Board of Governors Meeting

via Teleconference/Webinar

June 15, 2021
1:00 – 3:00 PM

pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Agenda

1:00	**Welcome, Call to Order and** **Consider for Approval:** May 24-25, 2021, Board Minutes
1:05	**Consider for Approval: Targeted PFAs for Cycle 3 2021** • *Migraine Prevention* • *Healthy Aging* • *Osteoporotic Fracture Prevention*
1:45	**Consider for Approval for Posting for Public Comment** • *Proposed National Priorities for Health*
2:45	**FY2021 Mid-year Financial Review**
3:00	**Wrap-up and Adjournment**

Board Vote

Call for a Motion to:	• **Approve** the Minutes of the May 24-25, 2021 Board of Governors meetings
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

Targeted PFAs for Cycle 3 2021

Alicia Fernandez, MD

Science Oversight Committee (SOC) Chair

Nakela L. Cook, MD, MPH

Executive Director

Picking Up Where We Left Off

Under our ***expedited and enhanced process*** to maintain pace on our Commitment Plan, in March the Board approved three Targeted PFAs for Cycle 2 2021

Cycle 2 2021 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

Today the Board considers:

- Approval of ***three Targeted PFAs*** recommended by SOC for Cycle 3 2021
- This follows Board approval in April of a large set of candidate topics for Targeted PFA development through the 2022 funding cycles

Summary of Topics Under Consideration Today for Cycle 3 2021

Topic	Funding
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
Total	**Up to $130M**

Comparative Effectiveness of Novel Pharmacologic and Evidence-based Nonpharmacologic Treatments for Migraine Prevention Targeted PFA

Stanley Ip, MD

Interim Program Director, Clinical Effectiveness and Decision Science

Recommendation for Targeted PFA

Question of interest:

What is the comparative effectiveness of novel pharmacologic and/or evidence-based nonpharmacologic treatments for the prevention of migraine?

Recommendation for Targeted PFA

Population	Patients with episodic and/or chronic migraine who are eligible for migraine preventive therapy
Interventions/ Comparators	Novel pharmacological options (e.g., calcitonin gene-related peptide (CGRP) inhibitors) and/or evidence-based nonpharmacological interventions (e.g., noninvasive neuromodulation devices, cognitive behavioral therapy) with established efficacy or in common use for migraine prevention
Outcomes	Reduction in frequency of headache/migraine days and/or other clinically justified outcomes such as quality of life, headache-related disability, functional impact, tolerability, adverse events
Timing	24-week follow-up or other clinically justified time-points
Setting	Primary and/or specialty care clinics

- Total requested for this PFA is $40M in total costs
- Estimated number of cycles: up to 3
- Estimated number of studies: 3-5
- Maximum project duration: 5 years

Board Vote

Call for a Motion to:	• **Approve** the development of a PFA on "Comparative Effectiveness of Novel Pharmacologic and Evidence-based Nonpharmacologic Treatments for Migraine Prevention" with funding up to $40M 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

Healthy Aging: Optimizing Physical and Mental Functioning Across the Aging Continuum Targeted PFA

Neeraj Arora, PhD

Associate Director, Healthcare Delivery and Disparities Research

Framework for Healthy Aging Targeted PFA

Interventions Optimizing Physical and Mental Functioning Across the Aging Continuum*

The Aging Continuum

Healthiest Older Adults

Maintain Function & Independence

- Healthy/1 or 2 well-managed chronic conditions
- Goal: stay healthy, prevent progression of condition

Manage Chronic Conditions

- Chronic/multiple chronic conditions sub-optimally managed
- Goal: slow/reverse progression of conditions

Support for Significant Functional Impairment

- At higher risk of adverse events
- Goal: Stabilize condition and maintain quality of life

End of Life Care

Caregiving Across the Continuum

* Diverse stakeholders have expressed enthusiasm for the proposed Targeted PFA and provided important input on critical gaps, decisional dilemmas, and key impactful outcomes

