Board of Governors Meeting

via Teleconference/Webinar

June 23, 2020
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 PM	**Call to Order, Roll Call, and Welcome**
1:00-1:05	**Consider for Approval:** • Minutes of May 5, 2020 Board Meeting
1:05-1:45	**Executive Director's Report** • Q2 FY2020 Dashboard • Mid-year Financial Report • Overview of Funding Opportunities • Strategic Planning Process
1:45-2:10	**Update on COVID-19 Initiatives** • HERO Registry and Trial • COVID-19 Targeted PFAs • COVID-19 Enhancements to Existing Projects **Consider for Approval:** Additional Funding for COVID-19 Enhancements and Targeted PFAs
2:10-2:35	**Consider for Approval: Funding Announcement** • Targeted PFA on Suicide Prevention: Brief Interventions for Youth
2:35-3:00	**Consider for Approval: Cycle 3 2019 Award Slates** • Broad PFAs • Limited Competition Dissemination and Implementation PFA
3:00	**Wrap-up and Adjournment**

Board Vote

Call for a Motion to:	• **Approve** the minutes of the May 5, 2020 Board of Governors meeting
Call for the Motion to be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Voice Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Executive Director's Report

Nakela Cook, MD, MPH

Executive Director

Executive Director's Report Overview

- Second Quarter of FY2020 Dashboard Review
- Mid-Year Financial Report
- Overview of Funding Opportunities
- Strategic Planning Process

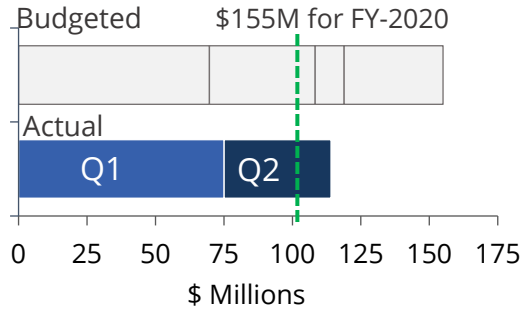
Dashboard Review
Second Quarter of FY2020

PCORI Board of Governors Dashboard

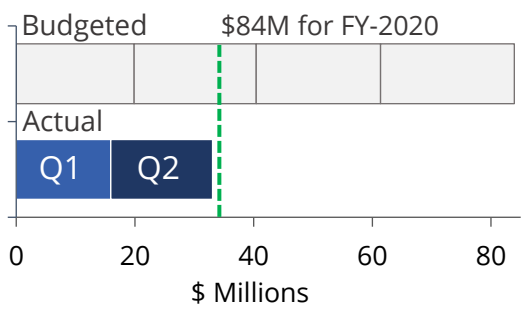
Second Quarter FY2020 (As of 3/31/2020)

Inputs → Process → Outputs → Uptake → Use → Impact

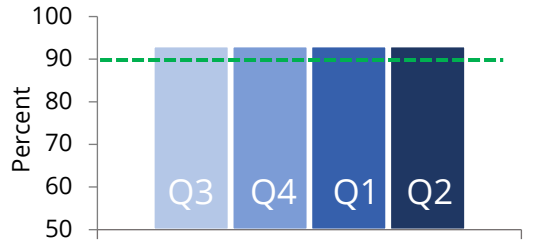
Funds Committed



Operational Expenses



Research Project Performance

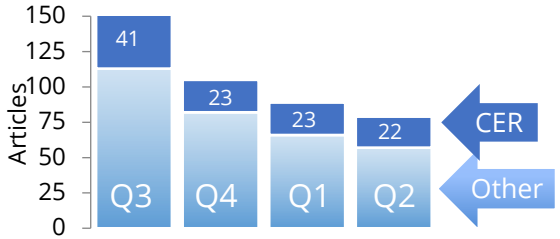


% of Research Projects On Track

Dashboard Key

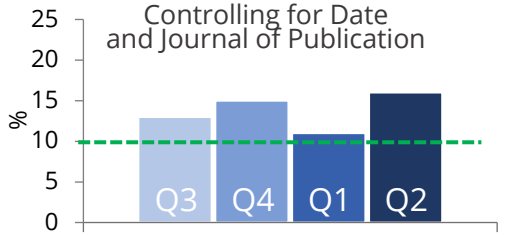
- Q3 2019
- Q4 2019
- Q1 2020
- Q2 2020
- Meeting Target
- Not Meeting Target
- Needs Board Attention
- Target in Development or Not Applicable
- Projected for 2020
- Q2 Target

Results Published in Literature



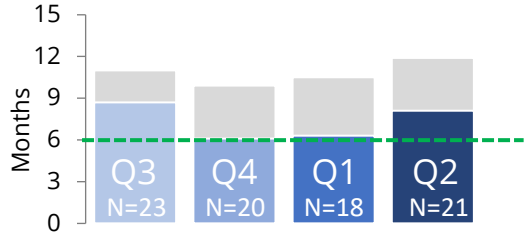
CER Results and Other Results Published in the Literature

Altmetric: Attention to PCORI Results



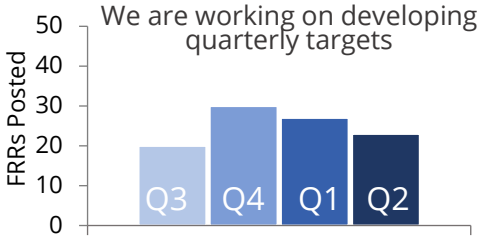
% of CER Results Publications in Top 10% of Attention

Speed of PCORI Peer Review



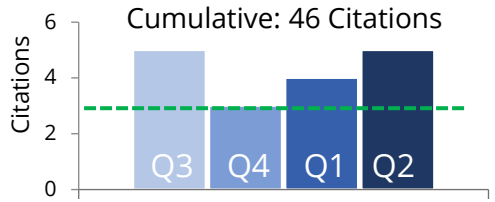
Median Time to Complete Peer Review (Grey = 75th Percentile)

Final Research Reports Posted to PCORI.org



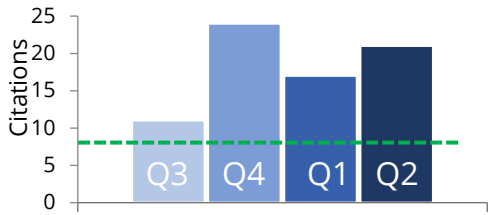
Final Research Reports Posted to PCORI.org

Uptake into UpToDate®



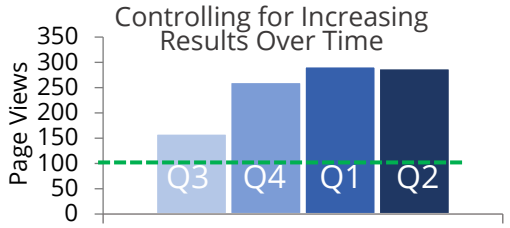
Citations in UpToDate® point-of-care decision tool

Other Examples of Uptake



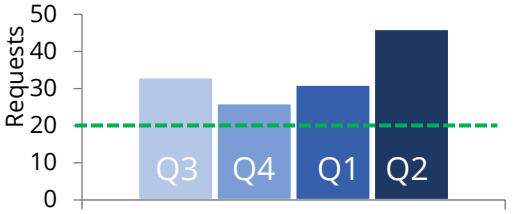
Citations in Systematic Reviews, Guidelines, & Policy Documents

Results Viewed on PCORI.org



Average Pageviews of Results Posted to PCORI.org

Front Door Requests to PCORnet



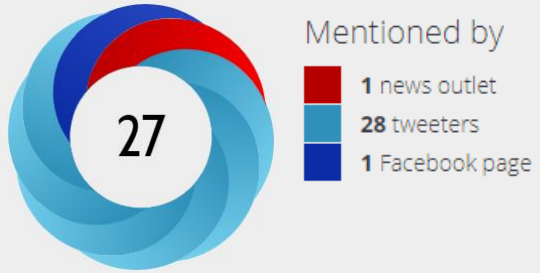
Front Door Requests Submitted to PCORnet

PCORI-Funded Study Results

Publication: A behavioral health home model is a best-practice solution to addressing health needs of adults with serious mental illness

PCORI Study	**Study Title:** Optimizing Behavioral Health Homes by Focusing On Outcomes That Matter Most for Adults with Serious Mental Illness **Principal Investigator:** James M. Schuster, MD, MBA, UPMC Center For High-Value Health Care
Results Publication	Schuster J, Nikolajski C, Kogan J, et al. **A Payer-Guided Approach To Widespread Diffusion Of Behavioral Health Homes In Real-World Settings**. *Health Aff (Millwood).* Feb 2018. 37(2):248-256. doi: 10.1377/hlthaff.2017.1115. PubMed PMID: 29401022. Link to full text.

