development of the translation tool has been issued, workshops have been planned for March, and interviews have been conducted to assess how electronic data systems are leveraged.

Gabriel pointed out that the Methodology Committee (MC) is engaging with the board in a number of ways, including utilizing liaisons Sigal and Norquist for the Patient-Centeredness Workgroup; providing input on the Research Agenda and

Pilot Projects; sharing highlights of the electronic data task; and soliciting candidates. She noted that 11 briefings had been submitted to the board since September 2011. She stated that the MC will continue to provide opportunities for liaison with the board, as well as briefings, status updates and presentations.

Gabriel stated that the MC wanted board input on the approach that is being taken to the role of methods. Two case studies were presented as examples to stress the importance of methods in improving outcomes, and Gabriel asked for the board's input on case studies as a way of communicating the issue to others.

Lipstein commented that using case studies could help people perceive the efficacy of methods; both Levine and Clancy agreed that the use of case studies was effective and compelling.

Becker commented, saying there are few robust study registries, and people don't build on them; he suggested perhaps PCORI should require that they do. Kuntz questioned to what degree patient-centeredness connects to the methods, and how the MC addresses the possibility of getting lost in the methods and thereby losing the patient-centeredness. Normand replied that patient-centeredness is included in every step of the process.

Gabriel noted that the MC is required to incorporate the methods it recommends into the grants that are funded.

Flum stated that themes derived from the focus groups have been synthesized and summarized, and that a final definition draft is expected by tomorrow morning.

Gabriel asked what could be learned from the process and how it could be used to move forward. Flum pointed out that the committee really listened, and that the focus groups provided another opportunity for engagement and explanation of the MC's process and rationale. Gabriel added that some lessons learned could be highlighted and generalized to all aspects of PCORI.

Washington stated that the "next steps" slide needed to be sent to the board.

IV. Adjournment

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

PCORI Board of Governors Meeting Minutes

January 19, 2012

Jacksonville, Florida

Public Session B: 8:00 am – 12:00 pm

Contents

I. Call to Order

Washington called to order the **public session** of the Board of Governors at 8:10 a.m. (EST) on January 19, 2012, in Jacksonville, Florida.

II. Roll Call

a) In Attendance

Dr. Eugene Washington (Chair), Steve Lipstein (Vice Chair), Kerry Barnett, Dr. Sharon Levine, Dr. Richard Kuntz, Lawrence Becker, Dr. Debra Barksdale, Dr. Carolyn Clancy, Dr. Arnold Epstein, Dr. Christine Goertz, Leah Hole-Curry, Gail Hunt, Dr. Robert Jesse, Dr. Harlan Krumholz, Dr. Freda Lewis-Hall, Dr. Grayson Norquist, Dr. Harlan Weisman, Dr. Robert Zwolak

Staff and Others

Dr. Joe Selby (PCORI), Dr. Anne Beal (PCORI), Shar'on Barclay (TMC), Mark Freeman (PCORI), Richard Schmitz (GolinHarris), Jessica Nadler (Deloitte), Gail Shearer (TMC), Josh Weisz (GolinHarris), Heather Meyer (PCORI), Judy Glanz (PCORI), Bill Silberg (PCORI), Melissa Stern (PCORI), Lori Frank (PCORI), Denise Earlington (PCORI), Jean Slutsky (MC), Mary Tinetti (MC), Robin Newhouse (MC), Al Berg (MC) [Tinetti and Berg not at earlier session, Helfand now absent]

b) Attending via Conference Call

Dr. Francis Collins, Dr. Allen Douma

c) Absent

Ellen Sigal, Dr. Robert Zwolak, Dr. Francis Collins [Sigal and Barnett no longer present-see closed minutes]

III. Approval of Minutes

Washington noted that there are typos and salutations to be corrected in the previous board meeting minutes. Becker moved to approve, Goertz seconded; the minutes were approved unanimously.

IV. Agenda Items

a) Finance and Administration Committee Report

2012 Budget

In Barnett's absence, Beal provided an update on the budget. She stated that the anticipated activities of each committee were considered, then cross-matched with PCORI's strategic plan. Beal noted that the budget looks only at spending planned for 2012, and that future funding estimates will need to be addressed as PCORI ramps up.

Beal pointed out that a vast majority of PCORI dollars are going out for purposes of grant making. Lipstein inquired as to how a pie chart for 2013 might look, and Beal replied that she would anticipate growth in the area of dissemination, because PCORI's goal is to ensure that its work has an impact.

Beal noted that areas to be addressed in 2012 include administrative and overhead costs, i.e., how they are conceived and distinguished. She also noted a need to decide how to account for multiyear programs.

