



PCORI Board of Governors Meeting Minutes

March 5-6, 2012

Baltimore, Maryland

Public Session: 8:00 am – 4:00 pm

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I. Call to Order

Washington called to order the **public meeting** of the Board of Governors at 8:48 a.m. (EST) on March 5, 2012, in Baltimore, Maryland.

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), Dr. Debra Barksdale, Lawrence Becker, Dr. Carolyn Clancy, Dr. Francis Collins, Dr. Allen Douma, Dr. Arnold Epstein, Dr. Christine Goertz, Leah Hole-Curry, Gail Hunt, Dr. Harlan Krumholz, Dr. Freda Lewis-Hall, Dr. Grayson Norquist, Ellen Sigal, Dr. Harlan Weisman, Dr. Robert Zwolak, Dr. Sharon-Lise Normand (Methodology Committee)

Staff and Others

Dr. Joe Selby, Dr. Anne Beal, Bill Silberg, Judy Glanz, Gail Shearer, Lori Frank, Susan Sheridan, Susan Hildebrandt, Melissa Stern, Martin Duenas, Mark Freeman, Heather Meyer, Erica Fisher (GolinHarris), Richard Schmitz (GolinHarris), Josh Weisz (GolinHarris), Jessica Nadler (Deloitte), Jean Slutsky (MC), Brian Mittman (MC), David Flum (MC)

b) Absent

Dr. Robert Jesse

III. Approval of Minutes from Last Meeting

N/A

IV. Agenda Items

a) Welcome and Executive Director's Report

Washington welcomed the group to the ninth board meeting of PCORI and noted that it would be live via webcast, as well as archived. He noted that March marked the second anniversary of the Affordable Care Act, which stipulated PCORI's creation, and stated that PCORI has made substantial progress over the last 17 months. He noted that there is still significant work to do, and said the

discussion today will help PCORI continue to fine-tune itself, strengthen its governance and optimize best practices.

Selby started by acknowledging the accomplishments of some board members who had received award, including Debra Barksdale for Outstanding Research Contribution on Cardiovascular Disease, Delta Sigma Theta Sorority; Christine Goertz for Chiropractor of the Year, American Chiropractic Association; and Freda Lewis-Hall for 2012 Alumni Award for Distinguished Postgraduate Achievement in the Fields of Medicine and Healthcare Leadership, Howard University.

He stated that several key staff members have been added in the last few months, including:

- Pam Goodnow as director of finance
- Susan Hildebrandt as director of stakeholder engagement
- Judith Glanz as director of patient engagement
- Sue Sheridan as deputy director of patient engagement
- Gail Shearer as senior adviser
- Martin Duenas as director of contracts management

He noted that positions for chief science officer and director of IT have been posted, and that interviews are underway for approximately nine scientists in 2012.

Selby stated that PCORI is projected to move into its new permanent offices at 1828 L Street NW, Washington, D.C., on April 1, 2012.

Selby noted that one of PCORI's first advisory groups will be addressing the institute's role in patient-centered data sets and exploring ways in which it can advance that role for the nation. He also mentioned that a broad funding announcement will be made in May 2012, with a large number of funding awards announced before the end of the year. He indicated that conference grants will be issued later in the spring, brainstorming workshops will occur over the summer, and advisory groups will meet in the fall. Selby stated that the Methodology Report will be presented to the board on May 10, with a public comment period lasting through July. Lipstein pointed out that the board approves the report only provisionally to send it out for public comment in May, and that a formal approval, after revisions, will be likely in the fall.

Selby stated that four funding announcements will be released in May, with applications due in July, but noted that a fifth announcement, targeting clinical research data networks and analytic methods, is slated for July. He also stated

that other targeted announcements will occur in the last quarter, and that the first four will be considered standing (but not static) announcements, with applications due every four months. Clancy suggested that the targeted announcements take place in August to allow some time for the board to digest what it gleans during the workshop in July.

In regard to patient and stakeholder engagement for 2012, Selby noted that PCORI will begin building communities of patients and stakeholders, and strengthening ties with advocacy associates, professional organizations, purchasers and the research community. Weisman asked for information regarding the plan to move forward with the advisory committee. Selby answered that PCORI's first focus will be on building a research network, and that an advisory committee on clinical trials is mandated, while an advisory committee on rare diseases is being considered. Gabriel also suggested an advisory committee on dissemination.

b) Program Development Committee Report

Kuntz began by stating that Washington had appointed a Pilot Project Selection Committee. Goertz stated that the committee has been working on the selection process to ensure that there is a balanced slate of awards, and noted that the staff will analyze award options and provide a list based on the working group's recommendations. The selection committee will then meet to review the material and recommend a slate of projects for funding consideration.

