Clinical Effectiveness and Decision Science

PCORI Virtual Advisory Panel Meeting

June 24, 2021 | 1:30–4 pm (ET)
June 25, 2021 | 1–4 pm (ET)
Welcome & Introductions

Stanley Ip, MD
CEDS Interim Program Director

Kari Gali, DNP, APRN, PNP-BC
CEDS Advisory Panel Chair

Julie Eller, MPH Candidate
CEDS Advisory Panel Co-chair
Housekeeping

• Today’s webinar is open to the public and is **being recorded**.
  • Pre-reading meeting materials were emailed beforehand.
    • Meeting information can be found at [www.pcori.org](http://www.pcori.org):
      • Meetings & Events → Advisory Panel Meetings → *Advisory Panel on Clinical Effectiveness and Decision Science Summer 2021 Meeting*
• No public comment period is scheduled.
• Please remember to **speak loudly** and **clearly into your microphone**.
• State your name and affiliation before you speak.
• Please avoid technical language in your discussion.
• As a reminder, please mute yourself when not speaking.
Disclosures of conflicts of interest of members of this panel are publicly available on PCORI’s website and are required to be updated annually. Members of this panel are also reminded to update conflict of interest disclosures if the information has changed by contacting your staff representative.

If this panel will deliberate or take action on a manner that presents a conflict of interest for you, please inform the Chair so we can discuss how to address the issue. If you have questions about conflict of interest disclosures or recusals relating to you or others, please contact your staff representative.
CEDS Panel Leadership

- **Kari Gali, DNP, APRN, PNP-BC**  
  CEDS Panel Chair

- **Julie Eller, BS, MPH Candidate**  
  CEDS Panel Co-Chair

- **Holly Ramsawh, PhD**  
  CEDS Senior Program Officer, Panel Manager

- **Amanda Barbeau, MPH**  
  CEDS Senior Program Associate, Panel Manager
Kari Gali, DNP, APRN, PNP-BC
Pediatric Nurse Practitioner, *Cleveland Clinic*

**Representation:** Clinicians
CEDS Advisory Panel Chair

Julie Eller, MPH Candidate
Director of Patient Centered Strategies, *Arthritis Foundation*

**Representation:** Patient Advocates/Patients
CEDS Advisory Panel Co-Chair
Day 1 Agenda, 1:30-4 pm (ET)

<table>
<thead>
<tr>
<th>Time</th>
<th>Duration</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:30 pm</td>
<td>(30 min)</td>
<td>Welcome and Introductions</td>
</tr>
<tr>
<td>2 pm</td>
<td>(15 min)</td>
<td>CEDS Research Area Overview</td>
</tr>
<tr>
<td>2:15 pm</td>
<td>(90 min)</td>
<td>Strategic Planning: National Priorities for Health and Research Agenda</td>
</tr>
<tr>
<td>3:45 pm</td>
<td>(15 min)</td>
<td>Closing Remarks</td>
</tr>
</tbody>
</table>
Patients, Caregiver Advocates, and Advocacy Organizations

Helen M. Beady, EdD, MEd

Michael Philbin, PhD
Payers, Industry, and Policy Makers

Adjoa Adofo Kyerematen, MS
Danielle Bargo, MSc
Eric Cannon, PharmD, FAMCP
David Webster, MD, MBA
Maureen White, MD, MS, MBA
CEDS Program Update

Holly Ramsawh, PhD
CEDS Senior Program Officer
The Clinical Effectiveness and Decision Science (CEDS) program seeks to fill clinical information gaps by producing valid, trustworthy, and useful new evidence comparing the effectiveness of different clinical options. In situations where there already is adequate evidence, CEDS seeks approaches to raise patients’ and caregivers’ awareness of this information so they can make use of it in choosing the best option for them.
CEDS Overview

Assessment of Prevention, Diagnosis, and Treatment Options

Improving Healthcare Systems

Communication & Dissemination Research

Addressing Disparities

Accelerating PCOR and Methodological Research
PCORI HAS AWARDED OVER $1 BILLION TO FUND 366 COMPARATIVE EFFECTIVENESS STUDIES IN CLINICAL EFFECTIVENESS AND DECISION SCIENCE

