

Board of Governors Meeting via Teleconference / Webinar

Tuesday, April 13, 2021

1:00-3:30 pm Eastern

MINUTES

Board Members Present:

Christine Goertz, DC, PhD, *Chairperson*; Sharon Levine, MD, *Vice Chairperson*; Kara Ayers, PhD; Kate Berry; Tanisha Carino, PhD; Michael Lauer, MD (designee for Francis Collins, MD, PhD); Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Christopher Frieze, PhD, RN; Russell Howerton, MD; James Huffman; Connie Hwang, MD, MPH; Michelle McMurry-Heath, MD, PhD; Barbara McNeil, MD, PhD; David Meyers, MD; Eboni Price-Haywood, MD, MPH; James Schuster, MD, MBA; Ellen Sigal, PhD; Kathleen Troeger, MPH; Danny van Leeuwen, MPH, RN; Robert Zwolak, MD, PhD

Board Members Absent: Michael Herndon, DO; Janet Woodcock, MD

Agenda Item	PCORI Speakers
Welcome and Call to Order Consent Agenda: Consider for Approval: - Minutes of the March 16, 2021 Board Meeting - Nomination of Advisory Panel on Clinical Effectiveness and Decision Science (CEDS) and Advisory Panel on Clinical Trials (CTAP) Chairs - Revised Board Compensation Policy <i>Christine Goertz, DC, PhD, Board Chairperson</i>	Dr. Goertz chaired and opened the meeting, welcomed all to the April 13, 2021 meeting of the PCORI Board of Governors, and read the Chair Statement on Conflict of Interest. She then reviewed the agenda for the meeting. Goertz then introduced the Consent Agenda and gave the opportunity to Board members to discuss any of the matters on the Consent Agenda. In response to a question inquiring how the Board Compensation Policy would be revised, Goertz replied that the proposed revision changes the base number of hours used for the monthly stipend for the Vice Chairperson to better reflect the number of hours required for this position. <i>The following motion was made by Robert Zwolak and seconded by Kara Ayers.</i> Motion: That the Board approve: - Minutes from the March 16, 2021 PCORI Board Meeting - Nomination of Kari Gali, DMP, APRN to serve as Chair, and Julie Eller, BS, to serve as Co-Chair, of the Advisory Panel on Clinical Effectiveness and Decision Science (CEDS AP) through August 2023 or until a replacement is appointed - Nomination of Michael L. Jones to serve as Co-Chair of the Advisory Panel on Clinical Trials through August 2023 or until a replacement is appointed - Proposed revised Board and Methodology Compensation and Reimbursement Policy with an effective date of January 1, 2021 <i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions).</i>

Consider for Approval: Set of Candidate Topics for Targeted PFA Development through FY2022 <i>Alicia Fernandez, MD, Science Oversight Committee Chair and Nakela L. Cook, MD, MPH, Executive Director</i>	Dr. Fernandez provided introductory remarks and stated that over the past few months, the Science Oversight Committee has discussed a set of candidate topics for targeted PFA development through 2022, which is being brought to the Board today for consideration and approval. Dr. Cook reminded the Board of its previous discussions regarding the expedited and enhanced approach to targeted PFA development and the Board's approval in March 2021 of the development of three targeted PFAs for Cycle 2 2021 with associated funding. She then discussed how the recommended candidate topics being considered by the Board today would facilitate effective planning for the development of PFAs for Cycle 3 2021 and of PFAs for 2022. Cook explained that if the Board approves the recommended candidate topics, the individual targeted PFA topics will be brought back to the Board for consideration of approval with associated funding when further developed. While the set of candidate topics includes funding programming through 2022, PCORI will still have the ability to incorporate emerging topics into PFA development. Cook stated that while PCORI is utilizing an expedited approach while strategic planning is underway, topic development still includes the core components of literature review, including examination of systematic reviews and clinical practice guidelines, portfolio review, and consultation with stakeholders and other funders. Cook explained that the enhanced approach will include a full range of options for PFAs, including study parameters that are designed to be more open, and targeted PFAs that are open for more than one cycle. Cook indicated that recommended candidate topics relate to themes emerging in PCORI's strategic planning efforts, leverage ongoing work, are high burden, and of interest to stakeholders. Cook indicated that the recommended candidate topics presented are at the idea stage, and that the Board's approval of the set of candidate topics for development will allow for longer-range prospective planning for PCORI as well as engagement with stakeholder communities. Topics in the candidate set are in addition to PCORI's COVID-19, Maternal Mortality and Morbidity, and Intellectual and/or Developmental Disabilities research priorities. The recommended candidate topics for development for targeted funding for Cycle 3 2021 are: • Healthy Aging: Optimizing physical and mental function across the aging continuum; • Osteoporotic fracture prevention; • Migraine Prevention • Addressing racism, discrimination, and bias throughout the care continuum*; • Leveraging telehealth for chronic disease management among vulnerable populations with complex needs*. <i>*Potential example of leading with a Special Area of Emphasis (SAE) and following up with a Targeted PFA.</i>
--	--

