Board of Governors Meeting

via Teleconference/Webinar

April 13, 2021
1:00 PM – 3:00 PM

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PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Call to Order

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Agenda

1:00-1:05	**Welcome, Call to Order and Consent Agenda:** • Minutes of the March 16, 2021 Board Meeting • Nomination of Advisory Panel on Clinical Effectiveness and Decision Science (CEDS) and Advisory Panel on Clinical Trials (CTAP) Chairs • Revised Board Compensation Policy
1:05-1:30	**Consider for Approval:** Set of Candidate Topics for Targeted PFA Development through FY2022
1:30-2:00	**Summary from** *Priorities on the Health Horizon March 2021 Meeting*, a collaboration with the National Academy of Medicine
2:00-3:00	**Strategic Planning Committee Report** and Discussion of Emerging Themes for National Priorities for Health
3:00	**Wrap-up and Adjournment**

Consent Agenda Items

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Board Vote

- That the Board approve:
  - Minutes from the March 16, 2021 Board meeting
  - Nomination of Kari Gali, DMP, APRN, as Chair and Julie Eller, BS as Co-Chair of the Advisory Panel on Clinical Effectiveness and Decision Science, to serve through August 2023, or until a replacement is appointed
  - Nomination of Michael L. Jones, PhD, MBA, RN, as Co-Chair of the Advisory Panel on Clinical Trials to serve through August 2023, or until a successor is appointed
  - Proposed revised Board and Methodology Committee Compensation and Reimbursement Policy with an effective date of January 1, 2021

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

Set of Candidate Topics for Targeted PFA Development for Future Cycles through FY2022

Alicia Fernandez, MD

Science Oversight Committee (SOC) Chair

Nakela L. Cook, MD, MPH

Executive Director

Reminders – Picking Up Where We Left Off

Under our ***expedited and enhanced process***, the Board approved three topics for development of targeted PFAs for Cycle 2

Topic	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

The set of candidate topics presented today are ***important and feasible for the next few Cycles*** to maintain pace on meeting commitment plan

Timeline Recap and Next Steps

January

- **SOC** consideration of approach and set of potential topics

February

- **SOC** consideration for approval of topics for targeted PFAs for Cycle 2 2021
- **Board** discussion of expedited approach for developing targeted PFAs

March

- **SOC** discussion of topics in development for upcoming cycles
- **Board** consideration for approval of development of targeted PFAs for Cycle 2 2021

April and Beyond

- **SOC** discussion of topics in development and consideration for approval of targeted PFAs for future cycles
- **Board** consideration of set of potential topics for development for future cycles. Future consideration for approval of development of targeted PFAs for future cycles

Today the Board will consider a set of candidate topics for development for future cycles.

- Set is *in addition to* COVID-19, IDD, and MMM topics
- The development of each TPFA for each cycle and associated funding will be recommended by the SOC to the Board for consideration for approval

Programming remains responsive to developments

Next Step in Expedited and Enhanced Approach to Developing Targeted PFAs

- Board considers *set of topics for development for future cycles*
  - Development of individual topics will be recommended by SOC to Board for approval after further work
  - Set is *in addition to* COVID-19, MMM, IDD topics

- Topics developed for *full range of options for PFAs*
  - Targeted PFA or Special Area of Emphasis in other PFAs

- Programming *remains responsive to developments*
  - Within proposed topic area
  - With respect to emerging topics
  - Inclusive of learning from each PFA

Advantages of Programming a Set of Topics for the Next Several Funding Cycles

- *Expedited development of topics includes standard:*
  - Literature review
  - Outreach to relevant patient groups and stakeholders
  - Review of PCORI's funded portfolio
  - Consultation with NIH, AHRQ, other relevant funders

- *Approval of a set of topics for Targeted PFA development:*
  - Allows longer-range planning
  - Focuses staff resources
  - Provides greater advance notice for research and stakeholder communities
    - Could increase readiness to submit applications
    - Might result in greater number of more fully developed applications

