PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Board of Governors Meeting via Teleconference / Webinar
Tuesday, March 8, 2022
9:00am – 3:30pm ET

MINUTES

Board Members Present:
Christine Goertz, DC, PhD, *Chairperson;* Sharon Levine, MD, *Vice Chairperson*; Kara Ayers, PhD; Kate Berry; Jennifer DeVoe, MD, DPhil; Alicia Fernandez, MD; Christopher Friese, PhD, RN; Mike Herndon, DO; Russell Howerton, MD; James Huffman; Connie Hwang, MD, MPH; Barbara McNeil, MD, PhD; Eboni Price-Haywood, MD, MPH; James Schuster, MD, MBA; Michael Lauer, MD (designee for Lawrence Tabak, DDS, PhD); Kathleen Troeger, MPH; Karin Rhodes (designee for Robert Valdez, PhD, MHSA); Danny van Leeuwen, MPH, RN; Robert Zwolak, MD, PhD

Board Members Absent: Ellen Sigal, PhD; Janet Woodcock, MD

Methodology Committee Members: Steve Goodman, MD, PhD, MHS, Chair and Robin Newhouse, PhD, RN, Vice Chair

Guest: The Honorable Lauren Underwood, MSN, MPH, United States Representative, Illinois, 14th District

Agenda Item	PCORI Speakers
Welcome and Call to Order **Consider for Approval** • February 15, 2022, Board Meeting Minutes *Christine Goertz, DC, PhD* *Board Chairperson*	Dr. Goertz opened the meeting of the PCORI Board of Governors (Board) and welcomed everyone. Goertz announced that Dr. Robert Otto Valdez was named as Director of the Agency for Healthcare Research and Quality (AHRQ), and, in accordance with PCORI's authorizing law, now serves on the PCORI Board. On behalf of the Board, Goertz thanked David Meyers, who previously served on the Board in connection with his position as Acting Director of AHRQ and noted that Karin Rhodes will continue as the designee for the AHRQ Director. Goertz read the Conflict of Interest Statement and then reviewed the meeting agenda. With no additions or corrections to the minutes offered, she presented the minutes of the February 15, 2022, Board meeting for approval. *The following motion was made by Russell Howerton and seconded by Barbara McNeil.* **Motion**: Approve the February 15, 2022, Board Minutes *Approved by majority vote of the voting Board members by voice vote (no opposed; no abstentions). Eboni Price-Haywood was not present during this vote.*
Executive Director's Report *Nakela L. Cook, MD, MPH* *Executive Director*	Dr. Nakela L. Cook, Executive Director, announced that the GAO indicated its intention to publish a notice for nominations in the Federal Register in the coming months for six open positions on the PCORI Board resulting from the conclusion of four Board members' terms at the end of September 2022 and the resignations of

two Board members. These appointments are expected to be announced by the end of September 2022.

Cook introduced new members of the PCORI Leadership Team: Maureen Thompson, MA (Director of Board Governance, Operations and Relations), Brian Trent, MPA (incoming Deputy Executive Director for Operations), Harold Feldman, MD, MSCE (incoming Deputy Executive Director for Patient-Centered Research Programs), and Erin Holve, PhD, MPH, MPP (Chief, Research Infrastructure).

Cook then provided an update on PCORI's ad hoc committee and work group activities relating to the PCORI Board of Governors charged with addressing high priority items.

Strategic Planning Committee

Cook outlined the timing of strategic planning activities from March through July 2022, which include drafting and refining the strategic plan document as well as ongoing work to implement strategies from July through December 2022.

PCORnet® Priorities Work Group

Cook recapped the activities completed by the Work Group during Stage 1, including the development of Prioritizing Principles for Infrastructure Funding Relating to PCORnet®, which were approved by the Board of Governors in January 2021. They align closely with PCORI's overall strategic planning and are used by PCORI to guide decision making about infrastructure funding for the next stages of PCORnet, the development of requirements for selection of Phase 3 awardees, monitoring of funding contracts, and decisions about future funding. They include a focus on Patient-Centeredness, National Scope, and Governance and Partnerships, and will guide decision-making about infrastructure funding for the next stages of PCORnet.

