Board of Governors Meeting

In-person and via Teleconference/Webinar

June 14, 2022
9:00 AM – 2:35 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: Consent Agenda
9:20-10:05	Executive Director's Report
10:05-10:35	Consider for Approval: Proposed PCORI Strategic Plan
10:50-11:20	Consider for Approval: Proposed Amendments and Framework to Implement Governance Framework for the Methodology Committee
11:20-11:35	Consider for Approval: Proposed Revisions to Governance Framework for Approval of Awards
11:35-12:30	Consider for Approval: Development and Funding of Targeted PCORI Funding Announcements • Telehealth to Optimize Management of Multiple Chronic Conditions Among Vulnerable Populations • The PCORI Health Equity Initiative – Addressing Social and Clinical Determinants of Maternal Health
1:30-2:00	Report from PCORnet® Priorities Work Group
2:00-2:30	Public Comment
2:35pm	Wrap-up and Adjourn

Consent Agenda Items

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Proposed Motion

- That the Board approve:
  - Minutes from the March 8, 2022, PCORI Board Meeting;
  - Appointment of the Deputy Executive Director of Operations *(ex officio)* as Treasurer to replace the Chief Operating Officer *(ex officio);* and,
  - Appointment of Dr. Cristina Murray-Krezan to serve as Co-Chair of the Advisory Panel on Clinical Trials through August 2024 or until a replacement is appointed.

Board Vote

Call for a Motion to:	• **Approve** each of the Motions on the Consent 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
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

PCORI Updates: Seeking Nominations for Methodology Committee

- PCORI's Board of Governors (Board) has responsibility for appointing up to 15 members to the PCORI Methodology Committee (MC)
- The call for nominations for new members of the MC is open from June 1-28, 2022
- Per PCORI's Authorizing Law, members appointed to the MC shall be experts in their scientific field such as Health Services, Research, Clinical Research, Comparative Clinical Effectiveness Research, Biostatistics, Genomics, and Research Methodologies
- In addition, PCORI is seeking new members for the MC with expertise in emerging areas of interest, including:
  - Analysis of potential burdens and economic impacts to patients and caregivers
  - Bioethics
  - Data science and informatics
  - Decision science
  - Diversity, equity, and inclusion
  - Engagement science
  - Health literacy/numeracy and risk communication
  - Implementation science
  - Program evaluation
  - Research rigor and reproducibility
  - Social determinants of health

PCORI Updates: Ad Hoc Committee and Work Group Activities Relating to the Board

	Strategic Planning Committee	PCORnet Priorities Workgroup	Healthcare Cost and Value Workgroup	Methodology Committee 2.0 Workgroup
Charge	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	Build upon the Prioritizing Principles and propose strategies to inform the evaluation framework; guide Board considerations including future investments; advance the strategic plan	Develop framework for activities to support PCORI's approach to collecting the full range of outcomes, informing the value conversation and supporting policy priorities	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
Composition				
Timeline	Aug 2020- July 2022	Stage 1: Nov 2020 - Jan 2021 Stage 2: Feb-Aug/Sept 2022	Oct 2021-Dec 2022	July 2021 – March 2022
Outcomes to Date	• National Priorities for Health • Research Agenda • Strategic Plan	• Prioritizing Principles for Funding • Charge for Stage 2 • Considerations for measuring success • Priorities for Data/ Population Expansion • Strategic opportunities	• Framework for Activities • Landscape Review • Stakeholder Listening Sessions	• Future State Vision • Implementation approaches

COMPOSITION KEY Members of Board of Governors; Methodology Committee Members; Staff Leadership

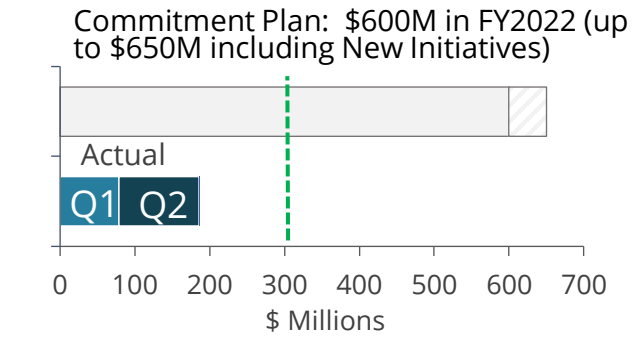
FY2022 Dashboard Midyear Review

Nakela L. Cook, MD, MPH
Executive Director

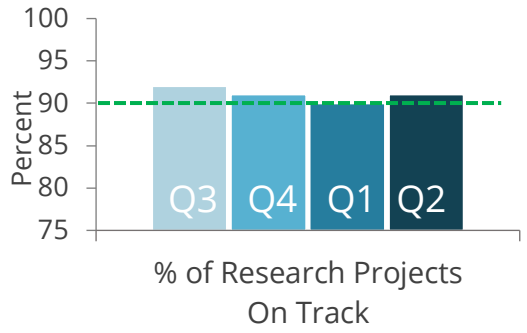
PCORI Board of Governors Dashboard
FY2022 Midyear Review (As of 3/31/22)

Inputs
Process
Outputs
Uptake
Use
Impact

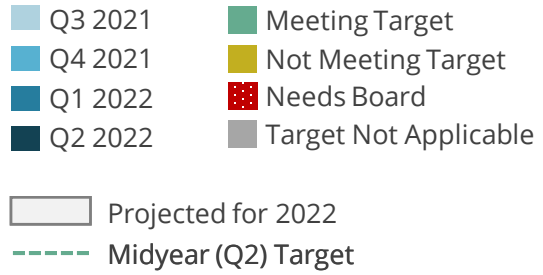
Funds Committed



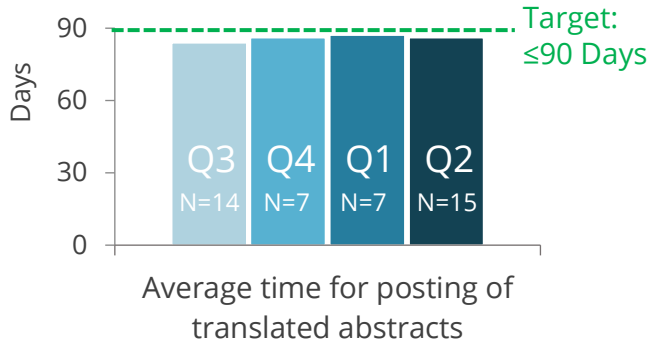
Research Project Performance



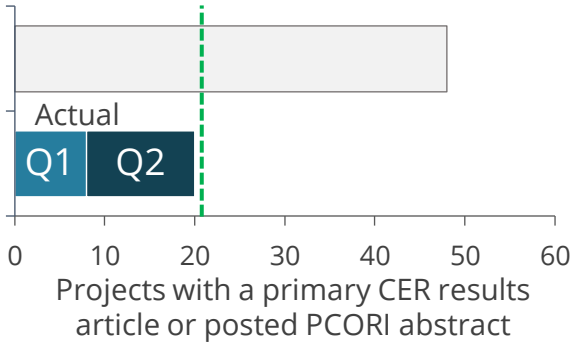
Dashboard Key



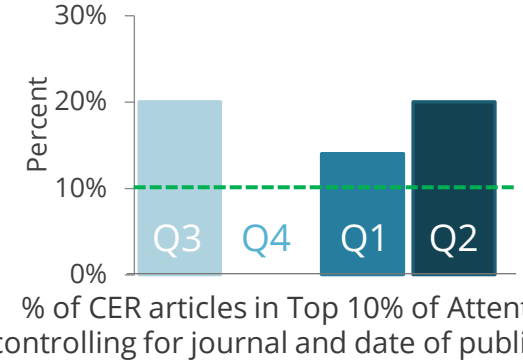
Time to Release of Research Findings



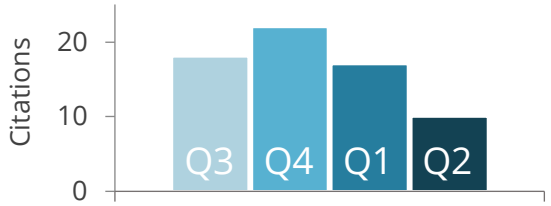
CER Results Publicly Available



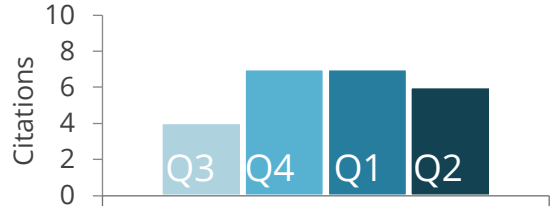
CER Results Altmetric Scores in Context



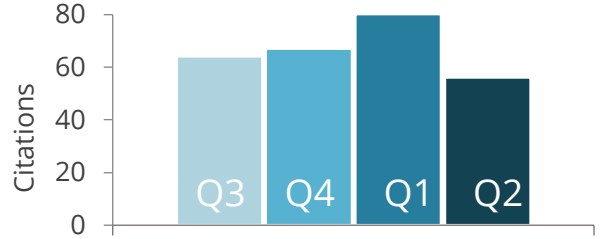
Uptake into Public/Patient Resources



Uptake of Results into UpToDate®



Other Examples of Uptake



Increasing Information for Health Decision-Making

Adding a patient-activated inhaled glucocorticoid to guideline-concordant care reduced rates of severe asthma exacerbations in Black and Latinx patients with moderate to severe asthma

