

PCORI Advisory Panel on Healthcare Delivery and Disparities Research

Spring 2021 Meeting

May 6, 2021

Housekeeping



- This webinar will be recorded.
- Members of the public can listen to this webinar live or view the recording on the PCORI website.
- Meeting materials will be posted on the PCORI website after the meeting.
- Anyone may submit a comment through the webinar question function, although no public comment period is scheduled.
- Visit www.pcori.org/events for more information.

COI Statement



Disclosures of conflicts of interest of members of the HDDR Advisory 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 (rbarnes@pcori.org).

If this Panel will deliberate or take action on a manner that presents a conflict of interest for you, please inform the Chair(s) 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.

Welcome & Introductions

Panel Leadership



- **Alicia Arbaje, MD, MPH, PhD**
HDDR Advisory Panel Co-Chair
- **Jane Kogan, PhD**
HDDR Advisory Panel Co-Chair
- **Steve Clauser, PhD, MPA**
Director, Healthcare Delivery and Disparities Research Program

HDDR Advisory Panel Members



Patient/Caregiver Advocate or Advocacy Organization

- **Barbara Warren, Psy.D**
Director for LGBT Programs and Policies in the Office for Diversity and Inclusion, Mount Sinai Health System and Assistant Professor of Medical Education
- **Carmen Pace, BSN, LPN, MPA, RN**
Facing Our Risk of Cancer Empowered (FORCE)
- **Kathy Phipps**
Community Health Worker, Memorial Hermann Health System
- **Ana Lopez, BSN, RN**
Facing Our Risk of Cancer Empowered (FORCE)

- **Jeffrey Oliver, MBA**
Training by Seeds LLC

Hospital/Health Systems

- **Xiaoduo Fan, MD**
Associate Professor, Psychiatry, University of Massachusetts Medical School

Payers

- **Marissa D. Sanders, MPH, CPHRM**
Manager, Quality Assessment, American Dental Association
- **Thomas James, III, MD**
Chief Medical Officer, WellCare/Centene of Kentucky

HDDR Advisory Panel Members



Researchers

- **Rainu Kaushal, MD, MPH**
Professor of Healthcare Policy and Research, New York-Presbyterian Hospital
- **Varleisha Gibbs, PhD, OTD, OTR/L**
Vice President, Practice Engagement and Capacity Building, American Occupational Therapy Association, Inc.
- **Kristina Cordasco, MD, MPH, MSHS** VA Health Services Research Center for the Study of Healthcare Innovation, Policy and Practice

Clinicians

- **Jennifer Potter, MD**
Professor, Beth Israel Deaconess Medical Center
- **Kathleen Kieran, MD, MSc, MME**
Physician, Seattle Children's Hospital
- **Brandi Ring, MD, FACOG, FAWM** Mile High OB/GYN, A Division of Women's Health Group

Healthcare Delivery and Disparities Research Team



**Steve Clauser,
PhD, MPA**
Program Director



Els Houtsmuller, PhD, Neeraj Arora, PhD
Associate Director



Associate Director



**Allison Ambrosio,
MPH**
Associate Director



**Carly Parry,
PhD, MSW**
Senior Advisor



Beth Kosiak, PhD
Program Officer



**Mari Kimura, MS,
PhD**
Program Officer



**Andrea Brandau,
MPP**
Program Officer



**Carly Khan, PhD,
MPH, RN**
Program Officer



**Vivian Towe, PhD,
MSc, MA**
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**Tabassum Majid,
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**Meghana Aruru,
PhD**
Program Officer



**Hillary Bracken,
PhD, MHS, MA**
Program Officer



Kelly Dunham, MPP
Senior Manager,
Strategic Initiatives



**Soknornta Prum,
MPH**
Sr. Program Associate



**Juliette Price,
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**Brendan
Weintraub, MPH**
Program Associate



**Candace Hall,
MA**
Program Associate



Marissa Cucinotta, MPH
Program Associate



Avani Hegde, MPH
Program Associate



Tshema Nash, MPH
Program Associate



Aaron Shifreen
Program Associate



Metti Duressa, MPH
Program Associate



**Elizabeth Zofkie,
MPH**
Program Associate



**Rachel Kotiah,
MPH**
Sr. Administrative
Assistant



Rachel Barnes
Project Assistant



Charlotte Freifeld
Project Assistant

Welcome New HDDR Staff



**Tabassum
Majid, PhD,
MAgS
Program
Officer**



**Meghana Aruru,
PhD
Program Officer**



**Hillary Bracken,
PhD, MHS, MA
Program Officer**



**Charlotte Freifeld
Project Assistant**



**Avani Hegde,
MPH
Program
Associate**



**Marissa
Cucinotta, MPH
Program
Associate**

Agenda



(Times in Eastern)

- 11:20 AM HDDR Program Update and Discussion
- 12:00 PM Break
- 12:30 PM PCORI COVID Activities
- 1:00 PM Leveraging Telehealth for Chronic Disease Management Among Vulnerable Populations with Complex Needs
- 2:00 PM Break
- 2:15 PM Strategic Planning: Identifying National Priorities for Health
- 3:00 PM Health Equity in a Comparative Effectiveness Research Framework
- 4:00 PM Wrap-Up



See supplemental materials I

Healthcare Delivery and Disparities Research Program Update & Discussion

Steven Clauser, PhD, MPA
Director, Healthcare Delivery and
Disparities Research

HDDR Updates

- Research Awards
- Research and Learning Networks
- Research Currently in Review
- Research in the Pipeline
- Updates on Priority Initiatives
 - Maternal Morbidity and Mortality
 - Intellectual and Developmental Disabilities

Research Awards: Current HDDR Portfolio



PCORI HAS AWARDED OVER

\$1 BILLION
TO FUND **254**

COMPARATIVE EFFECTIVENESS STUDIES IN
HEALTHCARE DELIVERY AND DISPARITIES RESEARCH.

As of May 2021

Funding Mechanism	# of Projects
Broad	189
Pragmatic	21
Targeted	44

New Research Awards



Recent Awards

1

Improving Healthcare Systems
Broad PFA Awards

1

Addressing Disparities Broad PFA Awards

1

Conducting Rare Disease Research using
PCORnet Awards



See supplemental materials II, III, and IV

New Research Awards



Study Title	PI Name	Site	PCORI Funding Announcement (PFA)
Helping Patients Achieve Kidney Transplants through Health System Change	Leigh Ebony Boulware	Duke University	Cycle 1 2020 Broad: Improving Healthcare Systems
Utilizing PCORnet to Support Transition from Pediatric to Adult-Centered Care and Reduce Gaps in Recommended Care in Patients with Congenital Heart Disease	Thomas Carton	Louisiana Public Health Institute	Cycle 2 2020: Conducting Rare Disease Research using PCORnet
Advancing Perinatal Mental Health and Wellbeing: The DC Mother-Infant Behavioral Wellness Program	Catherine Limperopoulos	Children's Research Institute	Cycle 1 2020 Broad: Addressing Disparities

Research and Learning Networks: Palliative Care Learning Network



HDDR has created a learning network of nine multi-site palliative care CER studies funded in FY2017 (~\$81 million)

- Six studies focus on models of **palliative care delivery** and three focus on **advance care planning**

Network goals:

- Foster co-learning across awardee teams
- Facilitate collective success of projects
- Contribute to field via joint presentations and publications

2020-2021 Network Activities:

- 4th annual awardee meeting held virtually December 4, 2020
 - Discussion focused on challenges due to COVID-19 pandemic and related solutions
 - Awardees most concerned about making appropriate adaptations to study enrollment, intervention, and analyses
 - Upcoming meeting including biostatisticians from each study team will provide opportunity to collectively discuss strategies for quantifying and accounting for COVID-19 impact to data and analytic plan for each study
 - Regular conference calls among investigators and project managers are organized by HDDR and contractor staff to foster continued engagement and co-learning across the network.

Research and Learning Networks: Learning Health Systems Initiatives



- *Next steps in the LHS space:*
 - Ongoing, guided by stakeholder conversations, meetings with PCORI board
- *AHRQ/PCORI Learning Health System Training program (K12):*
 - Year 3 of 5, \$40M initiative to train next generation of PCOR professionals
- *AHRQ/PCORI Learning Health System Small Grant Pilot program (R03)*
 - Funding announcement has standard R03 due dates, starting June 16, 2021
 - Supports small pilot projects in Learning Health Systems (LHS) that evaluate outcomes of interest to partner health systems AND evaluate the processes and outcomes of the embedded research approach.
 - Will address the stakeholder-identified needs of LHS, be rapid turnaround (12 mo. projects), relevant to LHS leaders, driven by collaborative relationships among pilot project partners, and rigorous in study design.