As of June 2021

<table>
<thead>
<tr>
<th>Funding Mechanism</th>
<th># of Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broad</td>
<td>305</td>
</tr>
<tr>
<td>Pragmatic</td>
<td>22</td>
</tr>
<tr>
<td>Targeted</td>
<td>39</td>
</tr>
</tbody>
</table>

Note: Funded awards do not include MOU’s, Pilot Projects, or IPD meta-analyses
New Research Awards

1. Conducting Rare Disease Research using PCORnet
   Targeted PFA Awards

2. Improving Methods for PCOR Broad PFA Awards

3. Assessment of Options Broad PFA Awards

4. Observational Type 2 Diabetes Mellitus
   Targeted PFA Awards

*AWARDED January 2021 & March 2021 (from Cycle 1 2020 Broads and Cycle 2 2020 Targeted)
## New Research Awards: A sampling

<table>
<thead>
<tr>
<th>Study Title</th>
<th>PI Name</th>
<th>Site</th>
<th>PCORI Funding Announcement (PFA)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Biologic Abatement and Capturing Kids’ Outcomes &amp; Flare Frequency in Juvenile Spondyloarthritis (BACK-OFF JSpA)</strong></td>
<td>Pamela Weiss, MD, AB</td>
<td>Children's Hospital of Philadelphia</td>
<td>Cycle 1 2020 Broad: APDTO</td>
</tr>
<tr>
<td><strong>Methods to analyze patient-centered outcomes missing due to death in cluster-randomized trials</strong></td>
<td>Michael Harhay, PhD, MPH, MA, MS</td>
<td>Trustees of the University of Pennsylvania</td>
<td>Cycle 1 2020 Methods</td>
</tr>
<tr>
<td><strong>Second-line Therapies for Patients with Type 2 Diabetes and Moderate Cardiovascular Disease Risk</strong></td>
<td>Rozalina McCoy, MD, MS</td>
<td>Mayo Clinic</td>
<td>Cycle 2 2020: Diabetes Targeted PFA</td>
</tr>
</tbody>
</table>
Currently in Review: Cycle 3 2020

Awards Will Be Announced July 2021

• Broad: Improving Assessment of Options, Communication & Dissemination Research, and Improving Methods
  • Special Areas of Emphasis:
    • Improving care transitions for those with intellectual and developmental disabilities (IDD)
    • Increasing Access to and Continuity of Patient-Centered Maternal Care

• Suicide Prevention: Brief Interventions for Youth

• Phased Large Awards for Comparative Effectiveness Research (PLACER)
Upcoming Targeted Research Opportunities

Maternal Morbidity and Mortality PFA

- Up to $50M available
- PFA posted: May 2021
- Awards to be announced: March 2022

What is the comparative effectiveness of multicomponent interventions to improve early detection of, and timely care for, risk factors for postpartum complications, and for complications during the first six weeks postpartum for Black, AI/AN, Hispanic, rural, and low-SES patients?
Upcoming Targeted Research Opportunities

• Up to $40M available
• PFA posted: May 2021
• Awards to be announced: March 2022

What is the comparative effectiveness of evidence-based approaches (e.g., specific pharmacologic and behavioral interventions) that address mental health conditions in individuals with intellectual and developmental disabilities?
Upcoming Targeted Research Opportunities

Urinary Incontinence

- Up to $40M Funds Available
- PFA posted: May 2021
- Awards announced: **March 2022**

This Targeted PFA seeks to fund high-quality, comparative effectiveness research projects that focus on efficacious interventions for nonpregnant women with stress, urge, or mixed urinary incontinence, addressing high-priority patient- and stakeholder-guided research questions.
Upcoming Broad Research Opportunities

2021 Cycle 2 Broad PFA

- Assessment of options: Up to $32M available
- Communication & dissemination research: Up to $8M available
- Improving Methods for PCOR: Up to $12M available

- PFA posted: January 2021
- Awards to be announced: March 2022
Upcoming Pragmatic Clinical Studies Research Opportunities

2021 Cycle 2
PCS PFA

- Funding available: $90M
- PFA posted: May 2021
- Awards to be announced: March 2022
Upcoming Phased Large Awards for Comparative Effectiveness Research Opportunity

- Funding available: TBD
- PFA posts: September 2021
- Awards to be announced: July 2022
2021 PCORI Annual Meeting

