Board of Governors Meeting

In-person and via Teleconference/Webinar

March 8, 2022
9:00 – 3:30 PM

pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Call to Order

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Agenda

9:00am	Welcome, Call to Order, and Consider for Approval: February 15, 2022, Board Meeting Minutes
9:15-10:00	Executive Director's Report
10:00-10:30	Consider for Adoption: Research Agenda
10:30-11:00	Consider for Approval: Methodology Committee Framework
11:30-12:15	Consider for Approval: Cycle 2 2021 Award Slates
12:15-12:45	Consider for Approval: Development of Targeted PFAs
1:45-2:00	Overview of PCORI's Work on Maternal Morbidity and Mortality
2:00-2:30	Maternal Health Discussion
2:30-3:00	Consider for Approval: PCORI/AHRQ Learning Health Systems 2.0 Initiative
3:00-3:30	Public Comment
3:30pm	Wrap-up and Adjourn

Board Vote

Call for a Motion to:	• **Approve** Minutes of the February 15, 2022, Board of Governors 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

Executive Director's Report

Nakela L. Cook, MD, MPH

Executive Director

Important Upcoming Announcement

- The Comptroller General of the United States (GAO) has responsibility for appointing up to 21 members to the PCORI Board of Governors
- As the result of terms ending in September 2022 and openings due to resignation, there will be several open positions on the PCORI Board of Governors
- GAO will announce in a notice in the Federal Register in the coming months a call for nominations in relevant categories

PCORI *Next* Vision

PCORI *Next* is our organizational transformation effort to invest in our Operational, Cultural and Professional Excellence. Our ultimate goal is to strengthen and optimize the delivery of our mission - focusing on Patient-Centered Outcomes Research that enables better-informed healthcare decisions.

New Members of PCORI Leadership Welcome!

Maureen Thompson, MA
Director of Board Governance, Operations, and Relations

Brian Trent, MPA
Incoming Deputy for Operations

Harold Feldman, MD, MSCE
Incoming Deputy for Patient-Centered Research Programs

Erin Holve, PhD, MPH, MPP
Chief, Research Infrastructure

Maureen Thompson, MA
Director of Board Governance, Operations, and Relations

Maureen Thompson comes to PCORI from the American Nurses Association (ANA), where she served as the Vice President of Governance and Planning. She led the strategy development and execution across the ANA enterprise, which comprises ANA and its two subsidiaries, the American Nurses Credentialing Center (ANCC) and the American Nurses Foundation (Foundation). She oversaw the day-to-day operations of ANA; ANCC; and the Foundation's Board of Directors, advisory groups, and governance committees.

Ms. Thompson is a seasoned executive with more than 15 years of experience in board governance, strategic planning, and volunteer administration. Prior to ANA, she held various board and advocacy leadership roles at American Speech-Language-Hearing Association.

Ms. Thompson received her Master of Arts in Audiology at George Washington University and her Bachelor of Arts in Hearing and Speech Sciences at the University of Maryland, College Park.

Welcome Brian Trent, MPA
Incoming Deputy for Operations

Brian Trent is joining us from the National Institutes of Health, National Eye Institute (NEI), where he has served as the Deputy Institute Director for Management (Chief Operating Officer), Federal Senior Executive Service (SES) since 2015. He oversees the day-to-day operations of the NEI including extramural, intramural and clinical program budgets, finance, information and technology, procurement, human capital, and facilities. His prior experience includes leadership positions at the Food and Drug Administration where he spearheaded the administrative operations of the Center for Tobacco Products and its rapid growth trajectory and at the US Department of Health and Human Services, Office of the Secretary where he served as the former Chief Operating Officer in the Immediate Office of the Assistant Secretary for Preparedness and Response.

Mr. Trent is a seasoned executive with more than 25 years of experience in financial management and operational leadership. He has co-chaired an NIH committee focused on the future of work and lessons learned from extending telework as a result of COVID-19. Additionally, he served as the Chair of an NIH committee that successfully streamlined the government contracting process and led an effort to automate administrative processes across the Institute.

Mr. Trent received his Master of Public Administration from George Mason University, Schar School of Policy and Government and his Bachelor of Science in Public Administration.

Harold I. Feldman, MD, MSCE
Incoming Deputy for Patient-Centered Research Programs

Harold Feldman is the George S. Pepper Professor of Public Health and Preventive Medicine. His focus is on novel approaches to understanding health and disease. He currently directs the Center for Clinical Epidemiology and Biostatistics, where experts from across the Perelman School of Medicine gather to investigate a broad array of population-health-science questions related to clinical medicine.

His research addresses the epidemiology of kidney diseases—particularly, disease management from chronic kidney dysfunction to end stage. He is the national study chair of the National Institutes of Health's Chronic Renal Insufficiency Cohort Study (CRIC)—NIH's largest-ever follow-up study of chronic kidney disease, its causes and consequences. Dr. Feldman also leads NIDDK's Hemodialysis Fistula Maturation Cohort Study and the coordinating center of its Chronic Kidney Disease Biomarkers Consortium. He directs several institutional training grants, which focus on the clinical epidemiology of kidney disease, cancer and neurological disorders.

Dr. Feldman is the editor-in-chief of the *American Journal of Kidney Diseases* and the past president of the American College of Epidemiology. His published scholarship—more than 200 research publications—has appeared in many leading biomedical journals. His work has also been recognized through membership in the American Society of Clinical Investigation, the Association of American Physicians, and the American Epidemiological Society.

He completed a residency in internal medicine at the University of California, Los Angeles, and a fellowship in nephrology at the University of Pennsylvania.

Erin Holve, PhD, MPH, MPP
Chief, Research Infrastructure

Erin Holve joins us from the District of Columbia (DC) Government where she served as the Director of the Department of Health Care Finance's Health Care Reform and Innovation Administration (HCRIA). In this capacity, she was responsible for the strategy and management of DC Medicaid's HCRIA and the development and implementation of new programs and innovations in healthcare delivery and program design. She also served as chair of the Mayor's Health Information Exchange Policy Board and led the District's investments in digital health.

Previously, Dr. Holve held roles at AcademyHealth, where she designed the first set of PCORnet® governance policies as a member of the PCORnet Coordinating Center Executive Committee, co-led the PCORnet Governance and Collaboration Task Force, directed the Agency for Healthcare Research and Quality Electronic Data Methods Forum, and was staff lead for the AcademyHealth Methods Council. Her prior experience includes roles with the Henry J. Kaiser Family Foundation; and the US Department of Health and Human Services.

Dr. Holve completed her PhD in health services research at Johns Hopkins University, Bloomberg School of Public Health in Baltimore and her Master of Public Health and Master of Public Policy at the University of California Berkeley and San Diego.

Update on Ad Hoc Committee and Work Group Activities

Update on Ad Hoc Committee and Work Group Activities Relating to the Board

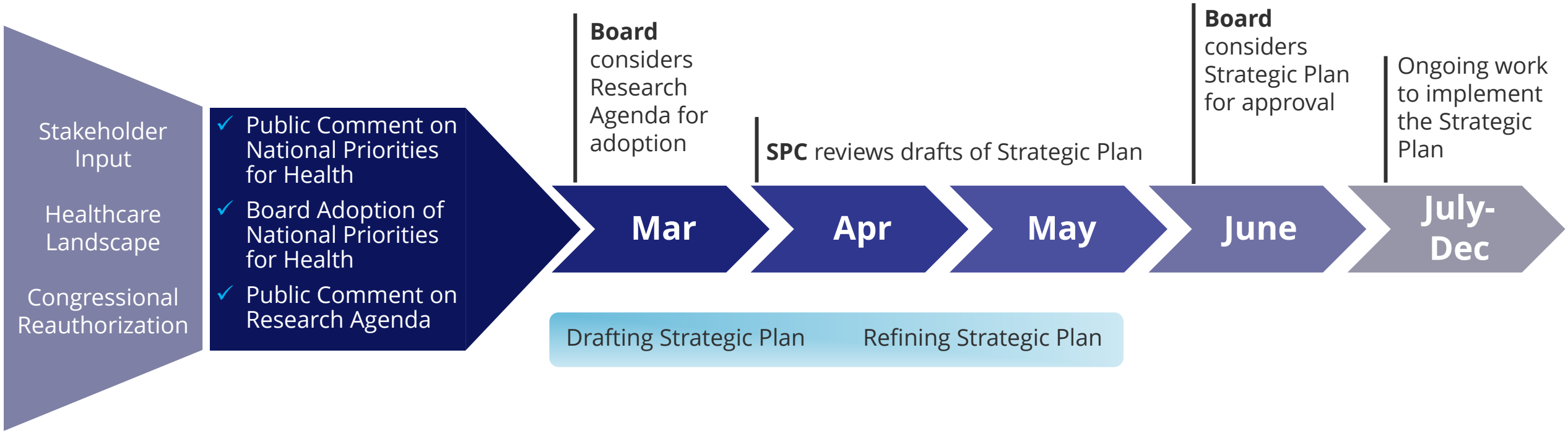
Committee/ Work Group	Charge	Composition	Timeline	Outcomes to Date
Strategic Planning Committee	Work on behalf of the Board to develop and oversee the conduct of a strategic planning process and the development of a strategic plan for approval by the Board	Members of PCORI Board of Governors, Methodology Committee and Staff Leadership	July 2021 - July 2022	National Priorities for Health, Research Agenda, and Strategic Plan
PCORnet® Priorities Work Group (Stage 2)	Build upon the Prioritizing Principles and propose strategies to inform the evaluation framework; guide Board considerations including future investments; and to advance the strategic plan	Members of PCORI Board of Governors	Stage 1: Nov 2020 - Jan 2021 Stage 2: Feb-Aug/Sept 2022	Prioritizing Principles for Funding Charge and Charter
Healthcare Cost and Value Work Group	Develop framework for activities to support PCORI's approach to collecting the full range of outcomes, informing the value conversation and supporting policy priorities	Members of PCORI Board of Governors, Methodology Committee and Staff Leadership	October 2021-December 2022	Framework for Activities and Landscape Review
Methodology Committee 2.0 Work Group	Envision the future focus of the MC as one that advances PCORI's evolving strategic directions, leverages MC members' expertise, and fulfills legislative intent for the MC's role	Members of PCORI Board of Governors, Methodology Committee and Staff Leadership	July 2021 – March 2022	Vision and Implementation approaches

Strategic Planning Committee Update

Scope of Strategic Planning Activities

- National Priorities for Health
- **Research Agenda**
- **Strategic priorities for PCORnet®**
- **Methodology Committee focus for PCORI's next phase**
- Commitment Planning and strategies to increase funding
- Scenario Planning based on the changes in landscape and environment
- Priorities from reauthorizing law
  - Maternal morbidity and mortality
  - Intellectual and developmental disabilities
  - **Full range of outcomes data**
- Monitoring progress and measuring success

Anticipated Timeline for Final Stage of Strategic Planning



PCORnet® Priorities Work Group (Stage 2)

Work Group (Stage 2) Membership

- Robert Zwolak, MD, PhD (Chair)
- Kara Ayers, PhD (Vice Chair)
- Kate Berry
- Alicia Fernandez, MD
- Christopher Friese, PhD, RN, AOCN, FAAN
- Russell Howerton, MD
- Michael Lauer, MD
- Barbara J. McNeil, MD, PhD
- Kathleen Troeger, MPH
- Daniel van Leeuwen, MPH, RN

PCORnet® Priorities Work Group (Stage 1)

Prioritizing Principles for PCORnet

- The PCORnet Priorities Working Group was established in 2020 to propose a set of **Prioritizing Principles for PCORnet** that would align closely with PCORI's overall strategic planning and be used by the PCORI Board and staff to guide decision-making about infrastructure funding for the next stages of PCORnet.
- The strategic prioritizing principles will be used to:
  - Inform PCORI's priorities and performance metrics for infrastructure funding of PCORnet
  - Inform PCORI's development of requirements and metrics for selection of PCORnet Phase 3 infrastructure awardees
  - Inform PCORI's development of metrics for performance monitoring for PCORnet Phase 3 awardee infrastructure funding contracts
  - Inform and provide a framework and metrics for decisions of the PCORI Board of Governors about future funding relating to potential expansion of PCORnet
- January 12, 2021, the Board approved the Prioritizing Principles for PCORnet

