



Patient-Centered Outcomes Research Institute Board of Governors Meeting

Almas Shriners Building
1315 K Street, NW
Washington, DC 20005

May 8, 2017

Board Members Present:

Grayson Norquist, MD, MSPH, *Chairperson*; Debra Barksdale, PhD, RN; Kerry Barnett, JD, *Vice Chairperson*; Larry Becker; Allen Douma, MD (via phone); Alicia Fernandez, MD; Christine Goertz, DC, PhD (via phone); Leah Hole-Marshall, JD; Russell Howerton, MD, FACS; Gail Hunt; Robert Jesse, MD, PhD; Harlan Krumholz, MD, SM; Michael Lauer, MD (representing Francis S. Collins, MD, PhD); Sharon Levine, MD; Freda Lewis-Hall, MD; Barbara McNeil, MD, PhD; David Meyers, MD (representing Sharon P. Arnold, PhD) Ellen Sigal, PhD; Kathleen Troeger, MPH; Robert Zwolak, MD, PhD

Board Members Absent:

Richard Kuntz, MD, MSc

Methodology Committee Members Present:

Robin Newhouse, PhD, RN, *Chair*; Steve Goodman, MD, MHS, PhD, *Vice Chair*; Naomi Aronson, PhD; Stephanie Chang, MD, MPH; Cynthia Girman, DrPH; Mark Helfand, MD, MS, MPH; Sally C. Morton, PhD; Neil Powe, MD, MPH, MBA; Adam Wilcox, PhD; and Susan Zickmund (Consultant)

Staff:

Joe Selby, MD, MPH, *Executive Director*; Yen-Pin Chiang, PhD; Mary Hennessey, Esq.; David Hickam, MD, MPH; Michele Orza, ScD; Jean Slutsky, PA, MSPH; Harold Sox, MD; Evelyn P. Whitlock, MD, MPH; Regina Yan, MA

MINUTES

AGENDA ITEM	RELATED MINUTES
<p>Welcome, Call to Order and Roll Call</p> <ul style="list-style-type: none"> - Grayson Norquist, MD, MSPH, Chairperson 	<p>Dr. Norquist chaired and opened the meeting, welcomed all to the meeting of the PCORI Board of Governors and read the Chair Statement on Conflict of Interest.</p>
<p>Consider for Approval: Consent Agenda</p> <ul style="list-style-type: none"> • Minutes of the March 21, 2017 Board Meeting • Revisions to Committee and Advisory Panel Charters <p>- Grayson Norquist, MD, MSPH</p>	<p>Dr. Norquist introduced the Consent Agenda which included approval of the March 21, 2017 meeting minutes and approval of the proposed revised charters of the Research Transformation Committee, the Science Oversight Committee, the Engagement, Dissemination and Implementation Committee, and the Governance Committee. No separate discussion was requested.</p> <p>The following motion was presented to the Board for approval:</p> <p>Motion: Approve each of the motions on the Consent Agenda as reflected below:</p> <ul style="list-style-type: none"> • Minutes from the March 21, 2017 Board Meeting • Proposed amended charters of the: <ul style="list-style-type: none"> ○ Research Transformation Committee ○ Science Oversight Committee ○ Engagement, Dissemination, and Implementation Committee ○ Governance Committee <p><i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions)</i></p>
<p>Joint Methodology Committee and Board Session</p> <p><i>PCORI's Role in Evaluating Precision Medicine Treatments</i></p> <ul style="list-style-type: none"> - Grayson Norquist, MD, MSPH and Robin Newhouse, PhD, RN, Chair, Methodology Committee 	<p>Dr. Selby stated that the purpose of this discussion is to gather the Board of Governors' and Methodology Committee's perspectives on how PCORI can and should move forward in the important area of precision medicine, consistent with PCORI's overall mission. In her opening remarks, Dr. Evelyn Whitlock, Chief Science Officer, emphasized that precision medicine is patient-centered and aligned with PCORI's goals to determine what works best for whom, under what circumstances. Dr. Steve Goodman, Vice Chair of the Methodology Committee, echoed these points and noted that it is important to avoid narrowly focusing on genomics and cancer. Dr. Naomi Aronson, Methodology Committee member, addressed some of the challenges and opportunities of the technology-driven aspects of precision medicine, including the need to focus on evaluating the effectiveness of any interventions (including tests). Dr. Robin Newhouse, Chair of the Methodology Committee, discussed the ways in which the healthcare system will be challenged by the shift toward</p>

	<p>precision medicine and emphasized the need to engage patients in the design of these systems.</p> <p>The discussion between members of the Board and Methodology Committee reflected a shared understanding that PCORI's commitment to patient-centered comparative effectiveness research is consistent with precision medicine, broadly understood as well as support for efforts to identify additional opportunities for investment in this area.</p> <p>Action Item: Led by Dr. Whitlock, volunteer Board and Methodology Committee members will form a workgroup to develop a framework to guide PCORI's efforts in precision medicine.</p>
<p>Consider for Adoption Recommended Revised Methodology Standards with Methodology Committee Report - Robin Newhouse, PhD, RN, and David Hickam, MD, MPH, Program Director, Science, Clinical Effectiveness and Decision Science</p>	<p>Dr. Newhouse informed the Board on the Methodology Standards revision process. The updated Methodology Standards as proposed by the Methodology Committee were posted for public comment from January 25, 2016 to April 11, 2016 and were subsequently revised based on public comment and Methodology Committee feedback. In summary, there are 48 standards in 12 categories, one new cross-cutting standard under the Standards for Causal Inference Methods, and five new standards for Research Designs Using Clusters. The updated Methodology Standards will be implemented for the Cycle 2 2017 funding cycle, which opens on June 23, 2017.</p> <p>The Methodology Report has been revised to reflect advances in methods and related efforts, revisions to the standards, public comments, and improve clarity and guidance.</p> <p>Dr. Newhouse closed with planned next steps to update the training and resources for use of the Standards, final revisions to the current Report, and developing additional Methodology Standards based on FY17 priorities. An updated release of the Methodology Report and Methodology Standards is anticipated for 2018.</p> <p><i>The following motion was made by David Meyers and seconded by Barbara McNeil.</i></p> <p>Motion: Adopt the updated PCORI Methodology Standards and Accept the Revised Methodology Report</p> <p><i>Approved by a majority vote of the voting Board members (18 in favor; 0 opposed; 0 abstentions). Drs. Jesse and Krumholz were not present during this vote.</i></p>