Epstein asked how percentages in the allocations for research funding were determined, and Selby answered that it's a combination of the pilot projects and the 2012 grants, as it is broken down in the Research Agenda. Selby stated that the public is invited to comment on the debate about assigning proportions to specific Research Agenda items.

Epstein pointed out that the budget is not yet final, and Norquist cautioned against publishing it in such a way that people perceive it as being finalized. Lipstein stated that funds will be allocated to all categories, although not necessarily in the proportions presented in the pie chart, as public comment and board deliberation will necessitate refinements.

Weisman noted that there is clearly a need for an operating budget, but stated he was reluctant to approve it as is. He suggested he was more inclined to approve it provisionally until the board has more information. Lipstein inquired whether the motion could then be made to approve it for operations for the first half of 2012, leaving it open to revision as we get public comment on the Research Agenda and move forward on the strategic plan. Weisman moved for approval; Levine seconded.

Lipstein called for a vote, with the understanding that the operating budget would be based on the presented pie chart through June, with revisions in July. Selby noted that the staff was comfortable with that, and the motion was

approved with two nay votes. (Zwolak and Kuntz were opposed, explaining that they would have approved it for the full year.)

Conflict of Interest Committee

Becker stated that for approval today, agreement is sought on the committee of Zwolak, Gabriel, and Becker. He noted that the charter required approval. In March, external committee members will be recommended.

Clancy pointed out that in regard to time frame restrictions needing to be placed on the funding announcements, June or July would be too late. Becker responded that he had misspoken, and that funding announcements would be made in May.

Selby noted that the Conflict of Interest Committee had been put together to address specific concerns about who can and cannot apply for funding, specifically Methodology Committee members. In regard to disclosures, he stated that every applicant must complete specific forms.

Barksdale inquired as to how the three members of the standing committee were selected, to which Becker replied that a call for volunteers had been made and then the chair appointed members. Washington stated that this is how he determines all committees.

Goertz noted that applicants for the pilot projects had not been asked to complete a disclosure form because the committee was not yet ready to implement that process.

Levine noted that timing is an issue because May 1 is quickly approaching and the Conflict of Interest Committee is to do work on behalf of the board, and then make recommendations to the full board.

Becker requested a motion. Clancy moved for approval, Kuntz seconded, and the motion was approved unanimously.

Nominating Committee

Becker stated that members of the Nominating Committee would include the chair, the vice chair, three board members and one Methodology Committee member.

He requested a motion to accept the members of the Nominating Committee as Washington, Lipstein, Hunt, Jesse, Lewis-Hall and Newhouse.

Epstein asked whether the terms would be staggered, and Washington replied he preferred one- and two-year terms. Lipstein noted that a revision would need to be made in the bylaws in regard to terms.

Lipstein moved for approval, Krumholz seconded, and the motion was approved unanimously.

Becker stated that for the Methodology Committee, terms are recommended, but not officially limited. He said Gabriel had indicated that volunteers determined who received four- and six-year terms. Gabriel added that the only stipulation was to stagger them, and requested that the revision be applied to the bylaws.

Barksdale moved for approval, Jesse seconded; the motion was approved unanimously.

b) Communications, Outreach and Engagement Committee Report

Levine noted that the formal comment period begins January 23 and goes through March 15. She stated that there are additional opportunities for non-online submissions of public comments. Additional engagement will occur on February 27, when a national patient and stakeholder dialogue event is planned for Washington, D.C., to be supplemented by a webcast and teleconference dial-in.

Levine stated that 12 focus groups were conducted throughout November and December in four cities, with 96 participants. Those focus groups provided early feedback on the Research Agenda and National Priorities. She stated that clinician focus groups are scheduled for February, and that the Program Development Committee is working on a discussion guide for facilitators.

She noted that a summary report will be published on the PCORI website and that a special board meeting in April will consider the recommended revisions to the National Priorities and Research Agenda.

c) Public Comment Period

- James Patterson – Parkinson's Disease Foundation
- Rich Hatfield – Epilepsy Foundation of Florida and Partnership to Improve Patient Care
- Andrew Kerwin – National Trauma Institute and University of Florida School of Medicine
- Tony Coelho (via phone) – Partnership to Improve Patient Care

d) Communications, Outreach and Engagement Committee Report (continued)

Levine noted that the Communication, Outreach and Engagement Committee's entire report is about stakeholder engagement, and that the February 27 meeting can accommodate up to 600 people. She stated that more traditional methods for communication and feedback are in place, as well as electronic methods. Levine noted that the website has been updated to include video, a general feedback form, and an easy form for subscribing to the email list, which has grown to more than 2,000 subscribers. She stated that PCORI is using Twitter in an effort to engage a larger, more diverse audience. Levine noted that all board meetings since March 2011 have provided for stakeholder interaction through forums, small group meetings, site visits and invited presentations. She also pointed out that PCORI board members and staff have presented at 49 speakers bureau opportunities since March 2011, and that several more presentations are scheduled.