PCORI Study	**Study Title:** The PREPARE Study for PeRson EmPowered Asthma Relief **Principal Investigator:** Elliot Israel, MD, Harvard Medical School
Results Publication	Israel E, et al. **Reliever-Triggered Inhaled Glucocorticoid in Black and Latinx Adults with Asthma** . *NEJM*. 2022 Feb. doi: 10.1056/NEJMoa2118813. Link to Publication

Summary: This is a pragmatic, open-label randomized controlled trial of patient-activated reliever-triggered ICS (PARTICS) plus guideline–concordant usual care, compared to guideline-concordant usual care alone, for management of asthma in Black and Latinx patients with moderate to severe asthma. These populations bear a disproportionate burden of asthma morbidity and mortality yet are underrepresented in studies of asthma management.

Primary results were presented at the 2022 Annual Meeting of the American Academy of Allergy, Asthma, & Immunology and published in the New England Journal of Medicine.

The study found that the provision of an inhaled glucocorticoid and one-time instruction on its use, added to usual care, resulted in lower risk of severe asthma exacerbations, improved asthma control, improved quality of life, and reduced days lost from work or school.

Altmetric Score (Attention)

Mentioned by

- **54** news outlets
- **4** blogs
- **90** tweeters
- **2** Facebook pages

Top 5% of Attention given the journal

***As of 5/16/21**

> Despite a focus on interventions, a disproportionate burden of asthma on underserved populations in the U.S. persists. . . Results of the PREPARE trial show us that we can help reduce the impact of asthma through the simple, patient-centered intervention of having patients use ICS whenever they use their rescue inhaler or nebulizer to treat symptoms.
>
> -Dr. Elliot Israel, Principal Investigator (from Brigham and Women's Hospital Press Release, 2/26/22)

Increasing Information for Health Decision-Making

For treatment-resistant children with Kawasaki Disease, Infliximab treatment was more effective than second IVIG

PCORI Study	**Study Title:** A Stakeholder-Driven Comparative Effectiveness Study of Treatments to Prevent Coronary Artery Damage in Patients with Resistant Kawasaki Disease **Principal Investigator:** Jane Burns, MD, UCSD School of Medicine
Results Publication	Burns J, et al. **Infliximab versus second intravenous immunoglobulin for treatment of resistant Kawasaki disease in the USA (KIDCARE): a randomised, multicentre comparative effectiveness trial**. *Lancet Child & Adolescent Health.* 2021 Oct. doi: 10.1016/S2352-4642(21)00270-4. Link to Publication

Altmetric Score (Attention)

Mentioned by

8 news outlets

39 tweeters

1 Redditor

Top 5% of Attention given the journal

***As of 5/16/21**

Summary: This study addressed treatment-resistant children with Kawasaki Disease (KD), a rare vasculitis triggered by one or more unknown environmental triggers and that disproportionately affects children of Asian and African-American descent. Ten to 20 percent of patients with KD manifest treatment resistance, experiencing persistent or recurrent fever after first-line treatment with intravenous immunoglobulin (IVIG). These patients are at increased risk of coronary artery aneurysms. Whether to re-treat these children with a second IVIG or use another immunomodulator like infliximab or corticosteroids is unknown. This randomized clinical trial compared second IVIG with infliximab for treatment-resistant children.

This study was published and shared via Visual Abstract in Lancet Child and Adolescent Health.

The study found that Infliximab treatment was superior to second IVIG in the proportion of patients achieving fever resolution, in shortening the duration of fever, in having shorter hospital stays, and in having fewer adverse events.

> Researchers in this field have been trying to answer the question of what we should use when the first dose of IVIG does not work since the 1980s. This clinical trial was designed to find out the safest and most effective way to stop the fever and get these children out of the hospital. Our results show that infliximab is the best treatment that does the job safely and quickly.
>
> -Dr. Jane Burns, Principal Investigator (from UCSD Press Release, 10/26/21)

Increasing Information for Health Decision-Making

Patients participating in "COVID Watch" remote monitoring via automated text message had improved survival compared with those not monitored, but adding home pulse oximetry did not improve patient outcomes

PCORI Study

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

Results Publications

Lee KC, et al. **Pulse Oximetry for Monitoring Patients with COVID-19 at Home – A Pragmatic Randomized Trial.** *New England Journal of Medicine.* 2022 April. doi: 10.1056/NEJMc2201541. Link to Publication

Delgado, MK, et al. **Comparative Effectiveness of an Automated Text Messaging Service for Monitoring COVID-19 at Home.** *Annals of Internal Medicine.* 2021 Nov. doi: 10.7326/M21-2019. Link to Publication

Altmetric Score (Attention)

Mentioned by

- **23** news outlets
- **5** blogs
- **967** tweeters
- **1** Facebook page
- **2** Redditors

*As of 5/16/21

Top 5% of Attention given the journal

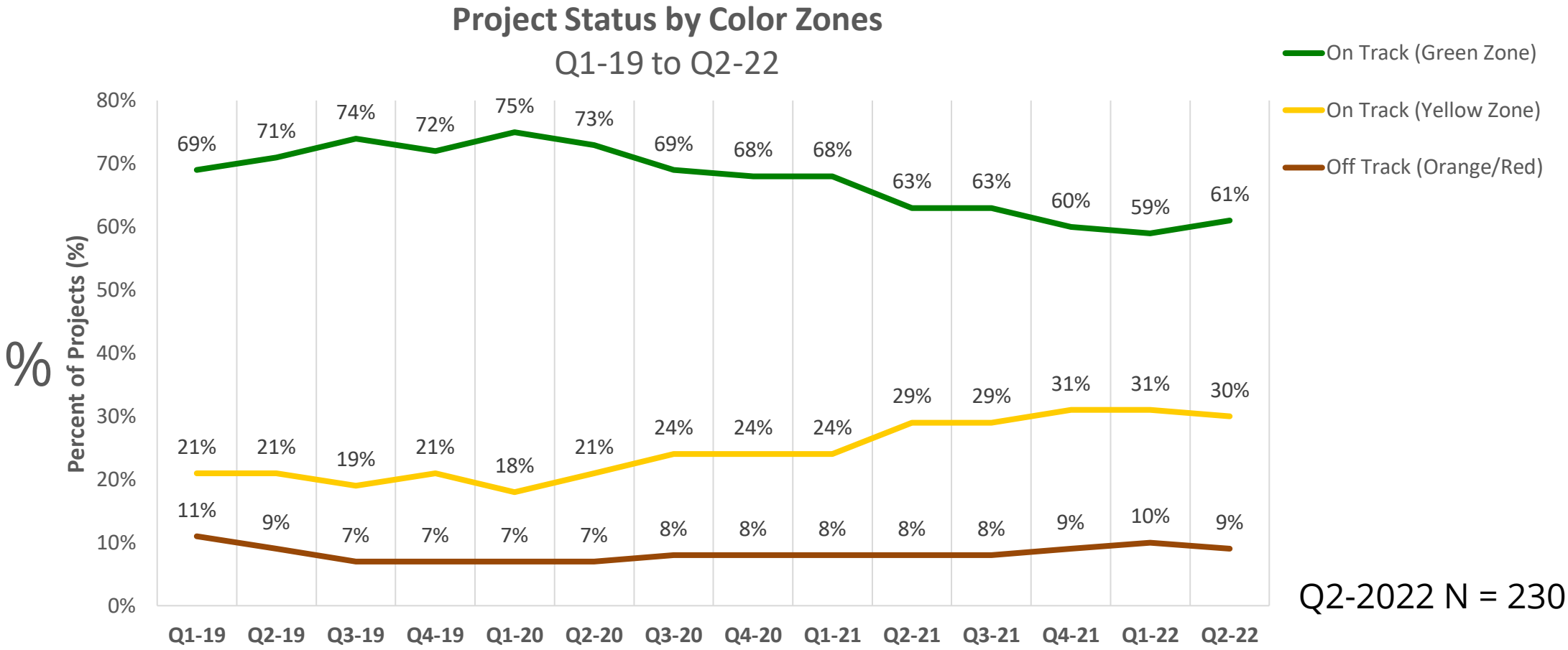
Summary: This project employed retrospective cohort analysis to examine whether outpatient enrollment in an automated remote monitoring service for community-dwelling adults with COVID-19 at home ("COVID Watch") was associated with improved survival. The study found that enrollment of outpatients with COVID-19 in "COVID Watch" was associated with improved survival, more frequent telemedicine encounters, and more frequent and earlier presentation to the ER. The program was associated with improved survival across racial and ethnic subgroups. Results were published in the Annals of Internal Medicine in November 2021.