Altmetric Score (Attention)



*Published in the Diffusion of Innovation Special Edition of *Health Affairs*

Summary: People with serious mental illness like bipolar disorder or schizophrenia often don't receive the physical health care they need. Community mental health centers can help people with serious mental illness manage their health and prevent later health problems.

This study compared the effectiveness of two behavioral health home approaches: wellness coaching plus a provider-supported integrated approach vs. a self-directed approach on patient activation in care, health status, and engagement in primary or specialty care among adults with serious mental illness. Patients were eligible to participate if they were Medicaid-enrolled and were receiving services at community mental health centers (CMHCs).

The study found that **both approaches significantly increased patient activation in care** (more quickly in provider-supported care), engagement in primary and specialty care, and perceived mental health status. The success of this behavioral health home intervention in improving important outcomes and the use of novel diffusion strategies has also led to its **uptake by forty-three additional providers across Pennsylvania.**

> Our findings suggest that payers may be able to leverage their unique relationships with community mental health providers to improve outcomes for patients, and to integrate physical health and wellness support into their existing care delivery settings.

PCORI Funded Study Results ⇨ Dissemination to Broader Audiences; Uptake and Use

- Through two awards, **PCORI is providing further funding for dissemination and implementation** of study findings:

Type of Project: Implementation Award

Title: Utilizing a Learning Collaborative Approach to Support Behavioral Health Home Dissemination

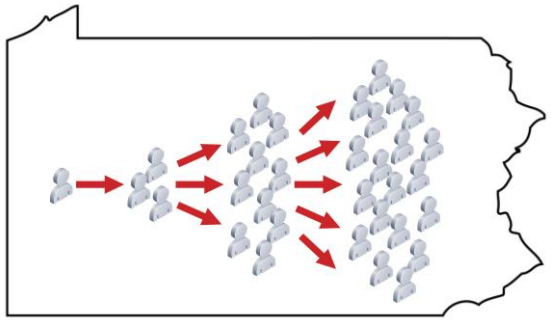
Principal Investigator: James M. Schuster, MD, MBA, UPMC Center for High-Value Health Care

Type of Project: Engagement Award for Dissemination

Title: Helping Adults with Serious Mental Illness Improve Their Health and Wellness

Project Lead: Alise Gintner, LCSW, The Rochester General Hospital

- The intervention was adopted statewide by **61 provider** organizations in **27 counties** in Pennsylvania.
  - 40 adult community behavioral health clinic sites
  - Adolescent providers: 3 community behavioral health clinic sites, 8 school-based sites



- The intervention was recognized by Substance Abuse and Mental Health Services Administration (SAMHSA) for Excellence in Wellness in 2016 (source)

FY2020 Mid-Year Financial Review

(As of 3/31/2020)

Lawrence Becker

Chair, Finance and Administration Committee

Nakela Cook, MD, MPH

Executive Director

FY2020 Revenue
(10/1/2019 – 3/31/2020)

REVENUE	*$ in millions*
From PCOR Trust Fund	
Federal Appropriation	$ 220.4
Interest	0.3
PCOR Fee True-Up	0.1
From Interest (U.S. Treasury Securities)	13.4
Total Revenue	**$ 234.2**

Cash Balance and Outstanding Award Obligations
(As of 3/31/2020)

CASH BALANCE	$ in millions
Cash -- PCOR Trust Fund	$ 0.0
Cash -- Operating Account	26.5
U.S. Treasury Securities	1,364.0
Total	**$ 1,390.5**

OUTSTANDING AWARD OBLIGATIONS	$ in millions
Cumulative Funding Commitments*	$ 2,634.1
Cumulative Award Payments**	(1,669.7)
Outstanding Award Obligations* **	**$ 964.4**

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

FY2020 Actual vs. Budget by Broad Categories
(As of 3/31/20)

	FY2020 YTD ACTUAL (through 3/31/20)	% of Total Actual	FY2020 YTD BUDGET (through 3/31/20)	% of Total Budget	FY2020 YTD VARIANCE (through 3/31/20)	
PROGRAM SERVICES	$ 154,882,103	88%	$ 164,917,507	87%	$ 10,035,404	6%
PROGRAM SUPPORT	5,871,239	3%	7,400,733	4%	1,529,494	21%
ADMINISTRATIVE EXPENSES	15,417,185	9%	17,349,851	9%	1,932,666	11%
TOTAL	$ 176,170,527	100%	$ 189,668,091	100%	$ 13,497,564	7%

Overview of Funding Opportunities

PCORI Funding Opportunities

Cycles Currently Under Review

- COVID-19 Targeted PFAs
  - Research, Dissemination, Engagement
- Cycle 1 2020 Broad PFAs
- Cycle 1 2020 D&I PFA: Limited Competition

Slates Being Considered for Approval Today

- Cycle 3 2019 Broad PFAs
- Cycle 3 2019 D&I PFA: Limited Competition

Open Funding Opportunities

- Cycle 3 2020 PLACER PFA (Phased Large Awards for Comparative Effectiveness Research)
- Cycle 2 2020 Targeted PFA: Conducting Rare Disease Research Using PCORnet® (Limited Competition)
- Cycle 2 2020 Targeted PFA: Observational Analyses of Second-Line Pharmacological Agents in Type 2 Diabetes
- Cycle 2 2020 D&I PFAs: Limited Competition and Shared Decision Making
- COVID-19 Related Project Enhancements
  - Research, Dissemination, Engagement

Upcoming Cycles (through 2020)

- Cycle 3 2020 Broad PFAs with Special Emphasis Topics:
  - Maternal Mortality
  - Intellectual & Developmental Disabilities
- Cycle 3 2020 D&I PFAs: Limited Competition and Implementation of Findings from PCORI's Major Research Investments

Targeted PFAs Being Considered for Approval Today

- Cycle 3 2020 Targeted PFA on Suicide Prevention

Strategic Planning Process

Strategic Planning: Encompassing Complex Components

Planning Schedule: Highlights

Summer 2020
Public Engagement

Fall 2020
Framing PCORI 2.0

Winter 2020-2021
Developing Key Components

Spring 2021
Public Engagement Cont'd, Formal Public Comment

Summer 2021
Bringing it Together, Drafting Strategic Plan

Fall 2021
Finalizing Strategic Plan

Planning Schedule: Highlights

Summer 2020
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National Priorities
- Advisory Panels
- Refreshing National Priorities
- Public Engagement

Research Agenda
- Intellectual and Developmental Disabilities
- Maternal Mortality

