Board of Governors Meeting

via Teleconference/Webinar

May 25, 2021
12:45 PM – 4:30 PM

pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Call to Order

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Agenda

12:45	Call to Order, Welcome and Consent Agenda
1:00-2:15	Strategic Planning – Facilitated Discussions
2:30-3:30	Executive Director's Report
3:30-3:45	Consider for Acceptance: PCORI Methodology Report
3:45-4:00	Consider for Approval: Funding for Partnership with AHRQ
4:00-4:30	Public Comment
4:30	Wrap-up and Adjournment

Consent Agenda

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Proposed Revised Supplemental Conflict of Interest Policy for PCORI Staff

- Today, at the recommendation of the Governance Committee, the Board is considering approving a proposed revised Supplemental Conflict of Interest Policy for PCORI Staff, which:
  - Addresses conflict of interest principles and expectations specific to employees;
  - Was originally approved by the Board in 2013 and has not been amended since that time;
  - Emphasizes the importance of appropriate conflict of interest disclosure;
  - Adds language requiring staff to cooperate with and to undertake conflict of interest management activities, such as recusals, firewalls, and declining to participate in certain activities;
  - Retains prohibition on royalties from and investments in health and healthcare related organizations, except for mutual funds;
  - Removes the prior outright prohibition on outside employment, honoraria, and consulting to align with a new District of Columbia law, while maintaining the obligations of disclosure and management of conflicts of interest and the obligations to fulfill employee's job functions; and
  - Removes 2013 language relating to an early transition period that has expired and language referring to a Board Committee that no longer exists.

Consent Agenda Motion

- That the Board:
  - Approve Minutes from the April 13, 2021Board Meeting
  - Approve the proposed revised Supplemental Conflict of Interest Policy for PCORI Staff

Consent Agenda 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

Strategic Planning: Day 1 Recap & Facilitated Discussion

Sonja Armbruster, MA

Preliminary Insights Generated from Yesterday's Discussions

- Incorporating **health equity** as a cross-cutting component relevant to all priorities and maintaining it as a distinct priority
- **Strategic partnerships** as key avenues for progress (multisectoral partners, traditional and non-traditional entities for engagement in PCOR)
- **Getting local** to move the needle (local community building for place-based or population-specific strategies and sustainability)
- Changing the **culture of research** (extending work in engagement, bi-directional communications that promote trust, influencing others)
- Being mindful of **unintended consequences** related to outcomes and impact
- Identifying **PCORI's unique role** and contribution within each priority
- Acknowledging draft National Priorities as **ambitious, aspirational** long-term goals and Research Agenda as more **measurable strategies** PCORI will take to achieve the goals

Advancing a Learning Health System: Further Refinement

- Insights from yesterday's dynamic discussion:
  - This area is relevant for PCORI's unique role and mission
  - Solely focusing on the "healthcare system" could be limiting
  - There is a need for refinement of boundaries and PCORI's specific niche when broadening to the "health system"
    - Elements that could enhance focus include:
      - Multifaceted interventions that cross sectors inclusive of public health, social systems, and clinical care settings
      - Interventions that focus on the local aspect to generate practice-based evidence
      - A focus on health outcomes for alignment with PCORI's remit
- What additional boundaries and areas of refinement would focus this priority for PCORI's unique mission, role, and opportunities?

Facilitated Discussion

- Where are the overlapping interests among the priorities and what opportunities might those create?
- What are the opportunities for these draft National Priorities to be translated to an operational research agenda?
- What's the next level thinking needed to assure PCORI makes progress on all five draft National Priorities?

Anticipated General Timeline: Sequenced to Build On Discussions

Spring 2021

May
- Refine draft **National Priorities for Health**

June
- Consider proposed National Priorities for Health for approval for posting for **public comment**

Summer 2021

July, August
- Discuss inputs and concepts for Research Agenda

September
- Consider **final National Priorities** for adoption
- Refine the Research Agenda

Fall 2021

October
- Refine the Research Agenda
- Determine concepts to include in **Strategic Plan**

November
- Consider draft Research Agenda for **public comment**

December
- Related **strategic discussions**

Winter 2022

February
- Consider **final Research Agenda** for adoption

March
- Begin drafting **Strategic Plan**

Spring 2022

April
- Continue drafting the **Strategic Plan**

May
- Consider **final Strategic Plan** for adoption

*Methodology Committee focus, MMM, and IDD decision points to be added when dates become available

BREAK

We will return at 2:30 PM ET

Join the conversation on Twitter via @PCORI

Welcome Back

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Executive Director's Report

Nakela L. Cook, MD, MPH

Executive Director

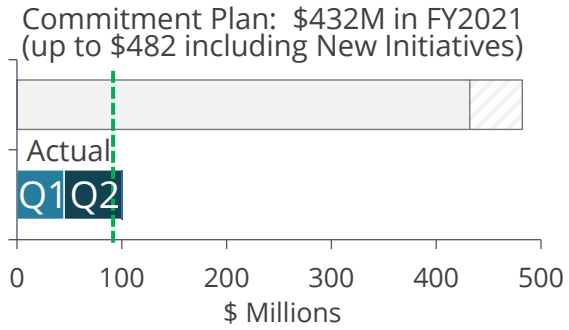
FY2021 Dashboard Midyear Review

PCORI Board of Governors Dashboard

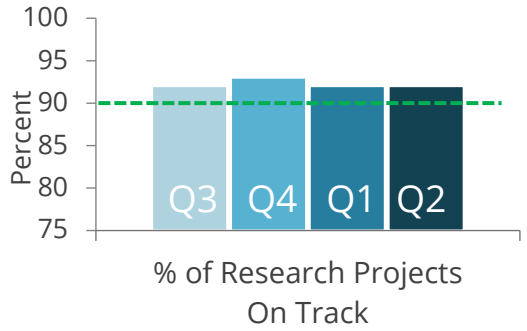
FY2021 Midyear Review (As of 3/31/21)

Inputs → Process → Outputs → Uptake → Use → Impact

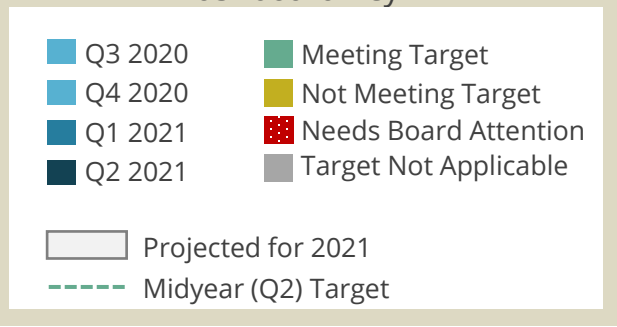
Funds Committed



Research Project Performance



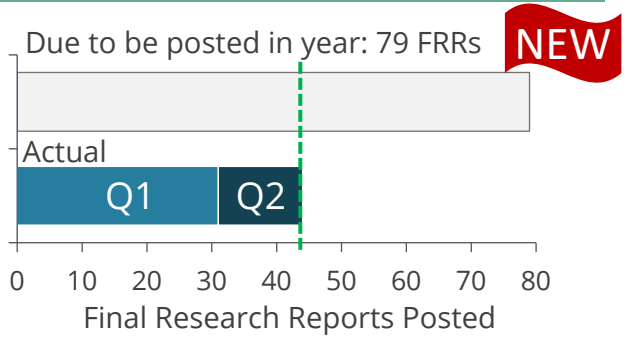
Dashboard Key



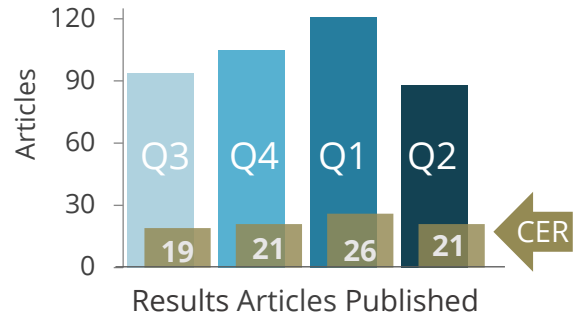
Posting of Results to PCORI.org

All abstracts to-date have been posted within 90 days of completion of PCORI Peer Review

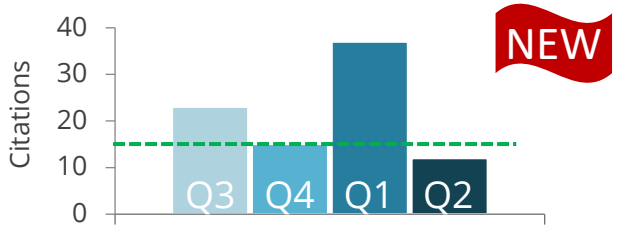
Final Research Reports Posted to PCORI.org