Currently in Review: Cycle 3 2020



- Broad: Improving Health Systems & Addressing Disparities
 - Special Areas of Emphasis:
 - Improving Care for Individuals with Intellectual and/or Developmental Disabilities (IDD) Growing into Adulthood
 - Increasing Access to and Continuity of Patient-Centered Maternal Care
 - Awards Announced: July 2021
- Suicide Prevention: Brief Interventions for Youth
 - Awards Announced: July 2021
- Phased Large Awards for Comparative Effectiveness Research (PLACER)
 - Awards Announced: July 2021

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



Intellectual and
Developmental
Disabilities PFA

- 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 Broad Research Opportunities



2021 Cycle 2
Broad PFA

- Addressing Disparities: Up to \$16M available
- Improving Healthcare Systems: Up to \$16M funds available
- PFA Posted: January 2021
- Awards to be Announced: **March 2022**

2021 Cycle 3
Broad PFA

- Addressing Disparities: Up to \$16M available
- Improving Healthcare Systems: Up to \$16M available
- PFA Posted: January 2021
- Awards to be Announced: **July 2022**

Upcoming Pragmatic Clinical Studies Research Opportunities



2021 Cycle 2
PCS PFA

- PFA Posted: May 2021
- Awards to be Announced: March 2022

Upcoming Phased Large Awards for Comparative Effectiveness Research (PLACER) Opportunity



2021 Cycle 3
PLACER PFA

- PFA Posted: September 2021
- Awards to be Announced: July 2022

2021 PCORI Annual Meeting



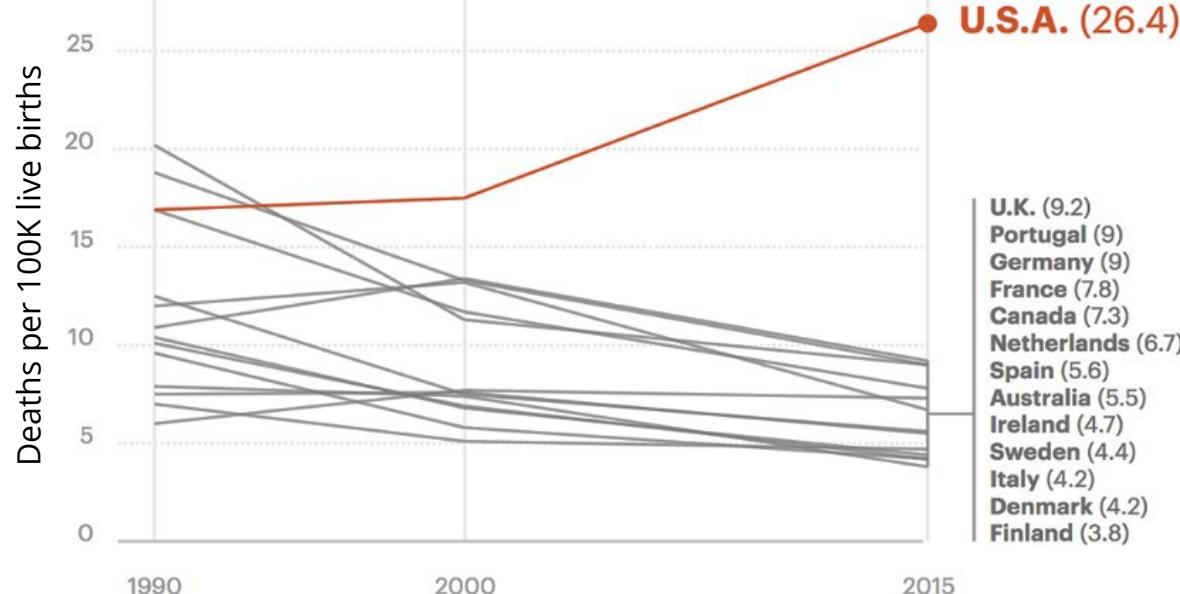
November 17-19, 2021
Virtual Meeting

Maternal Morbidity and Mortality

Els Houtsmuller, PhD

Associate Director, Healthcare Delivery
and Disparities Research Program

Maternal Mortality US Rates and Disparities



GBD 2015 Maternal Mortality Collaborators Agrawal P. 2015. Bulletin of the World Health Org. 93: 135. 2016. Lancet 388: 1775-1812.

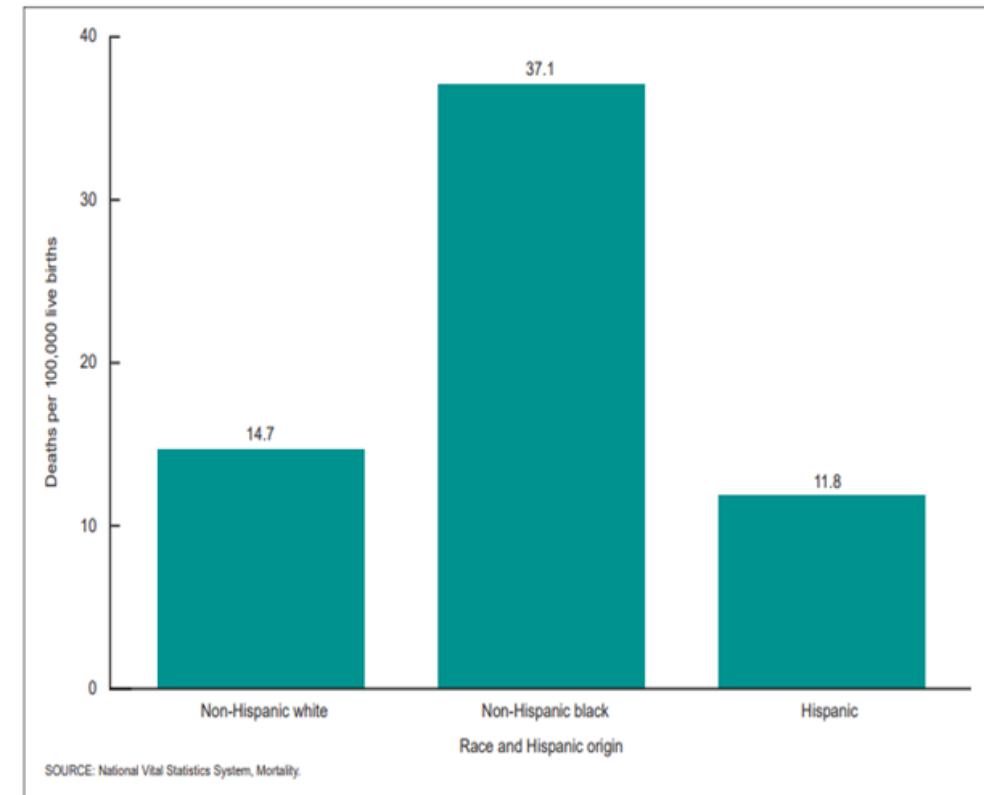
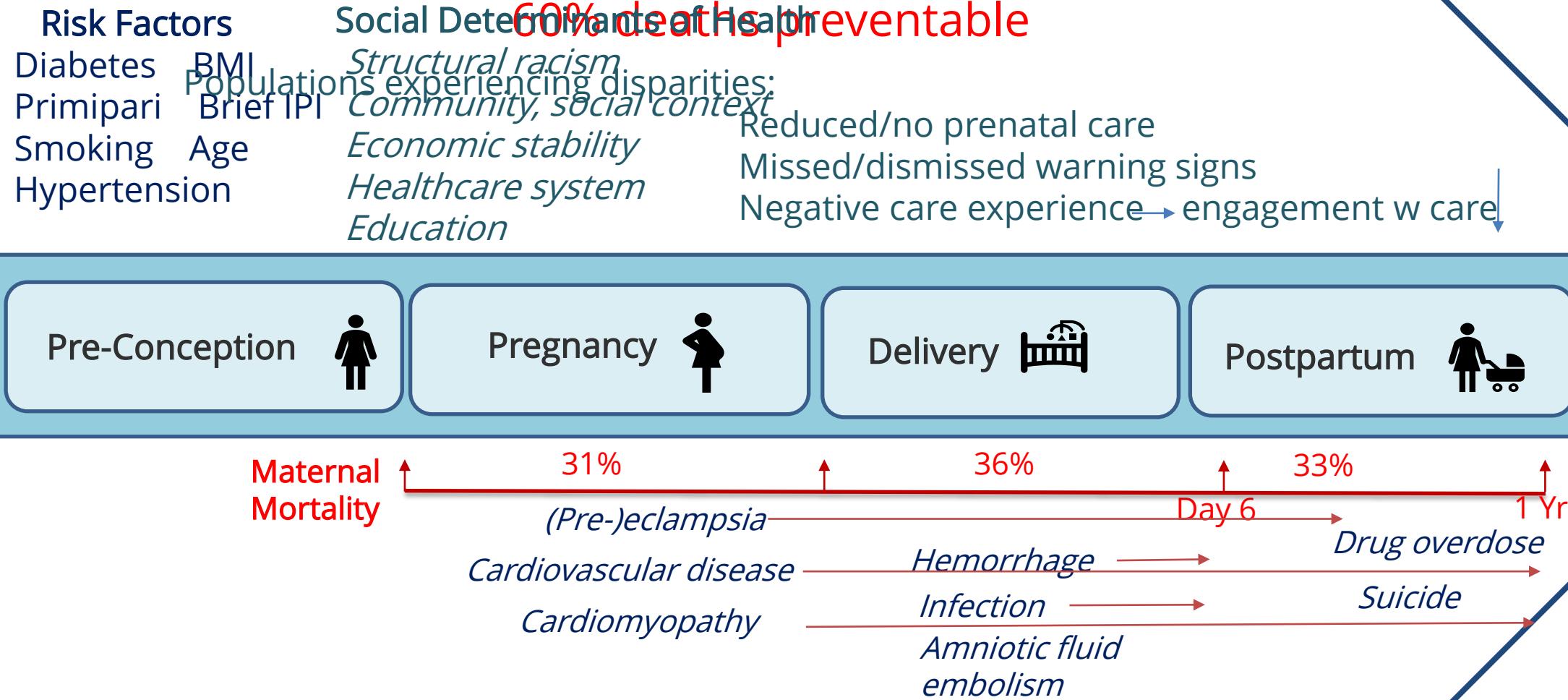


Figure 2. Maternal mortality rates, by single race and Hispanic origin: United States, 2018