November 17-19, 2021

Virtual Meeting
Strategic Planning:
Proposed National Priorities and
Updating the Research Agenda

Nakela L. Cook, MD, MPH
PCORI Executive Director
Purpose of Today’s Conversations

**Purpose**
- Update on strategic planning process
- Opportunity to engage with the proposed National Priorities for Health and gather perspectives

**Goal**
- Identify synergies among the National Priorities and consider what those may mean for the Research Agenda
- Identify needs to address through the Research Agenda
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
### Evolution of PCORI’s Strategic Framework: Original (2013)

<table>
<thead>
<tr>
<th>NATIONAL PRIORITIES for RESEARCH</th>
<th>STRATEGIC IMPERATIVES</th>
<th>OUTPUTS</th>
<th>GOALS</th>
<th>IMPACT</th>
</tr>
</thead>
<tbody>
<tr>
<td>How We Create</td>
<td>What We Create</td>
<td>What We Accomplish</td>
<td>Why We Do It</td>
<td></td>
</tr>
<tr>
<td>Engagement</td>
<td>Skilled Patient-Centered Outcomes Research Community</td>
<td></td>
<td>Increase Information</td>
<td>Better Informed Health Decisions</td>
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<tr>
<td>Methods</td>
<td>Patient-Centered Outcomes Research Methods</td>
<td></td>
<td>Speed Implementation</td>
<td>Improved Health Outcomes</td>
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<tr>
<td>Research</td>
<td>Portfolio of Patient-Centered Outcomes Research Studies</td>
<td></td>
<td>Influence Research</td>
<td>Better Health Care</td>
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<tr>
<td>Dissemination</td>
<td>Communication and Dissemination Activities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infrastructure</td>
<td>Patient-Centered Research Networks</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Priorities that Guide Our Research

- Addressing Disparities
- Assessment of Prevention, Diagnosis, and Treatment Options
- Communication and Dissemination Research
- Improving Healthcare Systems
- Accelerating PCOR and Methodological Research

**Better Health Care**

**Improved Health Outcomes**

**Better Informed Health Decisions**
Reminder about Revised Strategic Framework
Evolving to National Priorities for Health

<table>
<thead>
<tr>
<th>STRATEGIC IMPERATIVES</th>
<th>MID-TERM GOALS</th>
<th>NATIONAL PRIORITIES FOR HEALTH/LONG-TERM GOALS</th>
<th>IMPACT</th>
</tr>
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<tbody>
<tr>
<td>How We Create</td>
<td>What We Accomplish in the Mid-Term</td>
<td>What We Accomplish in the Long-Term</td>
<td>Why We Do It</td>
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<tr>
<td></td>
<td>Increase Information</td>
<td>National Priority 1</td>
<td>Better Informed Health Decisions</td>
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<tr>
<td>Engagement</td>
<td>Influence Research</td>
<td>National Priority 2</td>
<td>Improved Health Outcomes</td>
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<tr>
<td>Methods</td>
<td>Speed Implementation</td>
<td>National Priority 3</td>
<td></td>
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<tr>
<td>Research</td>
<td></td>
<td>National Priority 4</td>
<td></td>
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<tr>
<td>Dissemination</td>
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<td>National Priority 5</td>
<td></td>
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<tr>
<td>Infrastructure</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Better Health Care**
- **Improved Health Outcomes**

- **National Priority 1**
- **National Priority 2**
- **National Priority 3**
- **National Priority 4**
- **National Priority 5**
NATIONAL PRIORITIES FOR HEALTH

MORE TO COME: Continued Engagement, Related Activities, and Strategic Plan

PUBLIC INPUT

Public Comment

Congressional Re-authorization

Stakeholder Input

Learnings from the Past Decade

Stakeholder Input

Working Groups

Public Comment

External Priorities of Others

Priorities on the Health Horizon, National Academy of Medicine Convenings

RESEARCH AGENDA

NATIONAL PRIORITIES FOR HEALTH

PUBLIC INPUT

PUBLIC INPUT

PUBLIC INPUT

PUBLIC INPUT
Developing National Priorities for Health

- The themes below resulted from across the inputs
- At its April 2021 meeting, PCORI's Board of Governors supported developing and further shaping these themes for National Priorities for Health