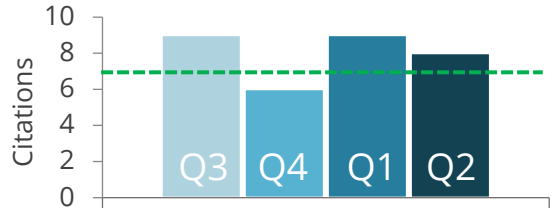
Results Published in the Literature



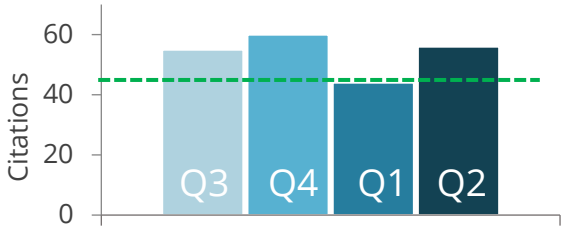
Uptake into Public/Patient Resources



Uptake of Results into UpToDate®



Other Examples of Uptake

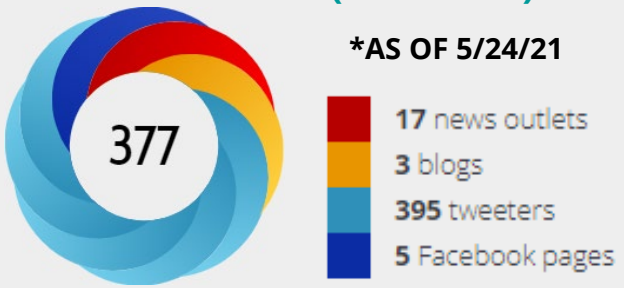


Goal 1: Increase Information for Health Decision-Making

Takeaway: No significant difference in either protective effects or bleeding risk between low dose and regular dose aspirin

PCORI Study	**Study Title:** Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE) **Principal Investigator:** William Schuyler Jones, MD, Duke University
Results Publication	Jones WS, et al. **Comparative Effectiveness of Aspirin Dosing in Cardiovascular Disease**. *NEJM*. 2021 May. doi:10.1056/NEJMoa2102137. Link to Publication.

Altmetric Score (Attention)



Summary: Aspirin has been used for more than 40 years to prevent heart attacks and strokes in people with heart disease. Doctors typically recommend either a regular strength (325 mg) or a low dose (81 mg) aspirin, but research has yet to determine the best dose to prescribe.

With over 15,000 patients enrolled in the trial, the ADAPTABLE study is the largest aspirin dosing trial conducted in routine care and clinical settings, and the first randomized controlled trial conducted using PCORnet®.

Results were presented at the May 2021 American College of Cardiology Annual Scientific Session, and simultaneously published in the New England Journal of Medicine.

The study found that people who took aspirin to lower their chances of having a heart attack or stroke experienced similar health benefits, including reduced death and hospitalization, whether they took the higher or lower dose aspirin.

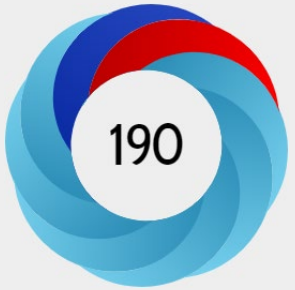
> We learned so many incredible things from ADAPTABLE about how to streamline processes and alleviate the burden of participating in research for both sites and patients… From its remote follow-up techniques to its engagement with patient partners, ADAPTABLE provides a blueprint for how research can be improved in the future."
>
> -Dr. William Schuyler Jones, Principal Investigator (from Duke University Press Release, 5/15/21)

Goal 1: Increase Information for Health Decision-Making

Takeaway: Nonpharmacological Interventions Safely Improve Breathlessness for Adults with Advanced Cancer

PCORI Study	**Study Title:** Interventions for Breathlessness in Patients With Advanced Cancer: A Systematic Review **Organization:** Memorandum of Understanding with Agency for Healthcare Research and Quality (AHRQ)
Results Publication	Gupta A, et al. **Nonpharmacological Interventions for Managing Breathlessness in Patients With Advanced Cancer: A Systematic Review**. *JAMA Oncology*. 2020 Nov. doi:10.1001/jamaoncol.2020.5184. Link to Publication.

Altmetric Score (Attention)



Mentioned by

17 news outlets

117 tweeters

2 Facebook pages

Top 5% of Attention given the journal

Summary: PCORI funded an AHRQ systematic review of pharmacological and nonpharmacological interventions for the management of dyspnea, or breathlessness, in patients with advanced cancer. Breathlessness affects upwards of 70% of patients with advanced cancer and is a major cause of patient and caregiver distress.

The systematic review evaluated evidence of the benefits and harms of 1) pharmacological interventions (opioids and anxiolytics) and 2) nonpharmacological interventions (e.g., respiratory interventions, oxygen therapy, respiratory training, behavioral therapy, and others). Evidence did not support the association of pharmacologic interventions with improved breathlessness (results published in *JAMA Network Open*).

The study found that **nonpharmacological interventions were associated with improved outcomes and adverse events were uncommon**. Nonpharmacological interventions associated with improved outcomes were fan therapy and bilevel ventilation in an inpatient setting, and acupressure, reflexology, and multicomponent interventions in an outpatient setting. See the full report on AHRQ.gov.

> Given the limited success and potential harms associated with pharmacological interventions, **nonpharmacological interventions should be considered as first-line treatment options** for managing breathlessness.

Goal 2: Speed Uptake and Use of Information

Results Incorporated into ASCO Clinical Practice Guideline

Results from this PCORI-funded AHRQ systematic evidence review on interventions for breathlessness in adults with advanced cancer were **taken up by the American Society of Clinical Oncology (ASCO) into their 2021 Clinical Practice Guideline** for Management of Dyspnea in Advanced Cancer. ASCO updated their clinical practice guideline **within 3 months** of the results publication.

- "ASCO convened an Expert Panel to review the evidence and formulate recommendations. An AHRQ systematic review provided the evidence base for nonpharmacologic and pharmacologic interventions to alleviate dyspnea (…) Funding for the AHRQ systematic review was provided by PCORI."
- **Recommendations:** Nonpharmacologic interventions that may be offered to relieve dyspnea include airflow interventions (e.g., a fan directed at the cheek), standard supplemental oxygen for patients with hypoxemia, and other psychoeducational, self-management, or complementary approaches. For patients who derive inadequate relief from nonpharmacologic interventions, systemic opioids should be offered.

[image source: Getty Images Plus, used with permission, accessed 4/29/21]

Full Citation:
Hui D, et al. **Management of Dyspnea in Advanced Cancer: ASCO Guideline.** J Clin Oncol. Feb 2021. DOI: 10.1200/JCO.20.03465

Goal 3: Influence the Culture of Research
Enhancing Veteran Engagement with PCORI Resources

Rachael R. Kenney, a Health Science Specialist at the Denver VA Medical Center, says PCORI's engagement resources have been valuable in building and managing a national Veteran Engagement Board. The board exemplifies patient engagement and supports peer recovery by providing feedback to researchers.

Kenney turned to PCORI's website, trainings, and the ***Engagement Tool and Resource Repository*** to help develop a board plan, including how to encourage diversity in its membership.

[image source: R. Kenney, used with permission]

"I really enjoy PCORI's emails and resources. I like using them to stay abreast of opportunities for the board that I manage and keeping the pulse on the wonderful world of patient engagement. PCORI is doing such important work."

Rachael R. Kenney, MA, PMP
Health Science Specialist,
Denver Center of Innovation for Veteran Centered and Value Driven Care, Denver VA Medical Center

To view more examples, visit PCORI's webpage for Influencing the Culture of Research

Trends in COVID-19 Disruptions/Delays to Research
FY2021 Midyear Update

- PCORI staff have been working closely with awardees to ensure that projects receive necessary modifications.
- Since we first collected data in July 2020 (Q3-20), **about half as many PCORI research studies** are experiencing pauses in study activity or are amid adaptations to their interventions.

Among Studies with COVID-related delays: (about 34% of active portfolio)

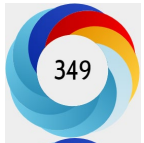
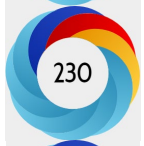
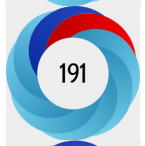
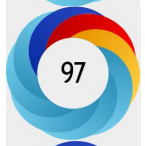
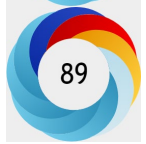
Disruption/Delay Type	Q3-20 %	Q2-21 %
Recruitment/activities significantly decreased	57%	73%
Feasibility concern	10%	13%
The award is completely paused	19%	8%
Intervention is being adapted	19%	8%
No new recruitment; continuing follow-up	16%	3%
Follow-up is prohibited or significantly decreased	7%	3%
Other non-enrollment related disruptions	14%	10%

We will share more details on COVID-19 related Adaptations and Enhancements in conjunction with the End-of-Year Dashboard.

Note: Awards may have more than one type of delay/disruption

Monitoring Attention to Published CER Results
FY2021 Midyear Update

Highlighted below are 6 CER Results publications with Altmetric scores ≥ 80. The score indicates attention in news articles (red), on social media (blues), and in blogs (gold).