Recommended Candidate Topics for Development for Targeted Funding for Cycle 3 2021

Funding mechanism	Cycle 3 2021
Targeted PFA or Special Area of Emphasis	• Healthy Aging: Optimizing physical and mental function across the aging continuum • Osteoporotic fracture prevention • Migraine prevention • Addressing racism, discrimination, and bias throughout the care continuum* • Leveraging telehealth for chronic disease management among vulnerable populations with complex needs*

Note: Set of topics is *in addition to* COVID-19, MMM, IDD which are underway and continue

*Potential example of leading with a Special Area of Emphasis (SAE) and following-up with a Targeted PFA
- Would provide advance notice to the research and stakeholder communities
- Applications received for the SAE could help inform development of the Targeted PFA
- In this instance, leading with an SAE in Broad PFAs is also intended to expedite applications relevant to the COVID-19 pandemic

Recommended Candidates Topics for Development for 2022

Funding mechanism	Cycle 1 2022	Cycle 2 2022	Cycle 3 2022
Targeted PFA or Special Area of Emphasis	• Prevention of drug addiction for adolescents • Early detection and treatment of delirium in older adults	• Leveraging telehealth for chronic disease management among vulnerable populations with complex needs* • Hypertension control • Advancing health equity*	• Visual impairment in older adults • Suicide prevention: National crisis hotline • Management of immune checkpoint inhibitor toxicity
Large Single Study	• Abdominal aortic aneurysm screening in women • Drug therapy for type 2 diabetes		

Note: Set of topics is *in addition to* COVID-19, MMM, IDD which are underway and continue

*Potential example of leading with an SAE

Board Vote

Call for a Motion to:	• **Approve** the Recommended Set of Candidate Topics for Further Development for Targeted Funding for Cycle 3 2021 through Cycle 3 of 2022
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

Summary from the *Priorities on the Health Horizon* March 2021 Meeting

J. Michael McGinnis, MD, MA, MPP
The Leonard D. Schaeffer Executive Officer
and Senior Scholar, National Academy of Medicine

Neil Powe, MD, MPH, MBA
Chief of Medicine, Zuckerberg San Francisco General Hospital

Priorities on the Health Horizon Meeting Series: Purpose, Goals, and Objectives

PRIORITIES ON THE HEALTH HORIZON

Purpose: Terrain scanning series to convene external stakeholders to gather input and "blue sky" thinking about priorities on the health horizon

Goal: Engage patients, clinicians, researchers, and other stakeholders from the broader health community in identifying priority issues in health and health care that can inform PCORI's identification of National Priorities for Health and its updated strategic plan

Objectives:

- Present essential perspectives related to current and emerging opportunities, priorities, and trends on the horizon in the health and healthcare landscape
- Discuss stakeholders' thoughts on these emergent topics

Meeting #1 Structure & Macro Topics

PRIORITIES ON THE HEALTH HORIZON

- 2-Day Meeting of ~40 invited participants
  - Day 1 – Presentations on Macro Topics and Reactor Panel
  - Day 2 – Facilitated Breakout Groups on Macro Topics & Full Group Discussion

- Macro Topics & Included Concepts:

Macro Topic	**Concepts Encompassed in this Topic**
Social & Environmental Factors	Disparities, population health, social determinants of health, access
Technologies	Data use, interoperability, precision medicine, connectivity, engagement
Optimizing Value	How “value” drives the health care system and the health outcomes of people and populations
Infrastructure	Systems, data, implementation, evidence mobilization, workforce

Day 1: Presentations & Reactor Panel

PRIORITIES ON THE HEALTH HORIZON

- Topic Briefs (prepared by NAM) supplemented presentations with additional background, data points and possible questions
- Presentations addressed the importance of the macro topic, how it affects health and health care, how it could drive innovation, research, and discovery, and impact on health equity
- Reactor panels reflected on additional considerations, trends, disruptors and opportunities

Presenters:

Rachel Hardeman, PhD, MPH. Associate Professor, University of Minnesota School of Public Health: Social & Environmental Factors:

Joshua Denny, MD, MPH, Chief Executive Officer, NIH All of Us Research Program

David Muhlestein, PhD, JD, Chief Strategy and Chief Research Officer, Leavitt Partners

Rainu Kaushal, MD, MPH, Senior Associate Dean of Clinical Research, Chair, Department of Population Health Sciences, Weill Cornell

Reactor Panel:

Karen DeSalvo, MD, MPH, MSc
Chief Health Officer, Google Health

Gwen Darien
EVP for Patient Advocacy and Engagement, National Patient Advocate Foundation

Bruce Siegel, MD, MPH
President and CEO, America's Essential Hospitals

Austin Frakt, PhD
Editor-in-Chief, *Health Services Research*; Director, Partnered Evidence-Based Policy Resource Center, Boston VA

Peter Embi, MD, MS, FACP, FACMI, FAMIA, FIAHSI
President & CEO, Regenstrief Institute, Professor of Medicine & Associate Dean, Indiana University School of Medicine

Presentations encouraged "*Doing a Different Thing*," rather than just "Doing Things Differently"

PRIORITIES ON THE HEALTH HORIZON

Presenters underscored compelling U.S. challenges needing research guidance:

- Structural racism and its manifestation, explicitly or implicitly, in health, health care, and research
- Research priorities, diverse and inclusive participation in research, and application of evidence in practice underscore the imperative for transformation of the health research ecosystem
- Fundamental misalignment of health care around service volume and price, rather than value, health, continuity, and patient and family priorities
- Health care trails other segments of society in the use of data to accelerate learning and improvement, and while the separation of research from practice has delayed discovery and its application, enlightened research strategies can lay the groundwork for change
- Opportunities to learn from the pandemic about innovative ways to redesign research and care (optimizing virtual care/telehealth, efficiency of decentralized trials)
- Co-design, engagement, and returning results to patients can accelerate progress toward a learning health system, as shown in PCORnet® & All of Us Research Program

Reactor Panelists Offered Corollary Challenges and Opportunities, and Identified Themes

PRIORITIES ON THE HEALTH HORIZON

The reactor panel added valuable input and connections across the macro topics:

- **Infrastructure:** Current health care system is built on a "broken chassis," necessitating wholesale systemic changes, including changes to public health infrastructure
- **Technologies:** Health inequities may be further perpetuated if data used to make health decisions is not representative, and technologies spread inequitably; this was described by a reactor as "***health data poverty***"
- **Social & Environmental Factors:** Getting uncomfortable and addressing power dynamics will be necessary steps in dismantling structural racism
- **Optimizing Value:** Understanding value through the patients' lens entails much more than a service inventory—e.g., access realities including time demands, opportunity costs, and the cognitive burden of navigating the current health system
- **Cross-Cutting:** The opportunity to rebuild a system of health—and its infrastructure—could begin by centering the system on a patient's / family's strengths, from a place of inclusivity; as a reactor observed, "***our values drive value***"

Breakout Groups: Deep Dive on Macro Topics Structured around Four Discussion Questions

PRIORITIES ON THE HEALTH HORIZON

Social & Environmental Factors, Technologies, Optimizing Value, Infrastructure

1. What are the additional concepts or topics to consider as part of this macro topic?
2. What are the potential, disruptors, opportunities, and key trends on the horizon related to this topic?
3. What are the major obstacles or challenges to advancing progress related to this topic?
4. What else would it take for this topic to have a measurable and positive impact on health/health care in the next 5 years?