Recommendation for Targeted PFA

PFA Goal	Identify effective interventions to optimize the physical and mental functioning of community dwelling older adults and their caregivers across the aging continuum
Domains	Maintain function and independence; Manage chronic conditions; Support for individuals with significant functional impairment; Reduce caregiver burden
Population	Predominantly older adults aged 60 and older Applications justifying targeting younger, middle aged populations will be considered
Example Outcomes	Physical function measures (Activities of Daily Living, Mobility); Mental health measures (Depression, Anxiety, Social isolation, Cognitive function); Quality of life & Caregiver burden; Delay to institutionalization & Healthcare utilization; Additional clinical measures (Blood pressure control, Antipsychotic use)
Setting	Primary and specialty care clinics, home, and community settings such as assisted living, senior housing, or retirement facilities, adult day care centers

- Total requested for this PFA is $50M in total costs
- Estimated number of cycles: up to 3
- Estimated number of studies: 9-12
- Maximum project duration: 5 years

Board Vote

Call for a Motion to:	• **Approve** the development of a PFA on "Healthy Aging: Optimizing Physical and Mental Functioning Across the Aging Continuum" 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

Comparative Effectiveness of Multimodal Interventions to Prevent Osteoporotic Fractures Targeted PFA

Meghan Warren, PT, MPH, PhD

Program Officer, Clinical Effectiveness and Decision Science

Recommendation for Targeted PFA

Question of interest:

What is the comparative effectiveness of multimodal treatment interventions (i.e., combination of pharmacologic and/or non-pharmacologic) on patient-centered outcomes in people with osteoporosis and a history of fractures?

Recommendation for Targeted PFA

Population	Postmenopausal women and men with osteoporosis and a history of fracture
Interventions/ Comparators	Multimodal interventions, including pharmacologic and/or non-pharmacologic interventions (e.g., Comparisons of care management strategies, such as Fracture Liaison Service and other team-based case-management models)
Outcomes	Fractures; validated measures of pain and functional status; functional independence; institutionalization; quality of life and other outcomes important to clinician and patient shared decision-making
Timing	Sufficient (approximately 4–5 years) to allow meaningful assessment of fracture outcomes; outcomes capturing post-fracture sequelae (e.g., functional status, nursing home placement) may employ shorter timeframes

- Total requested for this PFA is $40M in total costs
- Estimated number of cycles: Up to 3
- Estimated number of studies: 3-5
- Maximum project duration: 5 years

Board Vote

Call for a Motion to:	• **Approve** the development of a PFA on "Comparative Effectiveness of Multimodal Interventions to Prevent Osteoporotic Fractures " with funding up to $40M 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

Consider for Approval: Proposed National Priorities for Health for Posting for Public Comment

