

Board of Governors Meeting

Via Teleconference/Webinar

January 28, 2020
12:00 PM – 1:30 PM ET

Welcome and Introductions

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Josephine Briggs, MD

Interim Executive Director & Acting Chief Science Officer

THANK YOU!!

Senate Champions



Mark Warner (D-VA)



Bill Cassidy (R-LA)



Chris Van Hollen (D-MD)



Shelly Moore Capito (R-WV)

House Champions



Diana DeGette (D-CO)



Don Beyer (D-VA)



Features of PCORI's New Law



- 10-year extension
- Loss of Medicare Trust Fund transfer as a funding mechanism
- Increase of federal mandatory appropriations to compensate for the lost Medicare transfers
- Identifies intellectual and developmental disabilities and maternal mortality as research priorities
- Requires PCORI to balance long-term and short-term priorities when identifying research priorities
- Directs PCORI to collect economic data in the course of a study (i.e., burdens, economic impact, out-of-pocket costs, non-medical costs to patients, absenteeism)
- Increases private payer representation on the Board by 2 slots
- Shifts methodology committee appointment responsibility from the GAO to the Board
- Strengthens and formalizes PCORI's dissemination and implementation mandate
- Directs GAO to review any barriers to conducting research (e.g., cost of covering medical treatments) encountered by PCORI-funded researchers
- Directs GAO to analyze PCORI's dissemination program using a range of potential available data and performance metrics

PCORI's New Executive Director



Nakela Cook, MD, MPH
New PCORI Executive Director

Nakela Cook, MD, MPH, FACC

- Dr. Cook is a cardiologist with a long and distinguished career as a researcher and advocate for engaging patients, clinicians, and other stakeholders in key research initiatives
- We are excited to welcome her to PCORI on April 15th, 2020

Agenda



12:00-12:05 pm

Call to Order, Roll Call, and Welcome

12:05 – 12:10

Consider for Approval: Minutes of the December 9, 2019 board meeting

12:10-12:30

Consider for Approval: Additional Applications from Cycle 1 2019 Slate of Awards

12:30 – 12:45

Consider for Approval: PCORnet Coordinating Center Extension

12:45 pm

Wrap up and Adjournment

Board Vote

Call for a Motion to:

- **Approve** the Minutes of the December 9, 2019 Board Meeting

Call for the Motion to be Seconded:

- **Second** the Motion
- If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Voice Vote:

- Vote to **Approve** the **Final** Motion
- Ask for votes in favor, opposed, and abstentions