Related Discussions
- Hosting External Panels

Planning Schedule: Highlights

	National Priorities	Research Agenda	Related Discussions
Summer 2020 **Public Engagement**	• Advisory Panels • Refreshing National Priorities • Public Engagement	• Intellectual and Developmental Disabilities • Maternal Mortality	• Hosting External Panels
Fall 2020 **Framing PCORI 2.0**	• Measuring Success • Aligning Resources	• Intellectual and Developmental Disabilities • Maternal Mortality • Reviewing Existing Portfolio	• Reflecting and Moving Forward • Short- and Long-Term Priorities • Cost Outcomes Data
Winter 2020-2021 **Developing Key Components**	• Drafting National Priorities for Public Comment • Beginning of Public Comment	• Beginning of Public Input via Various Mechanisms	• Commitment Planning
Spring 2021 **Public Engagement Cont'd, Formal Public Comment**	• Public Comment Continued • Finalizing National Priorities • Review for Adoption	• Public Input via Various Mechanisms Continued • Drafting Research Agenda for Public Comment • Beginning of Public Comment	• Reviewing and Responding to Public Comment on National Priorities • Incorporating Public Input Received on Research Agenda
Summer 2021 **Bringing it Together, Drafting Strategic Plan**	• Incorporating into Plan	• Finalizing Research Agenda • Review for Adoption	• Outlining Strategic Plan
Fall 2021 **Finalizing Strategic Plan**	• Incorporating into Plan	• Incorporating into Plan	• Refining Draft Plan • Presenting Final Plan for Adoption

Discussion
Board & Staff Working Group on Strategic Planning

Purpose

- **Facilitate strategic planning** process by considering approach and process decisions and **making recommendations** to Board of Governors
- Working group comprised of Board, the Executive Director and senior staff would work collaboratively to:
  - **Brainstorm, generate, review and refine** options during the planning process
  - **Recommend directions** to ensure achievement of mission
  - Develop and provide first-line **review for draft documents**

Considerations

- **Discrete purpose** and anticipated timeline through completion of Strategic Plan; after that, Board would consider any future need
- Subset of Board working together with staff would do more **detailed work** and **bring to Board for wider discussion**
- Expected responsibilities of working group members include:
  - **Collaborative development** throughout planning process
  - Consistently attending **monthly meetings**
  - **Providing input**, reviewing, responding to documents outside of meetings

Discussion

- What other factors and responsibilities would make such a working group **optimally effective**?
- What **issues** should the working group **anticipate**?
- Who may be **interested in participating** in such a working group?

*Workgroup would adhere to PCORI Bylaws

Update on COVID-19 Initiatives and Request for Additional Funding

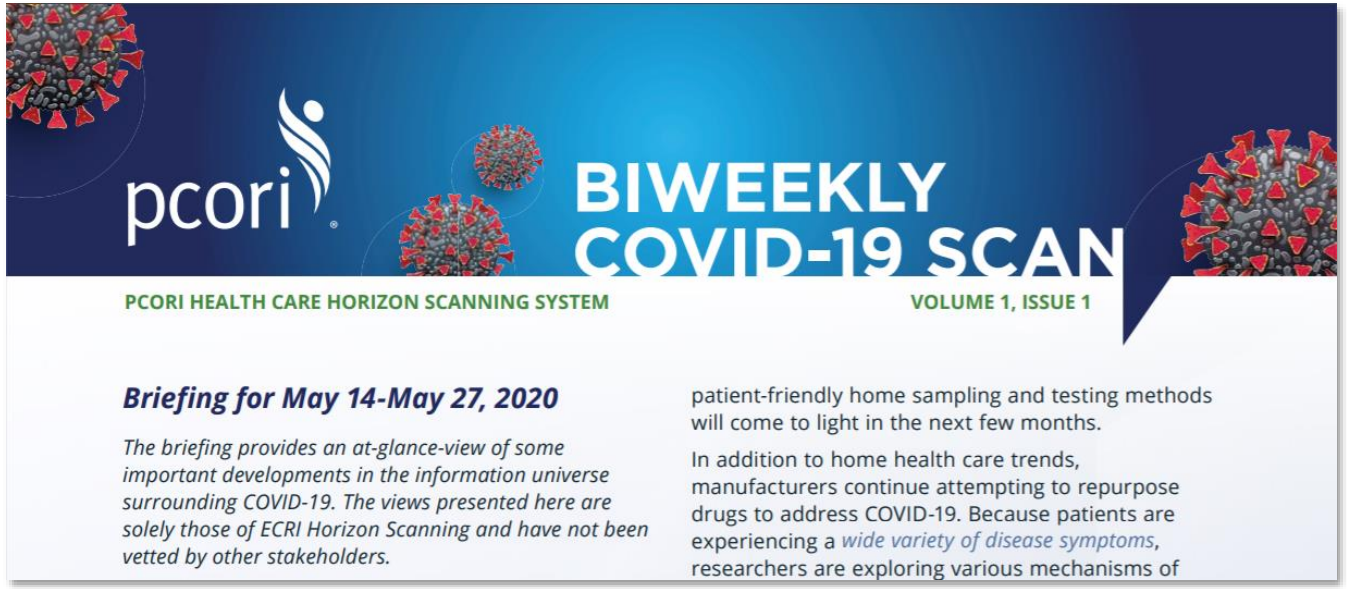
Nakela Cook, MD, MPH

Executive Director

Bi-Weekly COVID-19 Horizon Scan

- PCORI has launched a new briefing on COVID-19-related topics that could potentially affect health care in the United States within the next 12 months
- Horizon scanning is a systematic process that serves as an early warning system to inform decision makers about possible future opportunities and threats.

- The first scan discusses a home testing kit and the potential repurposing of the drug anakinra for treating patients with COVID-19 who are experiencing acute respiratory distress syndrome and hyperinflammation



https://www.pcori.org/sites/default/files/PCORI-Health-Care-Horizon-Scanning-System-Biweekly-COVID-19-Scan-May14-27-2020.pdf?utm_source=weeklyemail&utm_medium=email&utm_campaign=061620

PCORI-Funded HERO Research Program

Project Title: Preventing COVID-19 Infections: Healthcare Worker Exposure Response and Outcomes (HERO) Registry and Hydroxychloroquine (HERO-HCQ) Trial Program
Principal Investigators: Adrian Hernandez, MD, MHS; Emily O'Brien, PhD (HERO registry); Susanna Naggie, MD (HERO-HCQ trial)
Awardee Institution: Duke University

HERO Registry

- Create a community of healthcare workers (HCWs) who may be at risk of COVID-19 infection
- Identify HCWs interested in engaging in upcoming clinical trials related to COVID-19 and obtain preferences and willingness regarding participation
- Create a dataset of basic clinical and environmental COVID-19 risk factors and clinical and emotional outcomes for analysis
- Recruitment goal for the HERO registry is 100,000 HCWs