Breakout Groups affirmed importance of these topics and raised *additional* synergistic insights

PRIORITIES ON THE HEALTH HORIZON

- Evidence application: Closing the research to practice loop by ensuring dissemination and translation of evidence in a timely, sustainable, scalable, and understandable way
- Data Networks: Linkage of data, systems, and networks during the pandemic has supported the discovery process and potentially, serves a collective disruption opportunity – how can we hold the gains, maintain collaboration?
- Organizational structure, function and culture: Describing and incentivizing the attributes and requirements is central to progress—can we create a roadmap for an adaptable, technology-forward infrastructure that supports rapid learning?
- Collaboration: Interest in working across sectors has grown during the cooccurring crises of COVID-19 and racial equity; how can this interest be sustained over the long term?
- Intersection and integration: Health care's proclivity to consume resources diminishes other vital social and infrastructure investments, and health system change strategies must account for integration with public health and other services

Summary of Key Insights

PRIORITIES ON THE HEALTH HORIZON

Priorities for health must address *structural and systemic issues*

- Achieving health equity entails deeper exploration of how racism, bias, and power affect health and health care across the entire continuum

Reinvigorated *infrastructure* is critical to supporting transformation to a data-driven learning health system

- The COVID-19 pandemic underscores the deficits and vulnerabilities in our existing systems, illuminating the essential need to transform and integrate public health, care delivery, and research, in a way that is patient-centered, technology-forward, and leverages data

Create a *system of health*, rather than a health care system

- Shift from a fragmented system focused on services and volume, and orient a new, integrated system around patients' strengths and patients' values

Where do we go from here?

PRIORITIES ON THE HEALTH HORIZON

- Meeting 1 urged bold change – doing “a different thing”
- Meeting 2 (April 27) will provide an opportunity to explore output from Meeting 1 and discuss in depth:
  - What will it take to create a patient-centered learning health system (with respect to infrastructure, technologies, and engagement)?
  - How can PCORI use its research strategies, unique role, and activities to grow patient experience, outcomes, and value in health and health care?
- As with the first meeting, Meeting 2 will be underpinned by the integral importance of centering PCORI’s efforts in health equity

Discussion

- What are your thoughts on the March meeting ***takeaways***?
- How do you see this input informing ***strategic planning*** discussions?