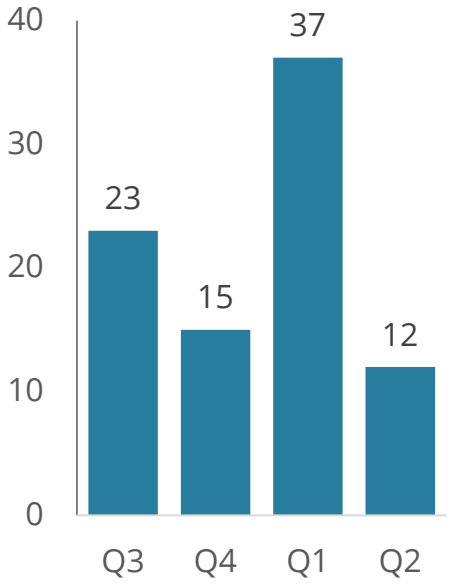
Altmetric	CER Results Publications Highlights	Score in Context*
	CODA Collaborative, Flum DR, et al. **A Randomized Trial Comparing Antibiotics with Appendectomy for Appendicitis.** *New England Journal of Medicine.* Oct 2020**.**	**Top 10%**
	Bramante CT, et al. **Metformin and risk of mortality in patients hospitalised with COVID-19: a retrospective cohort analysis.** *Lancet Healthy Longev.* Jan 2021**.**	**Top 5%**
	Stevans JM, et al. **Risk Factors Associated With Transition From Acute to Chronic Low Back Pain in US Patients Seeking Primary Care.** *JAMA Network Open.* Feb 2021**.**	**Top 10%**
	Gupta A,et al. **Nonpharmacological Interventions for Managing Breathlessness in Patients With Advanced Cancer: A Systematic Review.** *JAMA Oncology*. Nov 2020.	**Top 5%**
	Baer HJ, et al. **Effect of an Online Weight Management Program Integrated With Population Health Management on Weight Change: A Randomized Clinical Trial.** *JAMA*. Nov 2020.	**Top 30%**
	Nourbakhsh B, et al. **Safety and efficacy of amantadine, modafinil, and methylphenidate for fatigue in multiple sclerosis: a randomised, placebo-controlled, crossover, double-blind trial.** *Lancet Neurology*. Nov 2020.	**Top 10%**

*Level of attention is specific to the journal

Uptake of CER Results into Public/Patient Resources
FY2021 Midyear Update

We are developing methods for tracking citations and mentions of results from PCORI-funded studies in public/patient-facing resources and will be expanding sources for this metric over time. The initial target is for uptake of PCORI-funded study results to increase over time.

Uptake into Public/Patient-Facing Resources

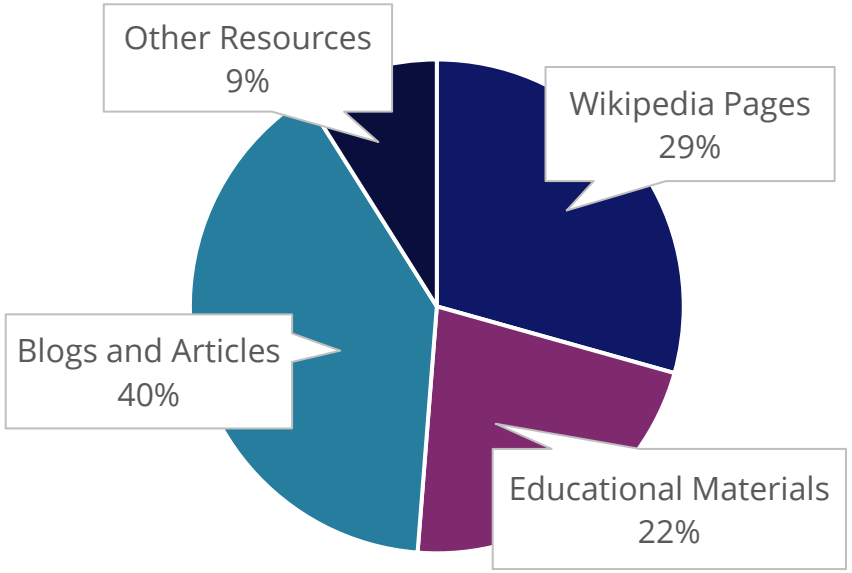


Cumulative: at least 197 citations or mentions in Public/Patient-Facing Resources

*Note: Current quarter counts can be artificially low because some articles are not indexed right away

Types of Resources Identified

(We aim to expand categories over time)



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

Discussion Questions

- Do our FY2021 Dashboard and associated background materials cover the topics that are most important for the Board to review?
- Do you have questions or comments about our performance on any of our Dashboard indicators?

Year in Review

Memorable Moments: Board Member Farewell

thank you!

Welcoming New Board Members

Tanisha Carino, PhD

Connie Hwang MD, MPH

James Schuster, MD, MBA

Eboni Price-Haywood, MD, MPH

Danny van Leeuwen MPH, RN

James Huffman

Kate Berry

PCORI's First Virtual Annual Meeting

Opening Keynote:
Blurred Lines, Flattened Hierarchies: The Evolution of Patient Stakeholders to Investigators
Liz Salmi

Standing Up to Racism, Discrimination, and Bias: A Dialogue on Health and Healthcare Equity
Lisa Cooper, Aletha Maybank, Bruce Siegel, Jessica Brooks, Mayra Alvarez, Cheryl Pegus

GAO Review

GAO issued its
3rd mandated review of PCORI
on November 18, 2020

COMPARATIVE EFFECTIVENESS RESEARCH: Patient-Centered Outcomes Research Institute and HHS Continue Activities and Plan New Efforts

GAO Highlights

Highlights of GAO-21-61, a report to congressional committees

November 2020

COMPARATIVE EFFECTIVENESS RESEARCH

Patient-Centered Outcomes Research Institute and HHS Continue Activities and Plan New Efforts

Why GAO Did This Study

The 2010 Patient Protection and Affordable Care Act (PPACA) authorized establishment of PCORI to conduct CER and improve its quality and relevance. PPACA also established new requirements for HHS to, among other things, disseminate findings from federally funded CER and coordinate federal programs to build data capacity for this research. To fund CER activities, PPACA established the Trust Fund, which provided a total of about $3.6 billion to PCORI and HHS for CER activities during fiscal years 2010 through 2019. The Further Consolidated Appropriations Act, 2020, added new CER requirements and extended funding at similar levels through fiscal year 2029.

PPACA and the Appropriations Act 2020 included provisions that GAO review PCORI and HHS's CER activities. This report describes (1) the CER activities PCORI and HHS carried out to meet legislative requirements, (2) how PCORI and HHS allocated funding to those CER activities, and (3) PCORI and HHS efforts to evaluate the effectiveness of their CER dissemination and implementation activities, such as changes in medical practice.

GAO reviewed legislative requirements and PCORI and HHS documentation and data for fiscal years 2010-2019. GAO also interviewed PCORI and HHS officials and obtained information from nine selected stakeholder groups that were familiar with PCORI's or HHS's CER activities. These groups included payer, provider, and patient organizations. GAO incorporated technical comments from PCORI and HHS as appropriate.

View GAO-21-61. For more information, contact John Dicken at (202) 512-7114 or dickenj@gao.gov.

What GAO Found

GAO found that the Patient-Centered Outcomes Research Institute (PCORI)—a federally funded, nonprofit corporation—and the Department of Health and Human Services (HHS) have continued to perform comparative clinical effectiveness research (CER) activities required by law since our prior report issued in 2015. CER evaluates and compares health outcomes, risks, and benefits of medical treatments, services, or items. The requirements direct PCORI and HHS to, among other things, fund CER and disseminate and facilitate the implementation of CER findings.

GAO's analysis of PCORI and HHS documents show that they allocated a total of about $3.6 billion for CER activities and program support during fiscal years 2010 through 2019 from the Patient Centered Outcomes Research Trust Fund (Trust Fund). Specifically, PCORI allocated about $2 billion for research awards and another $542 million for other awards, to be paid over multiple years. HHS allocated about $598 million for activities such as the dissemination and implementation of CER findings. PCORI and HHS also allocated about $470 million for program support.

PCORI and HHS Allocations for Comparative Clinical Effectiveness Research (CER) Activities, Fiscal Years 2010 through 2019

Source: GAO analysis of Patient-Centered Outcomes Research Institute (PCORI) and Department of Health and Human Services (HHS) data. | GAO-21-61

[a]Totals may not add up due to rounding.
[b]PCORI and HHS allocated $457 million and $13 million for program support, respectively.

PCORI assessed the effectiveness of its activities using performance measures and targets. Since fiscal year 2017, when early CER projects were completed, PCORI officials reported that the institute met its performance targets, such as an increased number of research citations of its CER findings in news and online sources. HHS described accomplishments or assessed the effectiveness of its dissemination and implementation activities. PCORI and HHS officials told GAO they are planning comprehensive evaluations of their CER dissemination and implementation activities as part of their strategic plans for the next 10 years.