Prioritizing Principles for Infrastructure Funding

Patient-Centered

I. Strengthen the central role of patient and caregiver engagement to produce true partnership in the full research process

II. Attend to and strengthen the diversity of the patient populations served and the inclusion of care sites that serve underserved populations

National Scope

III. Recognize and strengthen the unique ability of PCORnet® to generate definitive evidence through studies of national scope; prioritize investments that strengthen that capability particularly for studies focused on PCORI *Strategic Research Priorities*

IV. Build on the unique capabilities of the PCORnet data structures, prioritizing investments that will align with the PCORI *Strategic Research* Priorities

Governance and Partnerships

V. Continue to develop the shared governance model which builds trust among participating networks and is coupled with close milestone-based monitoring of PCORI's infrastructure funds. As appropriate, encourage the development of mechanisms for cost recovery for infrastructure use related to projects supported by other funders

VI. Recognize the importance of optimum distribution of core coordinating functions, with the dual goals of optimizing effective network function and capitalizing on the distributed expertise and capabilities of this complex network

VII. Recognize, enable and promote the value of PCORnet to contribute to a learning health care system through effective partnerships with all stakeholders. Strengthen the educational resources needed to achieve this goal

VIII. Recognize, enable and optimize the value of PCORnet for building partnerships with Federal Health Agencies

Phase 3 of PCORnet®
Goals as stated in PFA

- **Increased utilization of PCORnet for definitive research studies that are national in scope (e.g., PCORnet studies, Federal partnerships)**
- Focus on optimizing infrastructure to:
  - Increase diversity of populations and care settings
  - Efficiently implement research studies addressing PCORI's Strategic Research Priorities
  - Strengthen patient and stakeholder engagement
  - Deliver high-fidelity, high integrity data

pcornet®
The National Patient-Centered Clinical Research Network

PCORnet® Priorities Work Group (Stage 2)

- The contributions of this Work Group will support the Board's governance role for PCORI's infrastructure investments relating to PCORnet by proposing strategies through which to assess the return on investment and to evaluate program accomplishments

- Topics to be discussed with regard to advancing PCORI priorities for the PCORnet program could include:
  - Research implementation and efficiency
  - Stakeholder engagement and partnership
  - Partnerships with Federal Health Agencies
  - Network accessibility

PCORnet® Priorities Work Group (Stage 2)
Goals

- Building upon the Prioritizing Principles for Infrastructure Funding Relating to PCORnet, propose strategies to inform the PCORnet evaluation framework and guide future Board consideration of:
  - PCORnet accomplishments attributable to PCORI infrastructure funding, and
  - Decisions about future PCORnet investments.
- Propose strategies to integrate and leverage PCORnet assets to advance PCORI's National Priorities for Health and Research Agenda.
- Provide information, reports, and recommendations to inform deliberations of Strategy committees, the Board Strategic Planning Committee, and the Board.

PCORnet® Priorities Work Group
Working Timeline

The Work Group will convene monthly from February to July 2022 to achieve its goals, with consideration of the resulting strategies by the Board in September 2022.

Feb 2022
Work Group Meeting:
Goal Setting

March - May 2022
Work Group Meetings:
Evaluation, Governance, Research Implementation, and Engagement, and Advancement of Strategic Plan Discussions

June - July 2022
Work Group Meetings:
Deliberations and Recommendations
Draft Strategies
Board Update in June

Sep 2022
Board Meeting:
Consideration of
Proposed Strategies

Healthcare Cost and Value Work Group

Work Group Membership

- Neeraj Arora, PhD
- Kristin Carman, PhD, MA
- Nakela Cook, MD, MPH
- Claudia Grossmann, PhD
- Mike Herndon, DO
- James Huffman
- Connie Hwang, MD, MPH
- Bill Lawrence, MD, MS
- Sharon Levine, MD
- Greg Martin
- Caitlin McCormick, JD
- Neil Powe, MD, MPH, MBA
- Eboni Price-Haywood, MD, MPH (Chair)
- Joanna Siegel, SM, ScD
- Ellen Sigal, PhD

Framework for Activities

PCORI Approach to Healthcare Cost and Value: Framework for Activities

Collection of the Full Range of Outcomes

PCORI can ensure the appropriate and relevant data are identified and collected in PCORI awards

- Support broadening of PCORI guidance to awardees through literature reviews, patient & stakeholder focus groups to clarify types of potential burdens, costs, and economic impacts to be included in PCORI-funded research, and data sources
- Develop guidance for capture of specific types of potential burdens or costs consistent with a patient-centered perspective, as a basis for PCORI guidance to awardees and the field

Informing the Value Conversation

PCORI can help advance patient-centered approaches to the value conversation by supporting understanding of stakeholder perspectives on what constitutes "patient-centered value"

- Conduct a landscape review of current stakeholder statements, perspectives, and frameworks around value
- Convene patient and stakeholder groups to identify the components or attributes necessary in "patient-centered value"

Supporting Policy Priorities

PCORI can consider undertaking specific activities that contribute to priority policy goals (i.e., generating evidence to inform healthcare value discussions)

- Consider placing an emphasis on research focused on emerging technologies/therapies
- Consider building upon evidence synthesis capabilities to provide more timely information

Upcoming Activities

Collection of the Full Range of Outcomes

- Clarify current guidance for awardees and identify gaps.
- Undertake background reviews to assess current practices and recommendations relevant to collection of cost and economic data, to support additional guidance.
- Convene stakeholders as needed to provide input on background review findings.

Informing the Value Conversation

- Advance the discussion on "patient-centered value" based on listening to and learning from stakeholders.
- Conduct landscape review of stakeholder statements, perspectives, and frameworks on value.
- Conduct key informant interviews and convenings with stakeholders to identify the necessary attributes or components to stakeholders of "patient-centered value".

Supporting Policy Priorities

- Determine scope of activities around emerging technologies and therapeutics.
- Draw on patient and stakeholder views of "patient-centered value" in efforts to disseminate evidence from PCORI portfolio.

Methodology Committee 2.0 Work Group

Methodology Committee 2.0 Work Group

- Rationale: Launch of PCORI's Strategic Planning Process and Shift of Appointments to PCORI Board of Governors
- Charge: Propose future vision and focus for the Methodology Committee as part of PCORI's strategic planning that leverages the unique expertise of the Committee
- Composition: Representation from PCORI Board of Governors, Methodology Committee, and Staff
- Timeline: July 2021 through March 2022

Relevant Near-Term Priorities for PCORI's Next Phase

Strategic Planning

- National priorities for health
- Research agenda
- Topic development

Focusing on Key Areas

- Maternal morbidity and mortality
- Intellectual and developmental disabilities

Implementing Provision on Cost/Economic Data

- Expanding PCORI's role in collecting and generating relevant evidence
- Focusing on a deliberate and transparent process for implementation

COVID-19 Portfolio Highlights

PCORI's Response to the COVID-19 Pandemic

Award Funding
(159 Awards; ~$94M)

- Enhancements & Adaptations
- Targeted Solicitations
- PCORnet HERO Program

Information Sharing

- COVID-19 Horizon Scanning
- Webinar Series

COVID-19 Related Efforts

Collaborating

- PCORnet CDC Partnership
- FDA Evidence Accelerator
- ACTIV-6

Embedding

- Broad PFA COVID-19 Special Areas of Emphasis

PCORI's COVID-19 Portfolio

158 Awards to date

122 Enhancements Awarded, *$34.8 million*

53
Engagement Award Enhancements
$7 million

13
D&I Enhancements
$5.8 million

47
Research Enhancements
$19.2 million

8
Methods Enhancements
$2.3 million

1
PCORnet® Enhancement
$0.5 million

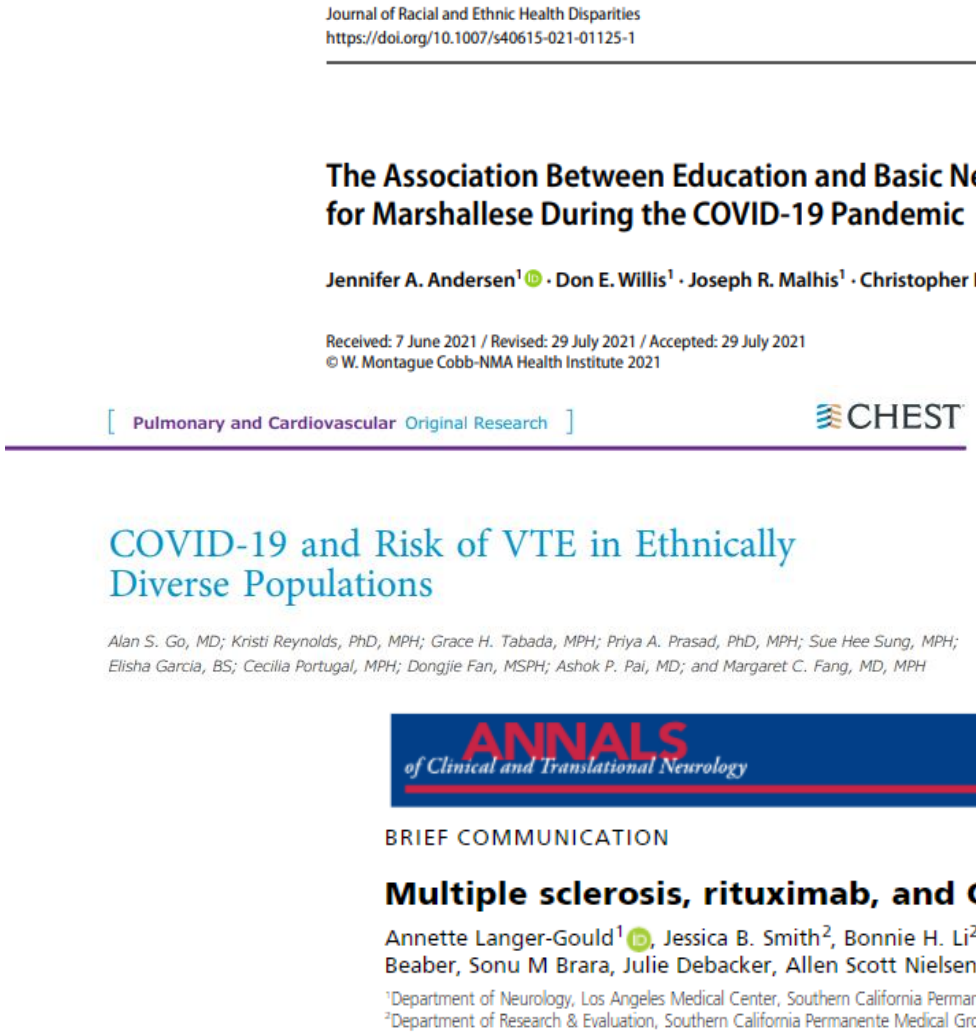
36 New Awards in Research & Engagement, *$44.5 million*

25
Engagement Award
Special Cycle
$3.7 million

11
Targeted Research Studies
(COVID-19 TPFAs)
$40.8 million

As of Aug 2021

COVID-19 Enhancement Publications



Journal of Racial and Ethnic Health Disparities
https://doi.org/10.1007/s40615-021-01125-1

Check for updates

The Association Between Education and Basic Needs Insecurity for Marshallese During the COVID-19 Pandemic

Jennifer A. Andersen[1] · Don E. Willis[1] · Joseph R. Malhis[1] · Christopher R. Long[1] · Pearl A. McElfish[1]

Received: 7 June 2021 / Revised: 29 July 2021 / Accepted: 29 July 2021
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[Pulmonary and Cardiovascular Original Research] CHEST