Cook outlined the goals for Phase 3 funding of PCORnet® as articulated in the PCORI Funding Announcement (PFA), which are to increase the utilization of PCORnet®, fund studies that are national in scope, optimize infrastructure to increase diversity in populations in care settings, and address PCORI's strategic research priorities. Cook then conveyed the Work Group's goals for Stage 2, which are to build on the Prioritizing Principles to inform the PCORnet evaluation framework; to integrate and leverage PCORnet assets to advance the National Priorities for Health and Research Agenda; and to provide resources that inform strategic discussions.

Healthcare Cost and Value Work Group

Cook addressed the importance of PCORI serving as a trustworthy informant in the cost and value conversation, providing situational awareness at the intersection of cost and value, as well as the desire to be timely and responsive using a phased approach. She reviewed a framework for activities developed by the Work Group, which emphasizes a patient-centered approach and supports PCORI's role in using our convening power to bring stakeholders together to understand how different communities define value. Cook outlined the framework's three pillars: Collection of the Full Range of Outcomes, Informing the Value Conversation, and Supporting Policy Priorities.

Methodology Committee 2.0 Work Group

	Cook reported that the Methodology Committee 2.0 Work Group was launched as a part of PCORI's Strategic Planning process and the shift of Methodology Committee appointments from the GAO to the Board in PCORI's reauthorizing law. The Work Group has been considering how to align Methodology Committee priorities for with priorities identified in PCORI's strategic planning, key areas in PCORI's reauthorizing law, and Methodology Committee contributions to PCORI's implementation of the provision in PCORI's reauthorizing law on the full range of outcomes data, including potential burdens and economic impacts. ***COVID-19 Portfolio Highlights*** Cook provided an overview of PCORI's response to the COVID-19 pandemic, which included 122 enhancements awarded and 36 new awards in research and engagement totaling $79.3 million in funding. Cook highlighted relevant publications with significant findings and noted a collaborative effort involving the Centers for Disease Control (CDC) that leveraged the PCORnet infrastructure common data model to support surveillance projects. She also provided an update on the HERO Research Program Registry of Healthcare Workers (HCW), which, as of January 2022, had over 55,000 participants, and the HERO Clinical Trial, which leveraged PCORnet. She noted that the cumulative expenses for both the HWC Registry and Clinical Trial total $13.9 million and that several HERO research program publications and other areas of focus for publications are under development. Board members discussed the potential impact (both challenges and opportunities) of PCORI's National Priorities for Health on the future Commitment Plan. They commented on the positive utility of PCORnet® and the future potential of an extended HCW Registry. They requested a future update on PCORI's priority areas (i.e., Intellectual and/or Developmental Disabilities and Maternal Morbidity and Mortality) and asked about lessons learned from the accelerated timeline funding mechanism used for COVID-19 related funding that could be integrated into future funding announcements.
Consider for Adoption • Research Agenda *Nakela L. Cook, MD, MPH* *Sharon Levine, MD* *Co-Chair, Strategic Planning Committee*	Dr. Levine introduced the agenda item and thanked stakeholders for their interest and input, which informed revisions to the proposed Research Agenda. Dr. Cook presented an overview of the feedback PCORI received on the proposed Research Agenda from a wide range of stakeholders. Input opportunities included a public comment period and meetings, discussions, and surveys. Cook reviewed insights gleaned from the feedback and noted that the feedback was relevant to multiple components in the strategic planning process including the Research Agenda, Research Project Agenda, Strategic Plan and Action Plans. Cook highlighted two suggested revisions to the Research Agenda: being more explicit about the need to impact structural racism and its effects on health; and being more inclusive of a broad range of historically excluded populations, such as rare disease communities, people with disabilities, and those who are homebound. Feedback related to other considerations for PCORI will be addressed in other components of strategic planning, including the Research Project Agenda, Strategic Plan, and Action Plans.