Sharon Levine, MD

Strategic Planning Committee, Co-Chair

Nakela L. Cook, MD, MPH

Strategic Planning Committee, Co-Chair

Purpose and Structure of Today's Conversations

Purpose

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

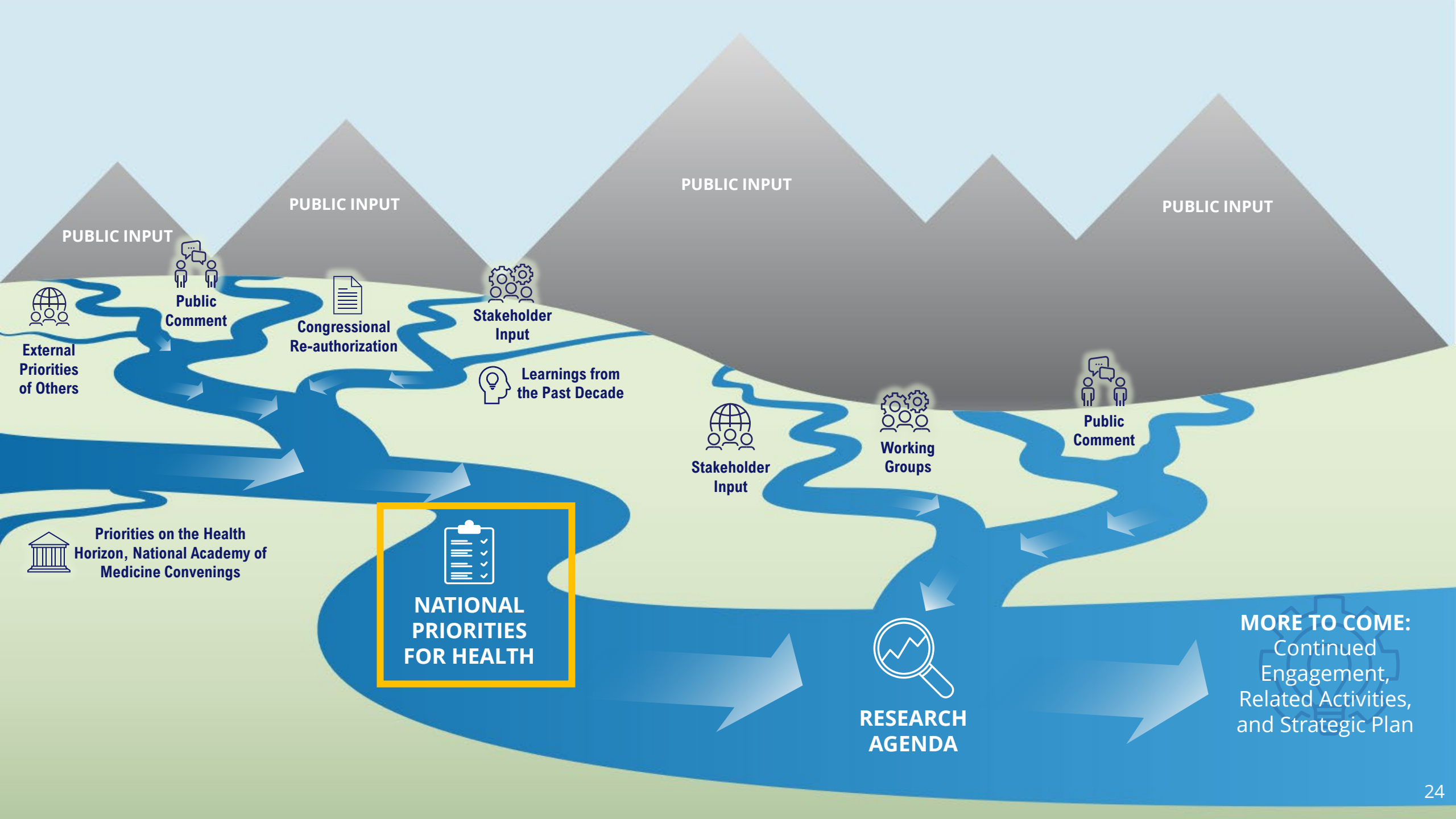
Structure

- Outline input gathering process
- Review revisions to National Priorities based on Board discussions from May meeting
- Overview of anticipated next steps
- **Board vote**

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
    - Full range of outcomes data

Reminder About Revised Strategic Framework
Evolving to National Priorities for Health


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

Reminder about May Meeting Purpose and Structure

May Meeting

- Board engaged with the draft National Priorities for Health and provided expertise and insights for further refinement
- Preparation of the Board for a vote at the June Board meeting to consider for approval the proposed National Priorities for Health for posting for public comment