Maternal Mortality



Special Area of Emphasis: Access to Effective Care

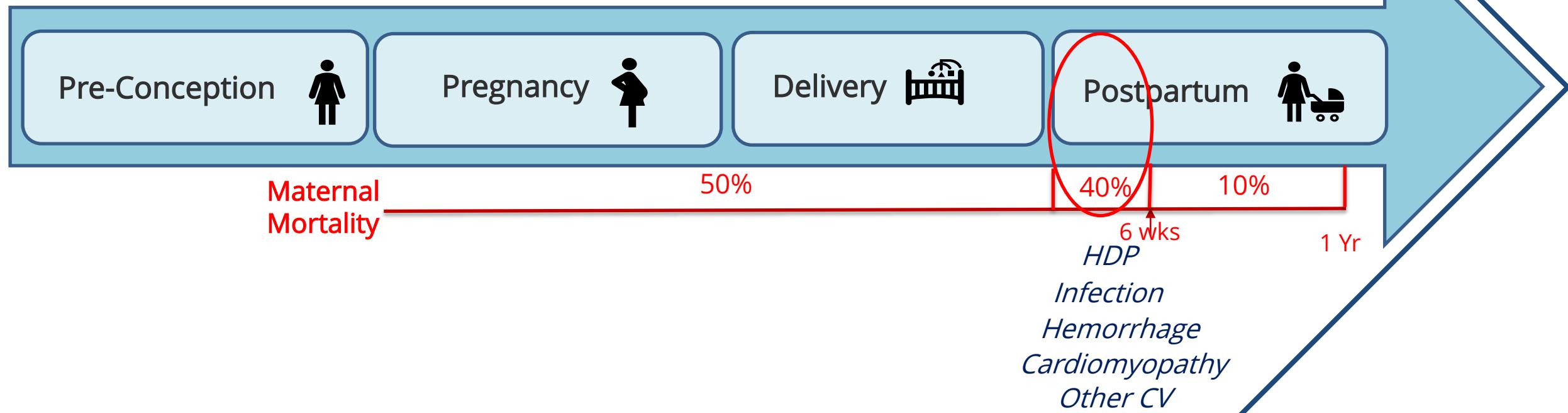


- Limited access to/engagement in care
 - Distance, time, lack of transportation, childcare, siloed care
 - Lack of patient trust
 - Clinician/staff/institution racism, cultural insensitivity, lack of comfort
- Cycle 3, 2020 Broad PFA onward
 - Multi-level, culturally adapted interventions that address barriers in access to and engagement in patient-centered maternal care.
 - 2020C3: 8 Applications Merit Review: April
 - 2021C1: 9 LOIs Applications Due: May

Postpartum Care



Evidence-based treatments and care protocols exist



Postpartum Care



- **Postpartum care is limited, fragmented and insufficient**
 - Many patients do not receive any postpartum care
 - Transition from obstetric to primary care
 - Patients and providers may miss, dismiss warning signs
 - Signs and symptoms may overlap with other conditions, recovery
 - Patient may not mention and provider (OB, PC, ED) may not ask recent pregnancy status
- **Significant inequities persist in receipt of timely and respectful postpartum care**
 - Provider bias
 - Language barrier
 - Cultural barrier
 - Social Determinants of Health (SDOH)

Targeted PFA Cycle 2, 2021



- **Research Question:** What is the comparative effectiveness of multicomponent strategies to improve early detection and timely care for complications up to 6 weeks post partum 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

Intellectual and Developmental Disabilities

Amanda Barbeau, MPH

Senior Program Associate, Clinical
Effectiveness and Decision Science
Program

Intellectual and Developmental Disabilities (IDD) Background



2010 - PCORI original authorizing legislation created 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 morbidity and mortality
- Individuals with intellectual and developmental disabilities

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

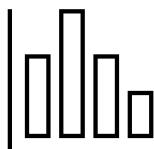
- In the months and years ahead, we will be hosting a variety of opportunities to engage with us on this topic

IDD Background: Definition



Intellectual and Developmental Disabilities:

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

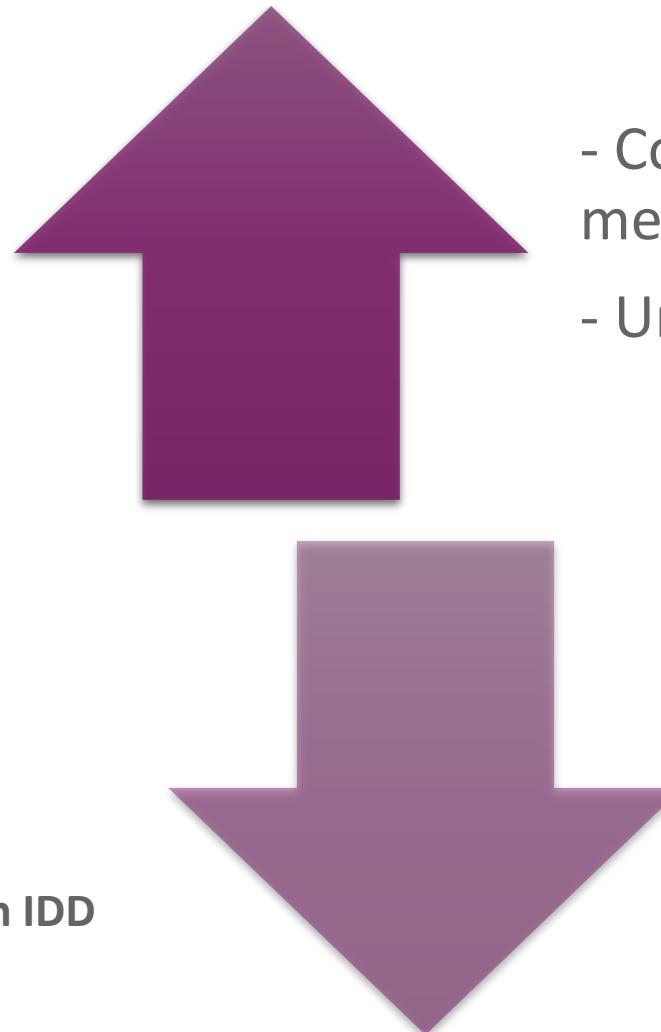


Data from the United States estimate that 17.8% of children and adolescents, and 0.5 - 1.5% of adults, have an IDD diagnosis; impacting a total of 7 to 8 million Americans.

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 racial and ethnic minority groups.

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

Gaps in IDD and Mental Health Evidence



Few treatment studies in this subpopulation of IDD exist due to highly restrictive inclusion criteria; 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 ID/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 severity 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 (TPFA) 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 Funding Announcement

Discussion

Q&A

Break

Meeting resumes at 12:30PM ET

PCORI COVID Activities

William Lawrence, MD, MS
Senior Clinical Advisor, OCEDO



Overview of PCORI's Response to the COVID-19 Pandemic

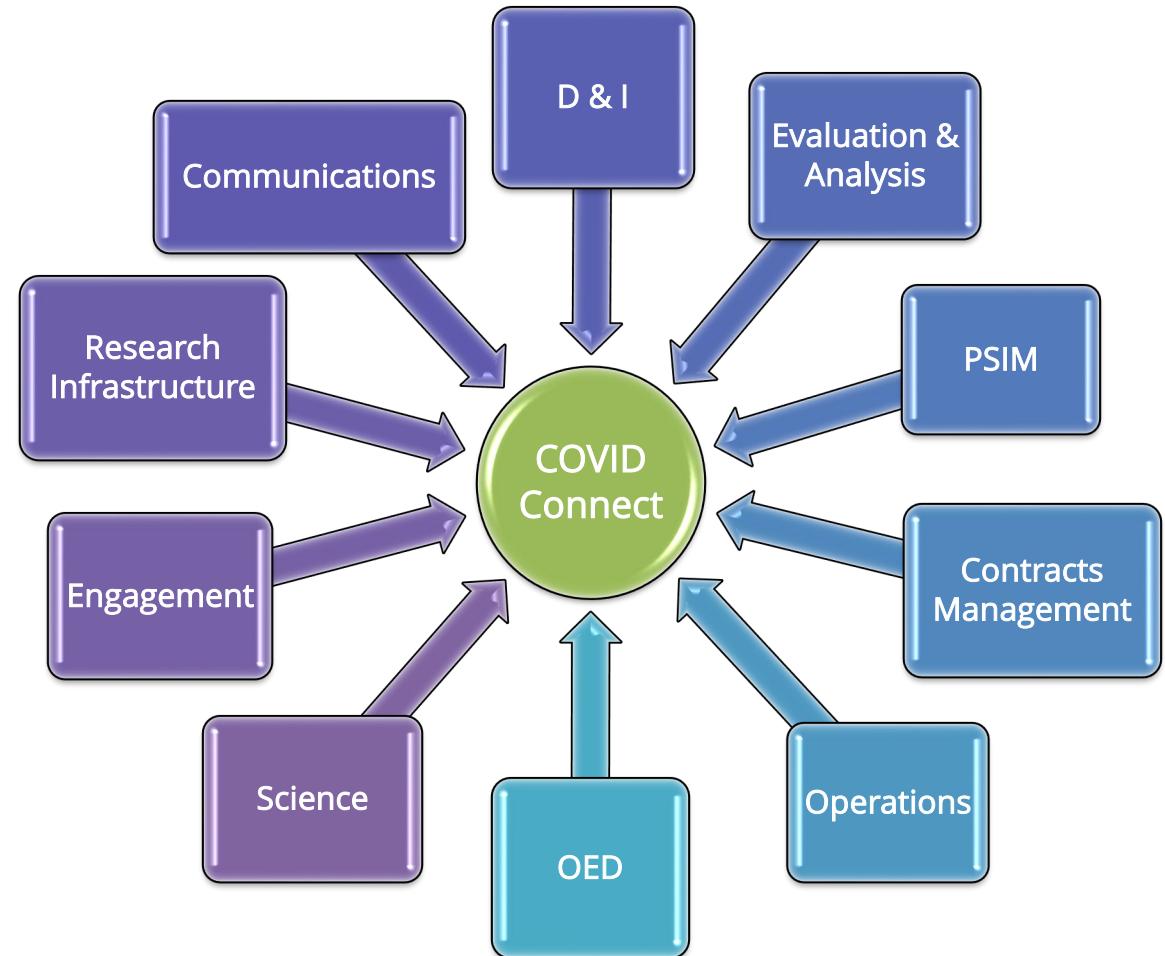


- COVID Connect
- Primary Focus on COVID-Related Research Efforts
- Brief Summary of COVID-Related PCORnet Efforts and Engagement Efforts
- Discussion