United States Government Accountability Office

What We Do and How We Work

What We Do

How We Work

Fulfilling the Mission

Collaboration & Teamwork

Diversity, Equity, & Inclusion

What We Do

Fulfilling the Mission

Support PCORI's mission by engaging in and aligning with organization-wide priority setting; nimbly, efficiently, and effectively supporting funding activities in alignment with Board-approved commitment plan

What We Do

Fulfilling the Mission

Strategic Planning

- Develop overarching plan*
- Respond to changes in external landscape
- Outreach, listen, engage
- Advance trust for patient & community engagement in research,
- Implementation of cost provision, and reach of stakeholders engaged

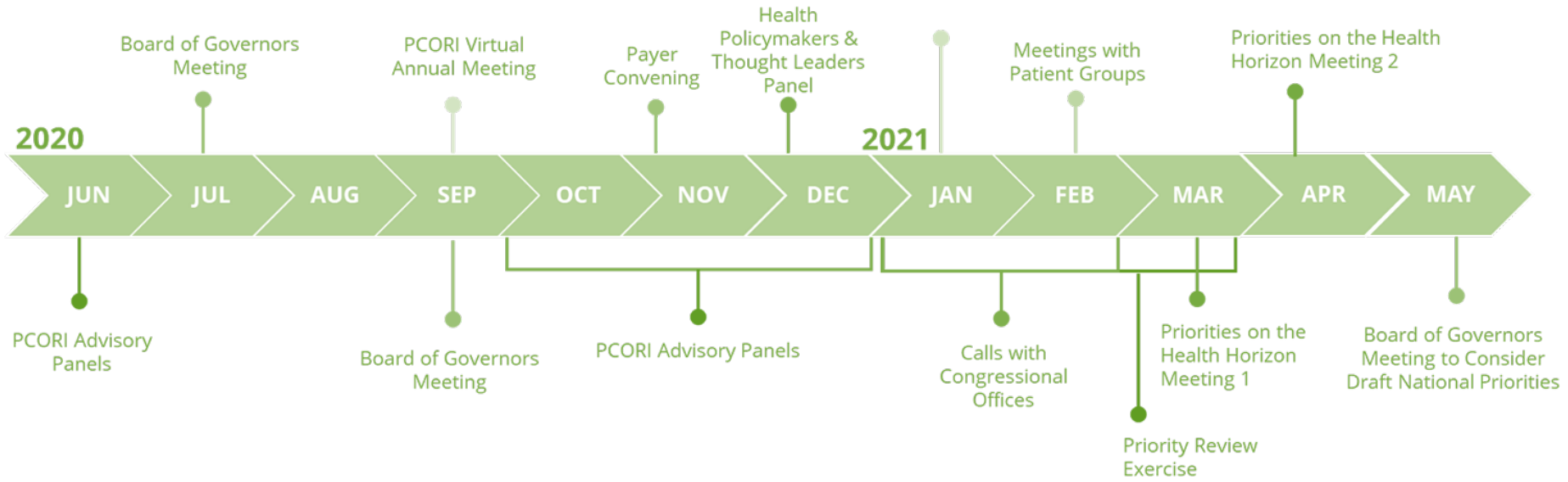
Funding Approaches

- Build and implement COVID-19 response
- Execute PFA Programming in alignment with commitment plan
- Implement rapid funding approaches

** Includes: Governance, National Priorities, Research Agenda, Priorities from Reauthorization, Priorities for PCORnet, Scenario and Commitment Planning, Methodology Committee Activities*

Strategic Planning Activities

- National Priorities
- Principles for the next phase of PCORnet®
- Commitment Planning
- Priorities from reauthorizing legislation
- Methodology Committee focus for PCORI's next phase



Priority Research Areas in Reauthorizing Legislation

Stakeholder Engagement

- Active
- Long-term
- Existing, new, diverse groups & lived experience

Funding Opportunity Development

Framing of Other Evidence Products (e.g., systematic reviews)

Implementation Plans for Data Collection

Special Areas of Emphasis:

- Increasing Access to and Continuity of Patient-Centered Maternal Care
- Improving Care for Individuals with Intellectual and/or Developmental Disabilities Growing into Adulthood

Targeted PFAs:

- Postpartum Maternal Outcomes
- Mental Health Conditions in Individuals with Intellectual and Developmental Disabilities

Principles for the Consideration of the Full Range of Outcomes Data in PCORI-Funded Research

Identifying Outcomes Important to Patients

- **Principle #1:** Considering the full range of outcomes *important to patients and caregivers*, including burdens and economic impacts, is central to PCORI-funded research.

Identifying Outcomes Important to Stakeholders

- **Principle #2:** PCORI-funded research may consider the full range of outcomes *relevant to other stakeholders*, when these outcomes have a near-term or longer-term impact on patients.

Criteria for Data Collection Opportunities

- **Principle #3:** The collection of data on potential burdens and economic impacts of treatment options must be appropriate and relevant to the clinical aims of the study.

Consideration of Economic Analysis

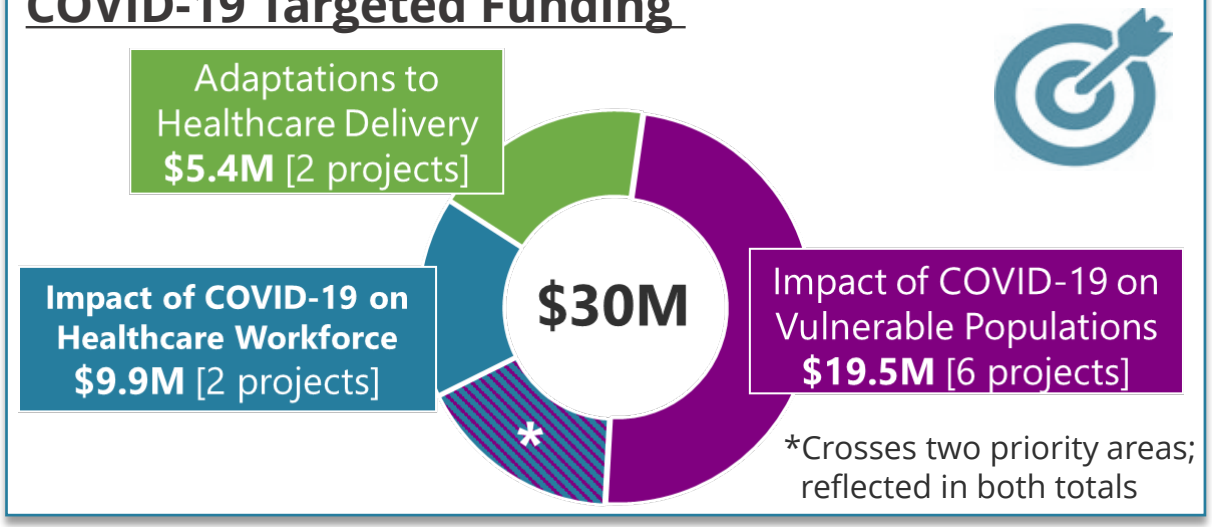
- **Principle #4:** PCORI may support the conduct of certain types of economic analyses, as part of a funded research study or independently, to enhance the relevance and value to patients and other stakeholders of information PCORI-funded investigators collect on potential burdens and economic impacts.

PCORI's Response to the COVID-19 Pandemic

- **Research Projects**
  - COVID-19 Enhancements to Existing Research Projects
  - COVID-19 Targeted Funding Announcement and Projects
  - Fast Funding Approach for COVID-19 Targeted PFA on Increasing Vaccine Confidence Among Long-Term Care Workers
  - Broad PFA COVID-19 Special Areas of Emphasis
  - Adaptations
- **PCORnet®**
  - HERO Program
  - PCORnet® CDC Partnership
  - FDA Evidence Accelerator
  - ACTIV-6
  - PCORnet®-NCATS Vaccine Collaboration
- **Engagement Projects & Information Sharing**
  - Horizon Scanning COVID-19 Supplements
  - Special Cycle Solicitations
  - Webinar Series
- **Dissemination and Implementation Projects**
  - COVID-19 Enhancements to Existing Projects