The project subsequently used a pragmatic randomized trial to compare monitoring of oxygen saturation via home pulse oximetry to standard monitoring alone among patients enrolled in "COVID Watch." Patients in the program who received a pulse oximeter did not experience more days alive and out of the hospital compared with those receiving standard monitoring. These results were published as a letter in the New England Journal of Medicine in April 2022.

> "Overall, these findings suggest that a low-tech approach for remote monitoring systems based on symptoms is just as good as a more expensive one using additional devices. Automated text messaging is a great way for health systems to enable a small team of on-call nurses to manage large populations of patients with COVID-19.
>
> -Dr. Krisda Chaiyachati, MD, co-Principal Investigator (Penn Medicine News Press Release 4/6/22)

Status of PCORI-Funded Research Projects:
Percent in Yellow status higher due to COVID-19 delays

We are monitoring trends and shifts in project status (most recent 10 quarters shown)

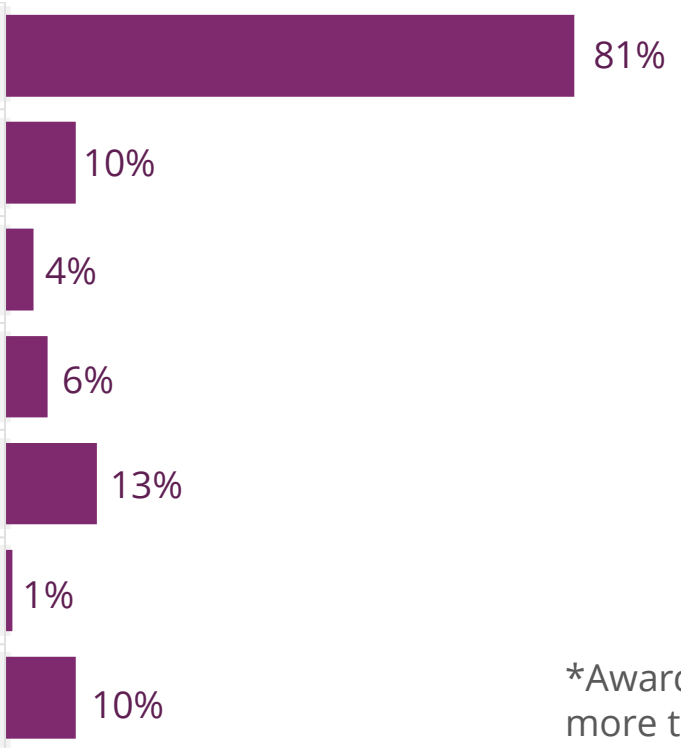


Q2-2022 N = 230

Monitoring the Impact of COVID-19 on Our Portfolio of Funded Research

Among 89 research projects that may not meet project milestones in the project period, 72 (81%) projects are experiencing COVID-19-related delays. Among those 72 projects:

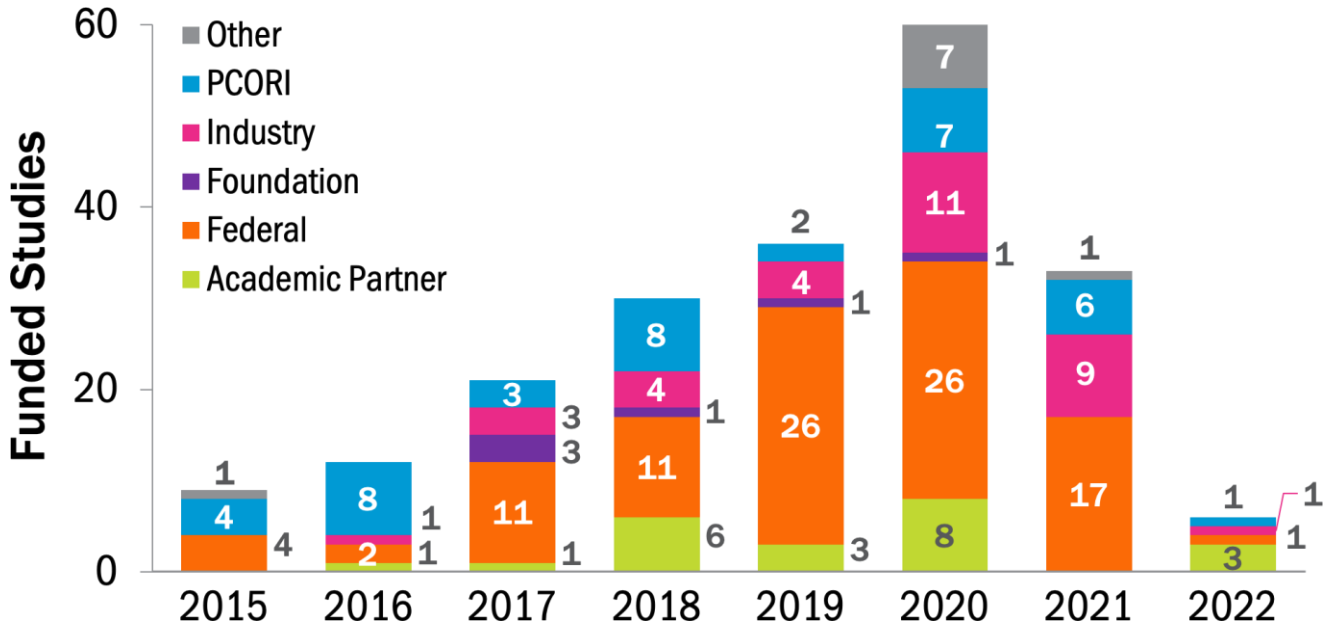
Disruption/Delay Type	# (%)
Study activities (recruitment, etc.) are significantly decreased	**58** / 72 (81%)
Intervention is being adapted	**7** / 72 (10%)
No new recruitment but continuing follow-up	**3** / 72 (4%)
Follow-up is prohibited or significantly decreased	**4**/ 72 (6%)
Other non-enrollment related disruptions	**9** / 72 (13%)
The award is completely paused	**1**/ 72 (1%)
Long-term feasibility concern	7/ 72 (10%)



*Awards may have more than one type of delay/disruption

Who is funding research utilizing PCORnet®?

PCORI funds many projects that utilize PCORnet® infrastructure; increasingly other sponsors recognize the value of funding research that leverages this network:



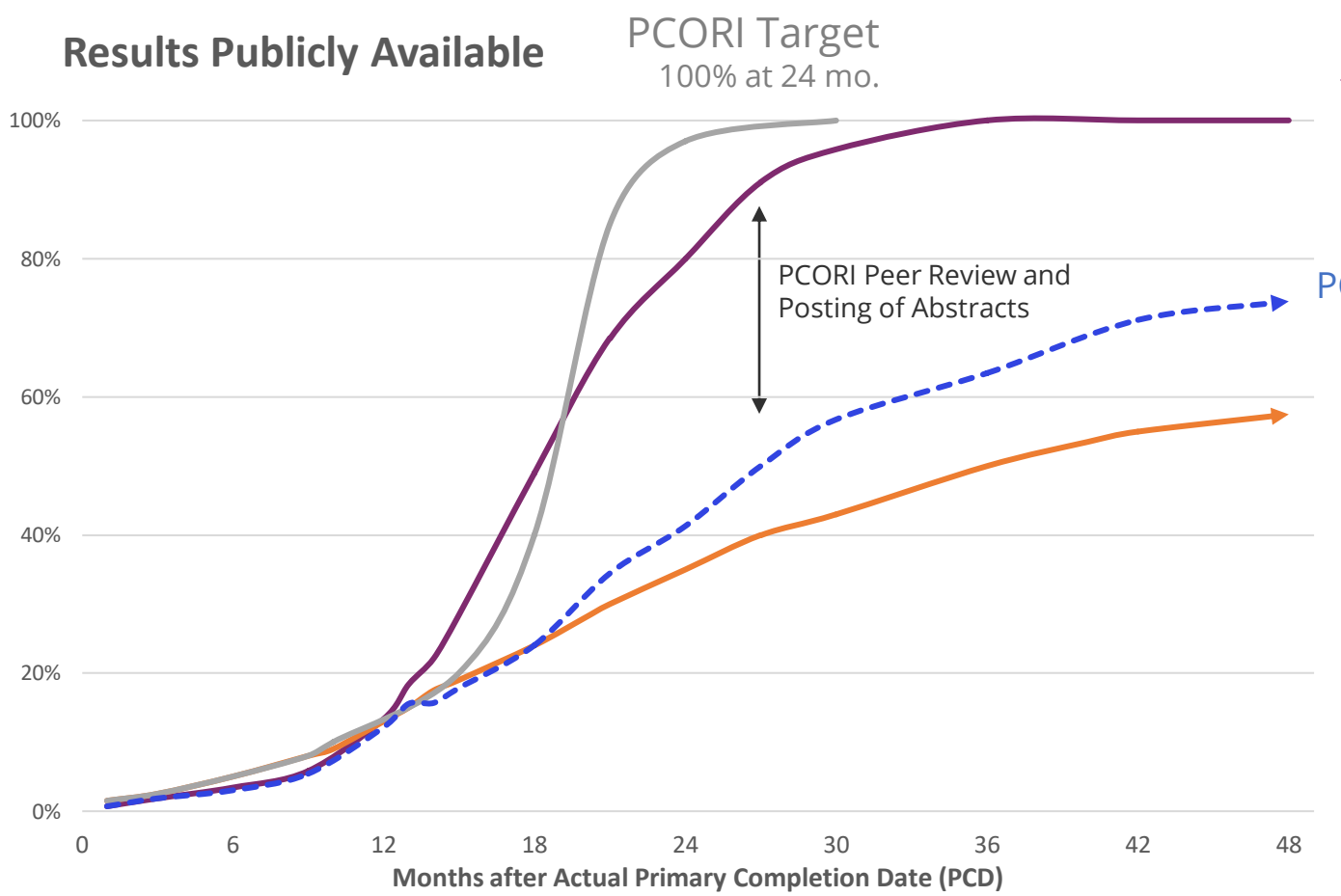
Notes:

- Cumulative Funding=$738 million
- Includes Legacy PCORnet Network Partners

pcornet®
The National Patient-Centered Clinical Research Network

PCORI's Process Provides Complete and Earlier Availability to the Public of Research Results from PCORI-Funded Trials

% CER Results Publicly Available (Publication or Posted Abstract) Relative to PCD



Public Availability of Results from PCORI-funded Trials

51% after 18 months
82% after 24 months
100% after 36 months

PCORI Results Publications

Benchmark
Max: 60% at 60 mo.

Benchmarks Based on:

- C Riveros, A Dechartres, et al. Timing and Completeness of Trial Results Posted at ClinicalTrials.gov and Published in Journals. Plos One, Dec 2013.
- R Chen, N Desai, H Krumholz, et al. Publication and Reporting of Clinical Trial Results: Cross Sectional Analysis Across Academic Medical Centers. BMJ, Jan 2016.

Version: 5/22/22
Cohort: PCORI's first 16 cycles (344 trials)

Attention to CER Results from PCORI-Funded Studies

CER Results publications from PCORI-funded studies with Altmetric scores ≥ 300, considered a very high score.

All six publications are in the top 5% of all research outputs scored by Altmetric

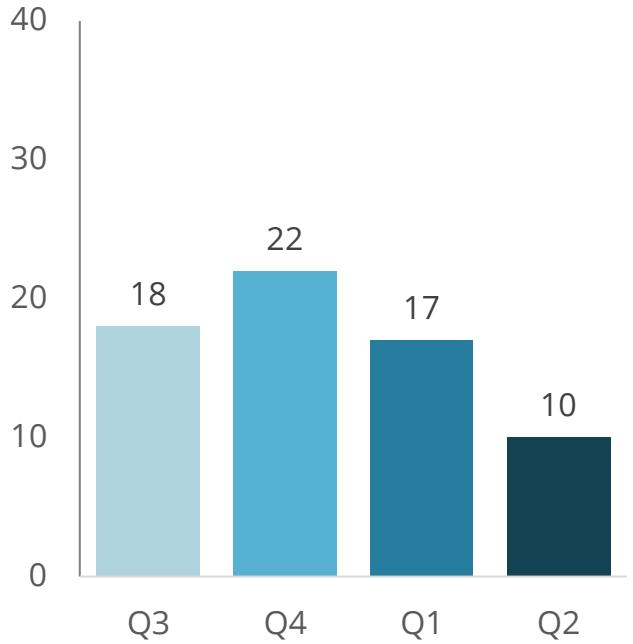
Altmetric	CER Results Publications Highlights	Score in Context*
	Neuman MD, et al. **Spinal Anesthesia or General Anesthesia for Hip Surgery in Older Adults.** *New England Journal of Medicine.* Nov 2021. **[Primary CER Results]**	**Top 20%** of attention, given the Journal and age
	Israel, E, et al. **Reliever-triggered Inhaled Glucocorticoid in Black and LatinX Adults with Asthma.** *New England Journal of Medicine.* Feb 2022. **[Primary CER Results]**	**Top 20%** of attention, given the Journal and age
	Delgado, MK, et al. **Comparative Effectiveness of an Automated Text Messaging Service for Monitoring COVID-19 at Home.** *Annals of Internal Medicine.* Nov 2021. **[Primary CER Results]**	**Top 10%** of attention, given the Journal and age
	Green BB, et al. **Clinic, Home, and Kiosk Blood Pressure Measurements for Diagnosing Hypertension: A Randomized Diagnostic Study.** *Journal of General Internal Medicine*. Mar 2022. **[Primary CER Results]**	**Top 10%** of attention, given the Journal and age
	Schwarz EB, et al. **Comparative Effectiveness and Safety of Intrauterine Contraception and Tubal Ligation.** *Journal of General Internal Medicine*. Feb 2022. **[Primary CER Results]**	**Top 15%** of attention, given the Journal and age
	Albritton, J, et al. **Video Teleconferencing for Disease Prevention, Diagnosis, and Treatment: A Rapid Review.** *Annals of Internal Medicine.* Dec 2021. **[Primary CER Results]**	**Top 5%** of attention, given the Journal and age

* Controlled for Journal and date of publication

Uptake of CER Results from PCORI-Funded Studies into Public/Patient Resources

We continue to develop ways to track citations and mentions of results from PCORI-funded studies in public/patient-facing resources and to welcome ideas for how and where to look

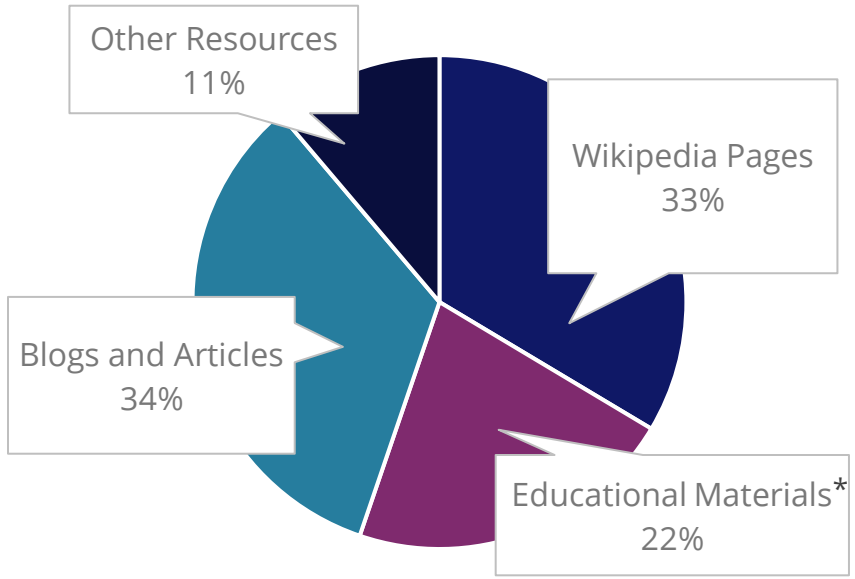
Uptake into Public/Patient-Facing Resources



Cumulative to date: at least 277 citations or mentions in Public/Patient-Facing Resources

Types of Resources Identified

(We aim to expand categories over time)

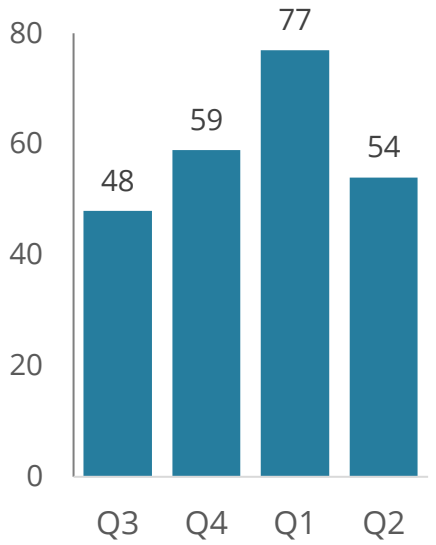


*Such as WebMD, Medline Plus, Verywell Health, UpToDate® Patient Education pages, etc.