	The recommended candidate topics for development for 2022 are: • Funding mechanism: Targeted PFA or Special Area of Emphasis ○ Cycle 1 2022 ▪ Prevention of drug addiction for adolescents ▪ Early detection and treatment of delirium in older adults ○ Cycle 2 2022 ▪ Leveraging telehealth for chronic disease management among vulnerable populations with complex needs* ▪ Hypertension control ▪ Advancing health equity* ○ Cycle 3 2022 ▪ Visual impairment in older adults ▪ Suicide prevention: National crisis hotline ▪ Management of immune checkpoint inhibitor toxicity • Funding mechanism: Large Single Study ○ Abdominal aortic aneurysm screening in women ○ Drug therapy for type 2 diabetes <i>*Potential example of leading with an SAE.</i> This set of candidate topics is in addition to COVID-19, MMM, IDD which are underway and continue. Board members encouraged specificity about the scope of topics as they move forward, especially with regard to addressing racism, bias, and discrimination, and advancing health equity topics, and urged consideration of broad range of health equity topics, including relating to ageism and ableism. Board members were supportive of the set of candidate topics and encouraged dissemination of the information about PCORI's plan to develop research funding opportunities relating to the candidate topics broadly to stakeholders. Cook indicated that work is being done on communication strategies to make the information widely available. <i>The following motion was made by Sharon Levine and seconded by Tanisha Carino.</i> Motion: Approve the Recommended Set of Candidate Topics for Further Development for Targeted Funding for Cycle 3 2021 through Cycle 3 of 2022 <i>Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions).</i>
Summary from <i>Priorities on the Health Horizon March 2021 Meeting</i>, a collaboration with the National Academy of Health	Dr. Cook described the goal of the collaborative meetings of the National Academy of Medicine and PCORI and introduced Dr. J. Michael McGinnis, The Leonard D. Schaeffer Executive Officer and Senior Scholar, National Academy of Medicine, and Dr. Neil Powe, Chief of Medicine, Zuckerberg

<i>Nakela L. Cook, MD, MPH; J. Michael McGinnis, MD, MA, MPP, The Leonard D. Schaeffer Executive Officer and Senior Scholar, National Academy of Medicine; and, Neil Powe, MD, MPH, MBA, Chief of Medicine, Zuckerberg San Francisco General Hospital</i>	San Francisco General Hospital, and a member of PCORI's Methodology Committee. McGinnis provided opening remarks and an overview of the Priorities on the Health Horizon (PHH) meeting series. The terrain scanning series aims to convene external stakeholders to gather input and "blue sky" thinking about priorities on the health horizon. Its goal is to engage patients, clinicians, researchers, and other stakeholders from the broader health community in identifying priority issues in health and health care that can inform PCORI's identification of National Priorities for Health and its updated strategic plan. Powe summarized the insights generated from the first convening, which was held on March 15 and March 16, 2021. An overarching theme that underpinned the first meeting was the concept of "doing a different thing," rather than just "doing things differently". This concept was a common thread across the different meeting discussions. The summary included takeaways from the core presentations, reactor panel, and breakout sessions. Synthesized points from the full meeting included the following: • Priorities for health must address structural and systemic issues: Achieving health equity entails deeper exploration of how racism, bias, and power affect health and health care across the entire continuum. • Reinvigorated infrastructure is critical to supporting transformation to a data-driven learning health system: The COVID-19 pandemic underscores the deficits and vulnerabilities in our existing systems, illuminating the essential need to transform and integrate public health, care delivery, and research, in a way that is patient-centered, technology-forward, and leverages data. • Create a system of health, rather than a health care system: Shift from a fragmented system focused on services and volume, and orient a new, integrated system around patients' strengths and patients' values. Following the presentation, Board members were asked to share their thoughts on the PHH March 2021 meeting summary. Board members discussed the March meeting topical areas and the level of detail for discussions. Powe noted the first meeting topics were broad in scope and participants were encouraged to reflect on higher-level aspects on the health horizon. Likely, Powe posited, the second meeting, expected to be on April 27, 2021, would address more detailed health and healthcare priorities like promoting a learning health system and informing patient-centered value. Board members inquired about insights for PCORI's role to support health equity. Powe commented that a key insight generated from the March 2021 meeting was the need to incorporate social determinants of health (SDoH) in health care and research, as the application of technologies (e.g., drugs, devices, information systems) alone do not account for the social circumstances in
--	--