COVID-19 and Risk of VTE in Ethnically Diverse Populations

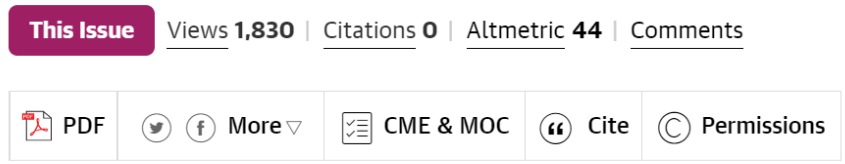
Alan S. Go, MD; Kristi Reynolds, PhD, MPH; Grace H. Tabada, MPH; Priya A. Prasad, PhD, MPH; Sue Hee Sung, MPH; Elisha Garcia, BS; Cecilia Portugal, MPH; Dongjie Fan, MSPH; Ashok P. Pai, MD; and Margaret C. Fang, MD, MPH

BRIEF COMMUNICATION

Multiple sclerosis, rituximab, and COVID-19

Annette Langer-Gould[1], Jessica B. Smith[2], Bonnie H. Li[2], the KPSC MS Specialist Group, Brandon E Beaber, Sonu M Brara, Julie Debacker, Allen Scott Nielsen, Samira Amirova & Oluwasheyi Ayeni

[1]Department of Neurology, Los Angeles Medical Center, Southern California Permanente Medical Group, Los Angeles, CA
[2]Department of Research & Evaluation, Southern California Permanente Medical Group, Pasadena, CA

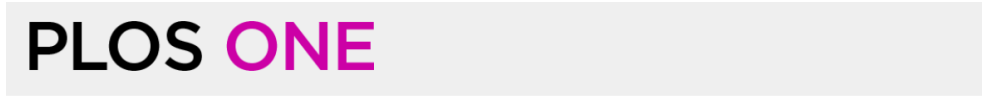


Research Letter | Substance Use and Addiction

July 14, 2021

Changes in Admissions to Specialty Addiction Treatment Facilities in California During the COVID-19 Pandemic

Tami L. Mark, PhD, MBA[1]; Brent Gibbons, PhD[1]; Alan Barnosky, MA[1]; et al



OPEN ACCESS PEER-REVIEWED
RESEARCH ARTICLE

Socioeconomic variation in characteristics, outcomes, and healthcare utilization of COVID-19 patients in New York City

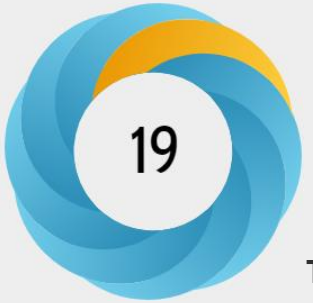
Yongkang Zhang, Dhruv Khullar, Fei Wang, Peter Steel, Yiyuan Wu, Duncan Orlander, Mark Weiner, Rainu Kaushal

Published: July 29, 2021 • https://doi.org/10.1371/journal.pone.0255171

Rituximab in Multiple Sclerosis: A Comparative Study on Effectiveness, Safety, and Patient-Reported Outcomes

PCORI-Funded Project	**Study Title:** Rituximab in Multiple Sclerosis: A Comparative Study on Effectiveness, Safety, and Patient-Reported Outcomes **Principal Investigator:** Fredrik Piehl, MD, PhD, Karolinska Institute (Sweden)
Enhancement-Related Publication	Langer-Gould A, Smith JB, Li BH; KPSC MS Specialist Group. **Multiple sclerosis, rituximab, and COVID-19**. Ann Clin Transl Neurol. 2021 Apr;8(4):938-943. doi: 10.1002/acn3.51342. Epub 2021 Mar 30. PMID: 33783140; PMCID: PMC8045943. Link to Publication.

Altmetric Score (Attention)



Summary of Project: Compares rituximab and other medicines for improving MS patients' quality of life, whether these medicines work differently for patients with different disease severity, and how safe or effective rituximab is for patients who have already tried another MS medicine.

Summary of Enhancement: Investigates the risks and benefits of disease-modifying therapies used in MS patients during COVID-19.

Findings from paper: MS patients treated with rituximab were more likely to be hospitalized from COVID-19, as compared to the non-MS population. The authors noted that MS patients on rituximab should be counselled to take extra precautions following infusions, and that using extended dosing intervals or lower doses could be considered.

> "Clinicians should consider extending dosing intervals of B-cell depleting treatments and using the lowest effective dose to minimize the risk of moderate-to-severe COVID-19.
>
> - *"Multiple sclerosis, rituximab, and COVID-19"* article

Supporting Families and Children with ASD/ADHD During the COVID-19 Pandemic

Enhancement Activities

- In response to COVID-19, many schools have stopped providing in-person special education services, leaving children with ASD and ADHD at risk for anxiety, changes in mood, and behavioral problems.
- This enhancement has adapted resources from UOT for parents and caregivers to use online at home, including a series of short videos in English and Spanish.

Early Results from Enhancement Project

- Stakeholder organizations distributed videos using a variety of channels.
- Videos disseminated across statewide education networks in Colorado and Virginia.
- Evaluation (98 caregiver respondents) found videos to be helpful. Also indicated:
  - Modest reductions in interference and frequency of child EF problems
  - Reductions in caregiver strain

Executive Function (EF) problems are common in children with autism spectrum disorder (ASD) or attention deficit/hyperactivity disorder (ADHD) and can lead to long-term problems in academics, independent living, and quality of life.

A PCORI-funded implementation project is expanding the use of a school-based program which has been shown to improve executive functioning and classroom behaviors for students with ASD or ADHD, called Unstuck and On Target (UOT).

Laura G. Anthony, PhD
University of Colorado Denver

Limited Competition Implementation Project
Awarded March 2020
Enhancement Awarded July 2020

Evaluating the Effectiveness and Implementation of an Automated Remote Monitoring Program for COVID-19 Patients

PCORI-Funded Project	**Study Title:** Evaluating the Effectiveness and Implementation of an Automated Remote Monitoring Program for COVID-19 Patients **Principal Investigator:** Mucio Delgado, MD, MS, University of Pennsylvania Perelman School of Medicine
Enhancement-Related Publication	Delgado MK, et. al. **Comparative Effectiveness of an Automated Text Messaging Service for Monitoring COVID-19 at Home.** Ann Intern Med. 2021 Nov 16. doi: 10.7326/M21-2019. Epub ahead of print. PMID: 34781715.. Link to Publication.

Altmetric Score (Attention)

Mentioned by

- **33** news outlets
- **4** blogs
- **288** tweeters
- **2** Facebook pages

Top 5% of Attention given the journal

Summary of Project: PCORI has identified COVID-19 as an important research topic. Patients, clinicians, and others want to learn: What are effective ways to prevent or reduce the impact of COVID-19, especially on vulnerable populations and the healthcare workforce? To help answer this question, PCORI launched an initiative in 2020 to Strengthen Understanding of COVID-19 Impact and Inform Healthcare Responses. The initiative funded this research project and others.

Summary of Enhancement: Although most patients with SARS-CoV-2 infection can be safely managed at home, the need for hospitalization can arise suddenly.

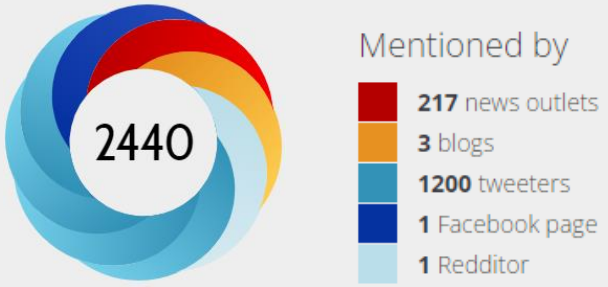
Findings from paper: Enrollment of outpatients with COVID-19 in an automated remote monitoring service was associated with reduced mortality, potentially explained by more frequent telemedicine encounters and more frequent and earlier presentation to the ED.

> “These results reveal a model for outpatient health system management of patients with COVID-19 and possibly other conditions where the early detection of clinical declines is critical.
>
> - *“Comparative Effectiveness of an Automated Text Messaging Service”* article

Racial and Ethnic Disparities in Receipt of Medications for Treatment of COVID-19-United States

CDC Funded Project utilizing PCORnet®	**Study Title:** Racial and Ethnic Disparities in Receipt of Medications for Treatment of COVID-19-United States, March 2020-August 2021 **Principal Investigator:** Jennifer L. Wiltz, MD, Centers for Disease Control (USA)
Related Publication	Wiltz, Jennifer L., MD **Racial and Ethnic Disparities in Receipt of Medications for Treatment of COVID-19-United States, March 2020-August 2021** Centers for Disease Control, Morbidity and Mortality Weekly Report (MMWR). Weekly / January 21, 2022 / 71(3);96–102 Link to Publication.

Altmetric Score (Attention)



Summary of Project: Analysis of data from 41 health care systems participating in the PCORnet, the National Patient-Centered Clinical Research Network suggested lower use of monoclonal antibody treatment among Black, Asian, and Other race and Hispanic patients with positive SARS-CoV-2 test results, relative to White and non-Hispanic patients. Racial and ethnic differences were smaller for inpatient administration of remdesivir and dexamethasone

Findings from paper: Equitable receipt of COVID-19 treatments by race and ethnicity along with vaccines and other prevention practices are essential to reduce inequities in severe COVID-19–associated illness and death.

> Efforts to reduce racial and ethnic disparities with equitable outpatient COVID-19 treatment access, practices, and supportive systems are urgently needed.
>
> - *"Racial and Ethnic Disparities in Receipt of Medications for Treatment"* article

PCORI-Funded HERO Research Program

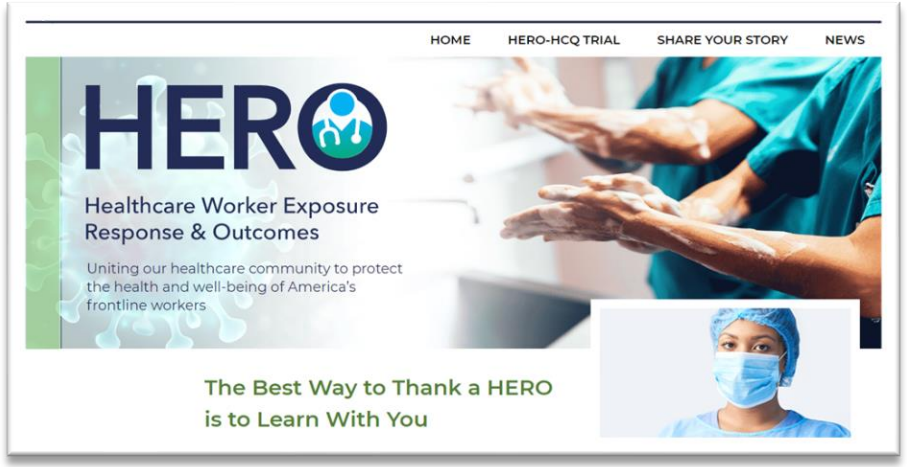
Principal Investigators: Adrian Hernandez, MD, MHS; Emily O'Brien, PhD (HERO registry); Susanna Naggie, MD (HERO-HCQ trial)
Awardee Institution: Duke University

HERO Registry

- Create community of healthcare workers (HCWs) at risk of COVID-19 infection
- Identify HCWs interested in engaging in clinical trials related to COVID-19
- Create dataset of basic clinical and environmental COVID-19 risk factors and clinical and emotional outcomes for analysis

HERO-HCQ Trial

- Randomized clinical trial to evaluate efficacy of hydroxychloroquine (HCQ) to prevent COVID-19 clinical infection in at-risk HCWs



www.heroesresearch.org

HERO Research Program

Clinical Trial

- Funded April 2020
- Leveraged PCORnet® infrastructure
  - 1,363 HERO members randomized
  - 30 days to site activation
  - 10 days to first patient enrolled
- Challenges related to enrollment & emerging evidence
- Results: HCQ appeared to be safe without significant clinical benefits in a group of HCWs
- The study was underpowered to determine whether HCQ can prevent COVID-19 infection in HCWs
- Results published to medRxiv for rapid dissemination
- Meta-analysis to be published with other HCQ pre-exposure prophylaxis studies

HERO Healthcare Worker Exposure Response & Outcomes

medRxiv THE PREPRINT SERVER FOR HEALTH SCIENCES

CSH Cold Spring Harbor Laboratory BMJ Yale

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Hydroxychloroquine for pre-exposure prophylaxis of COVID-19 in health care workers: a randomized, multicenter, placebo-controlled trial (HERO-HCQ)

Susanna Naggie, Aaron Milstone, Mario Castro, Sean P. Collins, Lakshmi Seetha, Deverick J. Anderson, Lizbeth Cahuayme-Zuniga, Kisha Batey Turner, Lauren W. Cohen, Elizabeth Fraulo, Anne Friedland, Jyotsna Garg, Anoop George, Hillary Mulder, Rachel E. Olson, Emily C. O'Brien, Russell L. Rothman, Elizabeth Shenkman, Jack Shostak, Christopher W. Woods, Kevin J. Anstrom, Adrian F. Hernandez

doi: https://doi.org/10.1101/2021.08.19.21262275

This article is a preprint and has not been peer-reviewed [what does this mean?]. It reports new medical research that has yet to be evaluated and so should *not* be used to guide clinical practice.