	The proposed Research Agenda presented to the PCORI Board for adoption is: Fund comparative clinical effectiveness research that: • Fills patient- and stakeholder-prioritized evidence gaps and is representative and inclusive of diverse and underrepresented patient populations and settings; • Advances the achievement of health equity and elimination of disparities with an emphasis on overcoming the effects on health and healthcare outcomes of racism, discrimination, and bias; • Builds the evidence base for emerging interventions by leveraging the full range of data resources and partnerships; • Examines the diverse burdens and clinical and economic impacts important to patients and other stakeholders; • Focuses on health promotion and illness prevention by addressing health drivers that occur where people live, work, learn, and play; and, • Integrates implementation science and advances approaches for communicating evidence so the public can access, understand, and act on research findings. Board members expressed agreement with the suggested edits to the proposed Research Agenda and noted they effectively address stakeholder feedback. Board members suggested adding supporting text in the Strategic Plan to reflect the importance of including historically excluded populations as well as language describing how comparative clinical effectiveness research (CER) advances health equity and elimination of disparities by generating data and providing evidence. *The following motion was made by Michael Lauer and seconded by Barbara McNeil.* **Motion**: Adopt the proposed Research Agenda *Approved by majority vote of the voting Board members by roll call vote (19 in favor, no opposed, no abstentions).*
Methodology Committee (MC) Framework • **MC 2.0 Work Group Update** • **Consider for Approval** ○ Governance Committee Recommendation on MC Conflict of Interest and Governance Framework *Nakela L. Cook, MD, MPH* *Sharon Levine, MD* *Chair, Governance Committee* *Mary C. Hennessey, Esq.* *General Counsel*	Dr. Goertz introduced a discussion of the Methodology Committee (MC) Framework, including considering the work of the MC2.0 Work Group and recommendations of the Governance Committee relating to the MC conflict of interest and governance framework. She noted the desire to more fully leverage the expertise of MC members to maximize the contributions of the MC. Dr. Cook provided an update on the MC 2.0 Work Group, comprised of Board members, MC members and PCORI staff, which has been considering the future state vision for the MC to support the MC's contributions to PCORI's strategic direction, leverages the expertise of the MC, and fulfills the intent of the MC in the authorizing law. She outlined key MC roles and functions in different arenas identified by the WG: development and update of standards; innovation and best practices; opportunities on the horizon; expertise and diversity of perspectives; engagement with the methodology community, relationships with other PCORI bodies and supporting integrity. She reported on key discussions of the WG to advance implementation of the future vision for the MC, including enhancing the PCORI staff and MC partnership and revising the conflict of interest framework for the MC.