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 needs of the organization.
- Membership is voluntary, and members can engage in **various levels of involvement**:
 - Full work group
 - Core sub-groups
 - Ad-hoc/liaison members



PCORI's COVID-19 Portfolio:

116 Enhancements, 9 Targeted Research Studies, and
25 Special Cycle Engagement Awards



116 Enhancements Awarded, *\$33.5 million*

53

Engagement Award
Enhancements
\$6.8 million

13

D&I
Enhancements
\$5.7 million

41

Research
Enhancements
\$18.1 million

8

Methods
Enhancements
\$2.3 million

1

PCORnet
Enhancement
\$526,020

34 New Awards in Research & Engagement, *\$33.5 million*

25

Engagement Award
Special Cycle
\$3.7 million

9

Targeted Research
Studies
(COVID tPFA)
\$29.8 million

Enhancements \$ from Enhancement Tracker
CER tPFA \$ from application amount
Engagement Special Cycle \$ provided by EA team

Research

Enhancements

COVID-19 Targeted Research PFAs

Special Areas of Emphasis



COVID Enhancements to Existing Research Projects



- Support enhancements to existing research awards that could be initiated quickly to influence outcome of pandemic and that have some relationship to original award, using existing teams currently funded by PCORI.
- Awarded on a 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

2 Developing clinical prediction models

2 Informing COVID-19 care

Other themes: data visualization, machine learning

Note: studies may include more than one theme



One PCORnet Enhancement

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

Condition Categories

of studies*



Mental & Behavioral Health

14



Nutritional & Metabolic

7



Neurological

6



Cancer

6



Cardiovascular

6

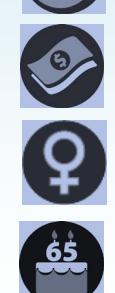
Priority Populations

of studies*



Black, Indigenous, and People of Color

18



Low Income

12



Women

9



Older adults

9

*Studies may include more than one condition or population

Telehealth



19 enhancements include telehealth components

COVID-19 Targeted PFA



- PFA developed and posted on accelerated timeline in response to urgency of 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

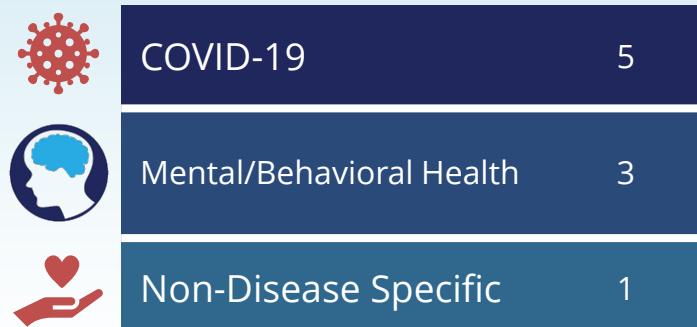
Themes



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

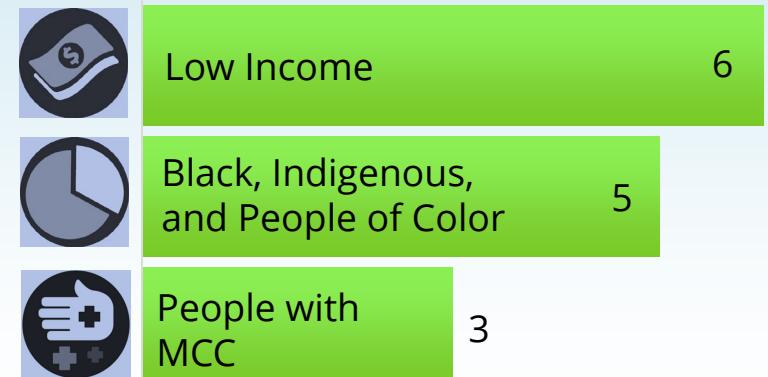
Key statistics about targeted studies:

Primary Condition



*Studies may include more than one condition

Priority Populations



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, 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 5 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 expedited mechanism; will follow more rapid review and award timeline
- PFA posted April 13, 2021
- Up to 3 years
- Up to \$5M
- What interventions are effective in increasing COVID-19 vaccine confidence and uptake among long-term care workers?

Broad PFA Special Area of Emphasis: Post-Acute COVID-19



Cycle 1 2021

- 16 of 99 LOIs addressed COVID special areas of emphasis
- Management and survivorship of post-acute COVID-19
- Impact of COVID-19 on disproportionately affected populations
- Impact of COVID-19-related social isolation and loneliness on health outcomes

Cycle 2 2021

- LOIs due 6/1/21
- Treatment and survivorship of post-acute COVID-19
- Health system and healthcare delivery management of post-acute COVID-19
- Strategies to improve outcomes of COVID-19 for disproportionately affected populations
- Impact of COVID-19-related social isolation and loneliness on health outcomes

Other PCORI Activities



PCORnet - HERO Program



- HERO Health Care Worker Registry
 - >26,000 HCW 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
 - Expect manuscript submission in April



Help us spread the word on social media by tagging [@heroesresearch](#) and using the hashtag #HERORegistry

HERO

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



- William Lawrence
 - wlawrence@pcori.org

Leveraging Telehealth for Chronic Disease Management Among Vulnerable Populations with Complex Needs

Carly Paterson Khan PhD, MPH, RN
Program Officer, HDDR

The PCORI Telehealth Team(s)



- Penny Mohr, Acting Program Director, Research Infrastructure
- Kristin Carman, Director, Public and Patient Engagement
- Neeraj Arora, Associate Director, HDDR
- Andrea Brandau, Program Officer, HDDR
- Vivian Towe, Program Officer, HDDR
- Soknorntha Prum, Senior Program Associate HDDR
- Metti Duressa, Program Associate HDDR
- Meghan Berman, Program Associate, Public and Patient Engagement
- Aleksandra Modrow, Program Coordinator, Public and Patient Engagement

Overview



- Trends in telehealth since COVID-19 pandemic
- Brief introduction to PCORI's investment in telehealth
- Discussion: Refinement of future funding topic

Trends in Telehealth since the COVID-19 Pandemic



- As a result of the COVID-19 pandemic, remote care delivery has rapidly been put into widespread use in the healthcare system
- A need has emerged to identify the most effective, evidence-based ways to incorporate telehealth as part of routine clinical workflow
- Further research is needed to address the disparities that exist in access to and use of telehealth
 - Ensure expanded use of telehealth ultimately mitigates, and does not exacerbate, existing documented health disparities in the U.S.



Telehealth in the Future



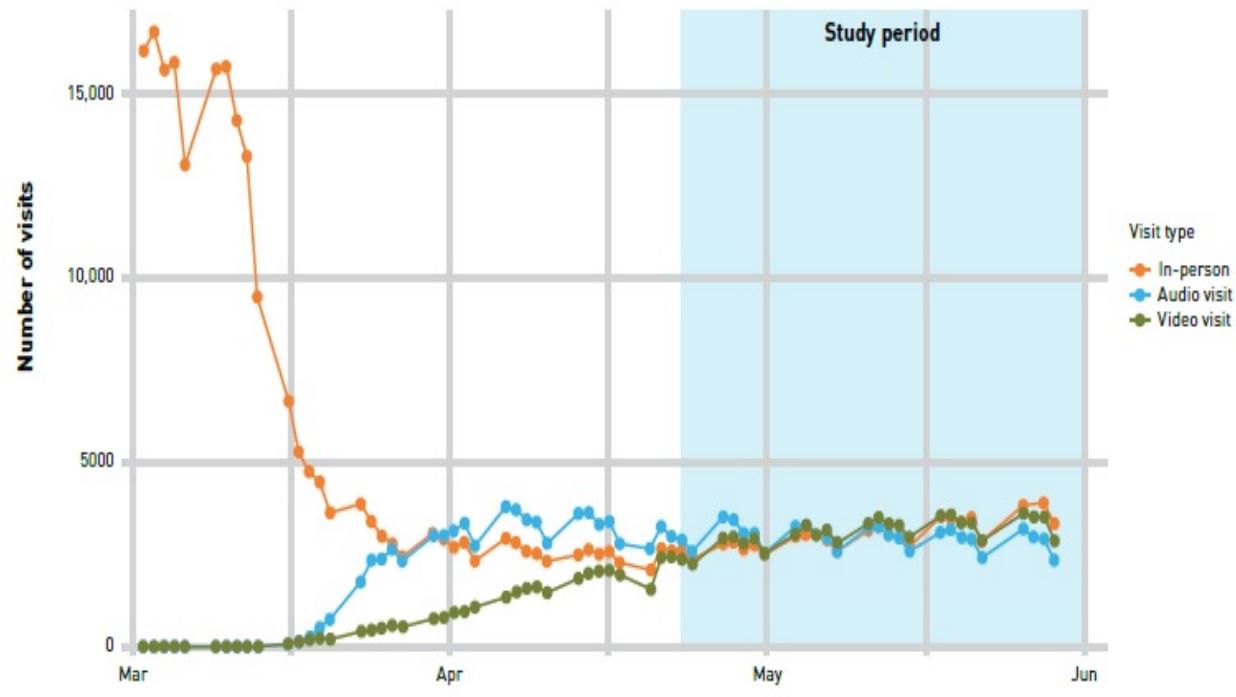
- The COVID-19 pandemic caused a disruption in routine care for those with chronic conditions
- There is the potential to sustain expanded use of telehealth as an integral part of the healthcare delivery system, especially for individuals dealing with chronic health conditions.
- As we think about the healthcare system beyond the pandemic, what are opportunities for future research that leverages telehealth for chronic disease management?