- Health Equity
- Emerging Innovations
- Communication, Dissemination, Implementation
- Infrastructure & Workforce
- Learning Health System
Going from Themes to National Priorities

Themes

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

Achieve Health Equity
Increase Evidence for Existing Interventions and Emerging Innovations in Health
Advance the Science of Dissemination, Implementation, and Health Communication
Enhance Infrastructure to Accelerate Patient-Centered Outcomes Research
Accelerate Progress Toward an Integrated Learning Health System

Proposed National Priorities for Health
Proposed National Priorities for Health
Creating Synergistic Opportunities for Progress

- At its June 2021 meeting, PCORI's Board of Governors approved the National Priorities for Health to be posted for public comment, which will open soon.
Proposed National Priorities for Health
Increase Evidence for Existing Interventions and Emerging Innovations in Health

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, underrepresented, and disadvantaged in CER research endeavors
- Support CER of evidence gaps in diverse populations, geographic areas, and settings to foster equitable uptake practices

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.
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
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 health care and health
• Engage stakeholders and communities in strategic partnerships across diverse settings to improve the uptake of evidence
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 underrepresented in research endeavors
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 multisector 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
Hearing from You
Taking Each Priority In Turn and Considering These Questions

• Imagining five years in the future, what potential impacts could these National Priorities for Health have on CER? Are there specific areas that PCORI could make a real impact on in this timeframe?

• These National Priorities will be used to guide our Research Agenda development. What specific objectives should PCORI consider as it updates the Research Agenda?

• Where are overlapping research interests among the National Priorities and what opportunities might those create?
Day 1 Closing Remarks

Kari Gali
CEDS Chair

Julie Eller
CEDS Co-Chair
Clinical Effectiveness and Decision Science

PCORI Virtual Advisory Panel Meeting

June 24, 2021 | 1:30-4 pm (ET)
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Welcome, Recap

Kari Gali
CEDS Chair

Julie Eller
CEDS Co-Chair
# Day 2 Agenda, 1–4 pm (ET)

<table>
<thead>
<tr>
<th>Time</th>
<th>Duration</th>
<th>Activity</th>
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<tbody>
<tr>
<td>1 pm</td>
<td>(5 min)</td>
<td>Welcome and Recap of Day 1</td>
</tr>
<tr>
<td>1:05 pm</td>
<td>(60 min)</td>
<td>COVID Funding Initiatives + Discussion</td>
</tr>
<tr>
<td>2:05 pm</td>
<td>(10 min)</td>
<td>Break</td>
</tr>
<tr>
<td>2:15 pm</td>
<td>(60 min)</td>
<td>IDD Funding Initiatives + Discussion</td>
</tr>
<tr>
<td>3:15 pm</td>
<td>(5 min)</td>
<td>Break</td>
</tr>
<tr>
<td>3:20 pm</td>
<td>(30 min)</td>
<td>Update on MM + Q&amp;A</td>
</tr>
<tr>
<td>3:50 pm</td>
<td>(10 min)</td>
<td>Closing Remarks</td>
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</table>
COVID-19

Jason Gerson, PhD
CEDS Senior Program Officer
Overview – PCORI’s Response to the COVID-19 Pandemic

• COVID Connect
• Primary focus on COVID-related research efforts
• Brief summary of COVID-related PCORnet and engagement efforts
• Discussion
COVID Connect: Coordinating PCORI’s COVID Response

- COVID Connect is a **cross-departmental** matrixed team with representation from all of PCORI.
- Membership **evolves** based on various stages of work and need of the organization.
- Membership is voluntary and members can engage in **various levels of involvement**:
  - Full work group
  - Core subgroups
  - Ad-hoc/liaison members
### PCORI’s COVID-19 Portfolio:
116 Enhancements, 9 Targeted Research Studies, and 25 Special Cycle Engagement Awards

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
<th>Amount</th>
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<tbody>
<tr>
<td>Engagement Award Enhancements</td>
<td>53</td>
<td>$6.8 million</td>
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<tr>
<td>D&amp;I Enhancements</td>
<td>13</td>
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</tr>
<tr>
<td>Research Enhancements</td>
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</tr>
<tr>
<td>Methods Enhancements</td>
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<tr>
<td>PCORnet Enhancement</td>
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<td>$526,020</td>
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116 Enhancements Awarded, $33.5 million