	Levine then reported on the work of the Governance Committee on considering the conflict of interest and governance framework for the MC given the anticipated contributions of the MC to PCORI's strategic direction. The Governance Committee sought input from the MC, the MC Chair and Vice Chair (Steve Goodman and Robin Newhouse), and the MC 2.0 Work Group. Dr. Levine then outlined the Governance Committee's recommendation that the Board approve a revised conflict of interest and governance framework for the MC that incorporates the following key elements: • all future MC members will be required to forego the opportunity to apply for PCORI funding during their term on the MC and thereafter consistent with PCORI's conflict of interest policies; • the MC will have a four-year staggered term structure (with appointments every two years), and • the Board will be authorized to appoint MC members to a second 4 year term to the extent necessary to fulfill the functions of the M, requirements of the authorizing law, or needs of PCORI. No MC member can be appointed to serve more than two full consecutive four-year terms. Dr. Levine then asked Mary Hennessey to provide background information. Hennessey noted that PCORI's reauthorization law shifted the authority to appoint MC members from GAO to PCORI's Board, and that soon after, at the recommendation of the Governance Committee, PCORI's Board approved a 6-year staggered term structure for MC members, with appointments every 2 years. At the time, a conflict of interest framework was not advanced because it was recognized that additional efforts would be underway to consider MC's contributions to PCORI's strategic direction. Hennessey outlined the historic conflict of interest framework that has applied to the MC since PCORI's early years, which included both members who retained eligibility to apply for PCORI funding and members who chose to forego the ability to apply for PCORI funding. Hennessey reported on the Governance Committee's recent discussions that recognized the value of and the desire to have all MC members contribute their expertise to PCORI's strategic direction, including advising on funding priorities, research agenda and funding announcements. Thus, the Governance Committee's recommended revised framework recognizes the need for future MC members to forego eligibility to apply for PCORI funding during their terms and thereafter for one year to be able to participate more fully in PCORI's work. Given this requirement, Governance Committee members, in accordance with Methodology Committee leaders, felt a four year term was more appropriate. *The following motion was made by Robert Zwolak and seconded by Barbara McNeil.* **Motion**: Approve the revised Conflict of Interest and Governance Framework for the Methodology Committee as recommended by the Governance Committee *Approved by majority vote of the voting Board members by voice vote (no opposed, no abstentions). James Huffman was not present during this vote.*
Consider for Approval Cycle 2 2021 Award Slates Resulting from the Following PCORI Funding	**Overview of Award Slates from Cycle 2 2021** Dr. Cook introduced the agenda item by giving an overview of the Cycle 2 2021 Award Slates to be considered for approval. The total funding amount being

Announcements (PFA)

- **Overview of Award Slates to be Considered for Approval**
- **Dissemination and Implementation (D&I) PFAs**
  - Limited Competition
  - Implementation of Findings from PCORI's Major Research Investments
- **Research PFAs**
  - Pragmatic Clinical Studies
  - Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities
  - Nonsurgical Options for Women with Urinary Incontinence
  - Broad

Nakela L. Cook, MD, MPH

Michael Herndon, DO
Chair, Engagement, Dissemination, and Implementation Committee
Joanna Siegel, SM, ScD
Director, Dissemination and Implementation

Barbara McNeil, MD, PhD
Chair, Selection Committee

Carly Khan, PhD, MPH, RN
Associate Director, Healthcare Delivery & Disparities Research (HDDR)

Els Houtsmuller, PhD
Associate Director, HDDR

presented to the Board was $80.4M. Cook then reviewed the LOIs, applications and funding rates for each of the slates, and provided today's proposed commitments in context of the FY2022 Funding Commitment Plan. She noted that the cumulative FY2022 Commitments with today's Dissemination and Implementation Award Slates was $9M of the $40M allotted in the FY2022 Commitment Plan for all D&I Awards, and the cumulative FY2022 Commitments with today's Research Award Slates was $121M of the $500M allotted in the FY2022 Commitment Plan for all Research Awards.

Slates from Cycle 2 2021 Dissemination and Implementation (D&I) PFAs
Dr. Herndon made introductory remarks on behalf of the Engagement, Dissemination, and Implementation Committee (EDIC), noting that at its February 2022 meeting, EDIC voted to recommend that the Board approve the recommended slates from the Limited Competition (LC) and Implementation of Findings from PCORI's Major Research Investments (IMRI) PFAs. Herndon then introduced Dr. Siegel to provide details on the two recommended slates.

Siegel provided an overview of the LC funding announcement, which provides awardee teams who have completed a PCORI-funded study the opportunity to take the next steps in promoting uptake of the evidence into practice. Siegel noted that both projects on this recommended slate propose to implement findings from studies funded through PCORI's Improving Health Systems priority area. The project titles are:

Implementing the Infusion Clinic Model In Sickle Cell Disease
Implementing Outcomes-Based Matching of Patients to Mental Health Care Therapists' Strengths

The total funds requested for the proposed slate is $6.4M.

