

Board of Governors Meeting via Teleconference / Webinar

Tuesday, December 8, 2020

11:30 am – 3:15 pm ET

MINUTES

Board Members Present:

Sharon Levine, MD, *Vice Chairperson*; Kara Ayers, PhD; Kate Berry; Tanisha Carino, PhD; Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Christopher Friese, PhD, RN; Michael Herndon, DO; Russell Howerton, MD; James Huffman; Connie Hwang, MD, MPH; ; Barbara McNeil, MD, PhD; Eboni Price-Haywood, MD, MPH; James Schuster, MD, MBA; Kathleen Troeger, MPH; Danny van Leeuwen, MPH, RN; Robert Zwolak, MD, PhD

Board Members Absent:

Christine Goertz, DC, PhD, Board Chairperson; Francis Collins, MD, PhD; Gopal Khanna, MBA; Michelle McMurry-Heath, MD, PhD; Ellen Sigal, PhD; Janet Woodcock, MD

Agenda Item	PCORI Speakers
Welcome and Call to Order - Sharon Levine, MD, <i>Vice Board Chairperson</i>	Dr. Levine 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. She then reviewed the meeting agenda.
Commitment Planning Consider for Approval: 3-Year Commitment Plan - Nakela L. Cook, MD, MPH, <i>Executive Director</i>	To provide background, Dr. Cook summarized the “Hybrid 1.5” commitment plan model spanning from FY21-FY30 that the Board had selected at its September meeting when evaluating an appropriate model for commitment planning, contrasting it with the 4 different options that the Board had considered. She provided context for the proposed 3-year commitment plan presented to the Board today based on the Hybrid 1.5 model, including details for near-term commitments, and projections for long-term commitments. She stated what the commitment plan would require, for example, a full complement of PFAs in all 3 cycles, an increase in research commitments, and an increase in staffing. Cook discussed how we are monitoring progress on the commitment plan by sharing upcoming PFAs, those under review, and those currently open. She shared a proposed approach to supporting the commitment plan, including guiding principles, key components, and next steps. She reviewed the three parallel tracks that are underway to support PCORI’s research agenda: Strategic Planning, revitalizing PCORI’s topic process, and developing Targeted topics in the near-term. Cook demonstrated how funding cycles would be put in context when brought to the Board, which will facilitate comparisons to historical averages. She then shared PCORI’s historical trends in research letter of intent acceptance rates and application success rates. Cook provided further details on potential metrics and methods for

	establishing targets and tracking PCORI's progress on funding commitments. She proposed an example generic outline for discussion of a funding cycle in context. Board members expressed interest in learning more details about the proposed 3-year commitment plan for Research Infrastructure. Cook stated that these will be provided in more detail at the January 2021 Board Meeting. <i>The following motion was made by Barbara McNeil and seconded by Jennifer DeVoe.</i> Motion: Approve the Proposed 3-year Commitment Plan for FY2021-2023, subject to annual review and update by the Board <i>The motion was approved by a majority vote of voting Board members: 17 in favor, 0 opposed, 0 abstained</i>
Update on Status of Cost Data Principles - Andrew Hu, Engagement, Public Policy and Joanna Siegel, ScD, Program Director, Dissemination and Implementation	Mr. Hu and Dr. Siegel, the staff leads of PCORI's Cost Data work group, provided an update on the status of PCORI's efforts to implement the consideration of full range of outcomes/cost data provision included in PCORI's reauthorizing legislation, specifically emphasizing progress on the proposed Principles for the Consideration of the Full Range of Outcomes Data. The presentation included an overview of reauthorization legislation, PCORI's overall implementation plan, progress made to date, a review of the Principles and key themes identified from public input, and an update on next steps. An overview of PCORI's Cost Data Implementation Proposal was presented by Hu, who detailed the progress and concurrent activity of the three Pillars. Pillar One involves the progress on Board-approved proposed "Principles" and the input received from the 60-day public comment period. The aims of Pillar One are to produce an updated set of "Principles" for Board consideration by March 2021 and guidance and FAQs for future applicants to help prepare for forthcoming proposals ready for Cycle 1 2021. Pillar Two is dedicated to updating methods and standards in coordination with the Methodology Committee. Pillar Three is centered around identifying opportunities where PCORI can contribute to the discussion regarding the use of cost and economic impact data. Hu also provided a reminder of the proposed Principles document that was released for public comment following the September Board meeting. • Principle One states that PCORI-funded research may consider the full range of outcomes important to patients and caregivers, including burdens and economic impacts; • Principle Two directs researchers to consider the outcomes important to respective stakeholders when those outcomes have a near-term or longer-term impact on patients; • Principle Three states that data on burdens and economic impacts of treatment options must be appropriate and relevant to the clinical aims of the study; and • Principle Four states that PCORI may support the conduct of certain types of economic analyses as part of a funded study to enhance the relevance and value of the information to health care decision-makers. Additionally, PCORI sought input on two questions:

- Should it be a requirement for all PCORI-funded studies to capture cost and economic data; and
- What types of economic analyses, within the scope of PCORI's authorizing law, would benefit stakeholders and what are their perspectives on the specific uses and advantages of each type?

The input and feedback received from the public comment period, webinars, and stakeholder engagement are now under review. PCORI received comments from a wide range of organizations and individuals representing the full spectrum of stakeholders. Emerging themes from the webinars and public comments included:

- Broad support for the consideration of costs and economic impact data in PCORI research;
- Focus on ensuring a patient-centered and holistic approach to the consideration of costs;
- Consider cost burdens and impacts from a societal and community level;
- Helpful to capture implementation or program costs;
- Suggestions that the availability of this type of data and information could be helpful in future value-based payment models; and
- A sense that while this is a positive activity, a requirement to collect this data for all PCORI-funded studies may not be appropriate.

In terms of next steps, PCORI staff are currently analyzing the comments and will plan to provide additional updates to the Board in the January and February 2021 meetings before presenting updated Principles to the Board for consideration in March 2021. Additionally, a guidance and FAQs for future applicants will be included in the Cycle 1 2021 PFA. PCORI staff are coordinating with the Methodology Committee on activities to update methods and standards around the capture of cost and economic impact data.

The Board discussed charges vs economic impact on patients and how best to measure real cost data. One Board member suggested approaching this in a two-part manner, the first manner being a focus on patients and caregivers and later focusing on other areas. He also informed Board members that staff are keeping policymakers informed on the progress being made in this directive through ways such as inviting them to the issue webinars.

At the conclusion of this agenda item, Nakela Cook announced that the meeting was progressing well and that the Public Comment period was anticipated to occur 30 minutes earlier than anticipated and encouraged anyone who was interested in providing public comment to register to do so ahead of time through PCORI's website.

Strategic Planning Committee Report and Discussion - <i>Nakela L. Cook, MD, MPH</i>	Dr. Cook presented a report on the Strategic Planning Committee's (SPC) efforts to advance strategic planning. The report included the scope of activities anticipated in strategic planning; an update on the schedule and timeline for upcoming Board decisions; and a summary of stakeholder and public input received. The report highlighted two emerging themes from the input received which were referenced in subsequent discussion: • Potentially evolving Addressing Disparities to Eliminating Disparities or similar strengthening of work in this area, and • Consider reflecting or embedding a public health and social ecosystem perspective within the National Priorities Board members reflected on the SPC report and the perspectives received the previous day during the Health Policy Panel. Board members expressed appreciation for the rich panel discussion and pointed out that conversations affirmed the direction the SPC and the Board were embarking on for strategic planning. Board comments provided emphasized the need to consider how health systems drive health outcomes and the value of understanding health systems as encompassing both public health and medical systems rather than one or the other. Discussion took place on the possible role for PCORI as a convenor for national and state agencies to support a multi-pronged approach to addressing public health challenges which are often multifaceted. Board members noted this possibility was consistent with the emerging themes from the stakeholder input received. Comments were also made about potential ways that PCORI could enhance understanding of value. Board members recommended future deliberations about how PCORI can use the array of opportunities it has to fulfill its mission and vision. Opportunities referenced included dissemination of research results, providing relevant information for complex healthcare decision making and strengthening relationships with PCORI's stakeholders and the broader public. Board members also noted the possibility of working in new areas such as value in health care and posited that PCORI may want to consider similar new areas for future work.
Public Comment Period - <i>Kristin Carman, MA, PhD, Director, Engagement, Public and Patient Engagement</i>	No members of the public requested the opportunity to make a public comment. Thus, there were no public comments presented during this time.
Wrap up and Adjournment - <i>Christine Goertz, DC, PhD</i>	Meeting adjourned at 1:34 pm

Minutes were approved by the PCORI Board of Governors 01-12-2021