Goertz noted that the priority score is the first thing the selection committee considers, and that other important criteria include area of interest, population, methods, geography, discipline of the principal investigator, seniority of the principal investigator, condition, and stakeholder involvement. She stated that there were eight areas of interest written into the funding announcement and that the selection committee is committed to transparency, so each of the criteria will have a concrete definition that will be made public before, during and after the process. Goertz pointed out that the selection committee will bring forth a recommended slate and that the board will make the official decision. Weisman noted that there will be a cut-off point of 40 projects. However, Goertz pointed out that discussions have led to the possibility of funding more than 40, and the selection committee may come to the board with that request.

Norquist jokingly expressed having "second thoughts" about chairing the committee and stated that he believed the group would look for things that are "way out there."

Goertz stated that funding announcements would be made in May 2012.

Hunt noted that PCORI wanted to learn from the initial review process in considering how to implement the next review process; therefore a survey was given to the reviewers, and 10 projects were randomly selected for PCORI personnel to review. Goertz pointed out that there was a separate survey for reviewers who were patients, with specific questions about their effect on the process. She stated that the learning experiences will be compiled in a report to the board. Selby noted that both scientific and patient reviewers were solicited online, and acknowledged that it is a good idea to establish a standing study section.

In reference to the public comment process and timeline, Kuntz noted that there would be a formal process of assessing suitability of themes, then categorizing them into big buckets and outlying comments. He stated that the initial evaluations will be conducted by staff, and that the Program Development Committee will have a preliminary vote on April 9, 2012, to reach consensus on the themes. On April 9 there will be an in-person voting conference, and the recommended changes will be made to the board on April 17. Lipstein pointed out that any interested board member or Methodology Committee member is invited to participate at any or all stages.

Krumholz remarked that the intent of public comment is to get people to help PCORI to be of value to patients, so that the overall research infrastructure can be strengthened. Gabriel noted that a process has been developed for reaching consensus moving forward.

Kuntz stated that it is critical to stick to the timeline and have the funding announcement released in mid-May. He stated that the selection committee is on track to send out the first PFAs, and referred to slides that indicated the following 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

In regard to the clinical research data infrastructure and rationale presented for contracting with AHRQ, Weisman stated he is substantively uncomfortable and questioned how he could air his concerns and have them addressed, to which Washington responded he would think on it and get back to him.

Goertz stated that the rationale for contracting with AHRQ is based on its experience and current knowledge of the science, gaps, and opportunities. She stated that AHRQ has expertise in running cooperative agreements, and PCORI's statute encourages collaboration with both NIH and AHRQ, to which Weisman responded that the FDA is another agency with a lot of experience in the realm of collaborative agreements. Goertz pointed out that the second RFA will be in close collaboration with the Methodology Committee.

Lipstein stated his belief that it is important to address any concerns board members have with this area of work of the Program Development Committee and Methodology Committee because it's moving fast; Washington agreed and replied that there may be time later to address the concerns.

Zwolak questioned whether financing and administration is keeping up with the Program Development Committee vis-à-vis the amount of funding necessary, to which Selby replied yes.

Clancy presented a proposed checklist of dissemination-accelerating components, and noted that, on April 13, AHRQ will be presenting and webcasting information on its use of a percentage of PCORI's budget. She noted the need to be more specific in the funding announcements in regard to stakeholder and patient engagement.

Kuntz stated that it appears the Program Development Committee is on track to get the PFAs out on May 15. He said the concerns expressed highlight a broader need for board members to start to consider how to scale down their level of involvement in order to allow the staff to handle many of the details and more of the work in general.

c) Public Comment Period

Speakers:

- Larry Kimmel – Hopewell Cancer Support
- Tony Coelho – Partnership to Improve Patient Care
- Paul Zimmet, DDS – Parkinson's Disease Association
- Bryan Lyles – People's Community Health Center
- Perry Cohen – Parkinson Pipeline Project
- Christine Williams – CFIDS Association of America

Washington thanked the participants who had provided comment, then resumed the previous discussion.