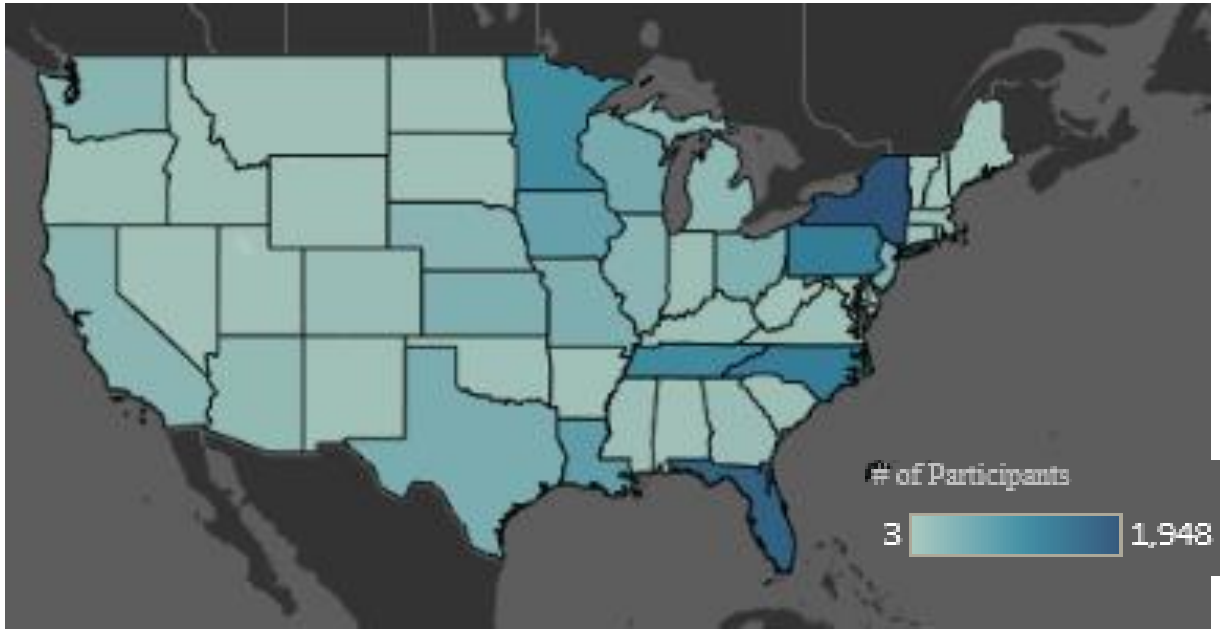
HERO-HCQ Trial

- Will randomize 15,000 at-risk HCWs into a randomized clinical trial to evaluate the efficacy of hydroxychloroquine (HCQ) to prevent COVID-19 clinical infection in HCWs
- HCWs eligible for the HERO-HCQ trial will work at one of the 40 PCORnet sites participating in the trial
- Secondary aims:
  - To evaluate the efficacy of HCQ to prevent viral shedding of SARS-CoV-2 among HCWs
  - Evaluate safety and tolerability of HCQ

HERO Registry Coverage and Trial Enrollment

HERO Registry

- 14,535 participants have signed the registry consent
  - Covers all 50 states



HERO-HCQ Trial

- 32 sites activated
- **28 sites have enrolled 918 participants**

As of June 15, 2020

Oversight of the HERO-HCQ Trial

- The **HERO-HCQ** trial oversight mechanisms include the following:
  - Trial conducted under Investigational New Drug Safety FDA requirements
  - Data Safety and Monitoring Board (DSMB) established by the sponsor
    - DSMB is engaged with other DSMBs of large COVID-19 related trials
    - Recommend continuation, revision or discontinuation of protocol
  - Trial subject to Institutional Review Board review
- Monitoring processes assure effectiveness, safety, or futility issues will be addressed promptly
- Consistent with best practices for trial oversight, early termination is possible if indicated by either safety or futility
- PCORI Advisory Panel advises PCORI's Executive Director about overall funding and monitoring questions and issues
- PCORI contractual mechanism and processes reduce financial impact of early termination

PCORnet COVID-19 Common Data Model
Background

- PCORnet is characterizing the cohort of COVID-19 patients to provide information on demographics and pre-existing conditions.

- Purpose:
  - To support CDC surveillance and develop a strategy for subsequent research

- Approach:
  - The network is creating a stand-alone version of the Common Data Model (CDM) that includes a subset of patients with respiratory illness since January 2020
  - Employing modified workflows to allow data refreshes much faster (days vs 3 months)
  - Query is reissued weekly; sites can join once they are ready

- Query information:
  - Demographics and state
  - Care setting
  - Pre-existing conditions and prescriptions for or medication administration of drugs of interest

COVID-19 Enhancement – Use Cases
Research Ready COVID-19 CDM

- PCORnet Coordinating Center and networks are expanding scope of work to:
  - Add non-CDM data of interest
    - COVID-19+ flag
    - SARS-CoV-2 test results (antigen & antibody)
    - Select medication use: e.g., Remdesivir use (order / administration)
    - Admission to ICU / Use of mechanical ventilation

- Partnership with CDC to support weekly information refresh needed for CDC surveillance activities
    - Broad network participation

- Use cases for COVID-19 coagulopathy and multisystem inflammatory syndrome in children
    - Utilize vanguard sites
    - Optimize and rigorously validate key COVID-19 elements
    - Curate and validate to establish Research Ready Data fit for purpose

COVID-19 PFAs for New Awards

- In May 2020, PCORI posted a COVID-19 **Targeted Funding Announcement** for new research studies, with three priority areas:
  - Adaptations to healthcare delivery
  - Impact of COVID-19 on vulnerable populations
  - Impact of COVID-19 on healthcare workforce well-being, management, and training
- PCORI also posted an **Engagement Award** Special Funding Award Opportunity to support projects that help communities increase their capacity to participate across all phases of the PCOR/CER process, while responding to contextual changes as a result of the COVID-19 pandemic.
- Both PFAs attracted significant interest, received a robust response, and applications are currently under review

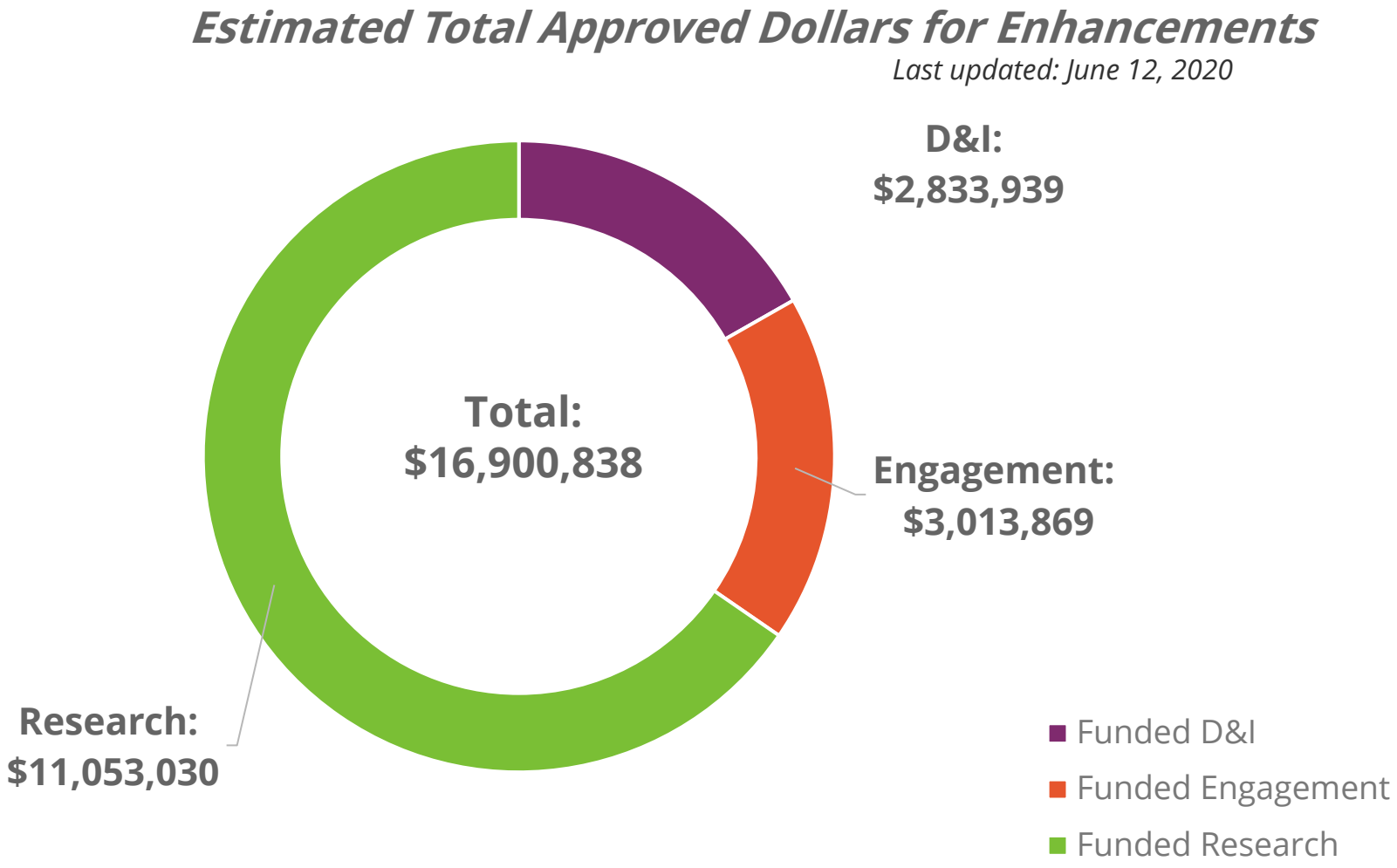
COVID-19 Targeted PFA: Research Award Examples