Additional Proposed Studies

Cycle 1 2019 Broad Award Slate

Barbara McNeil, MD, PhD

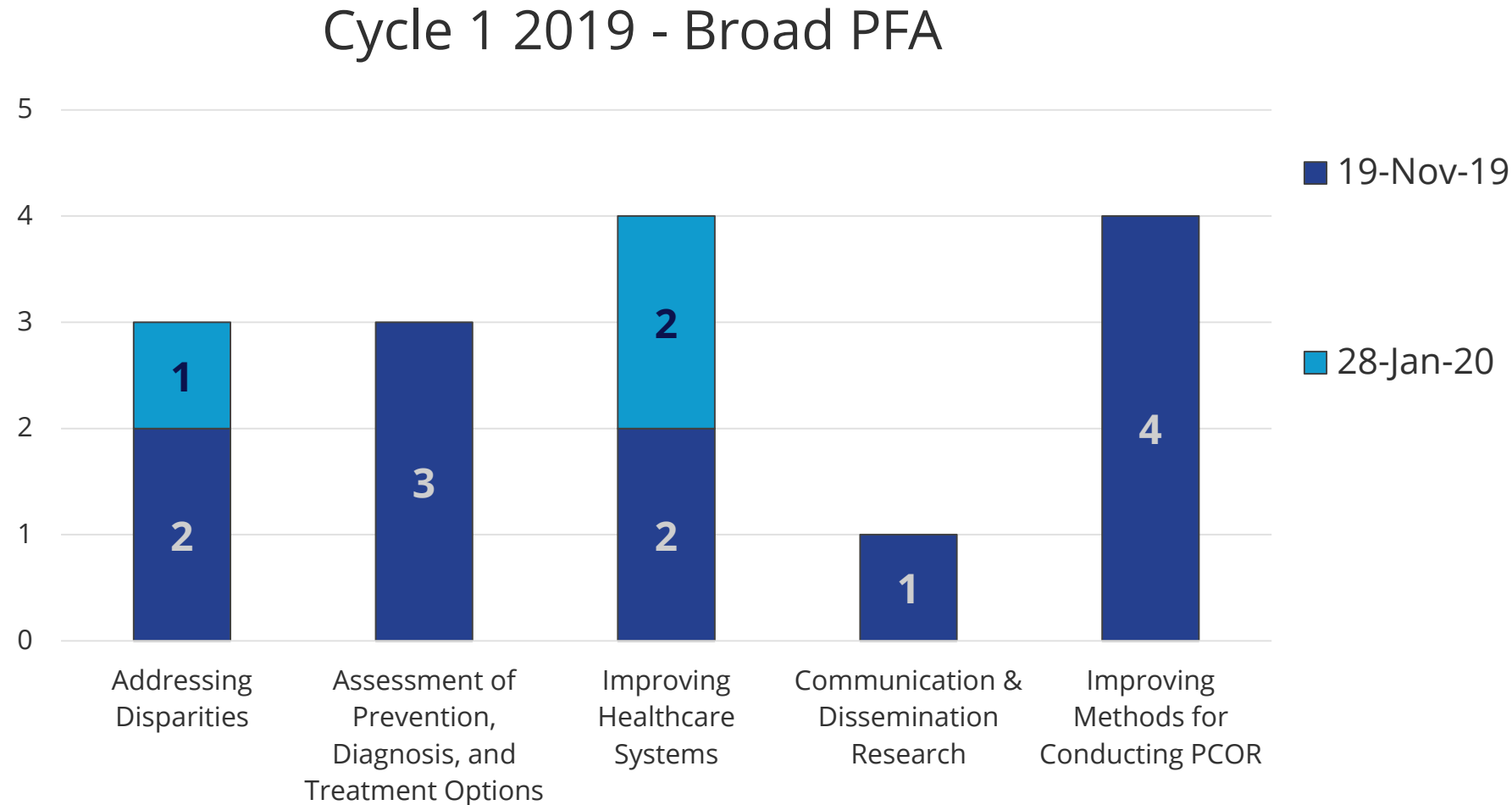
Chair, Selection Committee

Josephine Briggs, MD

Interim Executive Director & Acting Chief Science Officer

Cycle 1 2019 – Broad PFA Overview

- November 19, 2019 – Board of Governors approved funding for 12 out of 74 applications
- Three additional studies had been approved by the Selection Committee on October 1, 2019, but funding was not available at the time



Cycle 1 – Broad PFA Overview



Broad PFA	Amount Posted	Total Awarded*	New Proposed Total Award
Addressing Disparities	\$8M	\$8.4M	\$10.1M
Assessment of Prevention, Diagnosis, and Treatment Options	\$32M	\$10.9M	\$10.9M
Communication and Dissemination Research	\$8M	\$1.1M	\$1.1M
Improving Healthcare Systems	\$16M	\$9.1M	\$17.0M
Improving Methods for Conducting PCOR	\$12M	\$3.9M	\$3.9M
TOTAL	\$76M	\$33.5M	\$43.1M

*Awards approved by the Board of Governors on November 19, 2019

Cycle 1 2019 – Addressing Disparities

1 Additional Recommended Project



Project Title
Improving Communication and Healthcare Outcomes for Patients with Communication Disabilities: the INTERACT Trial
Care in the CCP Program vs. Care in the C4P Program vs. Care in Traditional Care Coordinator Program
Examination of the Evidence-Based Care Transitions Intervention Enhanced with Peer Support to Reduce Racial Disparities in Hospital Readmissions and Negative Outcomes Post Hospitalization

Note: All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Cycle 1 2019 – Improving Healthcare Systems

2 Additional Recommended Projects



Project Title
Comparative Effectiveness of Unobserved vs. In-Office Inductions for Medication Assisted Treatment
Comparing Two Approaches to Care Coordination for High-Cost/High-Need Patients in Primary Care
Comparative Effectiveness of Readmission Reduction Interventions for Individuals with Sepsis or Pneumonia
Improving Family-Centered Pediatric Trauma Care: The Standard of Care versus the Virtual Pediatric Trauma Center

Note: All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Cycle 1 2019 – Broad PFA

*Slate Overview: 3 Additional Recommended Projects**



Amount Budgeted	Previously Approved Award	Proposed Total Award
\$33.4M	\$33.5M	\$43.1M

* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Board Vote

Call for a Motion to:

- **Approve** funding for the recommended additional awards from the Cycle 1 2019 Broad PFA

Call for the Motion to be Seconded:

- **Second** the Motion
- If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Roll Call Vote:

- Vote to **Approve** the **Final** Motion
- Ask for votes in favor, opposed, and abstentions

Additional Proposed Study

Cycle 1 2019

Treatment Options for Age-Related
Hearing Loss Award Slate

Barbara McNeil, MD, PhD

Chair, Selection Committee

Josephine Briggs, MD

Interim Executive Director & Acting Chief Science Officer

Cycle 1 2019 – Treatment Options for Age-Related Hearing Loss

Objective of the PFA and Slate Overview



Priority Research Question of this Targeted PFA:

Which hearing devices and/or support services are most effective for the treatment of age-related hearing loss?

Overall Slate Includes Complementary Studies that Address Important Evidence Gaps

- Effectiveness of a broad-based hearing health care intervention for residents in assisted living facilities
- Models for provision of direct-to-consumer devices
- The comparative benefits of one versus two hearing aids

Cycle 1 2019 – Treatment Options for Age-Related Hearing Loss

1 Additional Recommended Project



Project Title
HearCARE: Hearing for Communication and Resident Engagement
Comparison of Direct-to-Consumer Treatments Using Hearing Devices
Addressing the Clinical Dilemma and Patient Preference for Unilateral versus Bilateral Hearing Aids

Note: All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Project 1: Addressing the Clinical Dilemma and Patient Preference for Unilateral versus Bilateral Hearing Aids



- **Research Question:** What is the comparative effectiveness of unilateral versus bilateral hearing aids for the treatment of mild-to-moderate age-related hearing loss?
- **Population & Setting:** New hearing aid users ≥ 50 years old with mild-to-moderate hearing loss from audiology clinics within 2 health systems
- **Comparators:**
 - Bilateral hearing aids
 - Unilateral hearing aid
- **Outcomes of Interest:**
 - *Primary:* Hearing aid benefit
 - *Secondary:* Hearing-specific health-related quality of life, hearing aid use, auditory performance measures
- **Potential Impact:** The study's goal is to determine the relative benefit of unilateral versus bilateral hearing aid use in the treatment of mild-to-moderate age-related hearing loss given the lack of high-quality evidence to support the recommendation of two hearing aids.

Cycle 1 2019 – Treatment of Age-Related Hearing Loss PFA

*Slate Overview: 1 Additional Recommended Project**



Amount Budgeted	Previously Approved Award	Proposed Total Award
\$6M	\$4.7M	\$7.3M

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Board Vote

Call for a Motion to:

- **Approve** funding for the recommended additional award from the Cycle 1 2019 Treatment Options for Age-Related Hearing Loss PFA

Call for the Motion to be Seconded:

- **Second** the Motion
- If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Roll Call Vote:

- Vote to **Approve** the **Final** Motion
- Ask for votes in favor, opposed, and abstentions

PCORnet Coordinating Center Extension

Kathleen Troeger, MPH

Chair, Research Transformation Committee

Josephine Briggs, MD

Interim Executive Director & Acting Chief Science Officer

Research Transformation Committee (RTC) Recommendations



- On January 16, 2020, the RTC reviewed the proposal to authorize additional funding and extend the contract for the PCORnet Coordinating Center
- The estimated costs are \$6.1 M
- These funds were included in the funding commitment plan for the continuous support of the PCORnet Coordinating Center which the Board reviewed in September 2019
- Thus, with the RTC's recommendation, the Board is now asked to approve the award of \$6.1 M to the PCORnet Coordinating Center to extend the contract
- The RTC assessment is that the extension of Coordinating Center funding is essential to enable the on-going work of PCORnet

PCORnet Update and Coordinating Center Extension

Josephine Briggs, MD

Interim Executive Director & Acting Chief Science Officer

PCORnet Coordinating Center Expenditures



Annual expenditures for the PCORnet Coordinating Center peaked in 2017 due to a **focus on Network expansion** and **development of novel tools** for data querying and analysis

- Expenditures in 2017 totaled \$7.3M

Since 2017, **expenditures have steadily decreased**

- Over the last two years, annual Coordinating Center costs have averaged approximately \$6M a year.
- This decrease in cost is due to:
 - Moving from a 'building' phase to an 'implementation' phase
 - Ability to leverage reusable tools
 - A smaller, more efficient Network of Networks
- The budget estimate of \$6.1M for the current extension holds costs essentially constant with some increase in scope.