34 New Awards in Research & Engagement, $33.5 million

<table>
<thead>
<tr>
<th>Category</th>
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<th>Amount</th>
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</thead>
<tbody>
<tr>
<td>Engagement Award Special Cycle</td>
<td>25</td>
<td>$3.7 million</td>
</tr>
<tr>
<td>Targeted Research Studies</td>
<td>9</td>
<td>$29.8 million</td>
</tr>
</tbody>
</table>

Enhancements $ from Enhancement Tracker
CER TPFA $ from application amount
Engagement Special Cycle $ provided by EA team
Research

Enhancements
COVID-19 Targeted PFAs
Special Areas of Emphasis
COVID Enhancements to Existing Research Projects

- Support enhancements to existing research awards that could be initiated quickly to influence the outcome of the pandemic and that have some relationship to the original award, using existing teams that are currently funded by PCORI
- Awarded on rolling basis
- $500,000 total costs limit
- May not increase project timeline by more than 12 months
- Primary outcome assessments collected within 2 to 12 months of study initiation
COVID Enhancements to Existing Research Projects

PCORI funded **Fifty Enhancements to Research Awards** totaling $21.7 million

Focus of 41 CER enhancements

13 enhancements about COVID-19 as a condition

28 enhancements about providing care during a pandemic

Themes from 8 Methods Enhancements

- Developing clinical prediction models
- Informing COVID-19 care

Other themes: Data visualization, machine learning

Note: Studies may include more than one theme

Key statistics about CER Enhancements:

**Priority Populations**

- Black, Indigenous, and People of Color: 18
- Low Income: 12
- Women: 9
- Older Adults: 9

Condition Categories

- Mental & Behavioral Health: 14
- Nutritional & Metabolic: 7
- Neurological: 6
- Cancer: 6
- Cardiovascular: 6

*Studies may include more than one condition or population

One PCORnet Enhancement

“optimize and rigorously validate key COVID-19 data elements related to the treatment and outcomes associated with COVID-19 coagulopathy”

Telehealth

19 enhancements include telehealth components
COVID-19 Targeted PFA

- PFA developed and posted on accelerated timeline in response to the urgency of the pandemic; accelerated merit review and programmatic review to ensure timely decision making
- Priority areas:
  - Adaptations to healthcare delivery
  - Impact of COVID-19 on disproportionately affected populations
  - Impact of COVID-19 on healthcare workforce well-being, management, and training
- PFA posted in May 2020; 9 awards announced in August 2020
- Studies up to 2 years in duration; actionable findings within first 12 months
- Small studies: Up to $2,500,000; Large studies: Up to $5,000,000
COVID Targeted PFA Research Projects

PCORI funded 9 Targeted COVID-19 Research Awards totaling $29.8 million

**Focus of Awards**
- 5 awards focus on COVID-19 as a condition
- 4 awards focus on ways to provide care during a pandemic

**Themes**
- 3 targeted awards are relevant to nursing homes or other congregate living settings

**Key statistics about targeted studies:**

<table>
<thead>
<tr>
<th>Primary Condition</th>
<th># of studies*</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19</td>
<td>5</td>
</tr>
<tr>
<td>Mental/Behavioral Health</td>
<td>3</td>
</tr>
<tr>
<td>Non-Disease Specific</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Priority Populations</th>
<th># of studies*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Income</td>
<td>6</td>
</tr>
<tr>
<td>Black, Indigenous, and People of Color</td>
<td>5</td>
</tr>
<tr>
<td>People with MCC</td>
<td>3</td>
</tr>
</tbody>
</table>

*Studies may include more than one condition

**Telehealth**
- 5 targeted awards include telehealth components
Evaluating the Comparative Effectiveness of Telemedicine in Primary Care: Learning from the COVID-19 Pandemic

What This Study Does

- Deeply characterizes features of new or expanded telemedicine programs in primary care implemented during the COVID-19 pandemic
- Compares the effectiveness of three primary care practice delivery models under COVID-19: primarily synchronous telemedicine, telemedicine supplemented with in-person visits, and primarily in-person visits

Design

- Observational cohort with strong qualitative component
  - Sample size: 205,000
  - Clusters: 110 primary care practices

Key Outcomes

- **Primary**: Avoidable ED visits, unplanned hospitalizations, continuity of care, days at home
- **Secondary**: Patient satisfaction, communication quality, accessibility/convenience of care

Population & Setting

- Adult patients with one or more of five chronic conditions (asthma, COPD, CHF, diabetes, hypertension) receiving care at primary care practices

Why It Matters

Could provide much needed information on how to effectively implement telemedicine in primary care, particularly for patients with chronic disease, and for other vulnerable populations.