Strategic Planning Committee Report

Sharon Levine, MD
Strategic Planning Committee, Co-Chair

Nakela L. Cook, MD, MPH
Strategic Planning Committee, Co-Chair

Strategic Planning Committee
Purpose and Today's Report Structure

Committee Purpose

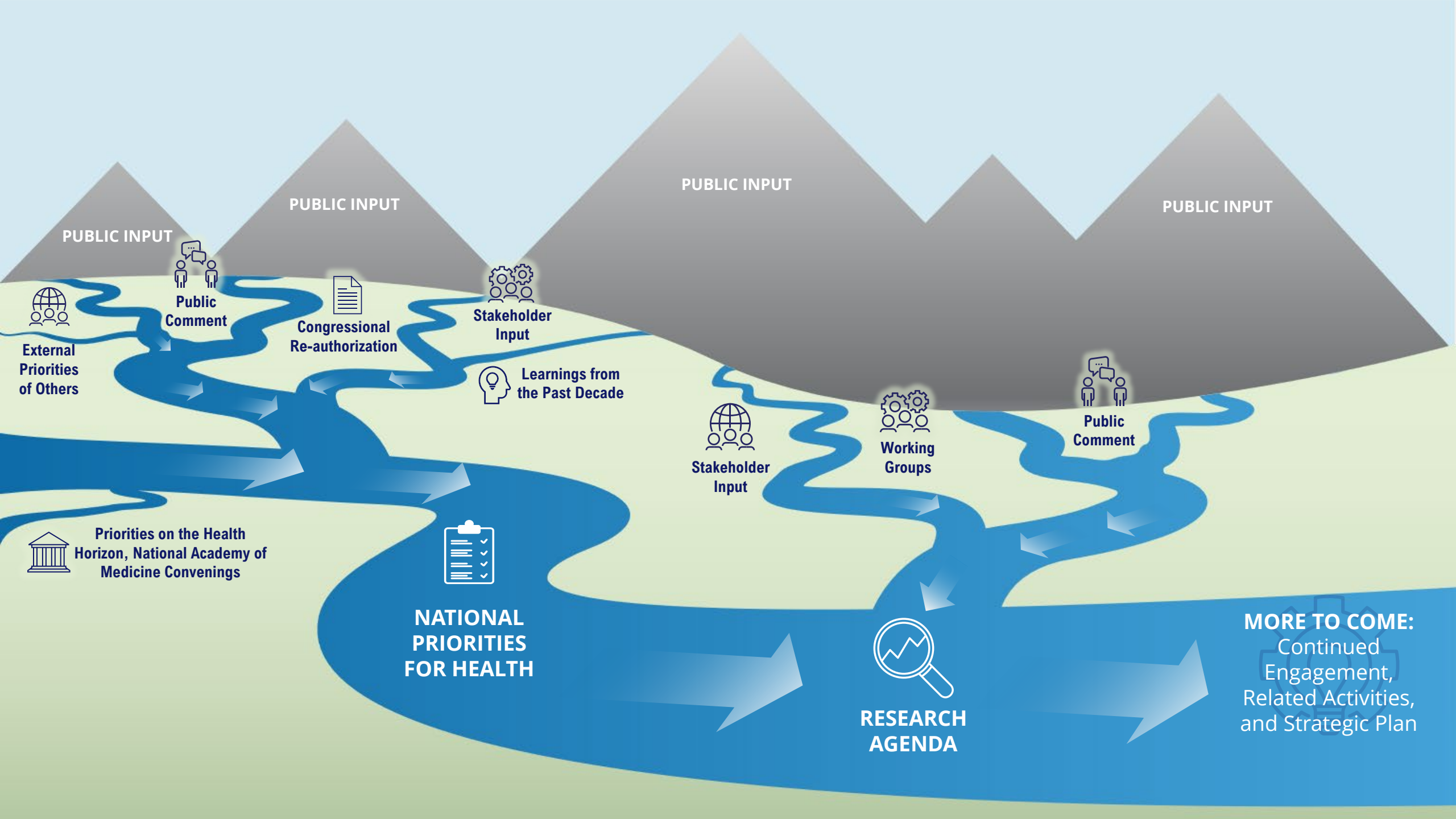
The Strategic Planning Committee works on behalf of the PCORI Board of Governors, to develop and oversee the conduct of a strategic planning process and the development of a strategic plan for approval by the Board of Governors

Report Outline

- Input gathering process thus far
- Identifying themes (overarching comments and comments specific to thematic areas)
- Discussion of potential National Priorities for Health

Scope of Strategic Planning Activities

- **National Priorities**
- Research Agenda
- PCORnet strategic vision for PCORI's next phase
- Methodology Committee focus for PCORI's next phase
- Commitment Planning and strategies to increase funding
- Scenario Planning based on the changes in landscape and environment
- Priorities from reauthorizing legislation
    - Maternal morbidity and mortality
    - Intellectual and developmental disabilities
    - Cost outcome data