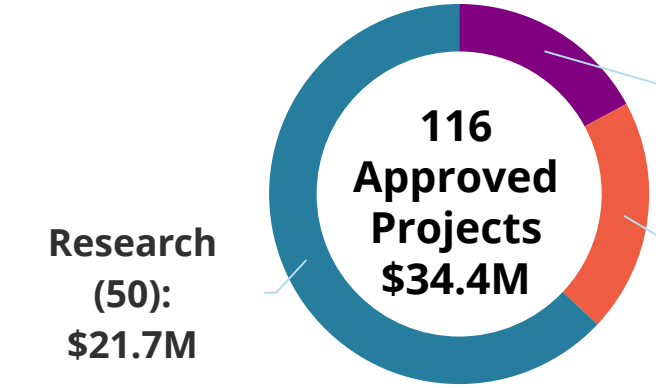
PCORI COVID-19 Funding to Date

COVID-19 Targeted Funding



*Crosses two priority areas; reflected in both totals

COVID-19 Enhancement Projects

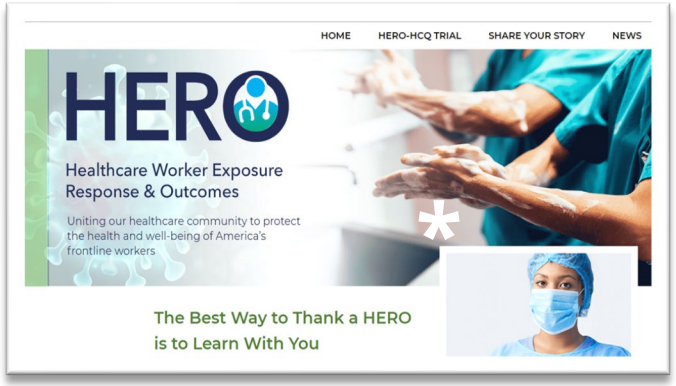


Dissemination & Implementation (13): $5.8M

Research (50): $21.7M

Engagement (53): $7M

Specific conditions and populations



www.heroesresearch.org

PIs: Adrian Hernandez, MD, MHS; Emily O'Brien, PhD; Suzanna Naggie, MD

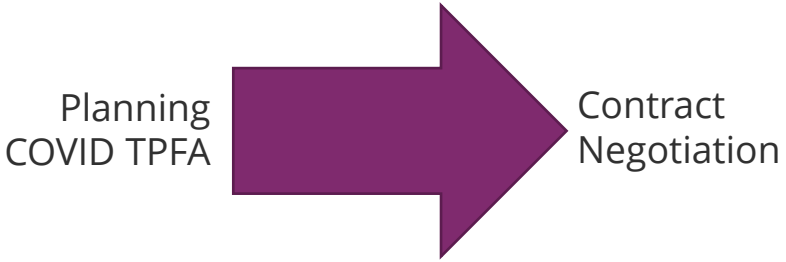
Institution: Duke University

- Healthcare Worker Registry
- HCQ Trial

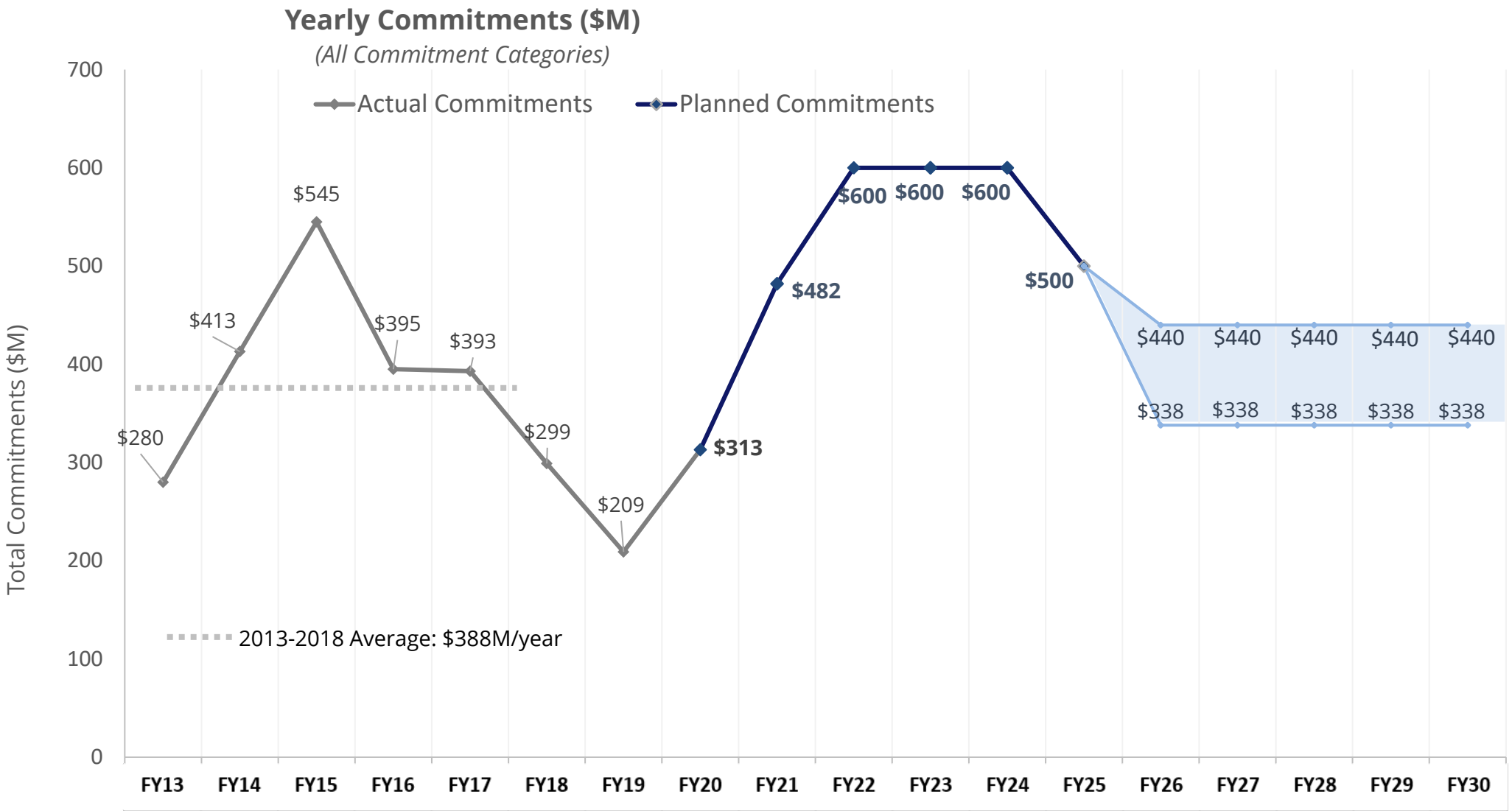
Fast Funding Approaches

Typical Implementation

Fast Implementation: 12 weeks



3-Year Commitment Plan



Blue Range:
Average Commitment under Two Different Assumptions about PCOR Fee Level

Targets shown assume the flexible funding described on the next slide is committed equally each year, but it may vary from year to year

Expedited Approach to PFA Development While Strategic Planning is Underway

January
- Board consideration of expedited approach to PFA development while strategic planning is underway

February
- Board approval of expedited approach for developing targeted PFAs

March
- Board approval of development of targeted PFAs for Cycle 2 2021

April
- Board approval of set of potential topics for development for future cycles

June
- Board considers for approval development of targeted PFAs for Cycle 3 2021, recommended by SOC

PFA Topic
Improving Postpartum Maternal Outcomes for Populations Experiencing Disparities
Comparative Effectiveness of Interventions Targeting Mental Health Conditions in Individuals with Intellectual and Developmental Disabilities
Nonsurgical Interventions for Women with Urinary Incontinence

How We Work

Collaboration & Teamwork

Work with colleagues across PCORI on activities and projects, lending and sharing expertise to maximize outcomes.

Support: Leadership learning labs

How We Work

Collaboration & Teamwork

PCORI Culture

- Create a unified cultural vision; optimize virtual environment
- Develop cohesive and collaborative leadership team and cross-departmental staff teams

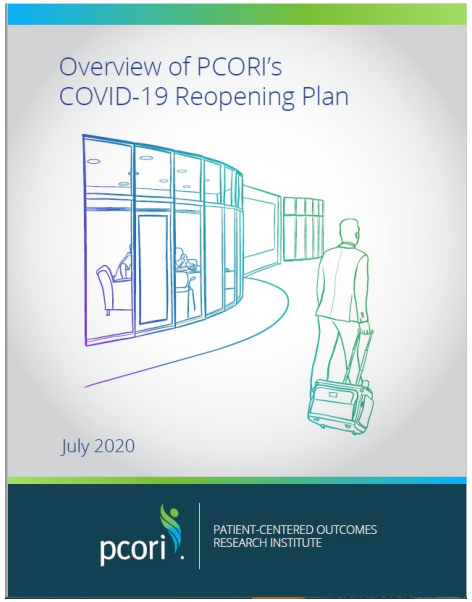
Workforce and Workplace

- Build & Implement Staffing Plan for PCORI *Next*
- Secure sustainable space plan
- Implement COVID-19 response

Organization Transformation

- Execute organizational assessment and future state model
- Implement recruitment & onboarding strategies
- Optimize processes for effectiveness and efficiency

Remote Work and Return to Office Plan



Staff functioning well remotely and with accelerated work in response to COVID-19 and commitment plan

Guiding Principles

- Safety and Well-Being of PCORI's Workforce
- Flexible Approach for Needs and Circumstances of the Workforce
- Compliance with Requirements of Local and Federal Authorities
- Advanced Notice & Flexibility Between Phases

Gradual Staff Access to Offices

Phase 0	Phase 1	Phase 2	Phase 3	Phase 4
Workforce Members Teleworking	Workforce Members Teleworking; Only Designated Staff Permitted	Workforce Members Generally Teleworking; Initial Small Percentage Permitted	Telework Continues with Greater Office Accessibility	Workforce Members Expected to Return to Working in Office

Flexible approach for timing with **at least** 4 weeks between

Widely available effective prevention/ treatment; change in virus virulence or transmissibility

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 enable better-informed healthcare decisions.

Ongoing High-Priority Recruitments

Deputy Executive Director for Patient-Centered Research Programs

PCORI is currently seeking a Deputy for Patient-Centered Research Programs to provide strategic leadership and management oversight for the operational execution and implementation of activities related to funding of programs and projects. The successful candidate will optimize functional alignment and coherency of a new programmatic unit with the goal to align with the organization wide future-looking operating model that integrates across disciplines, and creates a collaborative, inclusive culture where employees can thrive and work to deliver on PCORI's mission.

Chief Information Officer

PCORI is currently seeking a Chief Information Officer (CIO) to align with the future state operating model's vision. The CIO has responsibility for leading PCORI's information and technology personnel and efforts, including data governance activities, transformation technology projects, and information and technology systems management. The CIO should bring strategic planning and oversight experience along with extensive knowledge and experience of managing Information and technology operations.

How We Work

Diversity, Equity, & Inclusion

Works with others in a manner that supports an inclusive workplace culture, one that values and derives strength from the diverse backgrounds, perspectives, talents, and experiences of PCORI employees and promotes all staff feeling included, connected, and engaged to bring their unique skills toward fulfillment of the mission.

Diversity, Equity and Inclusion

- Develop and execute PCORI-wide DEI initiative with external and internal components

Diversity, Equity and Inclusion Initiative Update

Seminal Reports on Health Disparities

"And although our health charts do itemize steady gains in the health status of minority Americans, the stubborn disparity remained—an affront both to our ideals and to the ongoing genius of American medicine."