Epstein inquired as to how the February 27 event will supplement engagement efforts, and how board members and others will be informed of the outcomes. Levine replied that the rationale for the National Priorities and Research Agenda will be presented, and the opportunity for input explained. She explained that more than three hours are allotted for open mic comments and noted that board members are invited to attend or participate via phone. Lewis-Hall suggested that when there are group discussions, feedback and input need to be collected and the information should then be made useful.

e) PCORI Dissemination Working Group Report

Clancy stated that she has learned from multiple board meetings that the Dissemination Workgroup needs to have a passion for the 16 percent of the PCORI's budget that goes to AHRQ for dissemination.

Levine stated that dissemination is required by the statute, and noted that AHRQ has a very specific role in broadly disseminating PCORI research and creating a repository of information. She stated that the workgroup is seeking the board's confirmation of the assumptions that will be presented in regard to the dissemination effort, and that success will be defined by the effect on practice and patient outcomes.

Levine noted that PCORI will disseminate results of PCORI-funded and -conducted research, and PCORI will also fund research on dissemination, but will complement and supplement what AHRQ/NIH are doing, rather than duplicate efforts.

Levine pointed out that the New England Healthcare Institute (NEHI) has defined existing hurdles to evidence dissemination in the healthcare system, and that it suggests policy choices for building a coherent strategy for dissemination, including:

- Use consistent evidence ratings
- Create partnerships with stakeholder groups
- Select high-priority targets for dissemination
- Integrate CER dissemination with health system IT
- Implement patient and clinician incentives
- Communicate directly with patients and the public

Clancy stated that PCORI's statute requires that results from funded studies be made public within 90 days, a cause of some concern in relation to publishing the findings. She noted that the Recovery Act provides some significant resources for dissemination, and also pointed out that AHRQ had funded a study that found it takes an average of 14 years for research findings to be put into practice.

Clancy stated that the goals of AHRQ's activities include fostering awareness and utilization of patient-centered outcomes research, informing professional and consumer audiences, and driving toward shared decision-making. She noted that the audience is broad and diverse, and suggested that messages must be framed differently for different audiences, noting an emphasis on user-driven synthesis.

Clancy noted a briefing with RAND, which has conducted several projects that included case studies of research that should have had a major influence on practice, yet little to no change in practice was seen. RAND attributed the slow uptake and incomplete translation to misalignment of financial incentives, ambiguity of results, biases, failure to address the needs of end users, and inadequate use of decision support.

Clancy stated that the potential for comparative effectiveness research to influence practice has not yet been realized, and that the translation process is ad hoc, therefore additional information on best practices and diffusion is needed. She suggested that PCORI engage cognitive psychologists, because a big part of the issue is how people think about things.

Clancy raised the question of how to address the black box disconnect between dissemination and uptake, and noted that RAND had suggested PCORI could be involved in generation of CER, more effective translation, evaluation of impact, and transparent governance.

Becker stated that the results of the Dissemination Workgroup report need to be made public. Epstein added that some foundations require that reports be made public before releasing funding, and noted that the topic should be included for consideration in the discussion about balancing and targeting PCORI's research portfolio. Goertz agreed that the results should be made public as soon as possible, but noted that it was important to stay aware of the need for a peer-review process.

Hole-Curry stated that she expected the update to include an assessment by the board of its ability to influence how the 16 percent of PCORI's budget is spent. Clancy replied that she would think about how to do a better job of talking about it while avoiding a conflict of interest in making AHRQ funding announcements, as she is precluded from giving advance notice of funding decisions. Selby pointed out that the desire to know in advance comes from the desire to avoid redundancy and be complementary. Clancy responded that it won't be an issue for two to three years, and that there isn't a good precedent for the partnership, but that she is committed to making it work.

Weisman asked whether PCORI has any say in how to spend the money now for things it wants to do about dissemination, to which Washington responded that PCORI has no governing authority over the money, but that the relationship with Clancy ensures cooperation and commitment.

f) Executive Director's Report

Selby noted that the public comment period for the National Priorities and Research Agenda begins January 23, 2012. He stated that the board will be working on how to identify criteria for balancing the funding for the pilot projects, and that the selection of grants will be in April.

Selby noted that the staff will be working with the Program Development Committee to prepare the broad funding announcements, and pointed out that the Methodology Report is due in mid-May.

Selby closed by saying that stakeholder engagement will become even more robust with staff now on board, and stated that for PCORI, 2012 will be the year of engagement.

V. Adjournment

Washington adjourned the meeting at 12:05 p.m.