Note: Current quarter counts can be artificially low because of a delay in indexing and identification of PCORI awardee publications

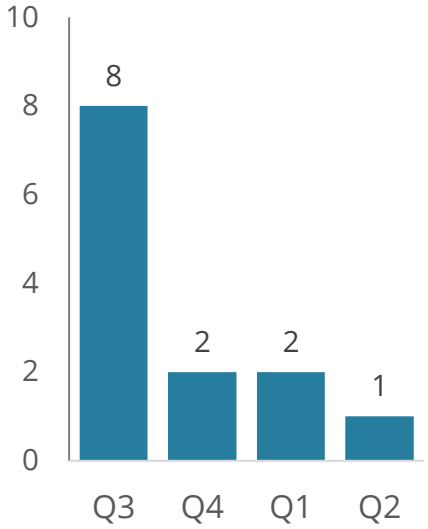
Uptake of CER Results from PCORI-Funded Studies into Other Types of Resources

Citations in Meta-Analyses and Systematic Reviews



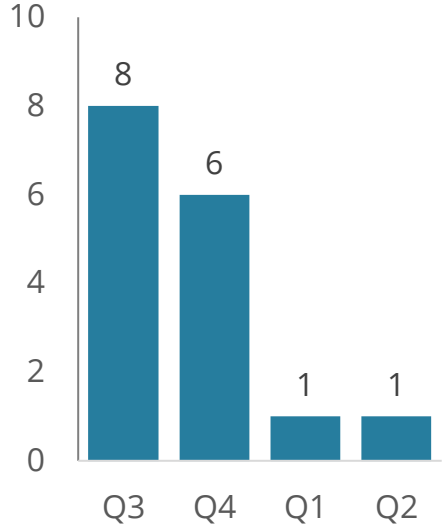
Cumulative to Date: 472

Citations in Other Evidence-based Clinical Recommendations



Cumulative to Date: 80

Citations in Policy Documents



Cumulative to Date: 162

Note: Current quarter counts can be artificially low because of a delay in indexing and identification of PCORI awardee publications

Discussion Questions

- Does our FY2022 Dashboard cover the topics that are most important for the Board to review at this time?
- Do you have concerns about our progress or performance on any of our Dashboard indicators?
- As we continue our strategic planning efforts and expand our focus on the uptake, use, and impact of results from our funded studies, what role and content do you envision for the Dashboard in monitoring progress and measuring success?

Consider for Approval: Proposed Strategic Plan

Nakela L. Cook, MD, MPH

Executive Director

Sharon Levine, MD

Strategic Planning Committee, Co-Chair

Reaching a Milestone

Informed by a variety of inputs including stakeholder feedback, Congressional reauthorization, and the evolving healthcare landscape, the deliberate process to develop a Strategic Plan to guide our future work included an array of activities, such as:

- Board Adoption of National Priorities for Health
- Board Adoption of Research Agenda
- Related strategic discussions (e.g., strategic priorities for PCORnet® phase 3, Methodology Committee focus for PCORI's next phase)

Informed by Board and SPC Feedback

The proposed Strategic Plan was refined through Board and Strategic Planning Committee (SPC) feedback which included:

- Maintaining the appropriate level of specific references to evolving activities to allow adaptation using the concepts reflected in the Plan
- Reflecting important concepts directly to enhance readability
- Strengthening reference to PCORI's responsiveness to emerging issues in the health and healthcare landscape
- Describing and clarifying terms where appropriate without narrowing concepts

Framing the Strategic Plan

Formats

- Core Strategic Plan document
- Digital format (e.g., clickable, interactive webpages)
- Printable “at-a-glance” handouts (e.g., two-page PDFs)

Purpose

- Demonstrate how PCORI will continue to achieve its mission
- Serve as the foundation for programmatic planning
- Provide an opportunity for stakeholders to see themselves in PCORI’s vision
- Serve as a communication tool

Audience

- Patients and caregivers
- Researchers and clinicians
- Congress and GAO
- Healthcare purchasers, payers, industry, hospitals and other health systems
- Broader health community

Our Strategic Plan

- Outlines a bold vision for PCORI's future including
  - An enhanced commitment to diversity, equity, and inclusion
  - A need for adaptability and responsiveness to an evolving healthcare and health research landscape
- Describes PCORI's holistic approach to generating and disseminating patient-centered comparative clinical effectiveness research (CER)
- Provides general approach for assessing PCORI's progress towards advancing the National Priorities for Health
- Is purposefully broad to allow our activities to remain responsive to changing and emerging needs

Key Messages in Our Strategic Plan

A bold vision

Guided by our multi-disciplinary Board of Governors and under the leadership of our Executive Director, the new Strategic Plan is a natural evolution of PCORI's growth and an aspirational roadmap for how PCORI will continue to pursue its mission.

Centered on the National Priorities for Health

The National Priorities for Health will guide all our work, including CER as well as related engagement, dissemination and implementation, and research infrastructure initiatives.

Expanded focus on health equity

We are redoubling efforts to encourage and fund CER that compares interventions that address health equity; identify ways to further inclusivity in research; and ensure quality, equitable, and respectful care for all people, regardless of their circumstances; and increase awareness of available evidence about how to address these needs and promote integration of evidence into practice.

Responsive to the overall health landscape

The integrated nature of the National Priorities for Health enable a nimble approach. Our holistic approach empowers PCORI to pursue the evolving needs for patient-centered research and implementation strategies as well as emerging public health and health care issues.

Holistic Approach

- Describes the essential elements of this approach - our CER funding, engagement, dissemination and implementation, and infrastructure initiatives
- Working in concert with one another, these components drive and facilitate our mission and enable us to be responsive

Holistic Approach: Patient-Centered CER

- Describes opportunities to continue developing a CER portfolio that remains relevant to stakeholder needs and attuned to challenges and opportunities posed by the broader healthcare landscape
- Includes discussion of the Research Agenda, which provides the framework for how we will advance the National Priorities for Health through CER funding and a high-level approach for refining our Research Project Agenda setting process

Holistic Approach: Engagement

- Highlights the continued importance of engaging patients, caregivers, and stakeholder communities in the work designed to help them better assess health options and inform healthcare decisions
- Aspects of engagement include advancing the practice and the science of engagement and expanding the collection of tools to help train researchers and patients involved in health research and in engagement practices

Holistic Approach: Dissemination & Implementation

- Reiterates importance of sharing relevant research results that are easily accessible and used by those who need them to make informed health and healthcare decisions
- Includes efforts to fund and support dissemination and implementation of the growing body of results from PCORI-funded studies with the greatest potential impact on practice and developing new information resources (e.g., systematic reviews, evidence maps and visualizations)

Holistic Approach: Infrastructure

- Describes the multiple elements that contribute to infrastructure:
  - The science and methods of CER, including our Methods portfolio and Methodology Standards
  - Core resources that can make research more efficient such as PCORnet®
  - The workforce and delivery systems that are at the heart of patient care, including workforce diversity and training in PCOR

Measuring Success and Monitoring Progress

- Articulates that as a learning organization, PCORI is committed to monitoring and evaluating our activities to promote continuous improvement
- Includes several principles that will guide PCORI's evaluation framework to assess our progress towards advancing the National Priorities for Health

Anticipated Next Steps

July and Beyond

- Ongoing work to implement the Strategic Plan, including developing implementation plans
- Refining Research Project Agenda setting process

Board Vote

Call for a Motion to:	• **Approve** the Proposed Strategic Plan
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