Trends in Use

Some Key Insights

- Growth in use was substantial. Medicare telehealth visits increased from 13,000 per week pre-pandemic to 1.7 million in final week of April 2020
- Telehealth use declined when in-person visits became more common in late summer but have plateaued at higher level than pre-pandemic. In-person visits have not regained pre-pandemic levels
- Growth in use varied widely by specialty
- Figure 1:
 - Use of audio visits critical to sustain access for some populations

FIGURE 1. Trends in Visit Type (March 1-June 1, 2020)*



*Excludes ambiguous encounters.

Source: Rodriguez et al. Differences in the Use of Telephone and Video Telemedicine Visits During the COVID-19 Pandemic. *Am J Manag Care*. 2021;27(1): 21-26.

Temporary Reimbursement and Statutory Changes Under the Public Health Emergency (PHE)

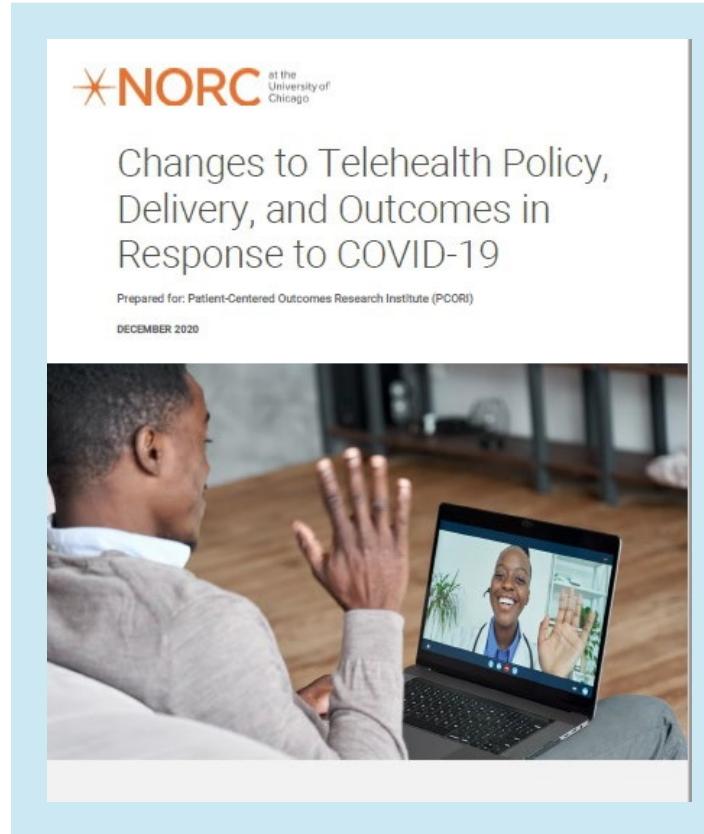
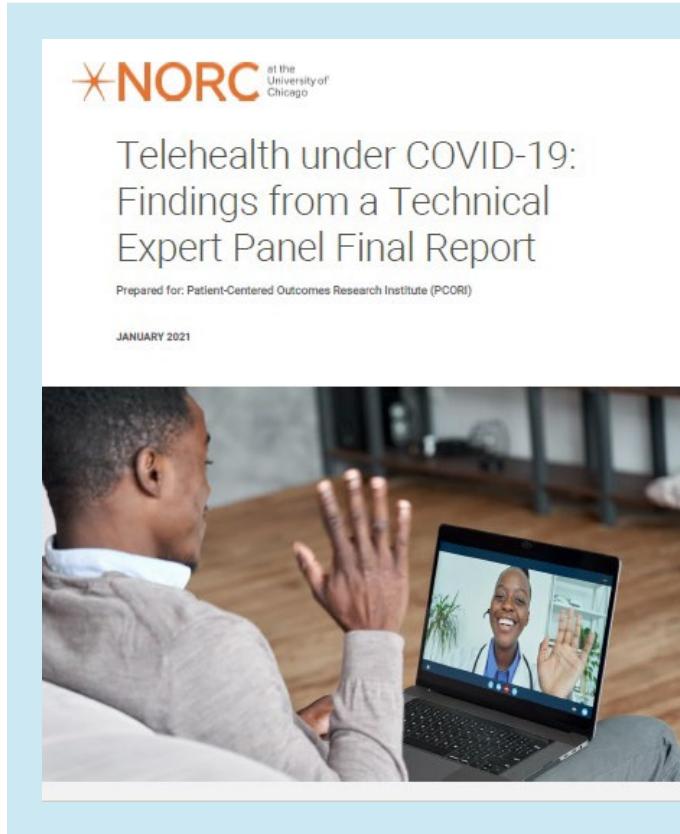


Temporary changes made in Medicare regulations have been reflected in policies set by private and other public payers

- Selected states added payment parity laws
- PHE extended through 2021

Topic	Coverage Prior to Pandemic	Temporary Coverage Through End of PHE
Location of patient	Patient must be at an originating site that is rural or designated as a health professional shortage area. Patient must receive care at a medical facility (with some exceptions).	No geographic restrictions. Services provided to patients in their homes are allowable.
Location of provider	Provider must be at designated point of service "distant site". FQHCs and RHCs cannot be distant sites.	No geographic restrictions, allows providers to provide services from their home. FQHCs and RHCs with telehealth capabilities may now serve as distant sites for telehealth services.
Services	100 codes for reimbursement	Added 93 codes for reimbursement (e.g., eye exams, speech audiology)
Modality	Services must be provided through synchronous live video.	Audio only and online digital patient communication allowed for certain services.
Provider licensure	Out of state providers must be also licensed in the state where they are providing services.	Providers licensed in one state can provide services in another state.

COVID-19's Impact on Teledelivery of Healthcare



What is shifting in the field of telehealth in relation to the COVID-19 pandemic, and how does that alter how PCORI should think about future investment in this area?

Key Considerations for the Sustainability of Telehealth



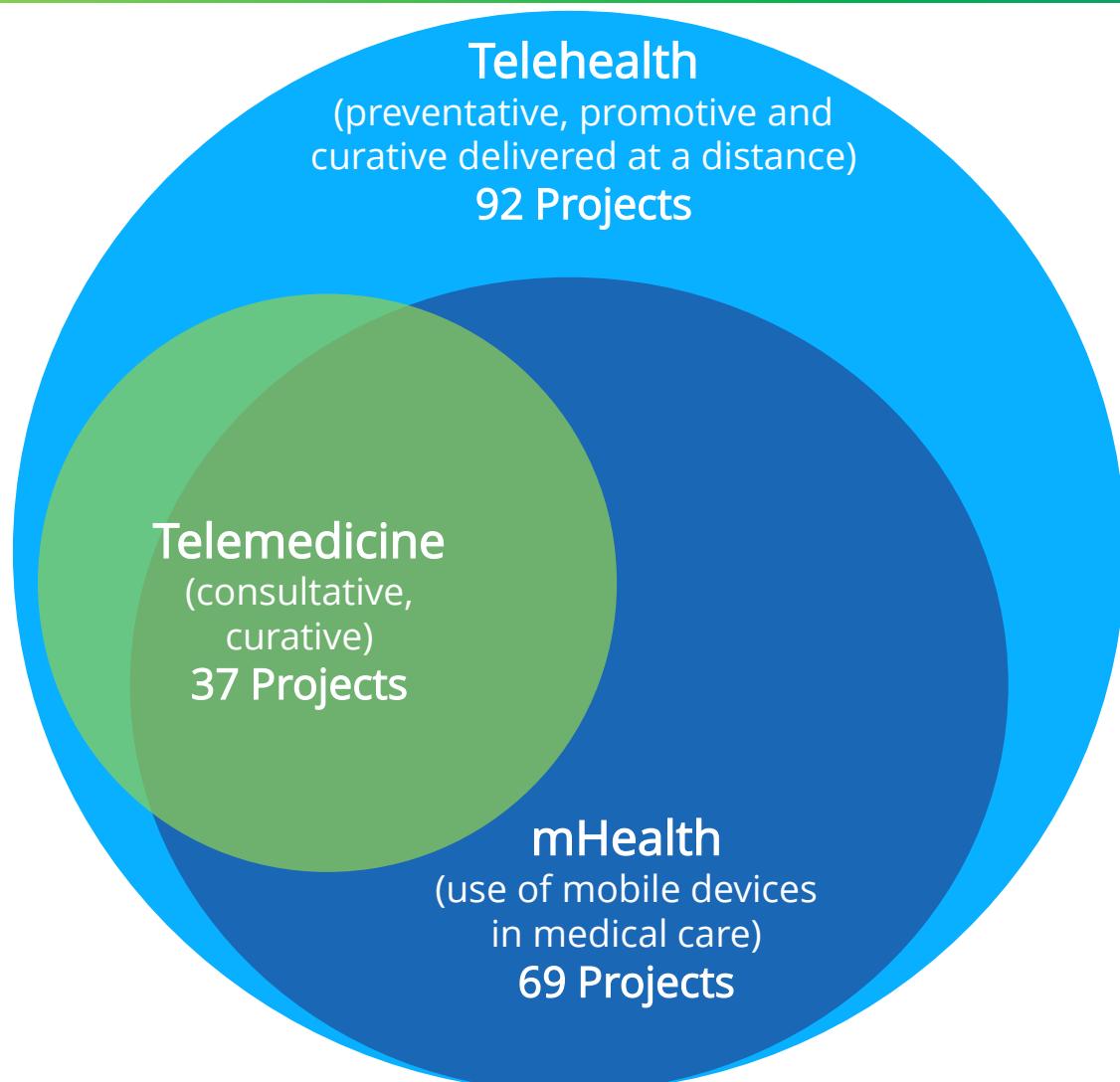
- More research needed on **best practices** for telehealth delivery and patient safety
 - Consider video and audio-only modalities
- Telehealth has potential to aid **care coordination**, especially in serving **hard-to-reach populations**
- More evidence needed to understand and address concerns related to **patient safety** and **quality of care** provided via telehealth
- Ongoing telehealth implementation will require a **standard set of quality measures** capturing the delivery of telehealth care and its impact