Jessica Ancker, PhD FACMI
Joan & Sanford I. Weill
Medical College of Cornell
University
COVID-19 Targeted PFA
Increasing Vaccine Confidence among Long-Term Care Workers – Targeted PFA

- Uses an expedited mechanism; will follow more rapid review and award timeline
- PFA posted April 13, 2021
- Up to three years
- Up to $5,000,000
- What interventions are effective in increasing COVID-19 vaccine confidence and uptake among long-term care workers?
<table>
<thead>
<tr>
<th>Cycle 1 2021</th>
<th>Cycle 2 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 16 LOIs addressed COVID special areas of emphasis</td>
<td>• 6 LOIs addressed COVID special areas of emphasis</td>
</tr>
<tr>
<td>• Management and survivorship of post-acute COVID-19</td>
<td>• Treatment and survivorship of post-acute COVID-19</td>
</tr>
<tr>
<td>• Impact of COVID-19 on disproportionately affected populations</td>
<td>• Health system and healthcare delivery management of post-acute COVID-19</td>
</tr>
<tr>
<td>• Impact of COVID-19-related social isolation and loneliness on health outcomes</td>
<td>• Strategies to improve outcomes of COVID-19 for disproportionately affected populations</td>
</tr>
<tr>
<td></td>
<td>• Impact of COVID-19-related social isolation and loneliness on health outcomes</td>
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</table>
Other COVID-19 Activities
PCORnet - HERO Program

HERO Healthcare Worker Registry
• >26,000 HCWs enrolled as of March 2021
• Addition of family members
• HERO Together: Pfizer-funded study on long-term vaccine side effects

Hydroxychloroquine Trial
• Completed Feb 2021
• 1,363 enrolled
• Manuscript submission in early summer
Engagement

- 53 enhancements to Engagement Awards
- 25 Engagement Awards in response to special cycle Targeted COVID-19 PFA
  - A special Targeted COVID-19 PFA is currently open
- 13 enhancements to Dissemination and Implementation Awards
- COVID-19 Supplement to the Health Care Horizon Scanning System
Discussion Questions

• Are there other activities we should consider?

• Are there specific topics that you would consider a priority for research?
Contact Information

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Intellectual and Developmental Disabilities

Holly Ramsawh, PhD
CEDS Senior Program Officer
2010 - PCORI original authorizing legislation created a process for setting national priority agenda but did not specify specific areas

2019 – Congress reauthorizes PCORI; amending legislation specifies two new national priority areas

- Maternal mortality
- Individuals with intellectual and developmental disabilities

This means IDD is set as a national priority area by law, thus a long-term priority area of investment → Ongoing opportunities for engagement

- In months and years ahead we will be hosting a variety of opportunities to engage with us on this topic
IDD Background: Definition and Prevalence

Intellectual and Developmental Disabilities:

- **Developmental disabilities** are chronic disabilities that originate at birth or in the developmental period and cause impairment in physical, learning, language, and/or behavioral areas.

- **Intellectual disabilities**, which fall under the umbrella term of developmental disabilities, involve limitations to cognitive function (i.e., reasoning, learning, problem solving) and adaptive behavior.

Data from the United States estimate that 17.8% of children and adolescents and 0.5 - 1.5% of adults have an IDD diagnosis, impacting 7 million to 8 million Americans.
IDD Background: Disparities

Compared to the general population:

- Co-occurring physical and mental health conditions
- Unmet healthcare needs
- Quality of life
- Participation in school, work, play

Greater disparities exist among those with IDD for communities that are historically underserved.
IDD Background: Co-occurring Mental Health Conditions

- Mental health conditions are more common; prevalence estimates of 37%-55%
- High degree of heterogeneity of symptoms, but commonly occurring conditions include mood and anxiety disorders
- Complicated by fragmentation of care delivery
- This presents a unique set of needs/challenges across the lifespan, such as:
  - Lower quality of care and worse health outcomes than the general population
  - Difficulty accessing services
  - Greater family burden
  - Poorer quality of life
  - Negative impact on education engagement and employment
  - Poorer achievement in adult life
Few treatment studies in this subpopulation of IDD exist due to highly restrictive inclusion criteria and of the studies that do exist, there are significant methodological limitations.