- Promising applications propose research on topics that include:
  - Psychological distress among healthcare workers
  - Prevention of COVID-19 in nursing homes
  - Homelessness, supportive housing, and COVID-19
  - Strategies for infection control (e.g., shelter-in-place)
  - Interventions to mitigate impact of COVID-19 among vulnerable and diverse racial/ethnic populations

Update on Enhancements for Currently Funded Projects

- In April 2020, PCORI posted three funding announcements to seek investigator-initiated proposals to address the COVID-19 public health crisis for **current awardees in the form of enhancements**
- PCORI has already received a high volume of proposals that offer exciting ways to transform existing funded awards that serve the award's original aims and result in findings related to COVID-19
- **Over 150 awards have submitted proposals** for Enhancements to date, with proposals from all award types (Research, D&I, and Engagement)
  - Approved Enhancements total $16.9M to-date
    - $11.1M in Research Enhancements
    - $2.8M in D&I Enhancements
    - $3.0M in Engagement Enhancements

Funded Enhancements
Total Budget = $20M



COVID-19 Enhancements – Current PCORI Funding

Health Condition	Research Awards & Intervention Strategy									Dissemination & Implementation Awards	Engagement Awards
	Drug	Other Clinical	Health Services	Tele-medicine	Training & Education	Screening	Tech-nology	Behavioral Inter-ventions	N/A		
Cancer			■			■					■
Cardiovascular Diseases		■	■						■	■	
Gastrointestinal Disorders			■								■
Genetic Disorders											■
Infectious Diseases										■	
Mental/Behavioral Health				■	■			■			■
Muscular & Skeletal Disorders									■		■
Neurological Disorders	■			■						■	
Nutritional & Metabolic Disorders	■				■						
Rare Disease											■
Reproductive & Perinatal Health				■						■	■
Respiratory Diseases							■			■	■
Other or Non-Disease Specific			■							■	■

A Stakeholder-Driven Comparative Effectiveness Study of Treatments to Prevent Coronary Artery Damage in Patients with Resistant Kawasaki Disease

Enhancement Research Question

- Seeks to characterize and compare a significant new pediatric inflammatory condition with similarities to Kawasaki disease (KD) and which has emerged in communities heavily affected by COVID-19. The team will compare clinical data and laboratory samples from three groups of patients: typical KD prior to Covid-19, typical KD during Covid-19, and multisystem inflammatory syndrome in children (MIS-C).

Potential Impact of Enhancement

- This will further characterize COVID-related MIS-C and offers the opportunity to better understand two rare diseases with significant morbidity.

Methods

- Observational study

The current award seeks to test the superiority of infliximab to a second intravenous immunoglobulin (IVIG) infusion for treatment of persistent or recrudescent fever in children with KD, who fail to become afebrile after the first IVIG infusion.

Jane Burns, MD
University of California, San Diego

Assessment of Prevention, Diagnosis, and Treatment Options,
Awarded December 2016

Expanding Access to the Infusion Center Model for People Living with Sickle Cell Disease (SCD)

Enhancement Activities

- Aims include 1) conducting a robust evaluation of telemedicine on access to care, patient experience and health outcomes for adults with SCD; and 2) assessing barriers and facilitators, potential benefits and risks, and satisfaction with telemedicine visits using semi-structured qualitative interviews with adults living with SCD.

Potential Impact of Enhancement

- This enhancement includes an evaluation of telemedicine as a viable option to improve outcomes and broaden access to care for adults living with SCD. If telemedicine proves to be valuable for adults living with SCD, it will be incorporated into the implementation toolkit that is being developed as a component of the original award.

Current award aims to understand the barriers and facilitators to successful implementation of an infusion clinic (IC) model for adults with SCD diverse group of key stakeholders. The objective of this award is to identify the best strategies for broad implementation of the model and develop, test, and evaluate an implementation toolkit.

Sophie Lanzkron, MD, MHS
Johns Hopkins School of Medicine

Capacity Building,
Awarded November 2019

Broad Implementation of Outpatient Stewardship (BIOS) Study

Enhancement Activities

- Pediatric outpatient settings have seen a dramatic shift to telehealth. Evidence suggests that antibiotic stewardship is less effective in telemedicine than during in-person visits. This enhancement will adapt educational content for clinicians, audit-and-feedback reports, and practice facilitation to address appropriate antibiotic prescribing for acute respiratory illnesses (ARTIs) during telemedicine visits.

Potential Impact of Enhancement

- Supports national goals for antibiotic stewardship, benefiting the public as well as children with ARTIs, for whom over-prescription of broad-spectrum antibiotics can cause unnecessary side effects such as diarrhea and vomiting. It is of immediate and ongoing relevance for improving outcomes for this target population.

Antibiotics are the most commonly prescribed medication for children, primarily in outpatient settings for treatment of acute respiratory tract infections (ARTIs). Contrary to current guidelines, many children are prescribed broad-spectrum rather than narrow-spectrum antibiotics as first-line treatment. The original D&I project adapts and implements a tested antibiotic stewardship program to improve outpatient prescribing at 350,000 ARTI visits in diverse practice settings across 5 health systems.