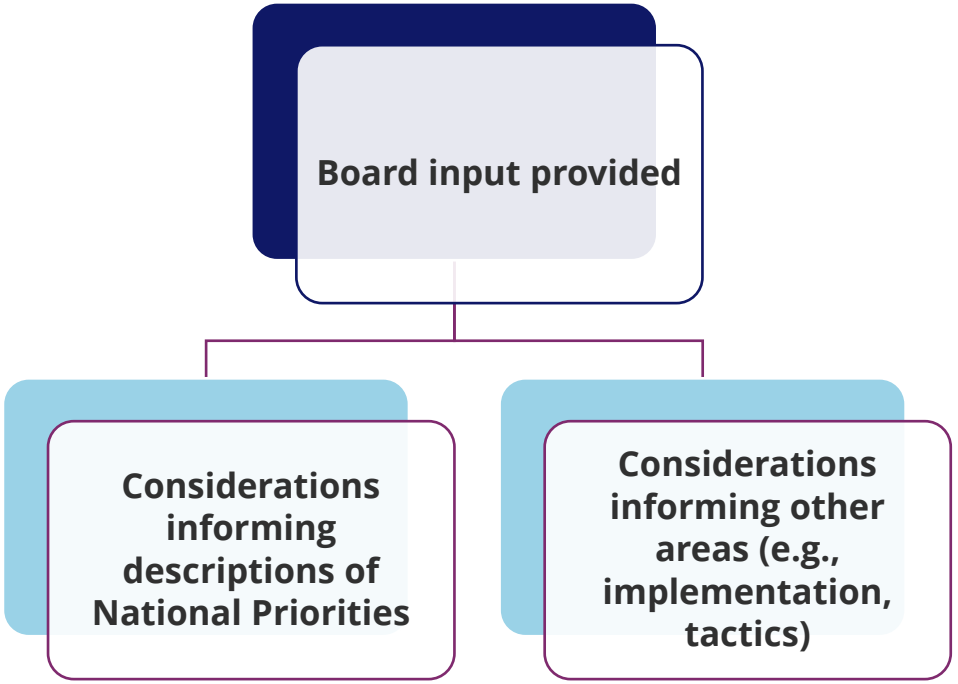
May Meeting Generated Insights Through

- Introduction of each of the draft National Priorities
- Initial comments from a panel of Board members
- Full Board discussion

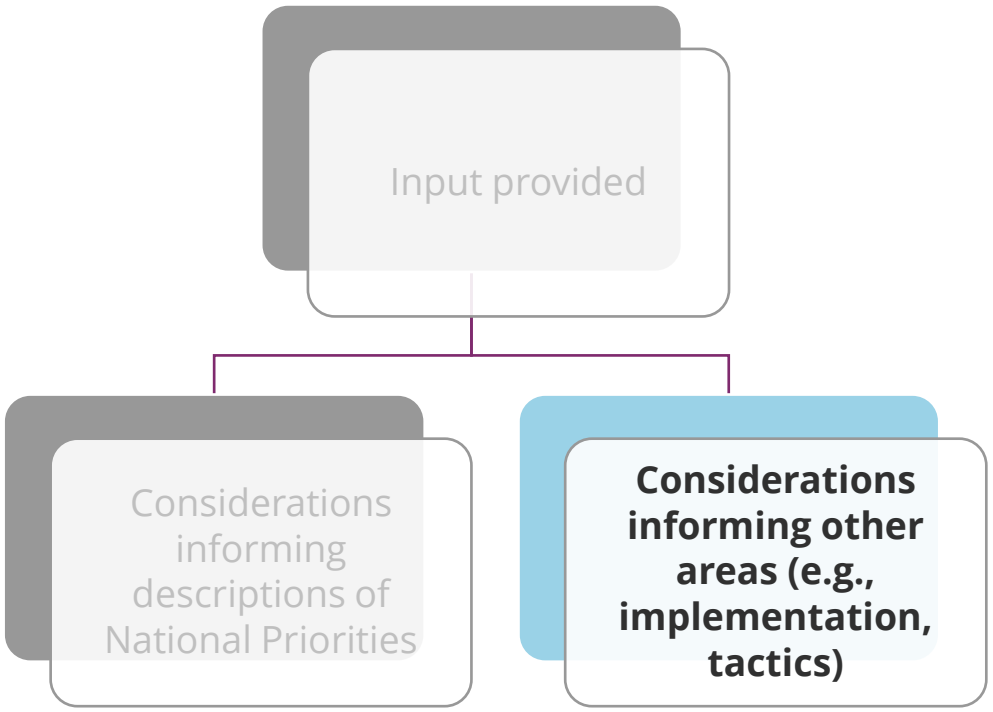
Themes Related to Two Areas

Overarching Themes from Board Input

- Identify PCORI's **unique role** and contribution within each priority
- Progress may require large **changes** in current practices (e.g., healthcare delivery, payments)
- Utilize strategic **partnerships** as key avenues for progress
- Get **local** to move the needle (local community building for place-based or population-specific strategies and sustainability)
- Integrate the **full range of outcomes** as a means for progress
- Enable **nimbleness and adaptiveness** in PCORI's funding process