**Gaps to be filled:**

- Evidence-based mental health treatments for IDD
  - E.g., studies that evaluate the effectiveness of psychotherapeutic and cognitive behavioral therapy (CBT) modalities in children with IDD
- Larger more rigorous clinical trials
- Adaptations to existing psychosocial interventions
- Accessible treatment for rural/underserved populations
- Evidence-based research across the spectrum of IDD impairment from mild to severe and across the lifespan
IDD Funding at PCORI

• Special Area of Emphasis in Broad PFA:
  • Cycles: 3 - 2020, 1 – 2021, and 2 - 2021
  • Focus: Improving Care for Individuals with Intellectual and/or Developmental Disabilities Growing into Adulthood

• Research priority in PLACER and Engagement Award PFAs

• Targeted PFA
  • Cycle: 2 – 2021
  • Focus: Interventions Targeting Mental Health Conditions in Individuals with IDD
Targeted PFA Overview

• **Priority Research Question:** What is the comparative effectiveness of evidence-based approaches (e.g., specific pharmacologic and behavioral interventions) that address mental health conditions in individuals with IDD?

• Interested in pharmacological, behavioral, other nonpharmacological or combination interventions administered via appropriate delivery modalities (e.g., telehealth, family-based, collaborative care, group, or individual).

- Total Direct Costs: Up to $3M
- Maximum Project Period: 3 years

• PCORI has allocated a total of up to **$40 million** for this Targeted PFA
## PICOTS

<table>
<thead>
<tr>
<th>Population</th>
<th>Pediatric, transitional age, and adult individuals with mild to moderate IDD-related impairment, as well as those with more severe impairment due to IDDs that have co-occurring mental health conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention/Comparators</td>
<td>Pharmacological, behavioral, other nonpharmacological, or combination interventions administered via appropriate delivery modalities (e.g., telehealth, family-based, collaborative care, group or individual)</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Symptom severity, functional impairment, quality of life, adverse events, health resource utilization, or relevant caregiver outcomes, as appropriate</td>
</tr>
<tr>
<td>Timing</td>
<td>Studies up to 3 years; Up to 12-month follow-up</td>
</tr>
<tr>
<td>Setting</td>
<td>Primary and/or specialty clinics, inpatient, outpatient/community, residential, or home-based settings may be appropriate depending on the population and proposed interventions</td>
</tr>
</tbody>
</table>
### IDD and Co-occurring Mental Health Conditions Targeted PFA Timeline

**PFA Posted on May 4th**

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letter of Intent Deadline</td>
<td>June 1, 2021</td>
</tr>
<tr>
<td>Applicants Notified of LOI</td>
<td>End of June 2021</td>
</tr>
<tr>
<td>Acceptance/Denial</td>
<td></td>
</tr>
<tr>
<td>Application Deadline</td>
<td>August 31, 2021</td>
</tr>
<tr>
<td>Merit Review</td>
<td>December 2021</td>
</tr>
<tr>
<td>Earliest Project Start Date</td>
<td>August 2022</td>
</tr>
</tbody>
</table>
Discussion Questions

Intellectual and Developmental Disabilities
Discussion Question 1

Which top three topics would you advise PCORI prioritize CEDS funds for?