BREAK

We will return at 10:50 AM ET

Join the conversation on Twitter via @PCORI

Consider for Approval: Proposed Amendments and Framework to Implement Governance Framework for the Methodology Committee

Sharon Levine, MD
Chair, PCORI Governance Committee
Mary C. Hennessey, Esq.
General Counsel
Nakela L. Cook, MD, MPH
Executive Director

Revised Framework for Methodology Committee (MC) Approved by Board

- Board-approved framework:
  - Future MC members will be required to forego opportunity to apply for PCORI funding during their term on MC and thereafter, consistent with COI policies
  - MC will have 4-year staggered term structure, with appointments every 2 years
  - Board authorized to appoint MC members to second 4-year term to 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
- To implement this framework Governance Committee recommends:
  - Proposed amended MC Charter
  - Proposed Conflict of Interest Policy Relating to PCORI Funding for Members of the Board of Governors, Members of the Methodology Committee, and Employees
  - Proposed governance framework for nominations and appointments of new MC members

Proposed Amended Methodology Committee Charter

- Six-year staggered term structure for Methodology Committee members revised to four-year staggered term structure

Proposed Conflict of Interest Policy Relating to PCORI Funding for Board, MC, Employees

- Proposed "Conflict of Interest Policy Relating to PCORI Funding for Members of the Board of Governors, Members of the Methodology Committee, and Employees"
  - Replaces "Conflict of Interest Rules for Research Funding," approved by the Board in 2012 and amended in 2013
- Adds requirement that new MC members forego eligibility to apply for PCORI funding during their term and thereafter consistent with policy (similar to Board members and employees)
- Prohibits some applications for PCORI funding following service
  - Cannot apply for funding for one year following service
  - Cannot apply in the future for any "targeted" funding in which they were involved in developing

Proposed Governance Framework for Nomination and Appointment of New MC Members

Proposed Governance Framework to Advance Nomination and Appointment Process of new Methodology Committee members includes the following elements:

1. Solicitation of Nominations
2. Review of Nominations
3. Consideration of Appointments
4. Transition Plan

Proposed Framework for MC Nominations and Appointments: Solicitation

1. Solicitation of Nominations to be informed by:
    - Desired Areas of Expertise
        - Grounded in PCORI's authorizing law
        - Address gaps in expertise resulting from current MC members rotating off
        - Consider new and expanding areas of desired expertise, informed by guidance of MC
    - Desired Characteristics
        - Individuals interested in supporting advancement of the future state vision for the MC (e.g., collaboration, inclusivity)

Proposed Framework for MC Nominations and Appointments: Review of Nominations

2. Review of Nominations
   - Tier 1: Review by Staff
     - Review for nomination completeness and adherence to eligibility requirements
     - Triage for alignment with desired areas of expertise and diversity (e.g., geographic, institution, experience)
     - Recommend subset of nominations to move forward
   - Tier 2: Review by Board-related Committee appointed by Board Chairperson, composed of Board members, MC members, staff
     - Review nominations advanced through Tier 1 against specific criteria developed by Committee
     - Vote to recommend slate of nominees to Board

Proposed Framework for MC Nominations and Appointments: Appointment and Transition

3. Consideration of Appointments
   - Board considers slate of nominees recommended by Committee and votes on appointments

4. Transition Plan
   - Transition plan to implement goal of staggered biennial appointment cycle in odd years with 4-year terms
     - Initial appointments by Board to take place in 2022 (for 1- and 3-year appointments)
     - Board to consider appointments in 2023 and thereafter in odd-numbered years

Proposed Motion

- Approve the:
  - Proposed amended Methodology Committee Charter
  - Proposed “Conflict of Interest Policy Relating to PCORI Funding for Members of the Board of Governors, Members of the Methodology Committee, and Employees” to replace the current “Conflict of Interest Rules for Research Funding”
  - Proposed governance framework for nomination and appointment of new Methodology Committee Members

Board Vote

Call for a Motion to:	• **Approve** the motion as presented.
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

Proposed Amendments to Selection Committees Charter and Sunsetting of Pre-Award Policy

Sharon Levine, MD
Chair, Governance Committee

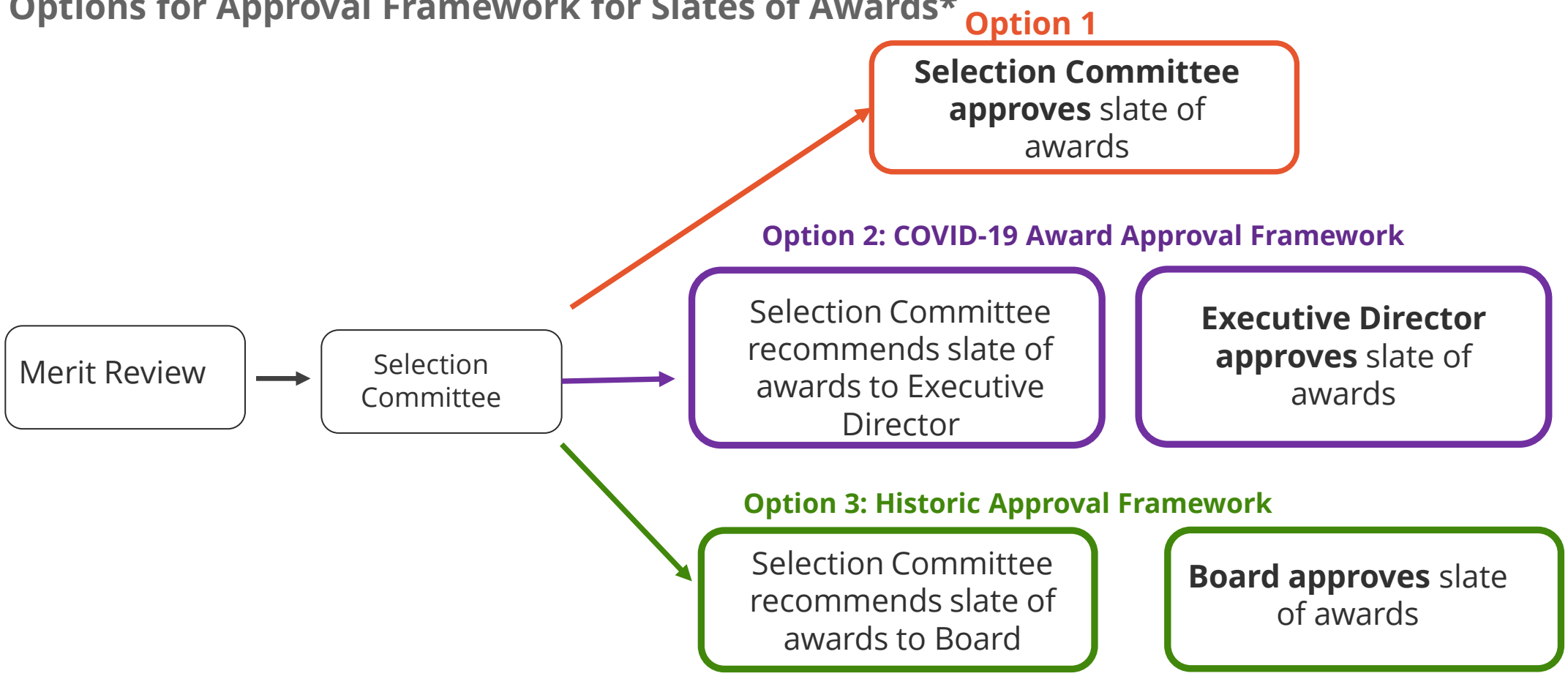
Mary C. Hennessey, Esq.
General Counsel

Recommendation on Revised Governance Framework for Approval of Award Slates

- Historically, the Board has considered approving slates of awards upon recommendation by the Selection Committee
  - Approach was rooted in a framework developed in PCORI's early years
- As PCORI matures, the Governance Committee has discussed whether an alternative approval framework should be considered
- In 2020, the Board authorized an alternative approval framework for approval of projects relating to COVID-19, under which the Executive Director was authorized to approve slates of awards recommended for funding by the Selection Committee, consistent with the Board-approved funding commitment
- The alternative approval framework for COVID-19 award slates has received positive feedback

Options Considered by Governance Committee for Revised Governance Framework for Approval of Award Slates