Jeffrey Gerber, MD, PhD
Children's Hospital of Philadelphia

Implementation of PCORI's Major Research Investments Awarded November 2019

Consider for Approval: Additional Funding for COVID-19-Related Project Enhancements and COVID-19 Targeted PFAs

Background on COVID-19 Funding Approval

- On April 1, 2020, the Board approved up to $110M in total for COVID-19-Related Funding:
  - $20M for COVID-19-related enhancements of currently-funded projects
  - $30M for funding new projects from Targeted COVID-19 PFAs

- In order to be able to fund meritorious proposals without delay we request up to **$50M in additional funding** for COVID-19-related:
  - Enhancements to currently-funded projects
  - New projects funded via Targeted PFAs

Rationale for Additional Funding for COVID-19-Related Project Enhancements and Targeted PFAs

- To fund meritorious proposals without delay, we are requesting up to $50M in additional funding for COVID-19-Related Project Enhancements and the COVID-19 Targeted PFAs for the following reasons:
  - The rapidly-evolving nature of the COVID-19 pandemic
  - High volume of meritorious applications from the research community for new projects submitted in response to Targeted PFAs
  - High volume of meritorious proposals from our awardees for project enhancements
  - PCORI's unique position to fund projects that provide answers to the challenging COVID-19 related dilemmas facing patients, caregivers, providers, health systems, and policymakers

Board Vote

Call for a Motion to:	• **Approve** an additional funding commitment of up to $50M to fund COVID-19 related enhancements to existing projects and to fund new COVID-19 related projects, subject to the approval processes previously authorized by the Board at its April and May 2020 meetings for COVID-19 related enhancements to existing projects and new COVID-19 projects, to apply in FY2020 and FY2021.
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

Targeted PFA Suicide Prevention: Brief Interventions for Youth

Robert Zwolak, MD, PhD

Chair, Science Oversight Committee

Els Houtsmuller, PhD

Associate Director, Healthcare Delivery and Disparities Research

Topic Selection and Development

Topic Origin

Increased rates

Disparities

PCORI Board of Governors

Congressional Black Caucus

Suicide Prevention

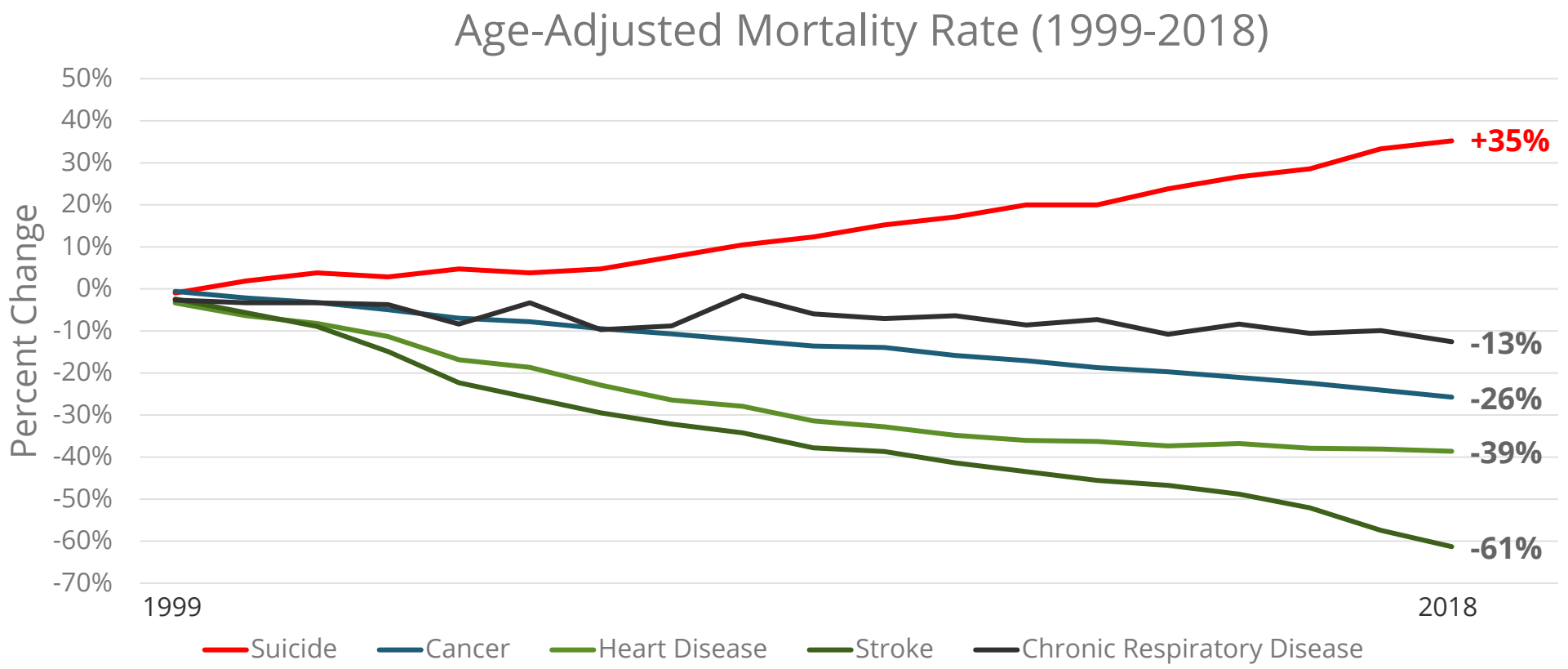
Stakeholder Input

- American Psychiatric Association
- Medicaid Medical Directors
- National Institute on Mental Health
  - Jane Pearson, Chair, NIMH
  - Suicide Research Consortium
- Grayson Norquist, former PCORI Board Chairperson
- National Action Alliance for Suicide Prevention
  - Colleen Carr, Director
- RI International - David Covington
- National Academy for State Health Policy

- PCORI 2-day stakeholder workshop, December 2019
  - People with lived experience, Providers, Payers, Health systems, Researchers

- Action Alliance
  - Crisis Services conference calls
  - Youth Suicide Prevention Stakeholder Meeting

Suicide Prevention Background



- Suicide rates in the US have increased by 35% (10.5 to 14.2 per 100,000) since 1999
- In 2018, suicide 2nd leading cause of death for ages 10-34

Data: https://wonder.cdc.gov.

Suicide Prevention: Youth (15-24)

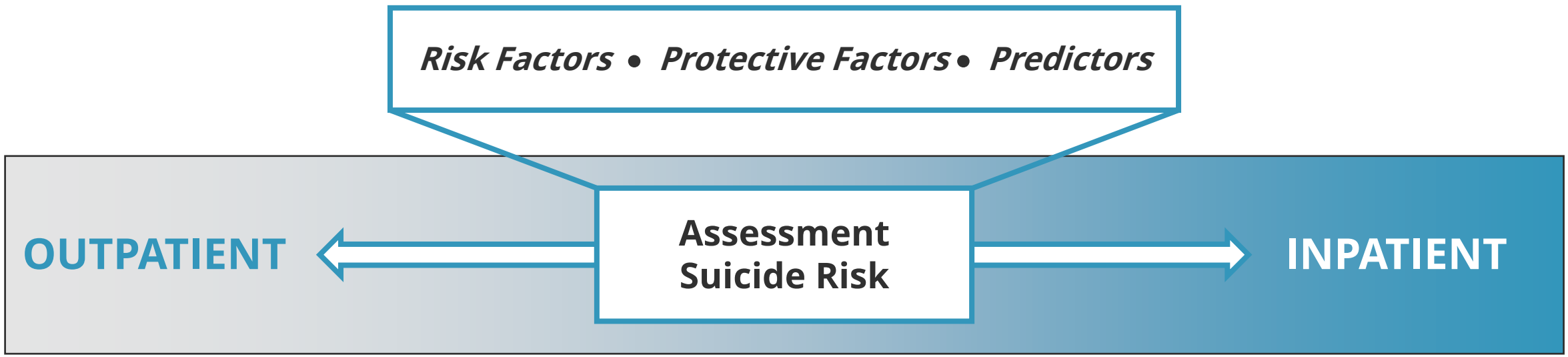
- Suicide rates for ages 15–24 rose 46% from 1999 to 2018 (9.9 to 14.5 per 100,000)
    - Suicide attempts 10-20 times more frequent

- Rates vary by gender, gender identity, race/ethnicity, geography, with higher rates for
    - LGBTQ
    - Rural
    - American Indian/Alaska Native
    - Males
    - Females (Suicide attempts)