Washington then asked whether other board members beside Harlan Weisman have concerns about items presented in the Program Development Committee Report, to which Hole-Curry responded that there are broader concerns about process and about internal preparation, so the board feels ready to express those concerns in this setting.

Weisman stated that his concerns stem from an obligation to the public to provide a vote or input that has been given adequate thought, and that some things discussed are fundamentally related to what PCORI is as an organization, such as transparency and responding to feedback, and as such may not be appropriate for delegation to staff and committees. He noted that he is impressed with the Program Development Committee's work, but stated he didn't fully comprehend it and needs more time to do so. Washington responded that the process works, but acknowledged the issue of time, and asked whether the process should be modified to allow more discussion time if concerns are expressed. He proposed that if board members don't feel they've been provided with adequate information or adequate time to voice concerns, an opportunity be provided to talk with him, Selby and other relevant board and staff members. Douma requested that the board receive materials further in advance, and that those materials clearly define the action being requested of the board.

d) Finance and Administration Committee Report

Becker stated that the Finance and Administration Committee has been working diligently since its last meeting to fill the remaining slots on the Conflict of Interest Committee. He stated that, while three people have turned down the opportunity, Bernie Lo, an ethicist, has agreed to serve, along with Art Levin, as a consumer member, and Annette Bar-Cohen, as a patient/consumer member. Becker noted that the staff was asked for recommendations, and Levine stated that several board members also forwarded recommendations.

Becker stated that the law firm Harris Beach, and specifically Karl Sleight, will serve as counsel, although Sleight will not be a member of the committee. Becker noted that the Conflict of Interest Committee will address concerns not specifically outlined in the statute. Becker asked for a motion to accept the recommended nominees. Clancy motioned to accept, Hunt seconded, and the motion was unanimously approved.

Barnett suggested that it will be difficult for the committee to churn out decisions quickly but that, like case law, it will evolve over time.

In response to the audit, Beal stated that the Government Accountability Office (GAO) is responsible for financial and programmatic audits, and that the

committee has engaged an external audit firm, whose audit of 2011 and the final months of 2010 will be reviewed by GAO. She stated that fieldwork will be completed by March 12, 2012, and the GAO will review the audit prior to the annual report to Congress on April 1, 2012.

Douma questioned the level of involvement needed from the board to review and approve the audit before April 1. Beal responded that there will have to be an off-cycle meeting. Barnett proposed that the committee review the audit in some detail, and questioned whether a full board vote of approval is needed before April 1; Washington replied that he thought it acceptable to delegate to the Finance and Administration Committee the authority to officially accept the audit. Barnett stated that a subsequent report would come to the board, and if any questions or concerns warrant it, the committee will take the initiative to approach the board. Washington noted that no motion was needed, as it is not general policy.

Becker stated that there are several assumptions and decisions to consider in developing a cash flow model and questioned whether the committee should plan to commit funds ahead of availability. Washington specified the options: option A, multiyear; and option B, annual. Washington synthesized the group's general opinion, and Barksdale motioned for approval of option A; Clancy seconded, and the motion was approved unanimously once it was clarified that the motion was only on the model, not on the amounts.

In regard to evaluating the involvement of patients, Hunt inquired as to who would be making the patient contact. Krumholz replied it would have to be a standardized assessment, and suggested Glanz would be heavily involved. He acknowledged that there was not a clear answer at this point, but that it is something for the board to consider strongly.

[Washington recessed the meeting at 12:50 p.m. for lunch.]

e) Methodology Committee Report

[Lipstein reconvened the meeting at 1:53 p.m.]

Gabriel stated that the Methodology Committee (MC) is working diligently to finalize the report due on May 10, and outlined the report according to chapters, stating that there will be a need for updates. She noted that the report-writing process is underway, and that workshops will be held tomorrow and Wednesday on the contractor findings.

Gabriel stated that in March, the MC will receive 15 reports from contractors, and that on April 3 the committee will meet to arrive at a consensus on

standards to be included in the first Methodology Report. A draft summary of recommended standards will then be circulated for input in April. Weisman asked whether a process for reaching consensus had been formalized. Gabriel explained that the first step is complete consensus in the workgroup, and step two is a two-thirds vote in the full MC, which will ensure its inclusion. Gabriel stated that justifications from the workgroups will be attached, and a written report will be included. The report will be put forward for public comment at the next board meeting following its delivery to the board on May 10.