Hydroxychloroquine for pre-exposure prophylaxis of COVID-19 in health care workers: a randomized, multicenter, placebo-controlled trial (HERO-HCQ) | medRxiv

HERO Research Program

Registry of Healthcare Workers (HCW)

- Over 55,000 participants enrolled as of January 2022
  - Addition of family members and surrounding community
- Intake Survey
  - Basic Information (e.g., demographics, employment characteristics, COVID-19 exposure/diagnosis, vaccination status)
- Monthly Hot Topic polls to gauge the health care workers' perspective on evolving issues
  - Vaccine confidence
  - Financial burden
  - HCW Burnout
  - Future survey planned on post-acute sequelae of COVID-19
- HERO Together
  - Pfizer-funded study on vaccine side effects
  - Registry used to recruit over 20K participants

Published Results

Impact of the Early Phase of the COVID-19 Pandemic on US Healthcare Workers: Results from the HERO Registry

Journal of General Internal Medicine 2021

➔ Informed Special Area of Interest in Broad PCORI Funding Announcement

Program Funding Update

March 2020 Board approved up to $50M for HERO Research Program

March 2020 PCORI approved an investment of up to $40.8 million in the HERO Research Program

Contracts are milestone driven and cost reimbursable

Current cumulative expenses for the registry and trial are $13.9 million

HERO Research Program Publications

HERO-HCQ

Hydroxychloroquine for Pre-exposure Prophylaxis of COVID-19 in Health Care Workers: A Randomized, Multicenter, Placebo-Controlled Trial
Pre-print on MedRXiv 2021

Other areas of focus:

- Racial differences in HCW experiences and outcomes
- HCW burnout
- Meta-analysis of HCQ PrEP trials
- Stakeholder engagement
- Nursing home HCWs

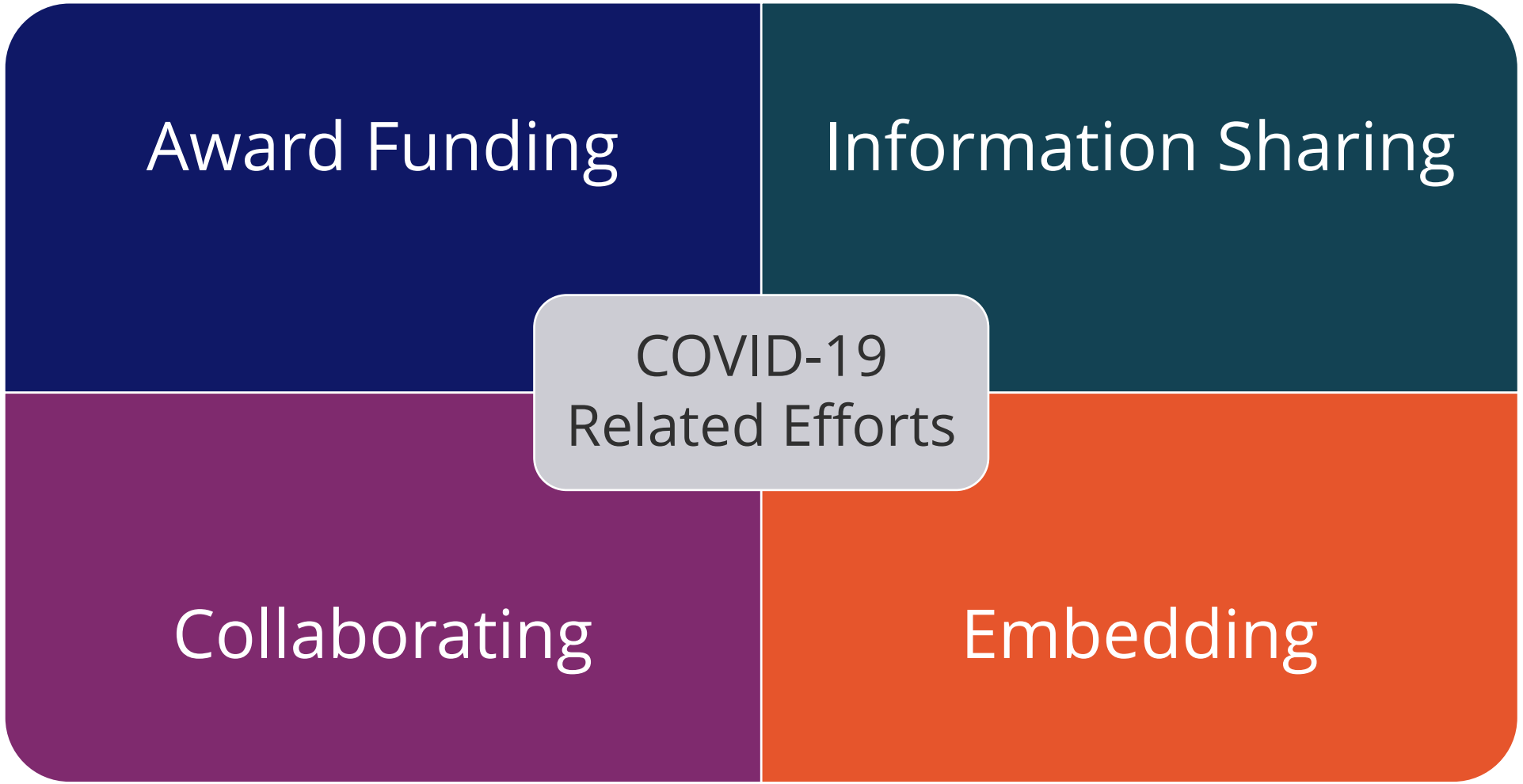
HERO Research Platform Design

Design of the Healthcare Worker Exposure Response and Outcomes (HERO) research platform
Contemporary Clinical Trials 2021

Early Phase Impacts

Impact of the Early Phase of the COVID-19 Pandemic on US Healthcare Workers: Results from the HERO Registry
Journal of General Internal Medicine 2021

PCORI's COVID-19 Response Summary



Discussion

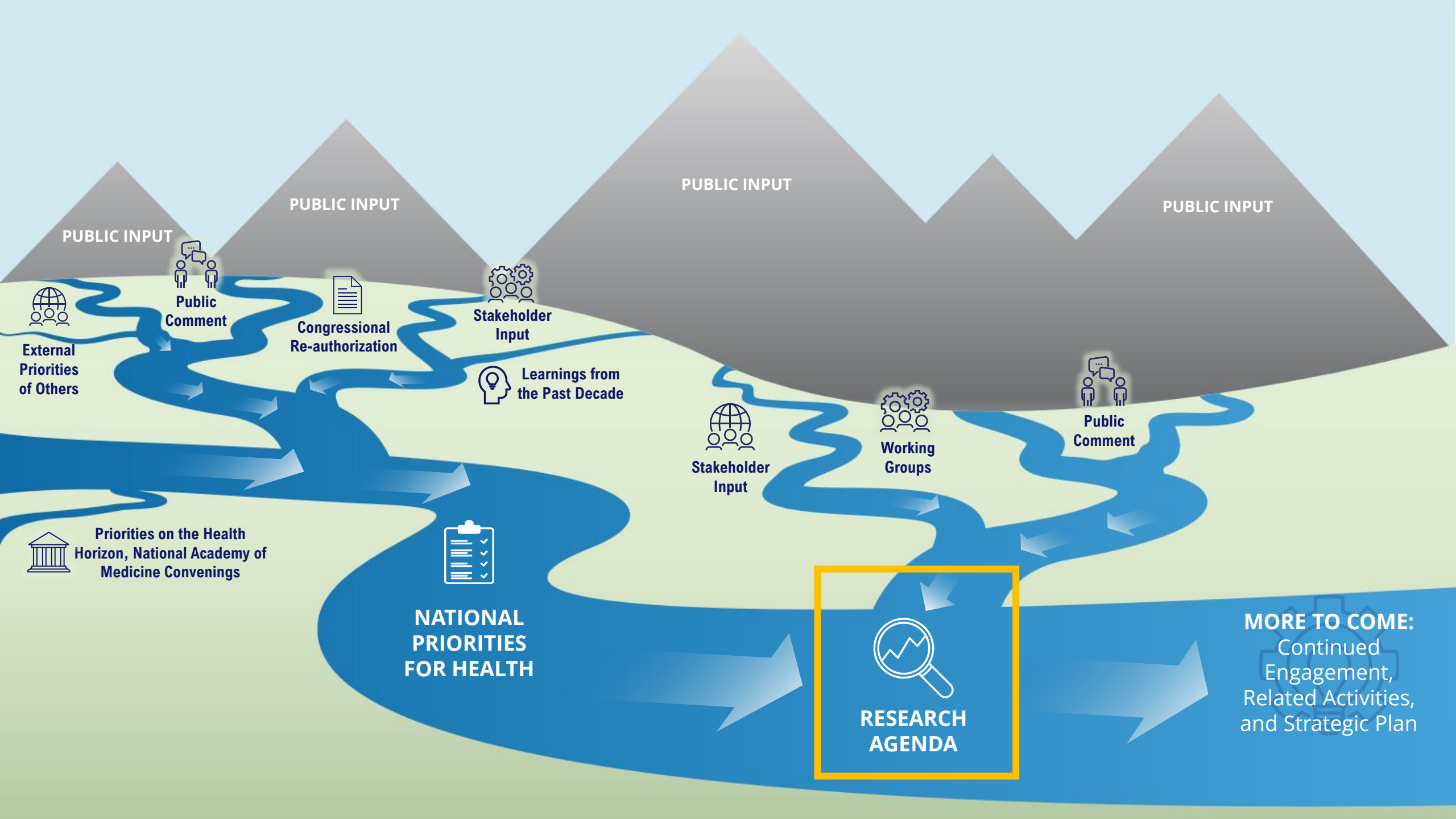
Consider for Adoption: Research Agenda

Nakela L. Cook, MD, MPH
Executive Director

Sharon Levine, MD
Co-Chair, Strategic Planning Committee

Strategic Planning Committee Members

- Steve Clauser, PhD, MPA
- Nakela Cook, MD, MPH (Co-Chair)
- Jennifer DeVoe, MD, MPhil, MCR, DPhil
- Alicia Fernandez, MD
- Christine Goertz, DC, PhD
- Russell Howerton, MD
- Connie Hwang, MD, MPH
- Sharon Levine, MD (Co-Chair)
- Laura Lyman Rodriguez, PhD
- Greg Martin
- Barbara McNeil, MD, PhD
- Robin Newhouse, PhD, RN
- Michele Orza, ScD
- Daniel van Leeuwen, MPH, RN
- Robert Zwolak, MD, PhD