	which patients are embedded. Incorporating SDoH in care and research could help to optimize health. McGinnis echoed this and added PCORI was uniquely situated to support infrastructure and continuous learning systems where SDoH were integrated and reflect the patient's experience. In terms of the broad topics that structured the PHH meeting, participants noted that there was no single research study that could "solve" health problems; rather, complex interventions comprised of multiple components that influence health were needed, including those that incorporate the many aspects that influence a person's health (i.e., SDoH). Another area of focus was how PHH framed economic-related aspects of health. Powe noted that ample discussion related to value was held and that the discussions were framed in terms of the value to patient and the opportunity to change the perspective on value to be more patient-centered. Board members commented on the opportunity to do something different in the context of comparative clinical effectiveness research (CER) and the possibility to define health more broadly in CER studies rather than in the capture of clinical outcomes. Including social and environmental outcomes could support whole-person health and take into account the multiple factors that influence health. Board members expressed support for thinking about the evolution of health outcomes captured in studies to be inclusive of SDoH and other non-clinical outcomes. Closing comments expressed appreciation for the PHH meeting series and the opportunity to hear from a variety of stakeholders. Board members encouraged leveraging existing resources developed by the National Academy of Medicine to align discussions and minimize duplication of content as the PHH second meeting was convened.
Strategic Planning Committee Report and Discussion of Emerging Themes for National Priorities for Health <i>Nakela L. Cook, MD, MPH and Sharon Levine, MD, Co-Chairs, PCORI Strategic Planning Committee</i>	Dr. Cook presented the Strategic Planning Committee report. The report reviewed the input gathering process to date and outlined several resulting themes from that input. From June 2020 to March 2021, PCORI received input from a variety of stakeholder groups to help inform Board discussions to identify National Priorities for Health. Based on the input gathered, five themes emerged related to potential National Priorities for Health: (1) <u>Health Equity</u>. This examines multi-faceted drivers of disparities, structural racism, and bias and also considers disparities in the health system and research environment. (2) <u>Emerging Innovations</u>. This is the application of new technologies as well as system innovations to support time-sensitive decision-making and needs in an evidence vacuum and will inform new delivery innovations. (3) <u>Learning Health System</u>. This theme focuses on thinking of health systems from a patient perspective and growing the national priority around improving health systems to creating connected, learning health systems. (4) <u>Communications, Dissemination, and Implementation</u>. This theme is focused on getting the right information to the right people, at the right time. The theme also focuses on doing

	dissemination and implementation and leveraging implementation science to amplify research findings. (5) <u>Infrastructure and Workforce</u>. This theme builds workforce development and capacity beyond the clinical setting and further focuses on data and human systems capacity building. Cook noted that next steps for identifying the National Priorities for Health include deeper discussion on these emerging themes in future Board meetings. Following the presentation, Board members concurred that the five resulting themes would be important and appropriate to consider as potential National Priorities for Health. One concern was raised about whether these themes can be operationalized and accomplished. Cook clarified that the themes will be further developed over the coming months and that the themes would be refined and operationalized based on further discussions with the Board. There was discussion about incorporating these priorities into PCORI processes in addition to the PCORI research portfolio, e.g., reflecting equity in the research funding process. Cook added that at a future Board meeting, there will be an agenda item on PCORI's Diversity, Equity, and Inclusion (DEI) initiative in which PCORI will be talking about process review as a funder and how the organization plans to address DEI for funding applications.
Wrap-up <i>Christine Goertz, DC, PhD</i>	Dr. Cook summarized some of the key points from the Board meeting. Dr. Goertz thanked all that joined the call. The Board meeting ended at 2:50 pm Eastern.

Minutes were approved by the PCORI Board of Governors 05-25-2021