—Margaret Heckler, HHS Secretary

Introductory letter to *Report of the Secretary's Task Force on Black and Minority Health, 1985*

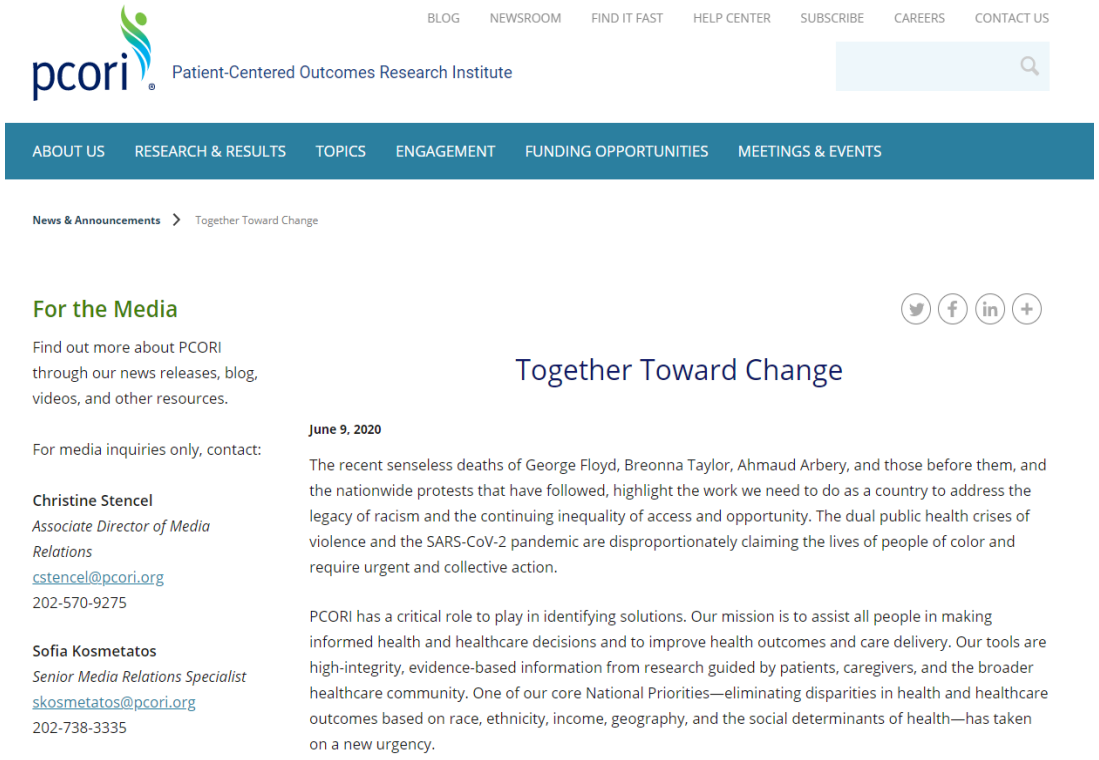
COVID-19 and Health Disparities

Rate ratios compared to White, Non-Hispanic persons	American Indian or Alaska Native, Non-Hispanic persons	Asian, Non-Hispanic persons	Black or African-American, Non-Hispanic persons	Hispanic or Latino persons
Cases[1]	1.7x	0.7x	1.1x	1.3x
Hospitalizations[2]	3.7x	1.0x	2.9x	3.1x
Deaths[3]	2.4x	1.0x	1.9x	2.3x

Source: CDC / March 12, 2021

[1] Data Source: Data reported by state and territorial jurisdictions (accessed 03/10/2021). Numbers are ratios of age-adjusted rates standardized to the 2019 US intercensal population estimate. Calculations use only the 53% of case reports that have race and ethnicity data available; this can result in inaccurate estimates of the relative risk among groups.
[2] Data source: COVID-NET (https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/purpose-methods.html, accessed March 1, 2020, through February 27, 2021). Numbers are ratios of age-adjusted rates standardized to the 2019 US standard COVID-NET catchment population.
[3] Data source: NCHS provisional death counts (https://data.cdc.gov/NCHS/Deaths-involving-coronavirus-disease-2019-COVID-19/ks3g-spdg, data through March 6, 2021). Numbers are ratios of age-adjusted rates standardized to the 2019 US intercensal population estimate.

Together Toward Change



pcori Patient-Centered Outcomes Research Institute

BLOG NEWSROOM FIND IT FAST HELP CENTER SUBSCRIBE CAREERS CONTACT US

ABOUT US RESEARCH & RESULTS TOPICS ENGAGEMENT FUNDING OPPORTUNITIES MEETINGS & EVENTS

News & Announcements > Together Toward Change

For the Media

Find out more about PCORI through our news releases, blog, videos, and other resources.

For media inquiries only, contact:

Christine Stencel
Associate Director of Media Relations
cstencel@pcori.org
202-570-9275

Sofia Kosmetatos
Senior Media Relations Specialist
skosmetatos@pcori.org
202-738-3335

Together Toward Change

June 9, 2020

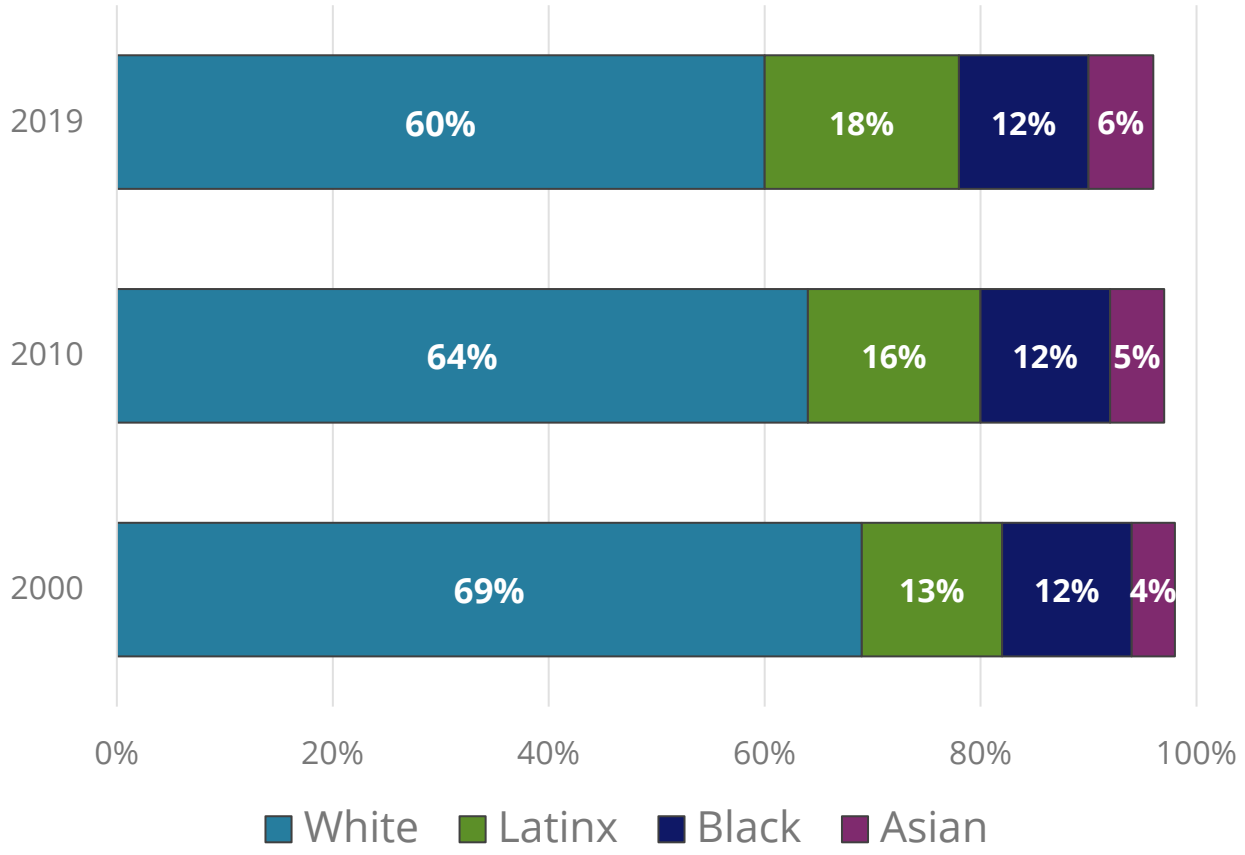
The recent senseless deaths of George Floyd, Breonna Taylor, Ahmaud Arbery, and those before them, and the nationwide protests that have followed, highlight the work we need to do as a country to address the legacy of racism and the continuing inequality of access and opportunity. The dual public health crises of violence and the SARS-CoV-2 pandemic are disproportionately claiming the lives of people of color and require urgent and collective action.

PCORI has a critical role to play in identifying solutions. Our mission is to assist all people in making informed health and healthcare decisions and to improve health outcomes and care delivery. Our tools are high-integrity, evidence-based information from research guided by patients, caregivers, and the broader healthcare community. One of our core National Priorities—eliminating disparities in health and healthcare outcomes based on race, ethnicity, income, geography, and the social determinants of health—has taken on a new urgency.