Specific Considerations for Implementation



- Telehealth should be considered as a complement—rather than a substitute—for in-person care.
- Implementation of telehealth modalities should consider and mitigate potential barriers to access.
 - Family, “telepresenters,” or other **support systems** may facilitate telehealth visits.
 - Telehealth delivery should be **culturally competent**.
 - Telehealth delivery should **consider technological challenges** to the target population (e.g., “what to expect” videos or navigation supports can help prepare patients to participate in telehealth visits, including priming them for the use of specific technology.)
 - Telehealth delivery should consider **accessibility of technology**, including preferred modes (text versus videoconference) and broadband access, offering alternative settings as needed.
- Telehealth uptake should examine the potential benefits, as well as limitations, of telehealth use by seniors, low-income communities, and communities of color underserved by traditional healthcare systems. For example:
 - Videoconference modalities can provide a lens into the home environment.
 - Some patients may prefer telehealth visits.

PCORI's Telehealth, Telemedicine, and mHealth Portfolio



**\$437 MILLION
SUPPORTING 105**

COMPARATIVE CLINICAL
EFFECTIVENESS RESEARCH
STUDIES IN TELEHEALTH

*As of March 2021
Projects may be classified as more than one type*

Telehealth Projects Target Vulnerable Populations



50

STUDIES

Use telehealth to address disparities

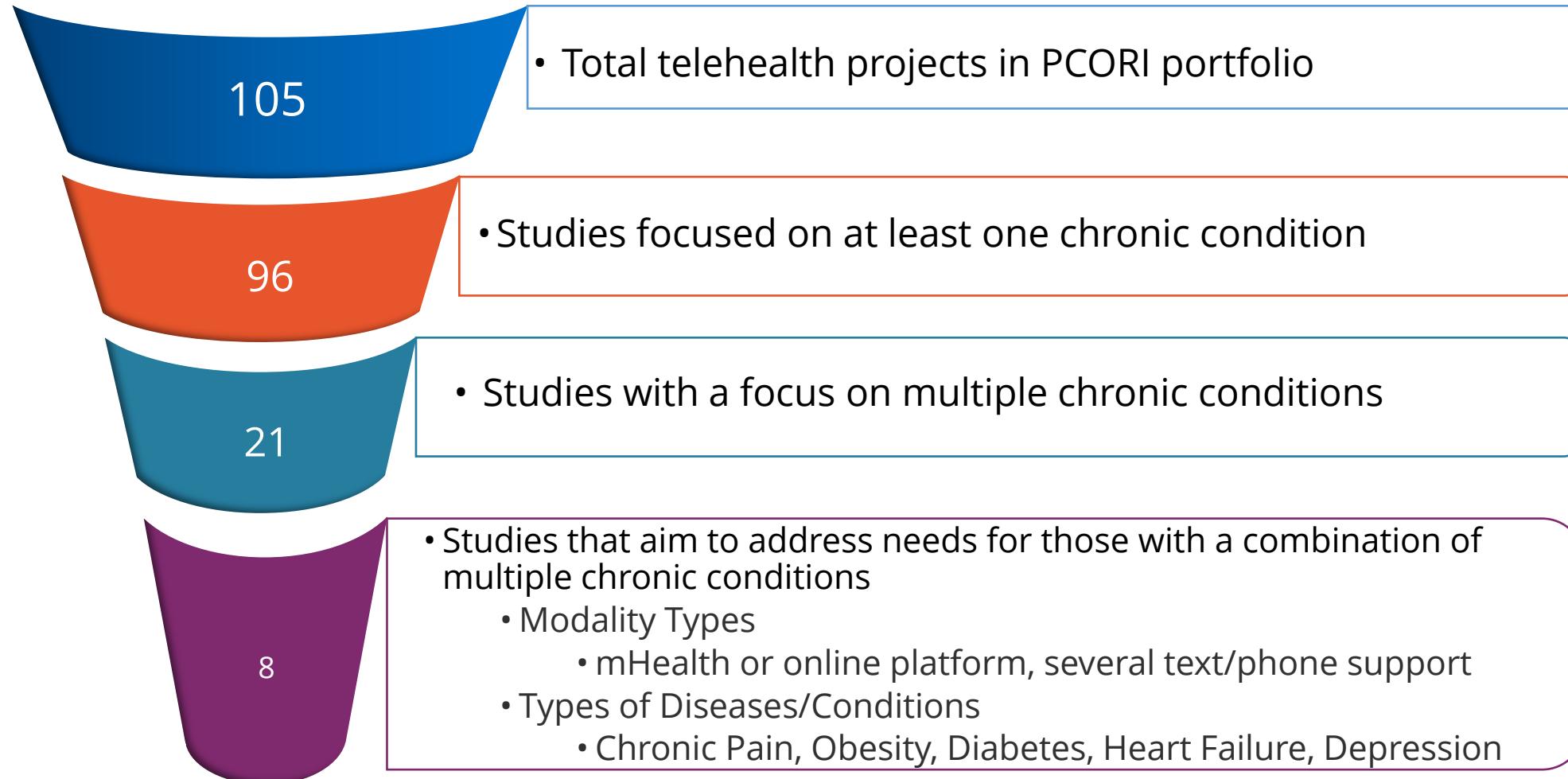
\$221

MILLION

Population	# of Studies
Low health literacy/numeracy	19
Rural	21
Low income	25
Racial/Ethnic minority groups	36
Populations or disabilities	6
LGBT	4

*N=50 as of March 2021.
Categories are not mutually exclusive*

Telehealth Projects Focusing on Multiple Chronic Conditions (MCC)



Specialty Medical Homes to Improve Outcomes for Patients with Inflammatory Bowel Disease (IBD) and Behavioral Health Conditions



What This Study Does

- Compares the effectiveness of team-based care with traditional in-person clinic visits to team-based care with telemedicine and digital behavioral health tools

Design

- Randomized Controlled Trial
 - Sample Size: 990

Key Outcomes

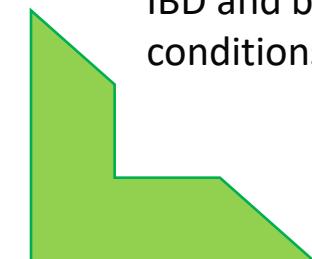
- Primary: IBD symptom severity, depression, anxiety
- Secondary: Functional impairment, healthcare utilization, IBD self-efficacy, IBD-related quality of life

Population & Setting

- Patients who have an IBD diagnosis with mild to severe behavioral health symptoms

Why It Matters

Results from this study may inform Specialty Medical Home providers considering ways to provide care for patients with IBD and behavioral health conditions



*Principal Investigator: Eva Szigethy, MD PhD
University of Pittsburgh Medical Center
IHS Cycle 3 2017 Broads*

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, 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 5 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*