Coordinating Center Extension



- PCORI staff anticipate a **robust process for strengthening Clinical Research Network (CRN) performance** to better understand the return on investment at the network site-level
- **Increase PCORnet Coordinating Center responsibilities** to include tracking CRN performance in these areas
 - Monitor data quality and linkage performance
 - Assess site-level research performance
- Funds are to extend the Duke Coordinating Center Contract and related Task Orders

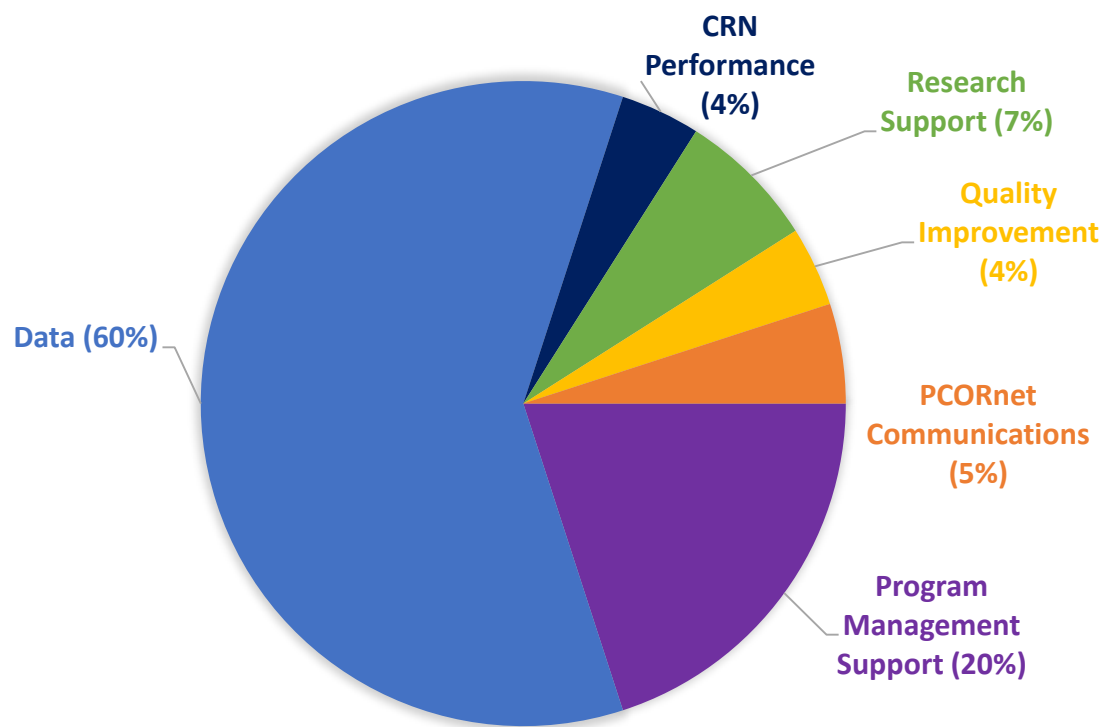
PCORnet Evolution



- Post reauthorization, PCORI staff, with input and advice from both the RTC and the Science Oversight Committee (SOC), are examining all aspects of PCORnet capabilities, anticipating that PCORnet will need to evolve to meet future needs of PCORI 2.0.
- Some important transitions are underway in response to decisions by the People-Centered Research Foundation (PCRF) Board.
- CRN infrastructure advancement projects that are funded by PCRF as sub-awards from the PCORI-funded PCRF award will be able to continue through new direct funding contracts from PCORI. This approach has been developed cooperatively with PCRF to support ongoing CRN progress and diminish disruption. This process should be complete by April of this year.
- PCORI staff anticipate this will result in more streamlined monitoring of progress of the CRNs and PCORnet.