Siegel then provided an overview of the IMRI funding announcement, which is an open competition funding initiative with the goal of promoting the uptake of findings from specific PCORI-funded research topics, in the context of the body of related evidence. The implementation project on the proposed slate is titled:

Implementation Strategies to Enhance Use of Conservative Management of Urinary Incontinence in Women

The total funds requested for the proposed slate is $2.5M.

The proposed project will increase access to, and delivery of, evidence-based, first-line conservative management treatment for urinary incontinence and is based on findings from a recent PCORI-funded systematic review update, conducted in partnership with AHRQ.

The following motion was made by Connie Hwang and seconded by Sharon Levine.

Motion: Approve funding for the two recommended slates of awards from the Cycle 2 2021 Dissemination and Implementation PFAs

Nora McGhee, PhD *Senior Program Officer* *Clinical Effectiveness and Decision Science* *Steven Clauser, PhD, MPA* *Program Director, HDDR* *Stanley Ip, MD* *Interim Program Director Clinical Effectiveness and Decision Science*	*Approved by majority vote of the voting Board members by voice vote (no opposed, no abstentions, 2 recusals: Jennifer DeVoe, James Schuster). Kara Ayers and James Huffman were not present during this vote.* **<u>Slates from Cycle 2 2021 Research Award PFAs</u>** At Dr. Goertz's request, Vice Chairperson Levine chaired the presentation and deliberation on the proposed Research Award slates. Dr. McNeil made introductory remarks on behalf of the Selection Committee stating that at its February 2022 meeting, the Committee considered applications for the Cycle 2 2021 Broad and Pragmatic Clinical Studies PFAs as well as the Urinary Incontinence and Maternal Morbidity and Mortality Targeted PFAs. She noted the Committee engaged in in-depth discussions regarding the proposed applications and recommends that the Board approve the proposed slate of awards for funding. ***Cycle 2 2021 Pragmatic Clinical Studies PFAs*** Dr. Khan presented the proposed slate of awards for the Cycle 2 2021 Pragmatic Clinical Studies Award PFA. She then reviewed details for the PFA. The project titles on the proposed slate are: *Efficacy of pharmacologic management of ADHD in children and youth with autism spectrum disorder* *Pragmatic Trial to Enhance Quality Safety, and Patient experience in COPD-EQuiP COPD* The total funds requested for the proposed slate is $18.9M. ***Cycle 2 2021 Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities PFA*** Dr. Houtsmuller presented the proposed slate of awards for the Cycle 2 2021 targeted Clinical Studies Awards PFA on Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities. The project title on the proposed slate is: *Trauma-informed approach to timely detection and management of early postpartum hypertension* The total funds requested for the proposed slate is $20.4M. ***Cycle 2 2021 Nonsurgical Options for Women with Urinary Incontinence PFA*** Dr. McGhee presented the proposed slate of awards for the Cycle 2 2021 targeted Clinical Studies Awards PFA on the topic of Nonsurgical Options for Women with Urinary Incontinence The project titles on the proposed slate are: *Tailoring incontinence care: onabotulinumtoxinA for urgency urinary incontinence among older women* *Comparative Efficacy of Advanced Practice Provider Co-Management vs. Electronic Decision Support in Improving Incontinence Outcomes in a Diverse Population of Aging Women* *Beta-Agonist versus onabotulinumtoxinA Trial for Urgency Urinary Incontinence (Best Trial)* The total funds requested for the proposed slate is $19.5M. ***Cycle 2 2021 Broad PFA Award Slates***