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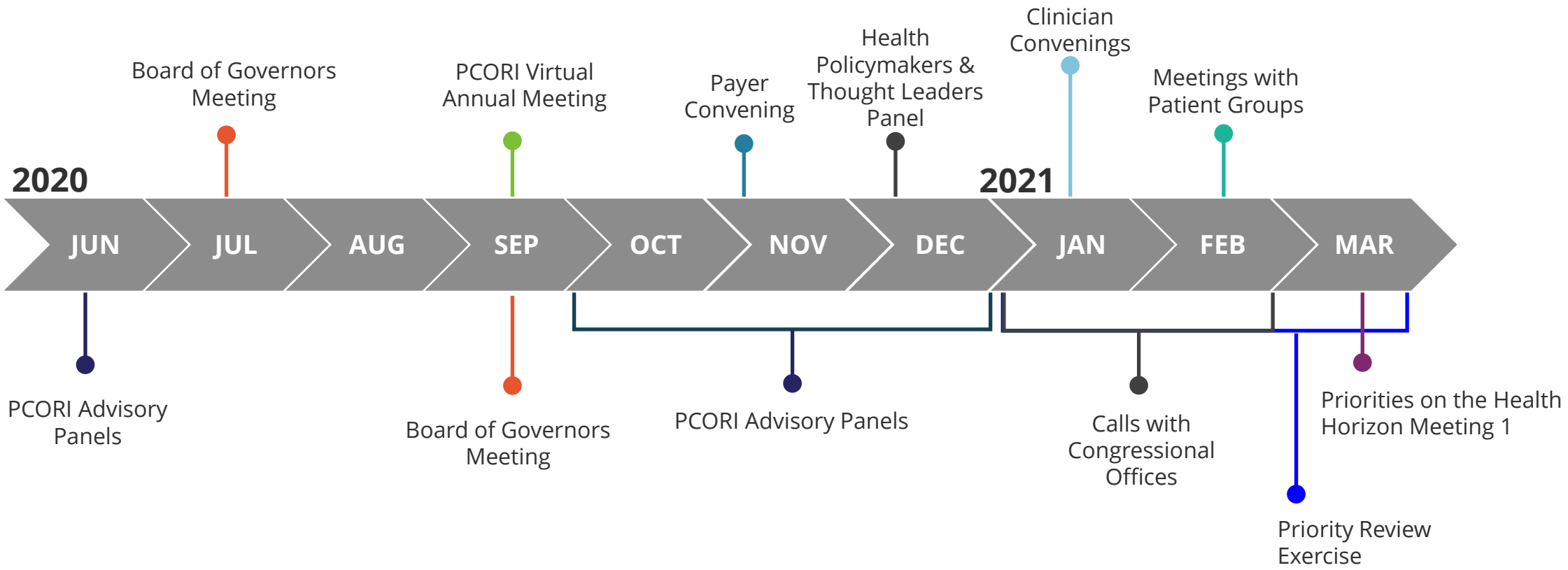
PUBLIC INPUT
Public Comment
External Priorities of Others
Congressional Re-authorization
Stakeholder Input
Learnings from the Past Decade
Stakeholder Input
Working Groups
Public Comment
Priorities on the Health Horizon, National Academy of Medicine Convenings
NATIONAL PRIORITIES FOR HEALTH
RESEARCH AGENDA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

Input Gathering Process and Discussions Thus Far

- From June 2020 – March 2021, PCORI received input on the National Priorities from multi-stakeholder groups in addition to holding discussion at Board of Governors meetings and several other activities to help identify priorities



Overarching Input Received

- Support for shift to **National Priorities for Health** (Priorities)
- Previous Priorities have served PCORI's mission well, so learn from existing portfolio and the work done over the past decade and be mindful of crossover between **Priorities and Strategic Imperatives**.
- Keep at a **high level** (ensure the language is clear, contextualize priorities) and think strategically about where the funded research could have the greatest impact for all populations.
- Balance critical concepts for individual priorities and **cross-cutting issues** relevant to all (e.g., health disparities, engagement, dissemination and implementation).
- Consider **reflecting a public health** and social ecosystem perspective within the Priorities (e.g., prevention as a key concept for health)
- Incorporate **learning and implications from COVID-19** across work (e.g., long-term impacts on health, lessons for infrastructure and technology).