- Comparison of early interventions for IDD
- Comparison of strategies to treat co-occurring health conditions in IDD (e.g., gastrointestinal disorders, seizures, dental/oral health, sensory impairments)
- Comparison of parent-/caregiver-mediated interventions for IDD
- Comparison of caregiver support strategies to improve resilience
- Comparison of nonpharmacological approaches for reducing self-injurious behavior in ASD
- Assess comparative benefits and harms and effectiveness by age of medication used in combination for children and adolescents with ADHD
Discussion Questions 2 and 3

• What other specific IDD topics are important to patients, caregivers, clinicians, patients, advocates, policy makers, and/or other stakeholders? (Please speak to the stakeholder group you represent)

• Where do you see additional CEDS CER gaps more broadly in the IDD space that can be addressed by PCORI funding?
BREAK
Maternal Mortality

Kim Bailey, MS
CEDS Associate Director
Maternal Mortality
US Rates and Disparities

Deaths per 100K live births

Maternal Mortality

Pre-Conception 31% Pregnancy 36% Delivery 33% Postpartum

Maternal Mortality Day 6 1 Yr
Maternal Mortality

Pre-Conception

Pregnancy

Delivery

Postpartum

Maternal Mortality

31% (Pre-)eclampsia

36% Hemorrhage

33% Drug overdose

Day 6

1 Yr

Cardiovascular disease

Cardiomyopathy

Infection

Suicide

Amniotic fluid embolism
Maternal Mortality

~60% of deaths preventable

Pre-Conception  Pregnancy  Delivery  Postpartum

Maternal Mortality

31%  36%  33%

(Pre-)eclampsia  Hemorrhage  Drug overdose
Cardiovascular disease  Infection  Suicide
Cardiomyopathy  Amniotic fluid embolism

~60% of deaths preventable
## Factors Driving Maternal Mortality

### Risk Factors
- Diabetes
- BMI
- Primipara
- Smoking
- Hypertension
- Age
- Brief intrapartum period

### Social Determinants of Health
- Structural racism
- Economic stability
- Neighborhood & physical environment
- Education
- Food security
- Community & social context
- Healthcare system
Effects of Disparities on Care and Care Experience

- Reduced access to care
- Delayed or missed prenatal care
- Missed or dismissed warning signs
- Negative care experience
- Reduced engagement with care
Special Area of Emphasis: Increasing Access & Continuity of Patient-Centered Care

- Disparities are exacerbated by limited access to care and reduced engagement in care
  - Structural barriers: Distance, time, transportation, social supports, siloed care
  - Lack of patient trust
    - Clinician/staff/institution racism, cultural insensitivity, communication challenges

- Special Area of Emphasis: Cycle 3 2020 Broad PFA onward
  - Multilevel, culturally adapted interventions that address barriers in access to and engagement in patient-centered maternal care with a focus on:
    - Maternal care coordination
    - Education or training for healthcare providers or patients
    - Add-on or wrap-around services
  - $30M allocation of funds
    - Studies of up to 5 years in duration and $10M in direct costs
Postpartum Care

- Pre-Conception
- Pregnancy
- Delivery
- Postpartum

Maternal Mortality

50%  40%  10%

6 wks 1 Yr

HDP
Infection
Hemorrhage
Cardiomyopathy
Other CV
Evidence-based treatments and care protocols exist

- Pre-Conception
- Pregnancy
- Delivery
- Postpartum

Maternal Mortality

- 50% 6 wks
- 40% 1 Yr
- 10%

Conditions:
- HDP
- Infection
- Hemorrhage
- Cardiomyopathy
- Other CV
Postpartum Care

- **Postpartum care is limited, fragmented, and insufficient**
  - Transition from obstetric to primary care is critical
  - Many patients do not receive any postpartum care
  - Patients and providers may miss or dismiss warning signs
    - Signs and symptoms may overlap with other conditions
    - Patient may not mention and providers (OB, PC, ED) may not ask recent pregnancy status

- **Significant inequities persist in the receipt of timely and respectful postpartum care**
  - Provider bias
  - Language barrier
  - Cultural barriers
  - Social determinants of health
• **Research Question:** What is the comparative effectiveness of multicomponent strategies to improve early detection and timely care for complications up to six weeks postpartum for Black, AI/AN, Hispanic, rural, and low SES women?
  
  • Strategies may include increased patient/provider contact; standing orders and standardized protocols; patient education; provider education/training; reminder systems; home visits; telehealth; blood pressure monitoring models; care coordination
  
  • Particular interest in community-based and tailoring approaches
  
  • Total commitment up to $50M
  • Estimated number of studies: 4
  • Project duration: 5 years
Q & A

Maternal Mortality
Closing Remarks/Adjourn

Kari Gali
CEDS Chair

Julie Eller
CEDS Co-Chair
Thank you!