	Dr. Clauser and Dr. Ip presented the proposed slate of awards for the Cycle 2 2021 Broad PFA Award Slates, including: • The Cycle 2 2021 Broad Improving Healthcare System Slate (requested funds totaling $8.6M) • The Cycle 2 2021 Broad Improving Methods for Conducting PCOR Slate (requested funds totaling $4.1M) (See *Attachment A* for project titles on the proposed slates.) *The following motion was made by Karin Rhodes and seconded by Russell Howerton.* **Motion**: Approve funding for the recommended slates of awards from the following Cycle 2 2021 Research PFAs: • Pragmatic Clinical Studies • Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities • Nonsurgical Options for Women with Urinary Incontinence • Broad: o Improving Healthcare Systems o Improving Methods for Conducting PCORI *Approved by majority vote of the voting Board members by voice vote (no opposed; no abstentions, 5 recusals: Kara Ayers, Jennifer DeVoe, Christine Goertz, Michael Lauer, Barbara McNeil, and James Schuster). James Huffman was not present during this vote.*
Consider for Approval Cycle 2 Targeted PFA Development • Health System Strategies to Address Disparities in Hypertension Management & Control • Advancing the Science of Engagement *Nakela L. Cook, MD, MPH* *Alicia Fernandez, MD* *Chair, Science Oversight Committee* *Els Houtsmuller, PhD* *Associate Director, HDDR* *Hillary Bracken, MA, MHS, PhD* *Program Officer, HDDR* *Kristin L. Carmen, PhD, MA* *Director, Public & Patient Engagement*	Dr. Cook updated the Board on the Cycle 2 Targeted PFAs released under the expedited and enhanced process and summarized the targeted PFA development being considered by the Board: Health System Strategies to Address Disparities in Hypertension Management and Control and Advancing the Science of Engagement. Dr. Fernandez who made introductory remarks on behalf of the Science Oversight Committee (SOC), which recommended that the Board approve the development of these PFAs at the SOC's meeting in February 2022. Dr Houtsmuller and Dr. Bracken presented the proposed development and funding of a Targeted PFA, *Health System Strategies to Address Disparities in Hypertension Management & Control*. Houtsmuller explained that studies to be funded under this PFA would compare the effectiveness of health system strategies to improve blood pressure control for populations experiencing disparities in outcomes, for example, people who are Black, Hispanic, live in rural areas, and/or uninsured. PCORI expects to fund 4-5 studies over 2-3 cycles of funding, with each project duration up to 5 years, and direct costs per research project of up to $10M for small studies and up to $15M for large studies. The total funds requested for this proposed targeted PFA is $50M in total costs. *The following motion was made by Mike Herndon and seconded by Daniel van Leeuwen.*

Laura Forsythe, PhD, MPH *Director, Evaluation & Analysis*	**Motion**: Approve the development of a *Health System Strategies to Address Disparities in Hypertension Management and Control* Targeted PFA with funding up to $50 million in total costs. *Approved by majority vote of the voting Board members through a voice vote (no opposed; no abstentions). Kara Ayers and James Huffman were not present during this vote.* Dr. Carman and Dr. Forsythe then presented the proposed development and funding of a Targeted PFA relating to *Advancing the Science of Engagement.* Carman explained that studies funded by PCORI under this PFA would address: • development and/or validation measures, including rapid measure development, to capture structure/context, process, and outcomes related to both engagement and research, from both the stakeholder and investigator perspective; and • development and/or testing of engagement approaches to generate evidence on which specific aspects of engagement are most effective, either alone or in combination, and how effectiveness varies by context, particularly for underrepresented populations. Board members discussed that this PFA will address the considerable evidence gap that exists in engagement science; the studies will lead to both better engagement and recruitment; and there may be a need to train scholars to refine engagement science. PCORI expects to fund up to 22 studies over up to 9 cycles of funding, with each project duration up to 3 years, and direct costs per research project up to $500K or up to $1.5M. The total funds requested for this targeted PFA is $36M in total costs. *The following motion was made by Karin Rhodes and seconded by Mike Herndon.* **Motion**: Approve the development of an *Advancing the Science of Engagement* Targeted PFA with funding up to $36 million in total costs *Approved by majority vote of the voting Board members by voice vote (no opposed, no abstentions). Kara Ayers, James Huffman, and Michael Lauer were not present during this vote.*
Overview of PCORI's Work on Reducing Maternal Morbidity and Mortality *Nakela L. Cook, MD, MPH*	Dr. Cook presented an update to the Board on PCORI's work on reducing maternal morbidity and mortality. She highlighted PCORI's prioritization of maternal morbidity and mortality, tied to PCORI's reauthorizing law. She outlined PCORI's framework of addressing interventions for risk factors, social needs, and clinical variables from pre-conception through postpartum. Cook highlighted 63 PCORI-funded CER and engagement projects totaling an investment of $91M since 2013, with an increase to a funding total of $110M including the project recommended for approval at today's meeting. Cook detailed ongoing engagement activities; survey feedback from diverse stakeholder representatives, stakeholder engagement on specific topics through individual meetings, Annual Meeting sessions, and webinars to discuss AHRQ/PCORI – funded projects. She highlighted systematic reviews that have been funded and are underway, as well as the rapid review that has been completed. She wrapped up