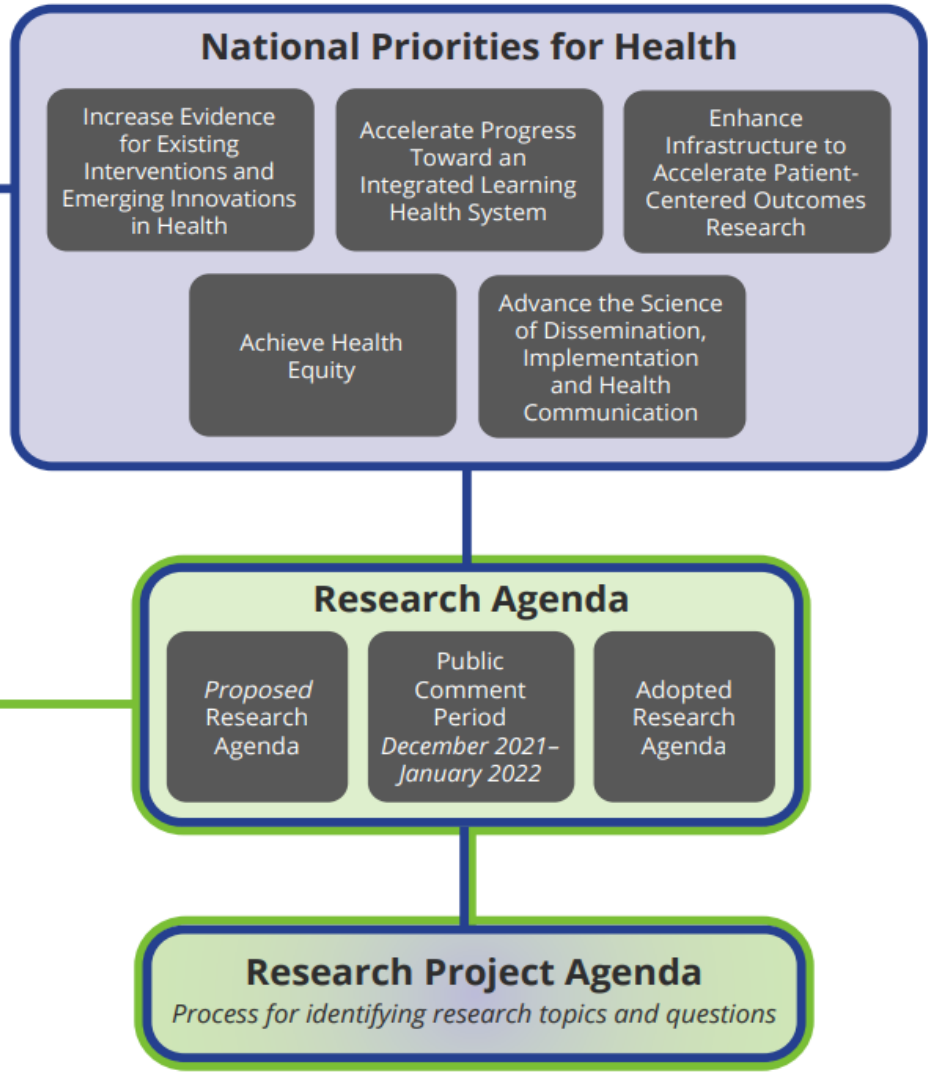

PUBLIC INPUT
PUBLIC INPUT
PUBLIC INPUT
PUBLIC INPUT
Public Comment
External Priorities of Others
Congressional Re-authorization
Stakeholder Input
Learnings from the Past Decade
Stakeholder Input
Working Groups
Public Comment
Priorities on the Health Horizon, National Academy of Medicine Convenings
NATIONAL PRIORITIES FOR HEALTH
RESEARCH AGENDA
MORE TO COME:
Continued Engagement, Related Activities, and Strategic Plan

Stakeholder and Public Input Inform Work

Example Inputs

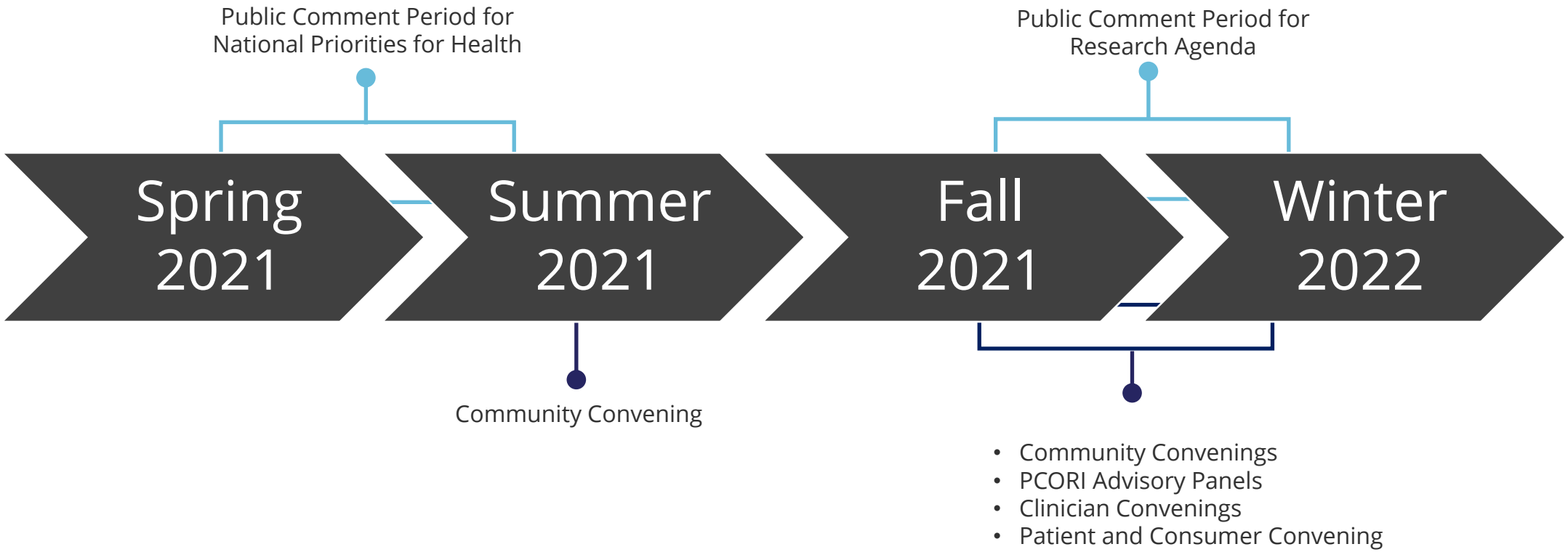
- Stakeholder outreach (e.g., patient/advocacy groups, Congress, clinician forums)
- National Academy of Medicine Priorities on the Health Horizon series
- PCORI advisory panels
- PCORI Annual Meeting
- Public Comment period

- Stakeholder outreach (e.g., patient/advocacy groups)
- Community convenings
- PCORI advisory panels



Input Gathering Process Reminder

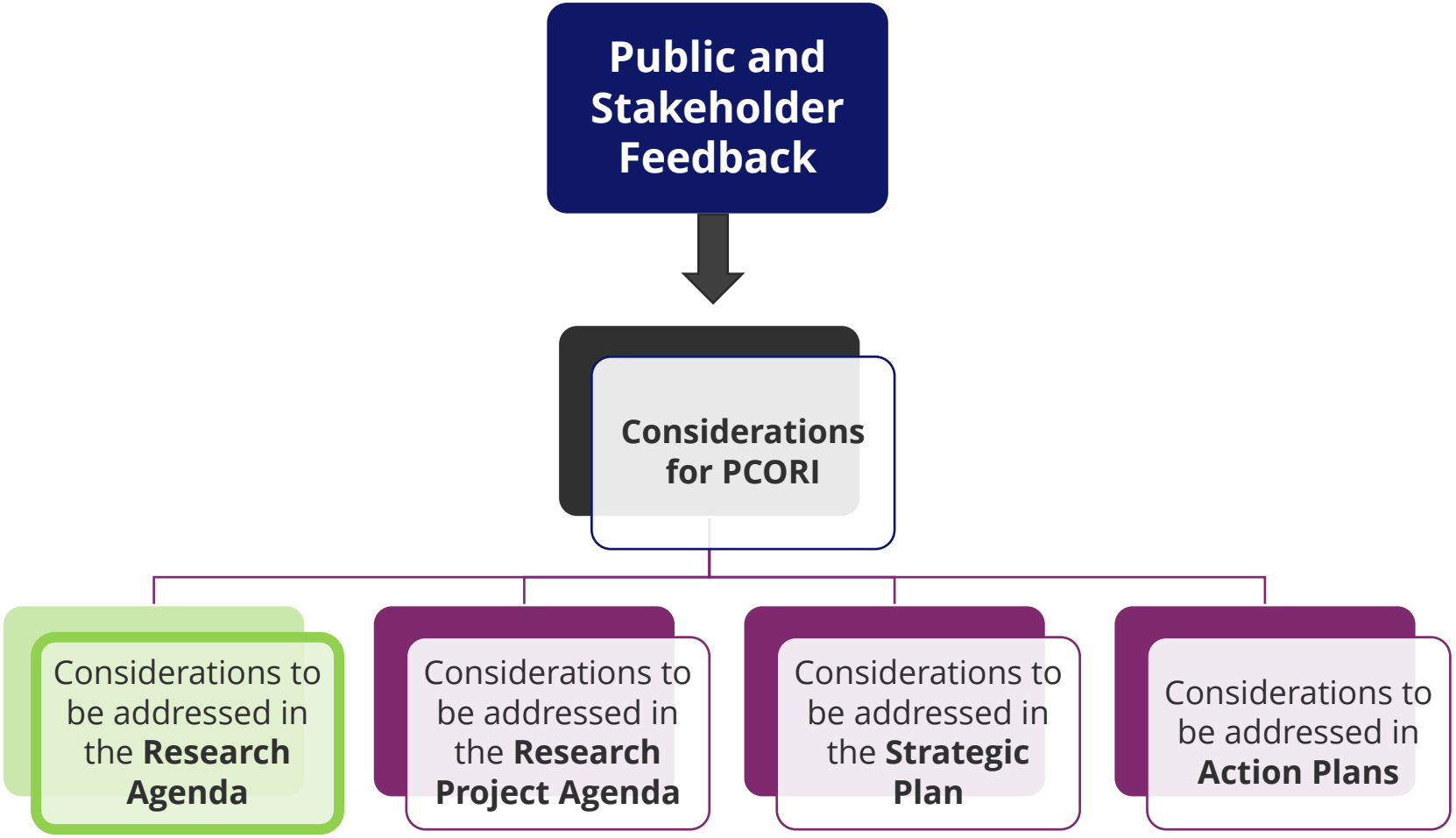
Throughout strategic planning, PCORI received input from a range of stakeholders that informed the Research Agenda in addition to public comment and hearing feedback during focused discussion, surveys, and other input opportunities with stakeholders and the Board.



Reminder: Proposed Research Agenda Posted for Public Comment

- Fund research that fills patient- and stakeholder-prioritized evidence gaps and is representative of diverse patient populations and settings
- Fund research that aims to achieve health equity and eliminate health and healthcare disparities
- Fund research that builds the evidence base for emerging interventions by leveraging the full range of data resources and partnerships
- Fund research that examines the diverse burdens and clinical and economic impacts important to patients and other stakeholders
- Fund research that focuses on health promotion and illness prevention by addressing health drivers that occur where people live, work, learn, and play
- Fund research that integrates implementation science and that advances approaches for communicating evidence so the public can access, understand, and act on research findings

Feedback Relevant to Multiple Areas



What We Heard

- **Takeaway 1**: The Research Agenda has broad support that can be further enhanced with minor clarifications or additions.
- **Takeaway 2**: Stakeholders are energized by the Research Agenda's focus on health equity and eager for PCORI to address systemic issues that perpetuate disparities.
- **Takeaway 3**: Embracing alternatives to traditional research teams, methodologies, and contexts could improve equity and representation in research.
- **Takeaway 4**: Technology and data sharing innovations are central to the future of CER.
- **Takeaway 5**: A deficit of trust in health information poses a significant barrier to improving health outcomes.