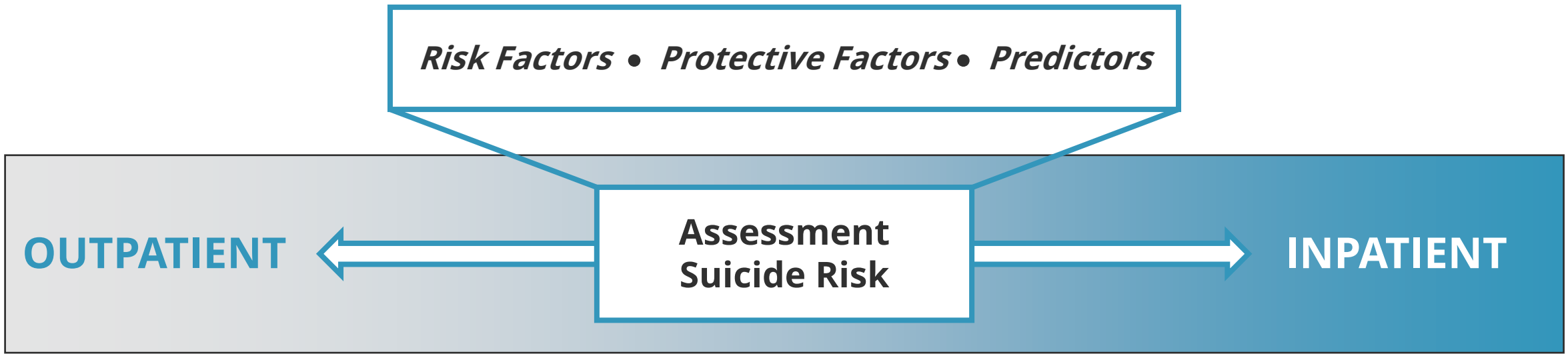
- Rates have increased for
    - Black youth
    - Latina youth

Suicide Prevention: Clinical Care

Suicide Prevention: Clinical Care



Suicide Prevention: Clinical Care



INTERVENTIONS

Brief Interventions
Psychological Treatments
Medications
Procedures

Suicide Prevention: Brief Interventions

- Goal: reduce acute suicide risk, connect to treatment
  - Brief
  - Variety of settings: Emergency Department, Primary Care, Hotlines, Juvenile Detention Center, School, Mobile Crisis Unit, Specialty Care, Inpatient Care
  - Range of healthcare workers (nurses, assistants, counselors)

Brief Interventions: Evidence and Use

- Evidence-based Brief Interventions (e.g., safety planning, motivational interviewing) evaluated primarily in adults
  - Used for general population, including youth

- Some evidence for Brief Interventions for youth (e.g., safety planning with phone follow-up)
  - Reduction in suicidality
  - Increased connection to treatment

- Telehealth: COVID-19 and beyond

Brief Interventions: Evidence Gaps

Comparative effectiveness of:

- Brief Interventions for Youth (15-24)
- Tailored approaches to Brief Interventions for youth from vulnerable populations (e.g., Black, Latina, LGBTQ, American Indian/Alaska Native, rural)
  - Tailoring may include
    - Involvement of People with Lived Experience
    - Telehealth (app, text-based, web-based, phone calls, video calls)
    - Cultural (Language, Family involvement, Rituals)
    - Specific setting (e.g., Primary Care, School, Home, Community)

Targeted PFA- Suicide Prevention: Brief Interventions for Youth

Research Question: What is the comparative effectiveness of different Brief Interventions to reduce suicidality and improve outcomes for youth age 15-24?

- Particular interest in tailored approaches for subpopulations with increased rates of suicidality (LGBTQ, American Indian/Alaska Native, Black, Latina, rural)

Targeted PFA- Suicide Prevention: Brief Interventions for Youth

Population	Youth (15-24) requiring intervention but not continuous monitoring based on clinical assessment
Intervention/ Comparators	Head to Head comparisons of Brief Interventions and/or Tailored Brief Interventions
Outcomes	Primary: Suicidal ideation, self-harm, engagement in mental health care Secondary: functional measures, school participation, employment, skills to manage suicidality, connectedness, quality of life, healthcare utilization (hospital or ED use)
Timing	Up to 12-month follow-up
Setting	Primary care, emergency care, schools, mobile crisis unit, community-based settings where youth may receive crisis or mental health care, home, inpatient care, juvenile detention centers

Requested Research Commitment

- Total requested for this PFA is $30M in total costs
- Estimated number of studies: 2-4
- Maximum project duration: 5 years

Board Vote

Call for a Motion to:	• **Approve** the development and release of Suicide Prevention: Brief Interventions for Youth Targeted PFA
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

Broad PFAs
Cycle 3 2019 Award Slate

Barbara McNeil, MD, PhD

Chair, Selection Committee

Stanley Ip, MD

Interim Program Director, Clinical Effectiveness and Decision Science

Steven Clauser, PhD, MPA

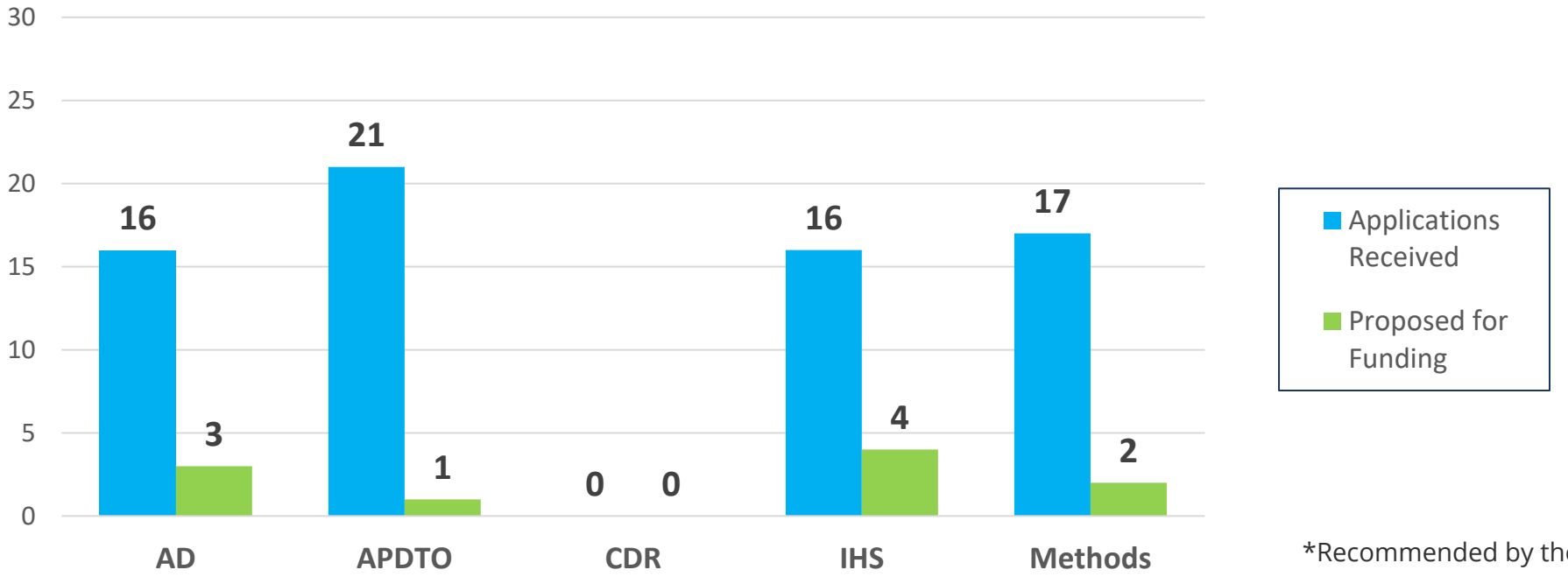
Program Director, Healthcare Delivery and Disparities Research

Cycle 3 2019 – Broad PFAs
Merit Review Criteria

Broad PFAs (excluding Methods)	Improving Methods for Conducting Patient-Centered Outcomes Research
1. Potential for the study to fill critical gaps in evidence 2. Potential for the study findings to be adopted into clinical practice and improve delivery of care 3. Scientific merit (research design, analysis, and outcomes) 4. Investigator(s) and Environment 5. Patient-centeredness 6. Patient and stakeholder engagement	**1. Study identifies critical methodological gap(s) in PCOR/CER** **2. Potential for the study to improve PCOR/CER methods** 3. Scientific merit (research design, analysis, and outcomes) 4. Investigator(s) and Environment 5. Patient-centeredness 6. Patient and stakeholder engagement

Cycle 3 2019 – Broad PFAs
Process Overview

- 176 Letters of Intent (LOIs) received
- 91 LOIs invited to submit a full application
- 70 applications were received
- The Selection Committee is proposing to fund 10 applications* out of 70 received applications for a funding rate of 14%.