Executive Director's Report and Q2 FY 2017
Dashboard Review: PCORnet Focus
- Joe Selby, MD, MPH, Executive Director

Executive Director's Report

Dr. Selby presented the current count of published comparative effectiveness results from PCORI-funded research, and described the range of topics these publications cover. He provided an overview of the 2017 Annual Meeting, expected to be held on October 31 to November 2, 2017, which will have eight breakout sessions featuring research results.

Dashboard

Dr. Selby presented the Q2-2017 Dashboard for the Board's review. The Dashboard demonstrated 4 green-flagged items (items that are on track) and 1 yellow-flagged item (items that are off target by more than 10%-15%, depending on the metric). The metric for Funds Committed to Research is yellow in Q2 because PCORI was under the target by more than 15%. There were no red-flagged items (items that are off-target and in need of attention or action by the Board). Dr. Selby described that metrics for peer review are still too early to evaluate.

Dr. Selby presented results of two PCORI-funded research studies of prostate cancer treatment, and results of a PCORI-funded study on stroke, all with high Altmetric scores (a measure of attention). Dr. Selby described that PCORI has 11 publications from Q2 with high Altmetric scores, demonstrating that PCORI-funded research is capturing public attention.

To provide an example of how PCORI is influencing the way others are doing research, Dr. Selby highlighted that PCORI is credited with inspiring the Editorial Board of the journal SLEEP to issue new editorial guidance to authors requiring the use of people-centered language in all publications.

Dr. Selby gave an update on research that is being conducted in PCORnet. He described two externally-funded research projects, one funded by the NIH and the other funded by AHRQ. He shared progress on PCORnet networks use of standardized Data Sharing Agreements and SMART IRB for data sites. He discussed the PCORnet Commons, a public platform for resources for people interested in health research to collaborate. Dr. Selby described that the PCORnet Front Door, operated by the PCORnet Coordinating Center, is now open to public queries.

Board members expressed interest in strategies for expanding outreach to potential applicants for research awards, and how to collaborate with other funders to exchange ideas related to PCORnet.

<p>- Evelyn Whitlock, MD, MPH, Chief Science Officer, and Robert Zwolak, MD, PhD, Chair, Science Oversight Committee</p>	<p>priority topic. In 2016, PCORI released targeted PFAs on models of care delivery and advanced care planning. This sequential targeted PFA would address a remaining top priority for research in the area. She presented the proposed research question, “What is the comparative effectiveness of two or more interventions, including at least one pharmacologic intervention, for symptom management in patients with serious advanced illness?”. She also reviewed the proposed Population, Interventions and Comparators, Outcomes and Timing (PICOT) for the proposed topic. The total commitment requested for this Targeted PFA is up to \$25 million in total costs, to fund up to 10 studies, each with total direct costs of \$2 million per study and a maximum project period of 3 years. The Board discussed that this study related to patients in palliative care and not in hospice care where the life expectancy was diminished.</p> <p><i>The following motion was made by Harlan Krumholz and seconded by Kerry Barnett.</i></p> <p>Motion: Approve \$25M (total costs) for the development of a targeted PFA for Symptom Management for Patients with Advanced Illness.</p> <p><i>Approved by a majority vote of the voting Board members (18 in favor; 0 opposed; 0 abstentions). Drs. Goertz and Levine were not present during this vote.</i></p>
<p>Mid-Year Financial Review - Regina Yan, MA, Chief Operating Officer, and Larry Becker, Chair, Finance and Administration Committee</p>	<p>Larry Becker, Chair of the Finance and Administration Committee (FAC) and Regina Yan, PCORI Chief Operating Officer, presented the Mid-Year Financial Review for BOG discussion. The FY2017 Mid-Year Financial review included a review of the FY2017 budget versus actuals for PCORI based on the first six months of FY2017 (October 1, 2016 – March 31, 2017). Ms. Yan noted the variance between the FY2017 budget and actuals for the period was 5%, down from 18% in FY2016 for the same period. This much smaller budget vs. actual variance signifies a refined ability to plan the budget and project expenses when compared to previous fiscal years.</p> <p>There were no additional questions following the presentation.</p>
<p>Public Comment - Greg Martin, Deputy, Chief Engagement and Dissemination Officer</p>	<p>No members of the public requested the opportunity to make a public comment. Thus, there were no public comments presented during this time.</p>
<p>Wrap-up and Adjourn Meeting of the Board - Grayson Norquist, MD, MSPH</p>	<p>The meeting adjourned at 3:00 pm EDT</p>

Minutes were approved by the PCORI Board of Governors 06-20-2017