Insights from Feedback that Inform Revisions to Research Agenda

Insight from Stakeholders: The Research Agenda could be more explicit about the need to impact structural racism and its effects on health.

Insight from Stakeholders: The Research Agenda statements could be more inclusive of a broad range of historically excluded populations such as rare disease communities, people with disabilities, and those who are homebound.

Considerations to be addressed in the **Research Agenda**

Suggested Revisions for Research Agenda

- Fund research that fills patient- and stakeholder-prioritized evidence gaps and is representative and inclusive of diverse and underrepresented patient populations and settings

Clarifies broad representativeness

- Fund research that ~~aims to achieve~~ advances the achievement of health equity and elimination of disparities ~~eliminate health and healthcare disparities~~ with an emphasis on overcoming the effects on health and healthcare outcomes of racism, discrimination, and bias

Underscores counteracting impact of racism, discrimination, and bias on health

- Fund research that builds the evidence base for emerging interventions by leveraging the full range of data resources and partnerships
- Fund research that examines the diverse burdens and clinical and economic impacts important to patients and other stakeholders
- Fund research that focuses on health promotion and illness prevention by addressing health drivers that occur where people live, work, learn, and play
- Fund research that integrates implementation science and that advances approaches for communicating evidence so the public can access, understand, and act on research findings

Takeaway 1 and Where We Will Respond to Feedback

The Research Agenda has broad support that can be further enhanced with minor clarifications or additions

Insights from Stakeholders

- The Research Agenda could be more explicit about the need to impact structural racism and its effects on health.
- The Research Agenda statements could be more inclusive of a broad range of historically excluded populations such as rare disease communities, people with disabilities, and those who are homebound.
- Concrete examples could be helpful for clarifying the relationship between underlying drivers of health disparities and funding goals.
- To support high quality research, PCORI's Research Agenda needs to prioritize patient perspectives, especially that of populations underrepresented in research.
- Include specific mention of the role of health systems and public policy in achieving the goals stated in the Research Agenda

Considerations to be addressed in

- Research Agenda
- Research Project Agenda
- Strategic Plan
- Action Plans

Takeaway 2 and Where We Will Respond to Feedback

Stakeholders are energized by the Research Agenda's focus on health equity and eager for PCORI to address systemic issues that perpetuate disparities.

Insights from Stakeholders

- PCORI has an opportunity to champion health equity issues and address perpetual disparities that were increasingly exposed during the pandemic.
- Barriers to care, rooted in social, racial, and economic inequities created by policy decisions, are drivers of health inequities and stress the need for research that examines how these factors and the social determinants of health lead to different health outcomes.
- There were questions raised about whether the broad scope of health equity is achievable with available resources and how macro-level concepts will be prioritized within each category of the Research Agenda.
- Study how implicit bias and discrimination limit the diversity of the health care workforce and negatively impacts patient outcomes.
- Fund research on the influences of different payment models on health disparities in clinical outcomes that include partnerships with payers and policymakers.
- Prioritize research to improve upon the widely recognized, persistent health disparities in maternal morbidity and mortality.

Considerations to be addressed in

- **Research Project Agenda**
- **Strategic Plan**
- **Action Plans**

Takeaway 3 and Where We Will Respond to Feedback

Embracing alternatives to traditional research teams, methodologies, and contexts could improve equity and representation in research.

Insights from Stakeholders

- Funding diverse research teams and participant recruitment efforts are needed to fill evidence gaps for populations that have been historically underrepresented and excluded in research.
- Community-based participatory research approaches, in which community organizations have sufficient authority and resources to be full partners in the research process, can diversify research participation and expand the relevance of research results.
- To build evidence that addresses gaps in data for historically excluded groups, researchers need the flexibility to design and conduct inclusive research using qualitative methods, natural histories, and other approaches.
- Academic researchers and community-based investigators need assistance from PCORI to support the development of learning health systems.
- Standardized metrics are needed to measure the clinical and nonclinical outcomes that are most important to patients.
- Explore and validate new measurement approaches to examine how psychosocial factors and systemic racism contribute to specific health outcomes.

Considerations to be addressed in

Research Project Agenda

Action Plans

Takeaway 4 and Where We Will Respond to Feedback

Technology and data sharing innovations are central to the future of CER.

Insights from Stakeholders

- Evaluate the efficacy and equity of telemedicine visits for different populations.
- Data interoperability across the health sector has significant potential to improve patient care and advance research.
- Building the data infrastructure necessary for a true learning health system will require significant resources.
- Cultural barriers driven by competing organizational goals and rewards pose barriers to data sharing.
- It is important to incentivize collaborative partnerships that promote data sharing between organizations.

Considerations to be addressed in

- **Research Project Agenda**
- **Action Plans**

Takeaway 5 and Where We Will Respond to Feedback

A deficit of trust in health information poses a significant barrier to improving health outcomes.

Insights from Stakeholders

- Effective, timely communication and dissemination of credible information is a critical component in improving both access to care and quality of care.
- Evidence-based practice is needed to select messages and messengers, and to disseminate strategies tailored to audiences.
- PCORI could leverage the many benefits of community-based participatory research to facilitate communication of research findings.
- PCORI could consider the impact of historical traumas, health system inequities, the inherent challenges of conveying risk information, and the spread of misinformation over digital channels to address mistrust of health information.
- Effective implementation science will require new standards and procedures as well as training for researchers related to the field of implementation science.

Considerations to be addressed in

- **Research Project Agenda**
- **Strategic Plan**
- **Action Plans**

Proposed Research Agenda for Board Consideration for Adoption

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
- Integrates implementation science and advances approaches for communicating evidence so the public can access, understand, and act on research findings

Board Vote

Call for a Motion to:	• **Adopt** the proposed Research Agenda
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

Methodology Committee Framework: MC 2.0 Work Group Update and Governance Committee Recommendation on Conflict of Interest and Governance Framework

Nakela L. Cook, MD, MPH
Executive Director

Sharon Levine, MD
Chair, Governance Committee

Mary Hennessey, JD
General Counsel

Methodology Committee Framework:
MC 2.0 Work Group Update

Nakela L. Cook, MD, MPH

Executive Director

Methodology Committee (MC) 2.0 Work Group
Background and Rationale

- **Advance PCORI's Strategic Planning**
  - Propose future vision and focus for the MC as part of PCORI's strategic planning
- **Leverage expertise of the MC**
  - Identify intersections with PCORI's priorities for the future
- **Enhance relationships with Board, Staff, other Committees/Panels**
  - Increase opportunities for exchange with the Board on relevant items
  - Identify intersections with work of other committees/panels

Purpose and Outcomes

- **Purpose:** Envision the future focus of the MC as one that advances PCORI's evolving strategic directions, leverages MC members' expertise, and fulfills legislative intent for the MC's role
- **Outcomes:**
  - **Role & Responsibilities**
  - **Relationships with**
    - Staff
    - Board
    - Board-related Committees
    - Clinical Trials Advisory Panel
    - Methods Community
  - **Composition**

Potential Areas of Future Focus that Informed Work Group Discussion

- **Methodology standards**
- **Methodological consultations**
- **Methods components of National Priorities for Health, Research Agenda, & Research Project Agenda**
- **Methodological issues for priority topics**
  - Maternal Morbidity and Mortality
  - Intellectual and Developmental Disabilities
  - Full Range of Outcomes Data
- **Implications of current methods portfolio**
- **Future needs to enable MC success**

Work Group Members

- Naomi Aronson, PhD
- Kara Ayers, PhD
- Arlene Bierman, MD, MS
- Nakela Cook, MD, MPH (Chair)
- Alicia Fernandez, MD
- Christine Goertz, DC, PhD
- Steve Goodman, MD, MHS, PhD
- Mary Hennessey, JD
- Stanley Ip, MD
- Sharon Levine, MD
- Robin Newhouse, PhD, RN
- Eboni Price-Haywood, MD, MPH
- James Schuster, MD, MBA
- Jean Slutsky, PA, MSPH
- Robert Zwolak, MD, PhD

Members include representation from PCORI Board of Governors, MC, and Staff

Future State Vision
Roles & Functions

Future State Vision
Roles and Functions

Development and update of standards

- Developing PCORI prioritized, inclusive, high-quality standards as mandated by PCORI's authorizing law for CER
- Utilizing flexible and transparent approaches

Innovation and best practices

- Facilitating the utilization of standards and cutting-edge methods for CER through guidance for the research community
- Convening and advancing methods for the use of real-world evidence in new areas of PCORI focus (e.g., science of engagement in CER)

Opportunities on the horizon

- Serving as a resource to PCORI on methodological approaches related to the new National Priorities for Health and Research Agenda (e.g., methods related to implementation science) as well as priority areas including those in PCORI's reauthorizing law

Future State Vision
Roles and Functions

Expertise and diversity of perspectives

- Providing diverse perspectives, intellectual talent, and methodological expertise that is leveraged toward achieving PCORI's strategic directions (e.g., expertise in the field of equity)

Engagement with the Methodology Community

- Engaging with the research community about rigorous methodological approaches for the conduct of patient-centered CER through convenings and meaningful exchanges with the broader community of methodologists

Relationships with other PCORI bodies & supporting integrity

- Revitalizing and fortifying relationships with other PCORI bodies that strengthen outcomes related to PCORI's strategic directions, including PCORI Leadership and Board of Governors and PCORI Advisory Panels

Key Discussions to Advance Implementation of the MC Future Vision

Enhancing PCORI Staff & MC Partnership

- Increase infrastructure support and capacity of PCORI staff to partner with the MC to increase their focus on their intellectual contributions
- Enhance the PCORI staff/MC partnership through multi-level connections at PCORI
- Connect with senior leadership at PCORI to enhance MC linkage to PCORI strategic directions
- Enable implementation MC activities with ongoing staff support

Advancing Future State Vision of MC:
Conflict of Interest Framework

- Supported all future MC members foregoing eligibility to apply for PCORI funding to enable MC to advance the MC's future state vision --- a vision that enhances the MC's role as a resource to Board and staff and closely aligns the MC's work with PCORI's funded portfolio

- Recognized the benefit of all MC members being able to contribute and advance the MC's work and to advise on funding priorities and plans

- Concurred that a shorter term (e.g., 4 years) may be a more acceptable time period for interested candidates to forego eligibility for PCORI funding rather than a 6-year term

Discussion

- **Does the future-state vision resonate with you?**
  - Development and Update of Standards
  - Innovation and Best Practices
  - Opportunities on the Horizon
  - Expertise and Diversity of Perspectives
  - Engagement with the Methodology Community
  - Relationship with Other PCORI Bodies and Supporting Integrity

- **Are there implementation ideas to consider as we refine the areas of focus within the domains of the future-state vision?**

Methodology Committee Framework:

Governance Committee Recommendation on Conflict of Interest and Governance Framework

Sharon Levine, MD

Chair, Governance Committee

Mary Hennessey, JD

General Counsel

Governance Committee Recommendation
Revised Methodology Committee Conflict of Interest and Governance Framework

- The Revised Conflict of Interest and Governance Framework for the Methodology Committee (MC) as Recommended by the Governance Committee:
  - 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 4-year staggered term structure (with appointments every two years)
  - 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 MC, requirements of the authorizing law, or needs of PCORI. No MC member can be appointed to serve more than two full consecutive 4-year terms

Methodology Committee Governance Framework
Initial Framework Following Reauthorizing Law

- Due to reauthorizing law, authority to appoint MC members shifted from the Government Accountability Office to PCORI Board of Governors
- Soon after reauthorizing law, at recommendation of Governance Committee, the Board approved a revised MC governance framework:
  - 6-year staggered term structure (with appointments every 2 years)
  - Appointment to second 6-year term if necessary to fulfill MC functions, authorizing law, PCORI needs; no more than two consecutive 6-year terms
- At the time, Governance Committee discussed MC conflict of interest framework but did not advance specific recommendation, recognizing that additional work would be undertaken relating to PCORI priorities and MC role, which would inform discussion

Methodology Committee
Historic Conflict of Interest Framework

- MC composed of members who choose to maintain eligibility to apply for PCORI funding and members who have chosen to forego eligibility to apply for PCORI funding
- MC members who maintain their eligibility to apply for PCORI funding must be firewalled from receiving advance or confidential information about PCORI funding priorities, research agenda, funding announcements, etc. and cannot serve as MC leadership, on committees or workgroups, or advise on advance internal information
- MC members who have foregone eligibility to apply for PCORI funding can serve as MC Chair or Vice Chair, serve on strategy committees and workgroups, attend closed meetings, and have access to and advise on advance internal information about funding priorities, research agenda, funding announcements, etc.