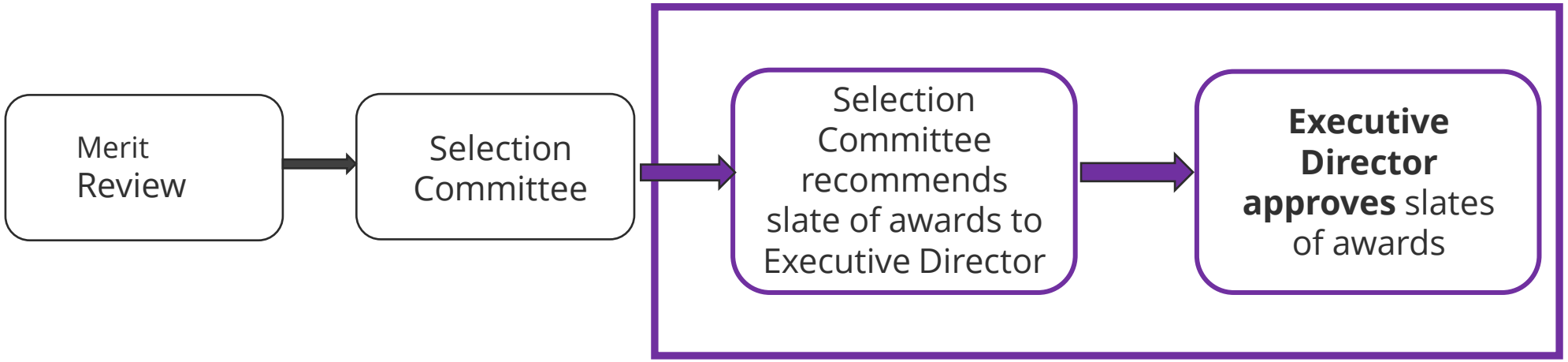
Options for Approval Framework for Slates of Awards*



*Consistent with Board-approved Commitment Plan

Governance Committee's Recommended Revised Governance Framework for Approval of Award Slates

Governance Committee's Recommendation for Revised Approval Framework for Slates of Awards: Option 2*



*Consistent with Board-approved Commitment Plan

Proposed Amended Selection Committees Charter

- To implement the recommended revised award approval framework, proposed amendments to the Selection Committees Charter will be considered:
  - The charter addresses the authority to approve slates of awards
    - Proposed amendments reflect that the Executive Director holds the authority to approve slates of awards recommended by the Selection Committee
  - Other proposed amendments reflect new executive staff titles (e.g., replace "Chief Science Officer" with "Deputy Executive Director of Patient-Centered Research Programs") and updated names of funding opportunities

Plans for Public Information about Approved Award Slates

PCORI will issue timely public announcements about approved slates of awards using multiple communications channels

- Communications may include:
  - Issuing a press release
  - Inclusion in PCORI's weekly email newsletter, PCORI Update
  - Posting to social media
- Information about projects included in approved slates of awards will be posted on PCORI's website
- Information about approved award slates will be addressed during PCORI Board meetings

Proposed Recommendations: Sunset Pre-Award Policy

- Pre-Award Policy:
  - This policy includes language addressing authority to approve slates of awards
  - This policy was adopted in PCORI's early stage and includes day-to-day processes and procedures and details more fitting for an internal process document than a Board-approved policy
  - It is recommended that this policy be sunset as a Board-approved policy to align with recommendation that the Executive Director approve slates of awards and to enable internal processes to be adapted as appropriate

Proposed Motion

- Approve:
  - the proposed amendments to the Selection Committees Charter; and
  - Sunsetting the Pre-Award Policy as a Board-approved policy.

Board Vote

Call for a Motion to:	• **Approve** the proposed amendments to the Selection Committees Charter, and Sunsetting the Pre-Award Policy as a Board-approved policy.
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 and Funding to be Considered for Approval Today

Nakela L. Cook, MD, MPH
Executive Director

Progress on Targeted PFAs

Under our ***expedited and enhanced process***, the Board approved the development of nine Targeted PFAs in 2021 and 2022

Cycle 2 & 3 2021, Cycle 1 & 2 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
Health System Strategies to Address Disparities in Hypertension Management & Control	Up to $50M
Total	**Up to $370M**

Progress on First Set of Board-Approved Candidate Topics for Focused Funding

Previously Approved and Released	For Future Consideration
✓ Nonsurgical interventions for women with urinary incontinence ✓ Healthy Aging: Optimizing physical and mental function across the aging continuum ✓ Multimodal interventions to prevent osteoporotic fractures ✓ Treatments for migraine prevention ✓ Addressing racism, discrimination, and bias throughout the care continuum * ✓ Leveraging telehealth for chronic disease management among vulnerable populations with complex needs* ✓ Prevention, early detection, and treatment of delirium in older adults ✓ Brief interventions for adolescent alcohol use ✓ Hypertension control	▪ ***Telehealth**** ▪ ***Advancing health equity**** ▪ *Visual Impairment* ▪ *Cancer immunotherapy* ▪ *Suicide prevention* ▪ *Abdominal aortic aneurysm in women*

Note: This set of topics is *in addition to* COVID-19, Maternal Morbidity and Mortality, and Intellectual and Developmental Disabilities, which are underway and continue

* Example of leading with a Special Area of Emphasis

A Next Step in Strategic Planning:
Refining Our Research Project Agenda Setting Process

Aims for Research Project Agenda setting process:

- Stakeholder-Driven
- Responsive
- Transparent
- Systematic
- Efficient

Continuing Focused Funding while Strategic Planning is Ongoing

2021

The Board approved a set of candidate topics under an expedited and enhanced approach while our National Priorities for Health and Research Agenda were in development

2022

While we refine our Research Project Agenda setting process, in July the Board will consider the next set of candidate topic themes, which benefit from extensive stakeholder input garnered through the process of developing our National Priorities for Health and Research Agenda

2023

Launch of our refined Research Project Agenda setting process for ongoing identification of topics for focused funding to complement our continuing broad PFAs open to all topics

Targeted PFA Development and Funding Under Consideration Today

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

Targeted PFAs for Development for Upcoming Cycles	Funding
Telehealth to Optimize Management of Multiple Chronic Conditions among Vulnerable Populations in Primary Care	Up to $50M
The PCORI Health Equity Initiative: Addressing Social and Clinical Determinants of Maternal Health	Up to $63M
Total	Up to $113M

Recommendations for Targeted PFA Development and Funding

Alicia Fernandez, MD

Chair, Science Oversight Committee

Telehealth to Optimize Management of Multiple Chronic Conditions among Vulnerable Populations in Primary Care

Carly Khan, PhD, MPH, RN

Associate Director, HDDR

Recommendation for Targeted PFA Development

Research Question:

What is the comparative clinical effectiveness of different approaches to incorporating access to and use of telehealth to optimize management of multiple chronic conditions in primary care, particularly among vulnerable populations?

Recommendation for Targeted PFA Development

Population	Community-dwelling individuals with multiple chronic conditions. Studies will also include a focus on at least one vulnerable population at risk for disparities in care.
Interventions/ Comparators	Example comparisons include: • Telehealth to optimize care delivery (e.g., different care delivery model elements delivered via telehealth for primary and/or specialty care) • Support personnel to facilitate telehealth use (e.g., strategies involving the use of interpreters) • Different state policy interventions regarding telehealth (e.g., regulatory changes involving payment parity across states that directly influence access to care and health outcomes)
Outcomes	Patient clinical or functional outcomes and other outcomes such as health-related quality of life, quality of care, patient care experiences and satisfaction with care, access to care, potential harms, and healthcare utilization
Timing	Periodic outcome assessments with follow-up through at least 12 months
Settings	The focal setting will be primary care, and studies can incorporate home-based care and inclusion of specialty care as appropriate

Parameters

- Funding commitment up to $50M
- Estimated number of studies: 5-7
- Awards consistent with parameters for Broad Pragmatic Studies PFA: up to $10M for large studies and up to $5M for small studies
- Project Duration: Up to 5 years

Board Vote

Call for a Motion to:	• **Approve** the development of a *Telehealth to Optimize Management of Multiple Chronic Conditions among Vulnerable Populations in Primary Care* Targeted PFA with funding up to $50M 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

The PCORI Health Equity Initiative: Addressing Social and Clinical Determinants of Maternal Health

Steven Clauser, PhD, MPA
Program Director, HDDR

Els Houtsmuller, PhD
Associate Director, HDDR

Overview

Our opportunity:

- To fund CER awards that support *Achieving Health Equity*, one of PCORI's National Priorities for Health
  - Addresses health drivers that occur where people live, work, learn, and play (Research Agenda)
  - Addresses maternal morbidity and mortality, a high priority health equity issue

- Consulted diverse stakeholder groups [and received valuable input from the Board as well as the Patient Engagement and Healthcare Delivery & Disparities Research Advisory Panels

Key recommendations:

- Focus on established researcher-community partnerships, governed by established PCORI processes
- Address complexity of maternal health needs by comparing multicomponent and multilevel interventions addressing health conditions and social and structural determinants of health
- Consider planning phase to enhance readiness of researcher-community partner teams for study execution
- Build a learning community of investigators and community partners
- Build research capacity for researchers from underrepresented communities

Research Award Components

Component	Description
Established partnerships	Research organization and community organization partnership required
Decision making	Shared leadership including research and community representation
Type of research	Comparative clinical effectiveness research
Phases	Planning phase up to 1 year, research phase up to 5 years
Planning phase activities	Define roles and decision-making authority, recruit research staff, refine research aims and plan, adapt interventions
Learning Network	Awardees collaborate as a research network; topics and methods for coordination determined by research and community partners
Training	Researchers under-represented in PCORI-funded research, researchers from underserved research communities
Awards	Up to three awards, flexibility in number of research projects per awardee

Priority Question

What is the comparative effectiveness of multicomponent, multilevel interventions to improve maternal outcomes for patients at increased risk?