Discussion: Future Funding Opportunities



Topic Development Progress



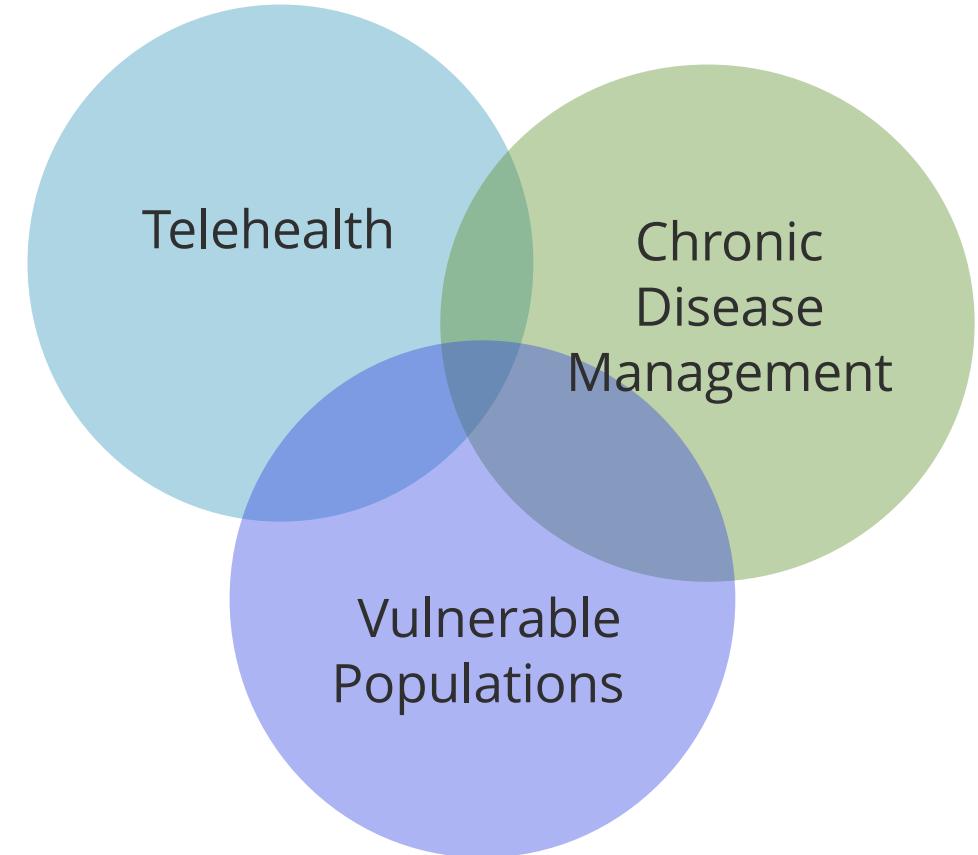
Leveraging Telehealth for Chronic Disease Management Among Vulnerable Populations with Complex Needs

- The PCORI Board of Governors approved this as a candidate topic for development for future targeted funding during the April 13th meeting
- Ongoing activities:
 - Characterization of PCORI funded portfolio to identify gaps
 - Review of scientific literature
 - Consultation with other relevant funders
 - Focused patient and stakeholder group discussions

Topic Development Discussion



- What are the critical areas for future comparative effectiveness research?
 - Multiple chronic conditions or chronic conditions more broadly
 - Intersection with complex needs
 - Consideration for the changing landscape for telehealth moving forward
- Other considerations
 - 3-5 year studies
 - Outcomes of interest
 - Study design considerations
 - Other considerations specific to vulnerable populations



References



- America's Health Insurance Plans (2020). Beyond COVID-19: Policy recommendations to strengthen and improve telehealth services.
- Kichloo A, Albosta M, Dettloff K, et al. (2020). Telemedicine, the current COVID-19 pandemic and the future: a narrative review and perspectives moving forward in the USA. *Fam Med Com Health* 8, e000530. doi:10.1136/fmch-2020-000530
- Mirsky JB, Horn DM. Chronic disease management in the COVID-19 era. *Am J Manag Care*. 2020 Aug;26(8):329-330.
- NORC at the University of Chicago (2021). Telehealth under COVID-19: Findings from a technical expert panel.
- Rodriguez, J.A., Betancourt, J.R., Sequist, T.D., & Ganguli, I. Differences in the use of telephone and video telemedicine visits during the COVID-19 pandemic. *American Journal of Managed Care* 27(1), 21-26. doi:10.37765/ajmc.2021.88573

Break

Meeting resumes at 2:15PM ET

Strategic Planning: Identifying National Priorities for Health

Steven Clauser, PhD, MPA

Program Director, Healthcare Delivery and
Disparities Research



Reminder About Revised Strategic Framework

Evolving to National Priorities for Health



To inform the National Priorities for Health, PCORI sought input from a variety of stakeholders including this Advisory Panel. We'll take a look at the multifaceted inputs shortly.

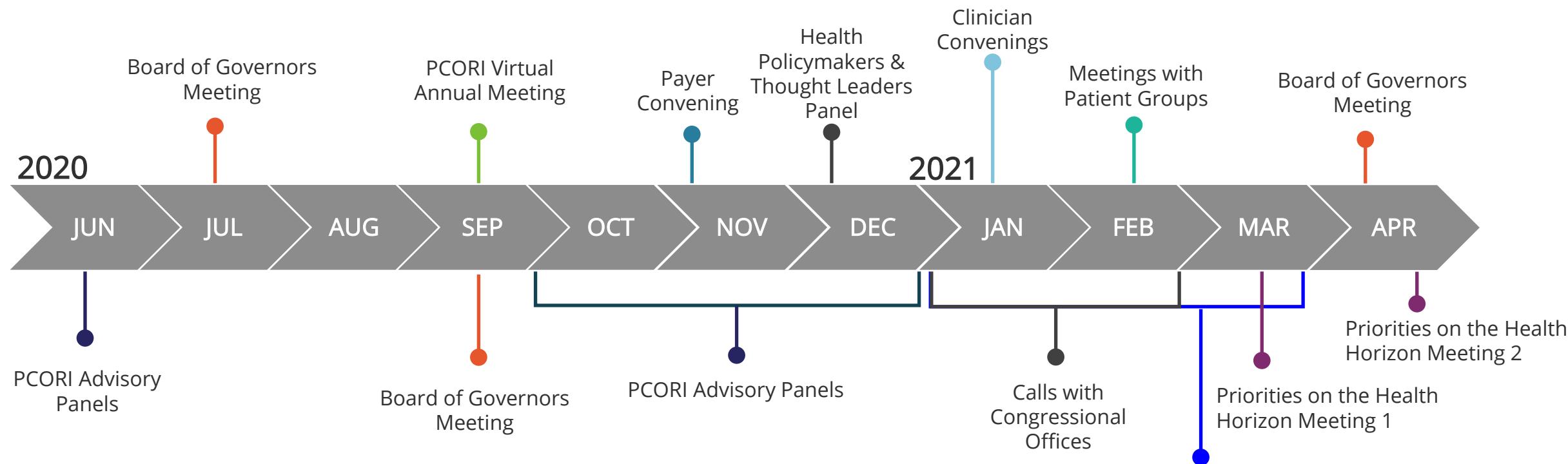
Picking Up From When We Last Spoke



- This panel considered revised framework and what reframing meant for National Priorities.
- What we heard from HDDR members during December meeting regarding PCORI's work in addressing disparities and improving healthcare systems:
 - Understand multifaceted drivers of disparities and work towards equity
 - Consider disparities encountered throughout the research and care continuum
 - Identify synergies between addressing disparities and health systems
- This was reinforced and complemented by input from other convenings, meetings, and discussions.

Input Gathering Process and Discussions Thus Far

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



Resulting Themes from Input and Support by Board of Governors



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

Health Equity

Emerging
Innovations

Learning Health
System

Communication,
Dissemination,
Implementation

Infrastructure &
Workforce

Resulting Themes from Across Inputs and Summary Points for Importance



In the coming questions, we welcome your input on any of the themes and especially on the **Health Equity** and **Learning Health System** themes

Health Equity

- Addressing disparities is more important than ever
- Systematic inequities appear across health, healthcare, and health research (structural racism, implicit bias, lack of data representativeness)

Emerging Innovations

- Application of **new technologies** and **systems interventions** will be important for future of health; need to address evidence gaps
- Support **time sensitive decision-making** needs in evidence vacuum
- Inform **new delivery innovations** focused on patient-centered outcomes

Learning Health System

- Reframing transitional care from care settings to transition between health states to better **reflect patient perspective**
- Support health systems that enable **coordinated care, easy navigation** and **utilization** for patients

Communication, Dissemination, Implementation

- Importance of **doing communication and dissemination**, not just research on how to do it
- Get **right information to right people at the right time** to make informed decisions (e.g., patients, providers, health systems)

Infrastructure & Workforce

- **Workforce development** and capacity is needed to strengthen and expand the healthcare system
- Need for building **capacity for patient-centered outcomes research** (data, systems, researchers, patient partners)

We'd Like To Hear From You on How to Further Shape These



- Imagine 5 years from now; what will health, health care, and the research ecosystem look like if PCORI were to make progress towards a priority for health related to each theme? Are there specific areas that PCORI could make a real impact on in this timeframe?
- What specific areas within these themes are particularly well suited to comparative clinical effectiveness research?
- How could cross-cutting issues that impact all the priorities be considered (for example, health disparities or health equity)?

Health Equity

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Advancing Health Equity in a Comparative Effectiveness Research Framework

Vivian Towe, PhD, MSc, MA
Program Officer
HDDR



Today's Agenda



- Background on health disparities and health equity
- Optimizing PCORI's research portfolio to advance health equity
- Gathering input on the PCORI Centers for Health Equity initiative

What is Health Equity? How is it Different from Health Disparities?



- **Health Disparities:** observed differences in health outcomes across groups of people that are mainly driven by economic, social or environmental disadvantage¹
 - e.g., race/ethnicity, income, cultures, disability status, sexual orientation
- **Health Equity:** principle underlying the goal that “Everyone has a fair and just opportunity to be as healthy as possible.”²
 - Achievement of this goal requires policy changes, financial investment, programming, and *interventions for specific groups*

¹Healthy People 2030

²Braveman, 2017

Is Addressing Disparities Research Considered Health Equity Research?



- Conducting health disparities research is one strategy within the larger goal of trying to achieve health equity
- Results of a study addressing a health disparity are not necessarily presented in a context that shows impact on health equity
- Measurement of changes in health equity differ from measurement of changes in health disparities

How are Changes in Health Disparities Measured Compared to Changes in Health Equity?