*Recommended by the Selection Committee on June 12, 2020

Cycle 3 2019 – Addressing Disparities
Slate of 3 Recommended Projects

Project Title
Comparative Effectiveness of Individual Versus Group-level Interventions to Reduce HIV Risk among African Immigrant Women
Diabetes Medical Nutrition Therapy in Southeastern African American Women
Online Cognitive Behavioral Therapy for Depressive Symptoms in Rural Patients with Coronary Heart Disease

Resubmissions in bold

Cycle 3 2019 – Assessment of Prevention, Diagnosis, and Treatment Options

Slate of 1 Recommended Project

Project Title
Addressing Anxiety among Low-Risk Chest Pain Patients in the Emergency Department Setting

Resubmissions in bold

Cycle 3 2019 – Improving Healthcare Systems
Slate of 4 Recommended Projects

Project Title
Elders Preserving Independence in the Community (EPIC)
Comparing the Effectiveness of Two Approaches to Preventing Severe Hypoglycemia
Comparing Fingerstick Blood Glucose Monitoring versus Continuous Glucose Monitoring in Primary Care
Comparative Effectiveness Trial of Perioperative Telemonitoring for Functional Recovery and Symptoms

Resubmissions in bold

Cycle 3 2019 – Improving Methods for Conducting PCOR
Slate of 2 Recommended Projects

Project Title
Missing Data When Transporting Treatment Effects from Clinical Trials to a Target Population
An Efficient Distributed Learning Framework for Integrating Evidence in Clinical Research Networks

Resubmissions in bold

Cycle 3 2019
Recommended Slate of 10 Projects

PFA	Amount Budgeted	Proposed Total Award*
Cycle 3 2019 Broad	$15M	$24.9M

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Board Vote

Call for a Motion to:	• **Approve** funding for the recommended slate of awards from the Cycle 3 2019 Broad PFAs
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

Limited Competition: Dissemination and Implementation PFA

Implementation of PCORI-Funded Patient-Centered Outcomes Research Results

Cycle 3 2019 Award Slate

Lawrence Becker

Chair, Engagement, Dissemination, and Implementation Committee

Joanna Siegel, SM, ScD

Director, Dissemination and Implementation Program

Cycle 3 2019 - Limited Competition Dissemination and Implementation PFA

Merit Review Criteria

Limited Competition PFA
1. Importance of research results in the context of the existing body of evidence
2. Readiness of the research results for implementation
3. Technical merit of the proposed implementation project
4. Project personnel and environment
5. Patient-centeredness
6. Patient and stakeholder engagement

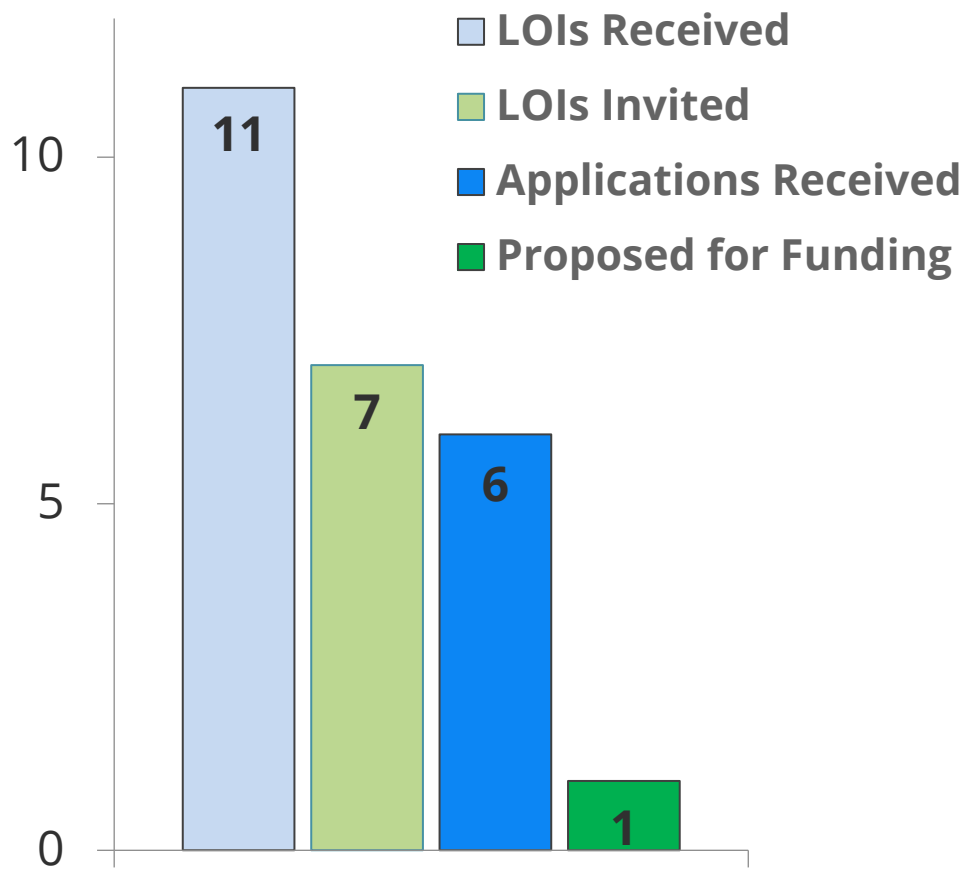
Cycle 3 2019 - Limited Competition Dissemination and Implementation PFA

Process Overview

- 11 Letters of Intent (LOIs) submitted
- 7 LOIs invited to submit a full application
- 6 applications received

Proposed funding slate is recommended by the Engagement, Dissemination, and Implementation Committee (EDIC)

- Proposing to fund 1 applications out of the 6 received
- **Funding rate is 17 percent**



Cycle 3 2019 - Limited Competition Dissemination and Implementation PFA

Slate of 1 Recommended Project

Project Title
Implementing Best-Practice, Patient-Centered Venous Thromboembolism Prevention in Trauma Centers

Cycle 3 2019 - Limited Competition Dissemination and Implementation PFA

Slate of 1 Recommended Project

PFA	Amount Budgeted [per Year]	Proposed Total Award*
Implementation of PCORI-Funded Patient-Centered Outcomes Research Results	$9.0M	$1.4M

Note: Budgeted amount is for up to 3 cycles per year; $6.1M awarded during first two cycles of 2019.

* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

Board Vote

Call for a Motion to:	• **Approve** funding for the recommended award slate from the Cycle 3 2019 Limited Competition Implementation of PCORI-Funded Patient-Centered Outcomes Research Results PFA
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

Wrap Up and Adjournment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