Gabriel noted that the statute advises PCORI to use the standards in its reviews for funding, and the hope is that they will become widely adopted by the broader scientific community. Sigal questioned whether there was enough flexibility in the guidelines. Gabriel assured her that there will be a degree of flexibility built in. Gabriel stated that, while the report will not be written in obvious alignment with specific priorities, all the priorities will be addressed.

In regard to communication and dissemination, Lewis-Hall noted that the report is inherently technical and asked whether any steps could be taken to make it easier to respond to. Gabriel replied that no work had been done yet to refine it for other audiences. Normand stated that the translation tool is something that may be used in different formats, and Gabriel added it may be used as another avenue for engagement.

Gabriel pointed out that, following the first report, the MC's goals will be to accelerate adoption of the recommended standards, and to act as a convener, communicator and catalyst. She stated that after the report is complete, committee members will be asked for feedback on the process and experience, and there will then be a retreat in June to produce plans for proceeding further, such as establishing advisory groups for particularly challenging areas. She noted that the first annual PCORI conference will be a platform to convene the research community.

Collins asked what the board process is for deciding on an advisory group, to which Washington replied there is an expressed intent, but no clear policy. Gabriel noted that the purpose of the advisory groups is that the MC listen and help identify goals and needs.

Washington stated that the board is committed to having its plan for the first annual conference in place before it meets in May.

In regard to the PCOR definition status, David Flum stated that the process started over a year ago, and has been refined by public input and comments. He noted that 12 distinct themes had emerged and that NORC had conducted six

focus groups nationwide. The last step in the process is the creation of a draft definition, the first part of which is intended for the public; the second is addressed more to the investigator community. Flum noted some key points in relation to how the draft evolved: communication was a major theme that emerged; there was confusion about benefits, risks, and harms; it was important to distinguish palliative care from other forms of care; and resource availability should be included. He stated that the working group recommended the definition presented.

Sigal and Epstein expressed concerns, stating that the definition was written in a confusing manner, to which Selby responded that the concerns appeared to be addressed in the bullet points underneath. Hole-Curry questioned whether PCORI intends to include the rationale document when the definition is published, to which Flum replied yes.

Washington questioned whether the definition should be approved as presented.

[A show of hands was requested for those in favor. Two opposed – Epstein and Becker. Sigal abstained.] The draft definition was approved.

f) Public Comment Period

- Ellen MacKenzie – National Trauma Institute; Johns Hopkins Bloomberg School of Public Health

g) Communications, Outreach and Engagement Committee Report

Levine noted that there are 10 days left in the formal comment period for the drafts of the National Priorities and Research Agenda, and stated that to date 101 comments have been received, with more comments coming from researchers than from any other group, and more coming from the DC region than from any other area in the country.

Levine reported that the stakeholder event on Feb. 27 was attended by more than 850, either in person or via webcast. The stakeholder event included two panels—patient and caregiver advocates, and clinicians and other stakeholders—and she noted that there were three hours of public comments that included 46 in-person commentators.

Levine stated that patient and caregiver focus groups were reported on at the Jacksonville meeting in January 2012, and that nine clinician focus groups were conducted in February. She noted that the process for gathering all this input and revising the National Priorities and Research Agenda includes a review of all

input received via the website, the dialogue event, focus groups, and anecdotal feedback to board and staff. The report will be published on the website, summarizing the input received, and how it led to changes in the draft versions. She added that feedback on stakeholder and community engagement associated with past board meetings will be solicited.

Hunt expressed concern about the low level of public comment on the National Priorities and Research Agenda, and suggested that when the report is written it should acknowledge the low response. Douma suggested a need for a bigger communications and marketing effort in the future and a need for more rigorous survey questions. Krumholz suggested that the way we frame what we are looking for could be reevaluated, and Washington asked about the best way to get feedback, and who the target is. Levine stated that PCORI's ability to disseminate requests for help and input through its trusted relationships with other organizations is critical.

Selby questioned whether efforts to ramp up response will make it more biased. Silberg responded that the group raised valid points, and that more outreach is planned in the next 10 days, including a series of online ads and alerts to both professional and consumer media.

Lewis-Hall cited an opportunity for PCORI to develop and refine its outreach efforts, suggesting that it needs to make a bigger effort to go to stakeholders rather than inviting them to come to PCORI. Levine encouraged the board to be thoughtful in response to the survey about engagement opportunities at board meetings.

V. Adjournment

Washington adjourned the meeting at 4:12 p.m.