Resulting Themes from Across Inputs

- Health Equity
- Emerging Innovations
- Learning Health System
- Communication, Dissemination, Implementation
- Infrastructure & Workforce

Resulting Themes from Across Inputs and Summary Points for Importance

Health Equity	Emerging Innovations	Learning Health System	Communication, Dissemination, Implementation	Infrastructure & Workforce
• **Addressing disparities** is more important than ever • **Systematic inequities** appear across health, healthcare, and health research (structural racism, implicit bias, lack of data representativeness)	• Application of **new technologies** and **systems interventions** will be important for future of health; need to address evidence gaps • Support **time sensitive decision-making** needs in evidence vacuum • Inform **new delivery innovations** focused on patient-centered outcomes	• Reframing transitional care from care settings to transition between health states to better **reflect patient perspective** • Support health systems that enable **coordinated care, easy navigation** and **utilization** for patients	• Importance of **doing communication and dissemination**, not just research on how to do it • Get **right information to right people at the right time** to make informed decisions (e.g., patients, providers, health systems)	• **Workforce development** and capacity is needed to strengthen and expand the healthcare system • Need for building **capacity for patient-centered outcomes research** (data, systems, researchers, patient partners)

What We've Been Hearing

- Importance of health disparities and moving towards health equity
- Health equity should be a National Priority and be weaved in through other National Priorities.
- Look at the multifaceted drivers of disparities (e.g., structural racism, lack of evidence, bias) and define disparities broadly
- Consider disparities encountered through health system and research environment (e.g., social determinants of health; participant recruitment; workforce diversity, equity, and inclusion; data/algorithm bias)
- Validation from external priority review; related themes from synthesis include *Health and Healthcare Equity*

Health Equity

What We've Been Hearing

- Support comparative trials of drugs, devices, technologies, health systems innovations, and other interventions
- Consider innovative delivery systems strategies for specific populations and patient-centered outcomes
- Balance evidence and information need for different decisional time frames
- Examine implications of innovative technology on health care quality and access, health equity, and patient trust
- Validation from external priority review; related themes from synthesis include *Proactive Changes in Healthcare* and *Systems that Support Care*

Emerging Innovations

What We've Been Hearing

- Grow *Improving Health Systems* to creating connected, learning health systems
- Reframe transitional care from care settings to transition between health states to better reflect patient perspective
- Consider health systems and infrastructure necessary to enable coordinated care, easy navigation and utilization for patients within diverse populations
- Identify synergies with health systems work and other National Priorities; promote patient-centered care and outcomes
- Validation from external priority review; related themes from synthesis include *Systems that Support Healthcare*

Learning Health System

What We've Been Hearing

- Importance of doing communication and dissemination, not just the research of it
- Get right information to right people, in a manner they can understand, at the right time (e.g., patients, providers, health systems)
- Building the evidence base around implementation of research findings to promote uptake and impact of PCOR
- Leverage implementation science to amplify
- Validation from external priority review; related themes from synthesis include *Systems that Support Healthcare* and *Proactive Change in Healthcare*

Communication, Dissemination, Implementation

What We've Been Hearing

- Think about the infrastructure (human and systems) needed to strengthen health and healthcare
- Need for building capacity for patient-centered outcomes research (e.g., data, systems, researchers, patient partners)
- Expand concept of "infrastructure" (e.g., enhance capabilities for underserved populations to be represented in research ecosystem)
- Workforce development and capacity is needed to strengthen and expand the healthcare system
  - Examining opportunities to combat workforce burnout and promote diversity in all levels of the health care workforce
- Validation from external priority review; related themes from synthesis include *The Workforce of Healthcare* and *Systems that Support Healthcare*

Infrastructure & Workforce

Anticipated Next Steps

Board Input on Shaped Topics

- April 2021 **Board** of Governors meeting
- Discuss developed topic areas
- SPC to take input and continue refining topics

Additional Input on Refined Topics

- May 2021 **Board** Meeting
- Assess and refine topic areas for National Priorities
- SPC to take input and continue refining themes

Consider National Priorities for Health

- June 2021 **Board** of Governors meeting
- Consider National Priorities for Health for posting for public comment

Resulting Themes from Across Inputs Discussion

- Do you concur with developing and further shaping these themes for National Priorities for Health
- How do you see further shaping them?

Health Equity

Emerging Innovations

Learning Health System

Communication, Dissemination, Implementation

Infrastructure & Workforce

Wrap Up and Adjournment


202.827.7700


info@pcori.org


www.pcori.org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