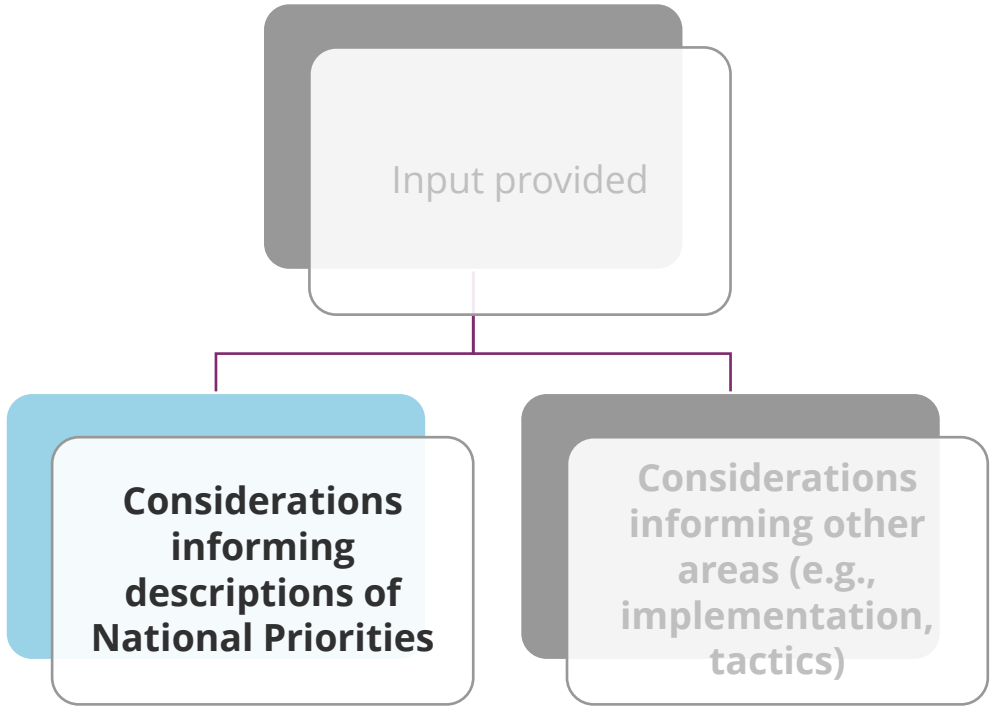


Input Informing Other Areas



- **Research Agenda and Evaluation**
  - Develop examples for and consider audacious research questions within each Priority
  - Learn from current portfolio to inform future work
  - Create actionable, relevant metrics to measure progress
  - Reinforce the patient focus in study design
  - Look beyond clinical measurements to evaluate impact (e.g., including non-clinical outcomes)
- **Implementation**
  - Establish trust with stakeholders for sustainable implementation of research findings
  - Coordination as appropriate with federal entities (e.g., Agency for Healthcare Research and Quality, Center for Medicare & Medicaid Innovation)
- **Internal Process**
  - Enable nimbleness and adaptiveness in funding process to reflect the innovation and urgency espoused in the National Priorities

Input Informing National Priorities



Proposed National Priorities for Health

Increase Evidence for Existing Interventions and Emerging Innovations in Health

- **What We Heard**
  - Validation that priority aligns with PCORI's mission
  - Considering costs for patients and current payment barriers related to emerging innovations
  - Considering unintended consequences when evaluating the impact of emerging and existing technologies
- **Revision(s) to Priority**
  - Noted studying unintended consequences, adverse events, barriers to care, burdens and economic impacts, and widened disparities in care outcomes as strategy to address priority

Proposed National Priorities for Health

Increase Evidence for Existing Interventions and Emerging Innovations in Health

Strengthen and expand ongoing comparative clinical effectiveness research focused on both existing interventions and emerging innovations to improve healthcare practice, health outcomes, and health equity

Strategies to address this priority include:

- monitor the research landscape for potentially high impact innovations
- evaluate existing and emerging innovations in clinical care interventions, systems changes, healthcare delivery, technologies, public health, and social determinants of health
- study unintended consequences, adverse events, barriers to care, burdens and economic impacts, and widened disparities in care outcomes associated with existing and emerging innovations
- expand the scope of stakeholders engaged in PCORI's work from topic inception through implementation of the results
- emphasize inclusion of populations who are underserved, under-represented, and disadvantaged in CER research endeavors
- support CER of evidence gaps in diverse populations, geographic areas, and settings to foster equitable uptake practices

Enhance Infrastructure to Accelerate Patient-Centered Outcomes Research

- **What We Heard**
  - Support for using infrastructure built in last decade as springboard for progress (e.g., PCORnet®)
  - Importance of enabling communities to participate in PCOR
  - Importance of informing and supporting data representativeness
- **Revision(s) to Priority**
  - Reinforced concept that robust infrastructure should connect effectively with healthcare systems and respond to patient needs to improve health

Proposed National Priorities for Health

Enhance Infrastructure to Accelerate Patient-Centered Outcomes Research

Enhance the infrastructure that facilitates patient-centered outcomes research to drive lasting improvements in health and transformation of both the research enterprise and care delivery

Strategies to address this priority include:

- develop and expand the universe of engaged patients and communities and representative leadership, research workforce, and clinician partners
- advance the accessibility and utilization of real-world data
- build synergies and leverage current work within health systems and by stakeholders
- integrate patient-centered outcomes research findings into learning health systems

Advance the Science of Dissemination, Implementation, and Health Communication

- **What We Heard**
  - Continuing collaboration with AHRQ and identifying unique roles
  - Importance of working locally to get information to those who need it and can act upon it
  - Need for expanded evidence base for implementation science (i.e., additional research on what implementation approaches work in which settings)
- **Revision(s) to Priority**
  - Reinforced supporting the practice of and the funding of research for dissemination, implementation, and health communication
  - Revised title

Proposed National Priorities for Health

Advance the Science of Dissemination, Implementation, and Health Communication

Advance the scientific evidence for and the practice of dissemination, implementation, and health communication to accelerate the movement of comparative clinical effectiveness research results into practice

Strategies to address this priority include:

- fund CER studies of delivery or implementation strategies
- communicate research findings effectively and in ways tailored to diverse audiences
- actively deliver information to targeted audiences to use to inform healthcare discussions and decisions
- promote the uptake of research findings into practice, to contribute to improved healthcare and health
- engage stakeholders and communities in strategic partnerships across diverse settings to improve the uptake of evidence

Achieve Health Equity

- **What We Heard**
  - Validation for priority and importance of work to achieve equity across all priorities
  - Framing health equity research as CER within PCORI's scope
  - Need for working with partners outside of academia (e.g., social and economic organizations) to support scope of priority
- **Revision(s) to Priority**
  - Noted funding projects across the health research spectrum including comparing interventions focused on addressing racism, discrimination, and social determinants of health while ensuring that the improvement of health outcomes remains central
  - Noted collaborating with multisector partners as a strategy to address priority

Proposed National Priorities for Health

Achieve Health Equity

Expand stakeholder engagement, research, and dissemination approaches that lead to continued progress towards achieving health equity in the United States

Strategies to address this priority include:

- fund CER to improve health outcomes for individuals of all backgrounds
- strengthen efforts to support inclusive and diverse stakeholder engagement
- disseminate and implement research findings with the intention of informing broader health equity strategies
- collaborate with health, research, advocacy, social service, educational, and other organizations to reduce health inequities
- identify and fund novel ways to support the professional development and increase the engagement of investigators of color, investigators with disabilities, and populations who are historically under-represented in research endeavors

Accelerate Progress Toward an Integrated Learning Health System

- **What We Heard**
  - Broadening to learning health system creates opportunities to include large impacts on health (e.g., social determinants)
  - Need to highlight integrative nature for accomplishing priority
  - Refinement of boundaries and PCORI's niche
- **Revision(s) to Priority**
  - Changed title and added language to emphasize integrative aim
  - Reframed the boundaries to include multisector interventions, importance of local relevance for evidence, and focus on health outcomes

Proposed National Priorities for Health

Accelerate Progress Toward an Integrated Learning Health System

Foster actionable, timely, place-based, and transformative improvements in patient-centered experiences, care provision, and ultimately improved health outcomes through collaborative, multisectoral research to support a health system that serves the needs and preferences of individuals