These funds were included in PCORI's FY2020 Commitment Plan

Breakdown of \$6.1M
for Coordinating Center activities



Coordinating Center Activities

Program Management Support – Coordinating Center leadership, meeting support, committees and workgroups, internal network communication, and PCORnet DSA

Data – Operations Center leadership, analytic tool development, data curation, CDM maintenance and enhancements, and query fulfillment

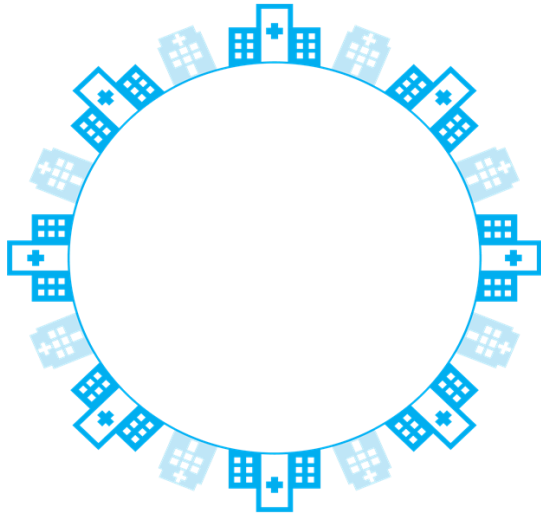
CRN Performance - Monitor data quality and linkage performance and assess site-level research performance

Research Support – Front Door including data network requests, network collaborator requests, proposal development, and consultations

Quality Improvement - Dashboard and QI metrics

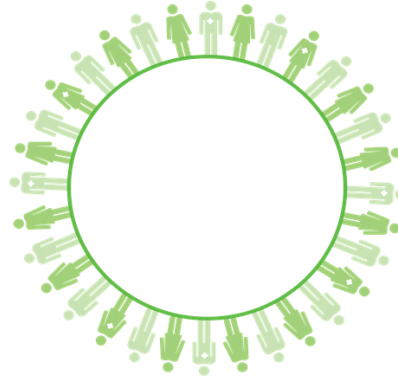
PCORnet Communications - PCORnet external communications (i.e., website, blogs, and social media)

What Are We Investing In?



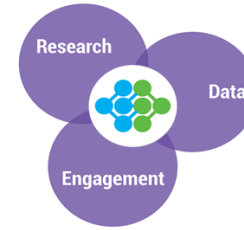
Pipes

Data infrastructure and connections (pipes) enabling a distributed research network



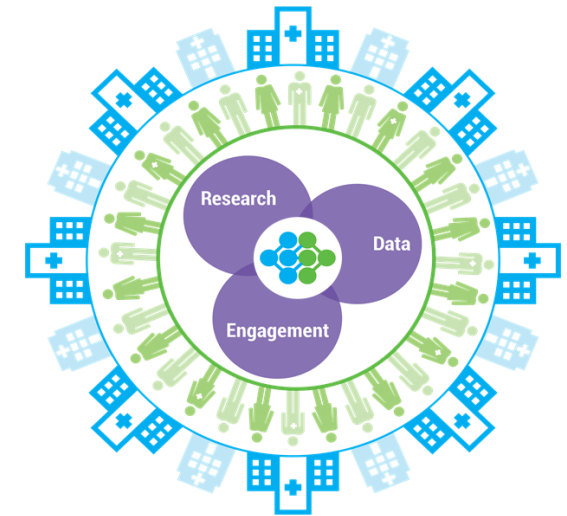
People

Scientist, informaticians, patients, clinicians, and other stakeholders enabling a patient-centered research network



Trust

Development of trust among participating health systems and the public



PCORnet, The National Patient-Centered Clinical Research Network

Next Steps

- PCORI staff will implement a robust process to capture lessons learned from the last phase of PCORnet funding and to improve monitoring of network performance to better understand the return on investment at the network site-level, a process facilitated by the new contracting arrangements.
- PCORI staff anticipate working closely with two Board strategy committees, the RTC and the SOC, to clarify the potential value of PCORnet for implementation of PCORI-funded research projects.
- While emphasizing the role of PCORnet for public sector funded work, we recognize untapped potential of this network for industry studies that serve the public interest and anticipate further dialog with the Board and colleagues at the FDA on this important issue.

Board Vote

Call for a Motion to:

- **Approve** \$6.1 million total cost to extend the Duke University Coordinating Center contract

Call for the Motion to be Seconded:

- **Second** the Motion
- If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion

Roll Call Vote:

- Vote to **Approve** the **Final** Motion
- Ask for votes in favor, opposed, and abstentions

Wrap Up and Adjournment

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 /PCORInstitute

 PCORI

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