Governance Committee

Value of Expertise and Contributions of Methodology Committee

- The Governance Committee recognizes the value of the MC's expertise and its contributions in advancing PCORI's strategic direction, including advising on funding priorities, research agenda, and funding announcements
- PCORI is strengthened and benefits from having all MC members available to advise on confidential funding priorities and announcements and serve on strategy committees and workgroups
- Having consulted with the MC and the MC 2.0 Workgroup, the Governance Committee advises that the Board adopt a revised conflict of interest framework under which all future MC members forego eligibility to apply for PCORI funding
- Given the obligation to forego eligibility to apply for PCORI funding, the MC term should shift from a 6-year term to a 4-year term

Governance Committee Recommendation

Revised Methodology Committee Conflict of Interest and Governance Framework

- The Revised Conflict of Interest and Governance Framework for the Methodology Committee as Recommended by the Governance Committee:
  - 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 4-year staggered term structure (with appointments every two years)
  - 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 MC, requirements of the authorizing law, or needs of PCORI. No MC member can be appointed to serve more than two full consecutive 4-year terms

Board Vote

Call for a Motion to:	• **Approve** the Revised Conflict of Interest and Governance Framework for the Methodology Committee as recommended by the Governance Committee
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

BREAK

We will return at 11:30 AM ET

Join the conversation on Twitter via @PCORI

Overview of Award Slates to be Considered for Approval Today

Nakela L. Cook, MD, MPH

Executive Director

Award Slates from Cycle 2 2021 Under Consideration for Approval Today

PFA Type	Amount	PFA
D&I	$6.4M	Limited Competition Dissemination & Implementation (LC)
	$2.5M	Implementation of Findings from PCORI's Major Research Investments (IMRI)
Research	$18.9M	Pragmatic Clinical Studies (PCS)
	$20.4M	Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities (MMM)
	$19.5M	Nonsurgical Options for Women with Urinary Incontinence (UI)
	$12.7M	Broad
Total	**$80.4M**	

Note: All requested budgets are subject to programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Cycle 2 2021 in Context
Dissemination & Implementation (D&I) Award Slates

All D&I PFAs	Historical Average	Cycle 1 2021		**Cycle 2 2021**		Cycle 3 2021	
LOIs Submitted	10	6		**12**		7	
LOIs Invited (% of LOIs Submitted)	65%	4	67%	**6**	**50%**	7	100%
Applications Submitted (% of LOIs invited)	77%	3	75%	**5**	**83%**	4	57%
Applications Proposed on Funding Slate (% of Applications Submitted)	38%	1	33%	**3**	**60%**		

Cycle 2 2021 in Context
Pragmatic Clinical Studies (PCS) Award Slates

PCS PFAs	Historical Average	Cycle 1 2021		Cycle 2 2021	
LOIs Submitted	56	36		**23**	
LOIs Invited (% of LOIs Submitted)	43%	19	53%	**9**	**39%**
Applications Submitted (% of LOIs Invited)	75%	16	84%	**7**	**78%**
Applications Proposed on Funding Slate (% of Applications Submitted)	22%	3	19%	**2**	**29%**

Cycle 2 2021 in Context
Targeted Award Slates

Cycle 2 2021 Targeted PFAs	IDD		MMM		UI	
LOIs Submitted	9		**26**		**14**	
LOIs Invited (% of LOIs Submitted)	2	22%	**17**	**65%**	**10**	**71%**
Applications Submitted (% of LOIs Invited)	1	50%	**12**	**71%**	**10**	**100%**
Applications Proposed on Funding Slate (% of Applications Submitted)	0	0%	**1**	**8%**	**3**	**30%**

Cycle 2 2021 in Context
Broad Award Slates

Broad PFAs	Historical Average	Cycle 1 2021		**Cycle 2 2021**		Cycle 3 2021	
LOIs Submitted	184	141		**82**		149	
LOIs Invited (% of LOIs Submitted)	51%	87	62%	**40**	**49%**	89	60%
Applications Submitted (% of LOIs invited)	75%	56	64%	**35**	**88%**	65	73%
Applications Proposed on Funding Slate (% of Applications Submitted)	15%	6	11%	**7**	**20%**	TBD	TBD

Today's Proposed Commitments in Context of FY2022 Commitment Plan

Cycle 2 2021 Slates Proposed for Funding Today	Commitment Target in FY2022	Cumulative FY2022 Commitments with Today's Slates
D & I • Limited Competition • Implementation	$40M For all D&I Awards	$9M
Research • PCS • MMM • UI • Broad	$500M For all Research Awards	$121M

Discussion

Cycle 2 2021
Dissemination and Implementation Award Slates

Michael Herndon, DO

Chair, Engagement, Dissemination, and Implementation Committee

Joanna Siegel, SM, ScD

Director, Dissemination and Implementation Program

Cycle 2 2021 Dissemination & Implementation (D&I) Award Slates

Limited Competition Dissemination & Implementation PFA Slate	
Implementing the Infusion Clinic Model in Sickle Cell Disease	
Implementing Outcomes-Based Matching of Patients to Mental Health Care Therapists' Strengths	
Total Funds Requested:	$6.4M*
Implementation of Findings from PCORI's Major Research Investments PFA Slate	
Implementation Strategies to Enhance Use of Conservative Management of Urinary Incontinence in Women	
Total Funds Requested:	$2.5M*

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

Motion for Consideration: Dissemination and Implementation (D&I) Award Slates

Approve funding for the recommended slates of awards from the following Cycle 2 2021 D&I PFAs:

- Limited Competition Dissemination & Implementation
- Implementation of Findings from PCORI's Major Research Investments

Board Vote

Call for a Motion to:	• **Approve** funding for the two recommended slates of awards from the Cycle 2 2021 Dissemination and Implementation PFAs
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

Cycle 2 2021
Research Award Slates

Barbara McNeil, MD, PhD

Chair, Selection Committee

Cycle 2 2021
Pragmatic Clinical Studies PFA

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

Cycle 2 2021 Pragmatic Clinical Studies Award Slate

Project Title	
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	
Total Funds Requested:	$18.9M*

* 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 2 2021
Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities
Targeted PFA

Els Houtsmuller, PhD

Associate Director
Healthcare Delivery and Disparities Research

Cycle 2 2021 Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities Award Slate

Project Title	
Trauma-informed approach to timely detection and management of early postpartum hypertension	
Total Funds Requested:	$20.4M*

* 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 2 2021
Nonsurgical Options for Women with Urinary Incontinence
Targeted PFA

Nora McGhee, PhD
Senior Program Officer
Clinical Effectiveness and Decision Science

Cycle 2 2021 Nonsurgical Options for Women with Urinary Incontinence Award Slate

Project Title	
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)	
Total Funds Requested:	$19.5M*

* 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 2 2021
Broad PFA Award Slates

Steve Clauser, PhD, MPA
Program Director, Healthcare Delivery and Disparities Research

Stanley Ip, MD
Interim Program Director, Clinical Effectiveness and Decision Science

Cycle 2 2021 Broad Improving Healthcare Systems Award Slate

Project Title	
Comparing Hospital to Home Transition Interventions for Children with Medical Complexity	
Comparative Effectiveness of Two Approaches to Symptom Monitoring in Hemodialysis	
Total Funds Requested:	$8.6M*

* 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 2 2021 Broad Improving Methods for Conducting PCOR Award Slate

Project Title	
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	
Total Funds Requested:	$4.1M*

* 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

Motion for Consideration: Research Award Slates

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:
  - Improving Healthcare Systems
  - Improving Methods for Conducting PCOR

Board Vote

Call for a Motion to:	• **Approve** funding for the recommended slates of awards from the Cycle 2 2021 Research PFAs
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

Overview of Targeted PFA Development to be Considered for Approval Today

Nakela L. Cook, MD, MPH

Executive Director

Progress on Targeted PFAs

Under our ***expedited and enhanced process***, we have released 8 targeted PFAs to date

Cycle 2 & 3 2021, Cycle 1 2022 Targeted PFAs	Funding
Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities	Up to $50M
Comparative Effectiveness of Interventions Targeting Mental Health Conditions in Individuals with Intellectual and Developmental Disabilities	Up to $40M
Nonsurgical Interventions for Women with Urinary Incontinence	Up to $40M
Comparative Effectiveness of Novel Pharmacologic and Evidence-based Nonpharmacologic Treatments for Migraine Prevention	Up to $40M
Healthy Aging: Optimizing Physical and Mental Functioning Across the Aging Continuum	Up to $50M
Multimodal Interventions to Prevent Osteoporotic Fractures	Up to $40M
Brief Interventions for Adolescent Alcohol Use	Up to $30M
Prevention, Early Identification, and Treatment of Delirium in Older Adults	Up to $30M
Total	Up to $320M

Progress on Board-Approved Candidate Topics

Funding Mechanism	Cycles 2 &3 2021	Cycle 1 2022	Cycle 2 2022	Cycle 3 2022
Targeted PFA or Special Area of Emphasis	✓ Nonsurgical interventions for women with urinary incontinence	✓ Brief interventions for adolescent alcohol use	*Visual Impairment*	*Telehealth**
	✓ Healthy Aging: Optimizing physical and mental function across the aging continuum	✓ Prevention, early detection, and treatment of delirium in older adults		
	✓ Multimodal interventions to prevent osteoporotic fractures		***Hypertension Control***	*Suicide prevention*
	✓ Treatments for migraine prevention			
	✓ Addressing racism, discrimination, and bias throughout the care continuum*		*Advancing health equity**	*Cancer immunotherapy*
	✓ Leveraging telehealth for chronic disease management among vulnerable populations with complex needs*			
Large Single Study	*Abdominal aortic aneurysm in women*			

Notes: Set of topics is *in addition to* COVID-19, MMM, IDD which are underway and continue; Timing is tentative
* Example of leading with a Special Area of Emphasis

Targeted PFA Development Under Consideration Today

The Science Oversight Committee recommends that the Board approve the development of the following Targeted PFAs:

Targeted PFAs for Development for Cycle 2 2022	Funding
Health System Strategies to Address Disparities in Hypertension Management and Control	Up to $50M
Advancing the Science of Engagement	Up to $36M
Total	Up to $86M

Discussion

Development and Funding of Targeted PFA: Health System Strategies to Address Disparities in Hypertension Management and Control

Alicia Fernandez, MD

Chair, Science Oversight Committee

Els Houtsmuller, PhD

Associate Director, Healthcare Delivery and Disparities Research

Hillary Bracken, MA, MHS, PhD

Program Officer, Healthcare Delivery and Disparities Research

Recommendation for Targeted PFA

Research Question:

What is the comparative 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 are uninsured?