Strategies to address this priority include:

- fund multi-sector interventional CER focused on health outcomes and grounded in the context of specific settings, communities, and needs
- implement research on precision and personalized medicine and whole-person health into practice
- incorporate the full range of outcomes to influence value that encompasses diverse outcomes and perspectives among patients, families, caregivers, and providers
- formalize partnerships to ensure an integrated learning health system that meets the needs of patients and caregivers
- use data analytic and informatic tools to inform and enable real-time decision making

Proposed National Priorities for Health

Overview of Public Comment and Potential Timeline

Consideration for Approval for Posting for Public Comment

June 15th

Possible Start of 60-day Public Comment Period

June 21st

National Priorities Launch Event

June 29th

Possible Close of 60-day Public Comment Period

August 20th

Presentation of Public Comment Synthesis and Revised National Priorities for Consideration for Adoption

September/ October 2021

Questions Posed for Public Comment

For each National Priority

- What are the opportunities?
- What are the challenges?
- What is PCORI's unique role or contribution?
- What does success look like?

For the set of National Priorities

- What other comments do you have?

Discussion

Do you concur with the revisions to the proposed National Priorities for Health?

Board Vote

Call for a Motion to:	• **Approve** the Proposed National Priorities for Health for Posting for Public Comment
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

FY2021 Mid-Year Financial Review

(As of 3/31/2021)

Russell Howerton, MD

Chair, Finance and Administration Committee

Nakela L. Cook, MD, MPH

PCORI Executive Director

FY2021 Revenue
(10/1/2020 – 3/31/2021)

REVENUE	*$ in millions*
From PCOR Trust Fund	
Federal Appropriation	$ 228.0
PCOR Fee	-
From Interest (U.S. Treasury Securities)	3.5
Total Revenue	**$ 231.5**

Cash Balance and Outstanding Award Obligations
(As of 3/31/2021)

CASH BALANCE		$ in millions
Cash -- PCOR Trust Fund	$	13.0
Cash -- Operating Account		51.8
U.S. Treasury Securities		1,423.0
Total	**$**	**1,487.8**

OUTSTANDING AWARD OBLIGATIONS		$ in millions
Cumulative Funding Commitments*	$	2,917.4
Cumulative Award Payments**		(1,966.6)
Outstanding Award Obligations* **	**$**	**950.8**

* Includes Research, PCORnet, Engagement, Dissemination, and AHRQ Workforce Training funding commitments.

** Award Payments are the amounts PCORI has disbursed in response to invoices received for costs incurred under awarded contracts.

*** Outstanding award obligations are the amounts of contracts awarded that will require payments during a future period. These amounts will become due and payable as research progresses over time.

FY2021 Actual vs. Budget
(As of 3/31/2021)

	FY2021 YTD ACTUAL		FY2021 YTD BUDGET		FY2021 YTD VARIANCE	
	$ in millions					
REVENUE	**$ 231.5**		**$ 231.0**		**$ 0.5**	**0%**
EXPENSES						
PROGRAM SERVICES						
Award Payments	143.2	81%	150.4	79%	7.2	5%
Other Programmatic Costs	14.2	8%	16.2	9%	2.0	12%
TOTAL PROGRAM SERVICES	**157.4**	**89%**	**166.6**	**88%**	**9.2**	**6%**
PROGRAM SUPPORT SERVICES	**7.5**	**4%**	**8.8**	**5%**	**1.3**	**14%**
ADMINISTRATIVE SUPPORT	**11.9**	**7%**	**14.2**	**7%**	**2.3**	**16%**
TOTAL EXPENSES	**$ 176.8**	**100%**	**$ 189.6**	**100%**	**$ 12.8**	**7%**

The Bottom Line and What's Next

- ***Budget for FY2021 on target at mid-year***, despite uncertainty resulting from pandemic
- ***Budget Development for FY2022 underway*** – Board considers in September
- ***Commitment Plan for FY2021*** – Board update in July as context for award slates
- ***Commitment Planning for 2022 forward*** – Board considers in late Fall

Wrap Up and Adjournment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