"We commit to funding comparative clinical effectiveness research that delivers actionable steps toward eliminating disparities and moving evidence into practice for the benefit of all Americans. We stand united with the people of this country to find and implement solutions to the public health crises of inequity and inequality of access and opportunity. Inaction is not an option."

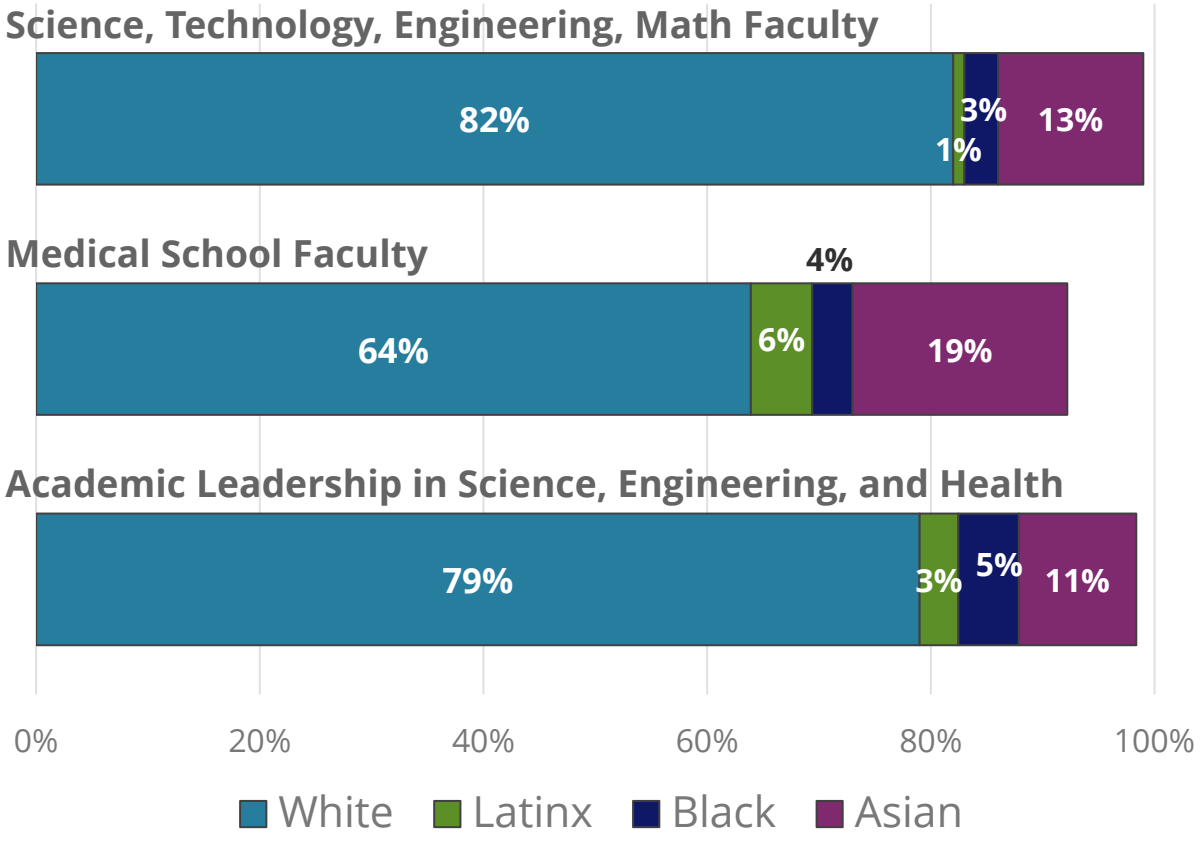
A Call to Action

America's Increasing Diversity



Source: US Census Bureau / Census Population Estimates / Released June 25, 2020
Note: Percentages do not sum to 100% given not all categories are shown.

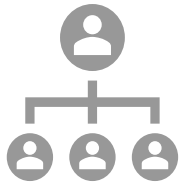
Yet Disproportionate Representation



Sources: Brookings Institute / STEM Faculty at Select Public Institutions / Released 2017;
AAMC / US Medical School Faculty/ Released 2019;
National Science Foundation / Academic Leadership Positions / Released 2019

Challenges for the Research Ecosystem

Data Demonstrate….



Organization

- Disproportionate representation in STEM
- Proportionately fewer BIPOC at higher ranks in academia
- Bias influencing perception
- Cultural taxation

Funder

- Disparities in Research Funding
- Less favorable scores for topics of relevance to communities and population health
- Potential for bias in research and funding processes

Partner

- Disproportionate representation in clinical trials
- Lack of trust and trustworthiness

PCORI's Commitment to Diversity, Equity & Inclusion

PCORI's commitment to diversity, equity, and inclusion is critical to achievement of its mission.

Internally Facing

Committed to cultivating a diverse workplace and a culture that values equity and derives strength from diverse backgrounds, perspectives, talents, and experiences and promotes all staff feeling included, connected, and engaged to bring their unique skills toward fulfillment of the mission

Externally Facing

Committed to being equitable in engaging diverse stakeholders, promoting diverse and inclusive convenings, as well as a diverse pool of applicants, awardees, and participation in research

Relevant Dimensions of Diversity

- **Representation**
  - Reflecting the diversity of the nation
- **Reach**
  - Including populations historically excluded in the biomedical, clinical, and behavioral and social sciences
- **Research Processes**
  - Stakeholders, applicants, reviewers, funded investigators, study participants

Advancing Equity Toward Equal Outcomes

Equity

What We Mean by Inclusion:

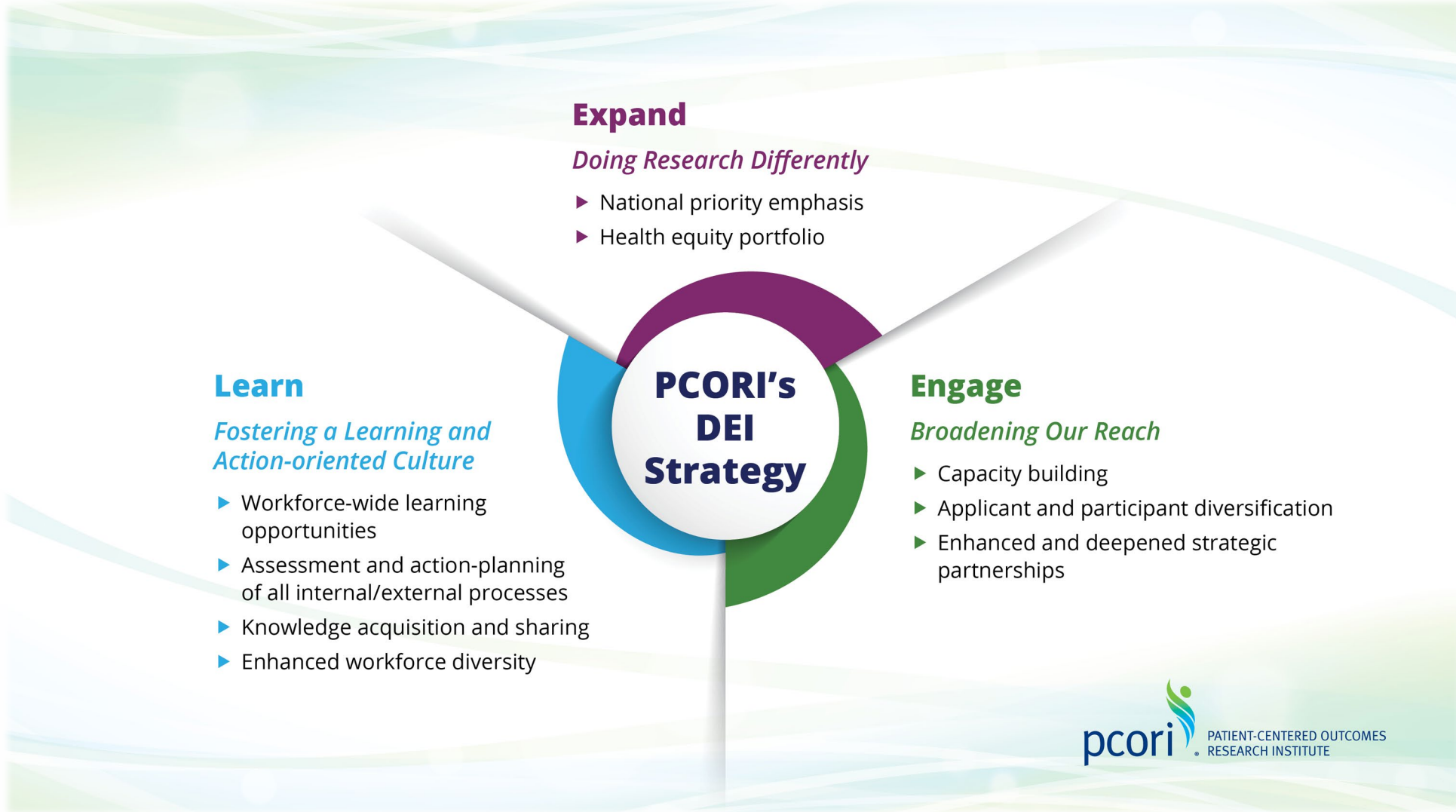
Inclusion

A set of behaviors that encourages everyone to feel valued for their unique qualities and to experience a sense of belonging

- Centers for Disease Control and Prevention

In research, often describes those included in studies in a manner appropriate to the scientific question so that knowledge gained is applicable to those affected