Recommendation for Targeted PFA

PICOTS	
Population	Adults with hypertension, especially people who are Black, Hispanic, live in rural areas and/or are uninsured
Interventions/ Comparators	• Practice facilitation • Team-based care • Support for medication access and adherence (e.g., fixed-dose combinations, simplified medication regimens, 90-day Rx, use of mail order pharmacies) • Telehealth • Risk communication and shared decision-making tools • Community linkage, referral or service provision, community health workers • Population-based health equity interventions (e.g., patient/clinical registries or dashboards); interventions to promote guideline-based care (e.g., clinical decision support tools; standardized blood pressure measurement and treatment intensification protocols) • Strategies to address interpersonal implicit bias (e.g., anti-bias, anti-racism or health equity training)
Outcomes	BP (e.g., change in systolic BP over 18 months, % of pts with BP <140/90 or <130/80 at 18 months); patient experience of and engagement in care; self-management; health-related quality of life; cost
Timing	≥ 18 months follow-up
Settings	Community, primary care, and safety-net settings

Recommendation for Targeted PFA

- Total requested for this PFA is $50M in total costs
- Estimated number of cycles: 2-3
- Estimated number of studies: 4-5
- Direct costs per study: up to $10M for small studies and up to $15M for large studies
- Project Duration: Up to 5 years

Board Vote

Call for a Motion to:	• **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
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

Development and Funding of Targeted PFA: Advancing the Science of Engagement

Kristin L. Carman, PhD, MA
Director, Public & Patient Engagement

Laura Forsythe, PhD, MPH
Director, Evaluation & Analysis

Recommendation for Targeted PFA

Questions of interest:

- **Development and/or validation of 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
- **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

Recommendation for Targeted PFA

- Total requested for this PFA is $36 million in total costs
- Estimated number of cycles: up to 9
- Estimated number of studies: up to 22
- Direct costs per study: up to $500K or up to $1.5M
- Maximum project duration: up to 3 years

Board Vote

Call for a Motion to:	• **Approve** the development of an *Advancing the Science of Engagement Targeted* PFA with funding up to $36 million in total costs
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

BREAK

We will return at 1:45 PM ET

Join the conversation on Twitter via @PCORI

Overview of PCORI's Work to Reduce Maternal Morbidity and Mortality

Nakela L. Cook, MD, MPH

Executive Director

Maternal Morbidity and Mortality as a Priority

2019 – Congress reauthorizes PCORI – Reauthorizing law specified two new priority research areas:

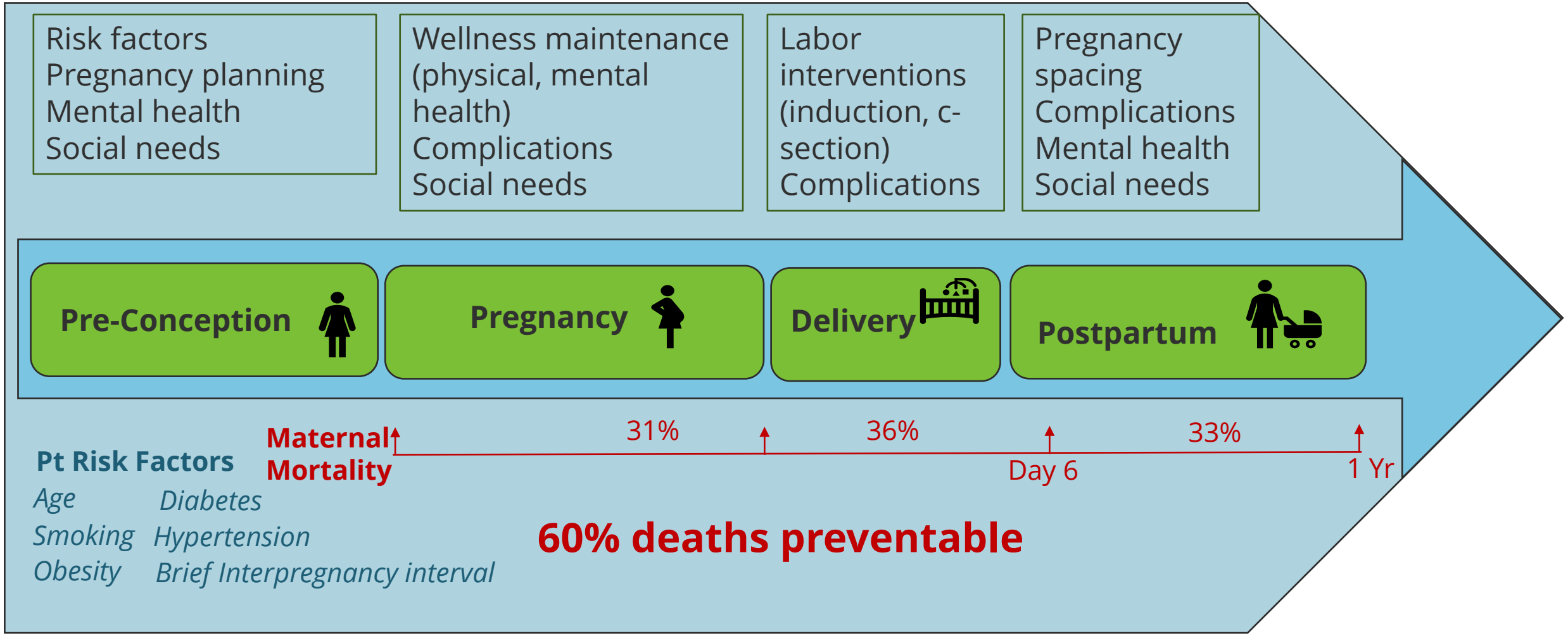
Maternal Morbidity and Mortality (MMM)	Individuals with intellectual and developmental disabilities (IDD)

Implementation will include:

A **long-term commitment** to priority areas of investment	Ongoing opportunities for engagement to identify stakeholder driven topics and patient-centered outcomes

PCORI will invest in these topics through all types of funding announcements, convenings, and other activities and initiatives

Maternal Mortality Framework: Opportunities for Healthcare Intervention



Maternal Morbidity and Mortality Funding since 2013
Portfolio Spotlight

SINCE 2013, PCORI HAS AWARDED

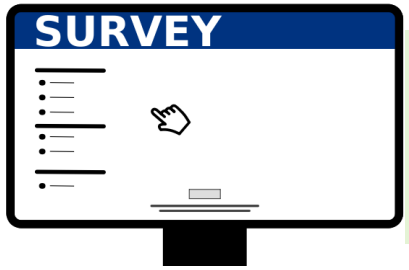
$91 MILLION TO FUND 63

comparative clinical effectiveness research and engagement projects with a focus on **maternal morbidity and mortality**

AS OF FEBUARY 2022

Ongoing engagement guiding the effort
Engagement activities with the maternal health community

Stakeholder Engagement:
Since reauthorization, PCORI has held **28 meetings with stakeholders in the maternal morbidity and mortality community** to inform the development of potential topics for funding announcements



Survey Feedback:
Surveyed **130 diverse stakeholder representatives** on priority areas and topics relevant to PCORI MMM efforts to inform plans and decisions

pcori VIRTUAL ANNUAL MEETING

Convenings:
- Hosted a panel at the 2021 PCORI Virtual Annual meeting on **Meaningful Stakeholder Engagement for Equitable Maternal Health Outcomes**
- Hosted webinars to gather stakeholder input to inform **PCORI/AHRQ funded Evidence Reviews**

Evidence Synthesis Initiative
Synthesis of Evidence on Key Maternal Health Topics

Currently, PCORI has funded **3 systematic reviews** and **1 rapid review** in the maternal health space

Systematic Reviews

- Cervical Ripening in the Outpatient Setting
- Peripartum and Postpartum Management of Women with Hypertensive Disorders of Pregnancy
- Postpartum Care for Women up to One Year After Birth

Rapid Review

- A Rapid Review of Telehealth Strategies for the Delivery of Maternal Healthcare

Read more at https://www.pcori.org/impact/evidence-synthesis-reports-and-interactive-visualizations

Ongoing and Future Efforts:

Recent Maternal Morbidity and Mortality Funding Announcements

Targeted Funding Announcement focused on

Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities

Postpartum 

Special Area of Emphasis focused on

Increasing Access to and Continuity of Patient-centered Maternal Care

in its Broad funding announcement

Maternal Care 

Next Steps and Future Directions

- Developing new funding opportunities
- Identifying areas of intersection with broader health equity efforts across PCORI
- Obtaining stakeholder input to inform and guide ongoing efforts
- Engaging with communities most affected
- Exploring opportunities for interventions that address Social Determinants of Health-related issues that underpin many challenges in this arena

Maternal Health Discussion with The Honorable Lauren Underwood, Co-Chair of the Black Maternal Health Caucus

Consider for Approval: PCORI/AHRQ Learning Health Systems 2.0 Initiative

Kathleen Troeger, MPH

Chair, Research Transformation Committee

Steve Clauser, PhD, MPA

Program Director, Healthcare Delivery & Disparities Research

Program Background and Purpose

- In phase one in 2018, PCORI and the Agency for Healthcare Research and Quality (AHRQ) funded 11 institutions to support the training of embedded researchers to conduct patient-centered outcomes research (PCOR) within Learning Health Systems (LHS); this program is now in its final year

- PCORI provides funding to AHRQ, AHRQ administers the program, and PCORI and AHRQ jointly oversee the program

- The purpose of the second phase of the LHS Training Program is to:

  Support institutions to produce the next cadre of embedded LHS researchers and scientists who have the skills to conduct, apply, and implement PCOR to empower equitable whole-person care across the lifespan, in order to improve system operations, quality, and health outcomes

LHS 1.0 Program Objectives

Purpose: To train clinical and research scientists to have the skills to support and lead efforts to apply PCOR methods and conduct PCOR research in a LHS and to facilitate rapid implementation of evidence that will improve quality of care and patient outcomes.

Objectives:

1. **Develop and implement a training program** including didactic and experiential learning, that embeds scholars at the interface of research, informatics, and clinical operations within LHS
2. **Identify, recruit, and train clinician and research scientists** committed to conducting PCOR in health care settings to generate new evidence facilitating rapid implementation to improve quality of care and patient outcomes
3. **Establish Centers of Excellence** in LHS Research Training focusing on the application and mastery of the updated core LHS researcher competencies
4. **Support a learning collaborative** across funded Centers of Excellence to promote cross institutional scholar-mentor interactions, cooperation on multi-site projects, dissemination of project findings, and methodological advances

LHS 2.0 Builds on Progress of Current Program

- Strong scholar and mentor participation
- Development of robust LHS training curricula
- Significant accomplishments and career advancement for scholars
- The addition of healthcare equity and justice as a core competency of LHS training based on input from the Centers of Excellence Learning Collaborative
- Health systems' engagement and support for research
  - Health Systems partners have noted the strong potential for embedded research scholars to improve practice in their delivery systems

Approach

- Each grant will consist of distinct components of a Program Project/Center grant that will be evaluated in the review process, such as governance, research and data; training; dissemination and implementation; and evaluation

- Research cores will focus specifically on AHRQ/PCORI primary care priorities, including improving health equity, primary care, maternal mortality and morbidity, Intellectual and Developmental Disabilities (IDD), and use of data resources like PCORnet

- Program scholar diversity will be increased, and partnerships will be expanded to include minority-serving institutions and federally qualified health centers and health systems committed to serving underserved populations

- The LHS 2.0 approach will yield greater opportunities for awardees to execute robust embedded LHS research, transition to PCORI and AHRQ research funding mechanisms, and directly engage system's stakeholders, with opportunities for co-sponsorship

Elements of Proposed PCORI and AHRQ Collaborative Funding Initiative

- Total PCORI funding for AHRQ requested: Up to $25 M in total costs
  - AHRQ will match PCORI's funding
  - Initial PCORI funding to AHRQ anticipated to begin in FY2023

- AHRQ will fund LHS recipients
  - Estimated number of projects: 10
  - Estimated project duration: 5 years

- Subject to finalization of Memorandum of Understanding (MOU) between PCORI and AHRQ

Board Vote

Call for a Motion to:	**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
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

Public Comment Period

Kristin L. Carman, MA, PhD

Director, Public & Patient Engagement

Closing Remarks

Wrap Up and Adjournment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