	with a review of PCORI's funding announcements in this area. Cook highlighted one targeted funding announcement in *Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities*, and one special area of emphasis (laid out in two Broad funding announcements) in In*creasing Access to And Continued Patient Centered Maternal Care*. Cook concluded with next steps including future funding announcements, continued stakeholder engagement especially in communities most affected by negative outcomes, and interventions for social determinants of health. Board members discussed whether poor maternal mortality was largely due to lack of high-quality care and, while confirming that research is important, Board members noted the important need for dissemination and more uniform high-quality care. Board members noted that collaboration with other agencies may highlight evidence gaps where PCORI can focus its attention.
Maternal Health Discussion with The Honorable Lauren Underwood, Co-Chair of the Black Maternal Health Caucus *The Honorable Lauren Underwood, MSN, MPH, Representative, 14th District, Illinois*	Dr. Goertz introduced Representative Lauren Underwood, who serves the 14th District of Illinois in the U.S. House of Representatives. Representative Underwood, together with Representative Alma Adams (12-NC), launched the Black Maternal Health Caucus to improve maternal outcomes. Goertz briefly highlighted PCORI's work, specifically relating to Maternal Morbidity and Mortality (MMM) and the shared goal toward improving maternal outcomes. Underwood commented on PCORI's unique mission to advance patient-centered research and noted that PCORI is uniquely situated to lift policy advancements broadly to help save lives. Underwood noted her career as a nurse. She highlighted her motivation to work on this issue and black maternal health being a key focus of her work in Congress. The Black Maternal Health Caucus now has over 100 bipartisan members and a large stakeholder following across the country including providers, researchers, community leaders, industry leaders, and large corporations. Through engagement with stakeholders across the country, the Caucus developed the Black Maternal Health Momnibus Act of 2021 to address this important issue and to address social determinants of health. Underwood also identified other issues and other legislation that Congress passed or has pending to address maternal health issues. Board members then had the opportunity to provide comments and ask questions. Topics discussed included the high rates of maternal morbidity and mortality in the U.S. and how outcomes can vary based on location and race/ethnicity; the need for a robust healthcare workforce; the need to align science, practice and policy to achieve improved health outcomes; and the need for more research relating to pregnant women with disabilities. In addressing these topics, Underwood provided information on the legislation before Congress for federal funding of Perinatal Quality Collaboratives. She suggested PCORI grantees may find this link in data sharing to be useful in informing and influencing this work in each state. She also noted that legislation to provide funding to grow and diversify the maternal workforce has been introduced (e.g., midwives, doulas, physicians, etc.). She noted that while there is a diverse population in rural communities, there is generally not a diverse healthcare workforce. Underwood also spoke to the possibility of PCORI connecting with states engaged on this issue, as PCORI offers a rich opportunity for cooperation. She encouraged PCORI funding to be as inclusive as possible, pointing to the shift in the