- Interventions in pre- and postnatal care should include health systems strategies to address disparities (e.g., data accountability measures; bias awareness training; trauma-informed care; team-based care; telehealth; standardized protocols for monitoring/treatment hypertension, substance use, depression, diabetes) and strategies to address social and/or structural determinants of health (e.g., food, housing, childcare, transportation).

Recommendation for Targeted PFA Development

Population	Pregnant/postpartum patients at increased risk for adverse maternal outcomes (such as African American patients with hypertension, publicly insured Hispanic patients with diabetes, patients with obesity who live in rural areas
Interventions/ Comparators	Multicomponent multilevel interventions in pre- and postnatal care that include health systems strategies to address disparities and strategies to address social and structural determinants of health
Outcomes	Clinical outcomes including, for example, composite outcomes (severe maternal morbidity, hypertensive disorders of pregnancy, other), gestational diabetes, excess gestational weight gain, depression, suicidality, substance use, violence; other patient-centered outcomes such as respectful care and quality of life
Timing	Prenatal and postnatal outcome assessments with follow-up through 12 months postpartum, as appropriate
Settings	Maternity Care (prenatal, delivery, and postnatal)

Requested Funding Commitment

- Propose to fund up to 3 awards with potential for multiple research projects
- Per Award
  - Propose up to **$1M for the planning phase**
  - Propose up to **$20M for the research phase**

Proposed funding: Up to $63M

Board Vote

Call for a Motion to:	• **Approve the development of a** Targeted PFA on the PCORI Health Equity Initiative: Addressing Social and Clinical Determinants of Maternal Health **with funding up to $63M 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 1:30 PM ET

Join the conversation on Twitter via @PCORI

Workgroup on PCORI Priorities for PCORnet® (Stage Two) Report

Robert Zwolak, MD, PhD
Chair, PCORnet Priorities Workgroup

Kara Ayers, PhD
Vice Chair, PCORnet Priorities Workgroup

Board Approved PCORI Prioritizing Principles for Infrastructure Funding Relating to PCORnet® (Work Group Stage 1)

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

PCORnet® Priorities Workgroup (Stage Two)
Goals

- Building upon the Prioritizing Principles for Infrastructure Funding Relating to PCORnet, propose strategies to inform PCORI's evaluation framework for PCORnet and guide future Board consideration of:
  - PCORnet accomplishments attributable to PCORI infrastructure funding
  - Decisions about future PCORI investments in PCORnet to support baseline network functions and opportunities for the infrastructure to expand and evolve
- Propose crosscutting 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 Workgroup (Stage Two)
Composition

- Robert Zwolak, MD, PhD (Chairperson)
- Kara Ayers, PhD (Vice Chairperson)
- 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
- Danny van Leeuwen, MPH, RN

PCORnet® Priorities Workgroup
Timeline

Feb 2022

Workgroup Meeting
Goal Setting

March 2022

Workgroup Meeting
Evaluation Overview and Discussion

Apr 2022

Workgroup Meeting
Governance, Research, Population, Advancing National Priorities Discussions

May 2022

Workgroup Meeting
Short- and Long-Term Evaluation Strategies Discussion

June 2022

Board Meeting
Workgroup Update

Workgroup Meeting
Deliberations and Recommendations
Draft Strategies

July 2022

Workgroup Meeting
Deliberations and **Finalize Proposed Strategies**

Sep 2022

Board Meeting:
Consideration of **Proposed Strategies**

Three Focus Areas of Workgroup Discussions

Overarching Strategies for Defining & Measuring Success

Priorities for Data/Population Expansion in PCORnet® Studies

Strategic Opportunities for PCORnet

Workgroup Discussions
Overarching Strategies

Overarching Strategies for Defining & Measuring Success

- PCORnet® evaluation framework should align w/ Prioritizing Principles for Infrastructure Funding, PCORnet maturity, and PCORI's larger evaluation strategy
- Consider PCORnet's niche: strengths and limitations as a disease-agnostic research network
- PCORnet builds capacity to continuously learn and improve
- Prioritize 'better' and 'faster' over 'cheaper'
- Benchmark PCORnet's performance against appropriate comparators whenever possible

Workgroup Discussions
Data and Population Expansion

Priorities for Data/Population Expansion in PCORnet® Studies

- Improve data quality (e.g., Common Data Model) across all participating networks
- Enhance data capacity to include several types of health data:
  - Social determinants
  - Patient-generated
  - Non-clinical
- Enhance participation in PCORnet to continue to expand coverage of diverse, underrepresented, and underserved populations
- Ongoing priority to ensure PCORnet is representative of full range of US population

Workgroup Discussions
Strategic Opportunities

Strategic Opportunities for PCORnet®

- Promote PCORnet to ensure the network is known as a national resource and a public good
- Ensure the front door is highly accessible and easy to use
- Expand partnerships and external use of PCORnet, including community-driven queries
- Incentivize use of PCORnet for PCORI-funded studies
- Develop PCORI's uses of PCORnet, such as rapid cycle query models to identify scalable ideas, inform PFA development
- Promote PCORnet's use for:
  - Definitive studies that are national in scope w/ implementable findings
  - Studies in rare disease, IDD, MMM
  - Studies along the trajectory of research, from topic generation to dissemination and implementation of findings
  - Platform trials, randomized trials, high-quality observational studies

PCORnet® Priorities Workgroup
PCORI Board Discussion Questions

- Are there ***additional strategic opportunities*** for the PCORnet infrastructure that the Workgroup should consider in each of the three focus areas:
  - *Overarching strategies for defining and measuring success*
  - *Data and/or population expansion*
  - *Strategic opportunities for PCORnet*
- How would you ***prioritize strategic opportunities for PCORnet***?
- Are there additional opportunities to leverage the PCORnet infrastructure and resources to ***support innovation in PCOR***?

PCORnet® Priorities Workgroup Focus Areas

Overarching Strategies for Defining & Measuring Success

PCORnet evaluation framework should align w/ Prioritizing Principles for Infrastructure Funding, PCORnet maturity, and PCORI's larger evaluation strategy

Consider PCORnet's niche: strengths and limitations as a disease-agnostic research network

PCORnet builds capacity to continuously learn and improve

Prioritize 'better' and 'faster' over 'cheaper'

Benchmark PCORnet's performance against appropriate comparators whenever possible

Priorities for Data/Population Expansion in PCORnet Studies

Improve data quality (e.g., Common Data Model) across all participating networks

Enhance data capacity to include several types of health data:

1.) social determinants 2.) patient-generated 3.) non-clinical

Expand participation in PCORnet to include diverse, underrepresented, & underserved populations

Ongoing priority to ensure PCORnet is representative of full range of US population

Strategic Opportunities for PCORnet

Promote PCORnet to ensure the network is known as a national resource and a public good

Ensure the front door is highly accessible and easy to use

Expand partnerships and external use of PCORnet, including community-driven queries

Incentivize use of PCORnet for PCORI-funded studies

Develop PCORI's uses of PCORnet, such as rapid cycle query models to identify scalable ideas, inform PFA development

Promote PCORnet's use for:

- Definitive studies that are national in scope w/ implementable findings
- Studies in rare disease, IDD, MMM
- Studies along the trajectory of research, from topic generation to dissemination and implementation of findings
- Platform trials, randomized trials, high-quality observational studies

Public Comment Period

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

Closing Remarks

Nakela L. Cook, MD, MPH
Executive Director

Wrap Up and Adjournment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