Three Main Goals of Our Strategy:
Learn, Expand, Engage



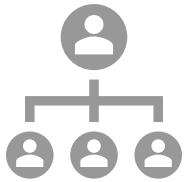
Three Pillars to our DEI Strategy

PCORI as an Organization

PCORI as a Funder

PCORI as a Partner

Our Strategy: PCORI as an Organization
Short- and Long-Term Activities & Initiatives



PCORI as an Organization

Strategy Domain	Short-Term Activities	Long-Term Planning
Practices	• Enhance data collection strategic framework to align with our DEI principles • Refine current procurement processes and procedures to include DEI principles • Incorporate DEI into our strategic plan	• Utilize DEI data collection framework to enhance assessment and evaluation • Continuously assess practices, policies and procedures for potential biases and address to align with and support DEI goals
Culture	• Articulate our commitment with a DEI Values Statement • Create a DEI strategic framework with workstreams • Incorporate DEI into our people strategy with shared expectations	• Enhance recruitment and retention strategies to support workforce diversity, equity and inclusion
Workforce	• Establish leadership to spearhead DEI efforts • Identify and deploy workforce DEI training opportunities	• Utilize relevant DEI tools, resources and best practices to advance our work • Provide ongoing DEI learning opportunities to our workforce

Our Strategy: PCORI as a Funder
Short- and Long-Term Activities & Initiatives

PCORI as a Funder

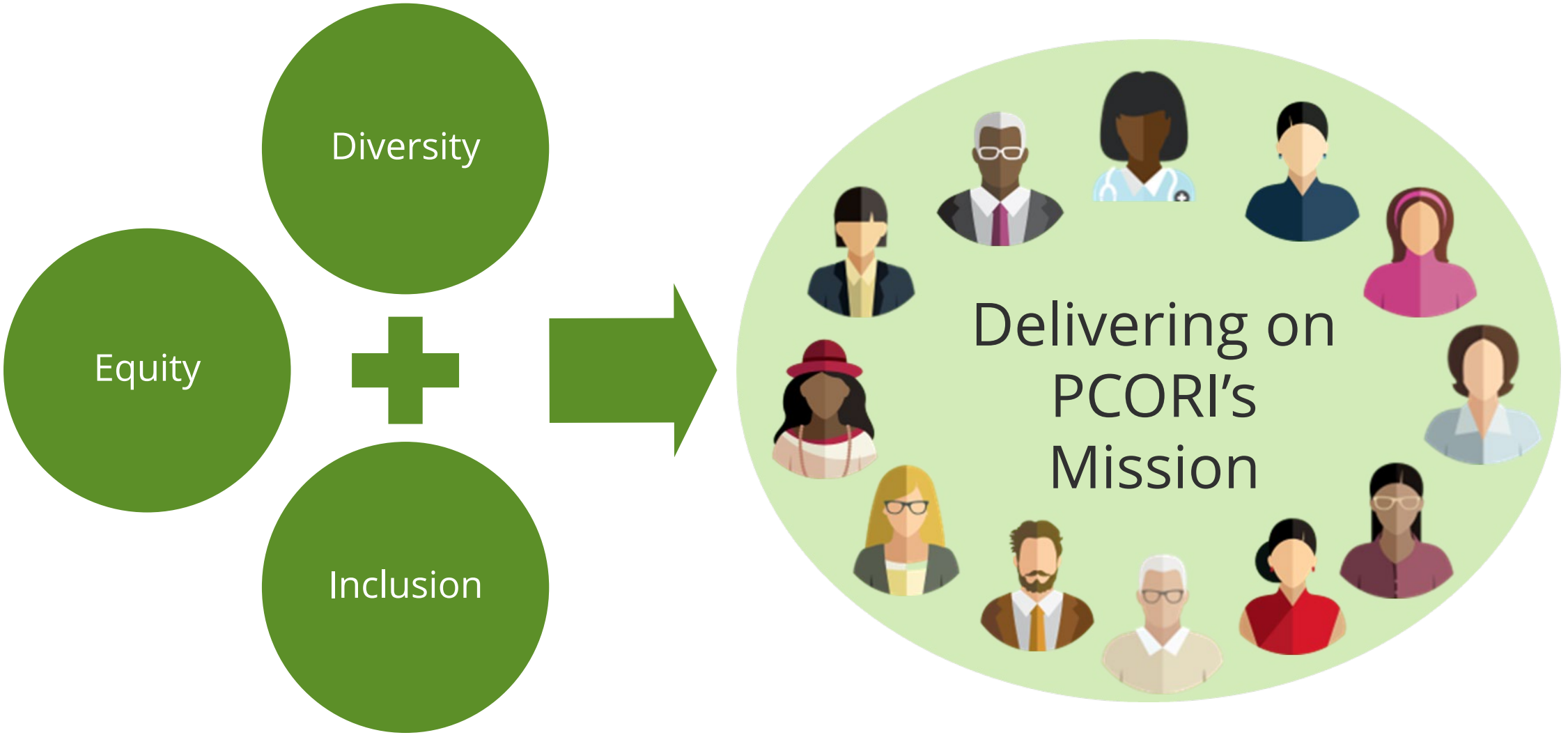
Strategy Domain	Short-Term Activities	Long-Term Planning
Portfolio	• Expand health equity research portfolio and initiatives convergent with developing National Priorities • Leverage our awards activities to support projects focused on DEI in PCOR and eliminating health disparities	• Build capacity and support historically excluded communities in PCOR-funded research
Practices	• Enhance Patient Engagement rubric to incorporate DEI principles	• Gather and monitor researcher, community, and convener input and feedback to inform practices
Evaluation	• Establish an evaluation approach for the DEI initiative • Enhance data collection strategic framework to align with our DEI principles • Further assess bias in current research and review processes	• Utilize DEI data collection strategic framework to continually evaluate our activities and initiatives • Implement strategies to address identified biases in support of DEI goals

Our Strategy: PCORI as a Partner
Short- and Long-Term Activities & Initiatives

PCORI as a Partner

Strategy Domain	Short-Term Activities	Long-Term Planning
Collective Action	• Increase opportunities to provide and collect relevant insight via a variety of thought leadership forums • Expand synergistic collaborations with organizations, funders, and agencies	• Advance strategies to remove barriers and create opportunities for historically excluded communities and populations
Relationship Building	• Identify opportunities for strategic sponsorship for diversity inspired initiatives and institutions • Expand connections to historically excluded populations through enhanced outreach strategies	• Share resources and strategies with external partners and communities • Engage populations historically excluded in research
Research Participation	• Identify challenges and potential strategies to build diverse pools of applicants for research funding • Build on engagement rubric to enhance strategies for diverse study participants	• Implement strategies that aim to ensure research reflects the nation's diversity • Focus on topics relevant to historically excluded populations

A Framework for Optimizing Achievement of Our Mission



Discussion and Questions

Methodology Committee - Request for Acceptance of the Updated Methodology Report

Steven Goodman, MD, MHS, PhD

Chair, PCORI Methodology Committee

Robin Newhouse, PhD, RN

Vice-Chair, PCORI Methodology Committee

Highlights:
Revisions to the Methodology Report

Additions:

- Rationale for and text of the following Methodology Standards and response to public comments for these standards, adopted by the Board in 2019
  - standards for qualitative methods (QM)
  - standards for mixed methods research (MM)
  - standards for individual participant-level data meta-analysis (IPD-MA)
- Recommendation for using the SPIRIT or NIH tools for drafting clinical research protocols

Updates:

- Methodology Committee membership
- Changes stemming from Reauthorization

Board Vote

Call for a Motion to:	• **Accept** the Updated PCORI Methodology Report
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

Sustaining Our Partnership with AHRQ for Systematic Reviews

Nakela L. Cook, MD, MPH
Executive Director

PCORI's Long-running Partnership with AHRQ to Conduct Systematic Reviews

Over the past five years, this successful partnership has produced systematic reviews and updates on a range of topics, including:

- *Rheumatoid arthritis*
- *Urinary incontinence*
- *PTSD*
- *Stroke prevention in atrial fibrillation*
- *Breathlessness for patients with advanced cancer*
- *Cervical ripening in the outpatient setting*
- *Radiation therapy for brain metastases*
- *Infantile epilepsy*

PCORI-AHRQ Partnership for Systematic Reviews: Envisioning the Next Five Years

Increasing need for Systematic Reviews, flowing from work with stakeholders on

- Research Agenda
- Topic Development
- Communication, Dissemination, and Implementation Efforts

Periodic MOU's with AHRQ for several Reviews at a time

- MOU's are typically in the $1.5M to $2.5M range
- Requesting approval for funding MOU's up to $6M per year for 5 years

In the works, new Systematic Reviews on:

- Maternal mortality and morbidity
- Intellectual and developmental disabilities

Board Vote

Call for a Motion to:

- **Approve funding of up to $6 Million per fiscal year**, not to exceed a total of $30 Million for 5 fiscal years, to the Agency for Healthcare Research and Quality (AHRQ) for **PCORI's partnership with AHRQ to fund the conduct of systematic reviews**, subject to finalization of Memorandum(s) of Understanding 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**

Roll Call Vote:

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

Public Comment Period

Greg Martin

Acting Chief Engagement and Dissemination Officer

Closing Remarks

Wrap Up and Adjournment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