	way data and disparities present itself and highlighting the language in the Momnibus bill which elevates a multicultural coalition. Goertz thanked Underwood for the work she is doing to help address these issues and welcomed the opportunity for future conversations. Underwood noted that no one should assume all agencies are aware of the work each is doing. There is an opportunity for collaboration and alerting others to the rich resources that PCORI can provide. Board members commented on connecting Methodology Committee and policy interventions that Underwood highlighted to broaden PCORI's horizons, as interventions cannot always be randomized. Board members also requested further information on completed study results from PCORI-funded projects to see what results could be implemented, possibly in a larger way than originally intended.
Consider for Approval • **PCORI/AHRQ Learning Health Systems 2.0 Initiative** *Steven Clauser, PhD, MPA*	Dr. Clauser presented the PCORI/AHRQ Learning Health Systems 2.0 Initiative (LHS), which would be another funding collaboration between PCORI and AHRQ. Clauser provided background on PCORI and AHRQ's collaboration in LHS 1.0, including successes and lessons learned. Under the collaboration, PCORI provided funding to AHRQ, and AHRQ funded 11 institutions to support the training of embedded researchers within Learning Health Systems. He relayed outcomes of LHS 1.0 to date, including the participation of 82 scholars with 30 completing the program and the publication of 300 articles by LHS scholars. He reported that the purpose of the proposed LHS 2.0 PCORI/AHRQ collaboration is to support institutions to produce the next cadre of LHS researchers and scientists who have the skills to conduct, apply, and implement PCOR to empower equitable wholesale person care across the lifespan, in order to improve system operations, quality, and health outcomes. LHS 2.0 is intended to focus on the core competency of healthcare equity, justice, and diversity of its scholars; will shift away from the K-award mechanism; and will work within a program project/center grant to better fit the initiative and create more opportunities for scholars. LHS 2.0 scholars will be encouraged to work with minority serving institutions, such as Historically Black Colleges and Universities and other community stakeholders. Additionally, there will be continuing collaboration with PCORI to include engagement science in the LHS curriculum. Key elements of the proposed PCORI and AHRQ LHS 2.0 Funding Collaboration include: PCORI will contribute up to $25M to AHRQ; AHRQ will match PCORI's funding; initial PCORI funding to AHRQ is anticipated to begin in FY2023. AHRQ will fund the LHS recipients; the estimated number of projects is 10; the estimated project duration is 5 years. The funding collaboration is subject to finalization of a MOU between PCORI and AHRQ. *The following motion was made by Alicia Fernandez and seconded by Christopher Friese.* **Motion:** Approve funding of up to $25 million to AHRQ for purposes of a PCORI and AHRQ collaborative funding initiative for a Learning Health System training program, subject to finalization of a MOU between PCORI and AHRQ

	The motion was approved by majority vote of the voting Board members by voice vote (no opposed, no abstentions, 1 recusal: Karin Rhodes)
Public Comment *Kristin Carman, MA, PhD Director, Public & Patient Engagement*	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 Adjourn *Christine Goertz, DC, PhD*	The meeting adjourned at 2:50 pm Eastern time.

Attachment A:

Cycle 2 2021 Broad Awards Funded

Improving Healthcare Systems	Comparing Hospital to Home Transition Interventions for Children with Medical Complexity
	Comparative Effectiveness of Two Approaches to Symptom Monitoring in Hemodialysis
Improving Methods for Conducting PCOR Award Slate	Improving Methods for Design and Analysis of CER with Complex Observational Healthcare Data
	Causal Mediation Analysis with Machine Learning to Understand Comparative Treatment Effects
	Randomized Trials and Their Observational Emulations – Benchmarking and Joint Analysis
	Robust Longitudinal Causal Inference Methods with Machine Learning

Minutes were approved by the PCORI Board of Governors 06-14-2022