- **Health disparities** are routinely measured by health systems and public health entities. Health outcomes by:
 - sex, race, disability, and sometimes income or proxies for income
- **Health equity** is measured by looking at a range of indicators capturing multiple facets where change needs to happen to achieve health equity
 - Reductions in health disparities
 - Policy changes targeting social determinants
 - Outcomes in social, education, employment sectors that are closely related to health
 - Surveys in the community to capture perceptions of equity

Optimizing PCORI's Research Portfolio to Advance Health Equity



Points of Entry Across Comparative Effectiveness Research Spectrum



Health-Adjacent Sectors

Health Sector

Social Determinants

- Housing
- Employment
- Education
- Income
- Racism/discrimination

Policy/Programs

- Insurers
- Health system
- State/federal
- Public health

Healthcare Access

- Uninsured
- Immigrant populations
- Non-English speakers

Prevention

- Screenings
- Early detection
- Counseling/education
- Immunizations

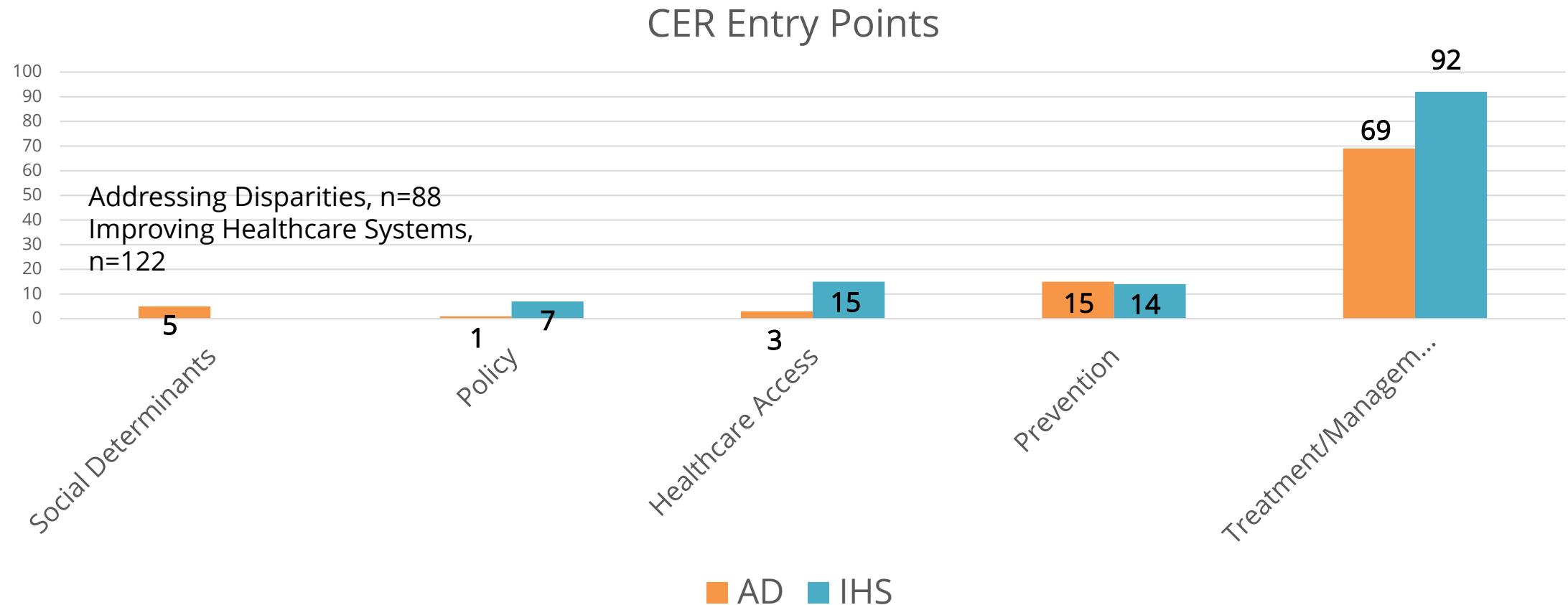
Treatment/Management
of specific conditions/ care delivery

Upstream

Drivers of Health

Downstream

HDDR Studies Across CER Spectrum



Examples of “Upstream” Funded Projects in PCORI’s Research Portfolio



- Comparative Effectiveness of Single-Site and Scattered-Site Permanent Supportive Housing on Patient-Centered and COVID-19 Related Outcomes for People Experiencing Homelessness
- Effect of High-Deductible Health Plans on Healthcare Use and Out-of-Pocket Costs for People with Bipolar Disorder
- Comparing Three Programs to Increase Access to Mental Health Care for Pregnant and Postpartum Patients
- Comparing Mobile Health Strategies to Improve Pre-exposure Prophylaxis Use (PrEP) for HIV Prevention

Potential Strategies for Increasing Upstream CER to Advance Health Equity



- Encourage researchers to leverage natural experiments to study social determinants or policies if trial designs not possible
- Put more emphasis on widespread or established practice as testable comparators in CER
- Examine certain social determinants of health and see what kind of efficacy work has already been done with health outcomes or conditions
- Look more carefully at healthcare access and prevention entry points and consider how PFAs may be modified to support more work in these areas
 - Length of time, conditions, outcomes, etc.

Getting More Equity Impact Out of More PCORI CER Studies



- Stronger encouragement for studies to power for subgroup analyses
- Superiority (A better than B) versus non-inferiority (A as good as B) trial designs

Diversifying Who Participates in CER at PCORI



- **Researchers**
 - Establish targeted mechanisms for supporting career development of investigators from underrepresented groups
 - Motivate collaboration with sectors with higher representation of POC and promoting broad representation on study teams
 - From sectors such as public health, social sciences, technology, that have higher representation
- **Applicant organizations**
 - Develop strategies to broaden the applicant pool to organizations new to PCORI who serve specific priority populations
- **Participants and their communities**
 - Support the identification of methods to recruit diverse study populations in affected communities

Putting PCORI Research Results into Health Equity Context



- Synthesizing and bundling research results across different projects with narrative that directly explains health equity influence of results
 - By target population and condition (e.g., Black Americans and diabetes), or across settings (e.g., clinical and community)
- Creating and disseminating materials about PCORI's portfolio of research findings, but also about our mission and values as they pertain to health and health equity, that target broader audiences, such as the public or communities of color
- Collaborations with other health research funders to show how work across agencies can be brought together to advance health equity

Discussion Questions for CER that Advances Health Equity



- Any thoughts about how to encourage researchers to submit applications more broadly across the research continuum?
- Any thoughts about how to diversify who is participating in CER at PCORI?
- Does it make sense to put PCORI's disparities research into more of a health equity context for dissemination?
- What funding agencies should PCORI collaborate with on health equity strategies?

Gathering Input on the PCORI Centers for Health Equity Initiative



Why Does PCORI Need a Centers Approach to Advance Health Equity?



- A center provides the opportunity to integrate research, training, and community engagement into one approach
- A center can address several issues:
 - Developing a new portfolio with a cluster of studies
 - Improving health equity researcher diversity
 - Stronger health equity researcher pipeline
 - Expanding approaches to engaging underrepresented communities
 - Increasing racial/ethnic concordant research
 - Improving the quality of health equity research through multidisciplinary and multistakeholder learning networks

Preliminary Thinking for Centers Initiative



- Two separate PFAs:
 - Health equity research centers (dedicated funding for each center; multiple awardees)
 - Coordinating center to support and coordinate the Centers' activities)
 - Duration of 5-7 years
 - Currently Considering Cycle 2 2022 Funding Cycle

Health Equity Research Center

Overall Goals



1. Conduct comparative effectiveness research that advances health equity
 - This may include some preparatory research work in high priority areas
2. Develop and execute health equity-focused training programs for researchers, particularly those from underrepresented communities (e.g., researchers of color, with disabilities, etc.)
 - Create a workforce pipeline
3. Implement innovative engagement strategies with underrepresented populations and communities to enhance their engagement and participation in CER
4. Create a healthy equity research learning network for collaboration and dissemination

- Solicit applications via open competition
- Example topics of interest:
 - Reducing maternal mortality and morbidity disparities
 - Reducing intellectual and developmental disabilities disparities
 - Addressing the impact of structural racism, discrimination and bias on health outcomes
 - Health system or institution level
 - Program or policy level
 - Community-based solutions
 - Practice-based solutions
 - Addressing social determinants of health
 - Public health approaches to reduce disparities

Health Equity Research Center PFA (cont.)



- Typically, Center's initiatives involve the following components:
- Applicants could propose two or three specific research projects
- Each applicant demonstrates certain "core" capabilities:
 1. Leadership and Administrative
 2. Project Initiation and Oversight
 3. Research Support and Analysis
 4. Central IRB (and agreement with sites they will participate in a central IRB) and DSMB
 5. Engagement and Community liaison
 6. Historically Excluded Investigator Development and Training

Health Equity Research Center PFA (cont.)



- Applicants typically have certain obligations beyond their Center activities related to their award:
 1. Participate in the Centers-wide committees, including activities involving the finalization of study research, engagement, and training protocols
 2. Agree to participate in quarterly meetings
 3. Create a learning network within the Centers program
 4. Participation in Study Advisory Committee Meetings

Coordinating Center PFA



- The separate coordinating center typically would have several functions:
 1. Convener for Center study calls and quarterly meetings
 2. Support network wide committees in the following areas:
 - Administrative Coordination
 - Methodology
 - Engagement
 - Training Programs
 - Communication and Publications

Discussion Questions for the Centers for Health Equity Initiative



- What is the breadth of health equity topics to consider in the initiative?
 - Should we consider pilot projects to precede CER?
- What should be the balance of research and training?
- What are the appropriate metrics for success?
- What is the best approach(es) to fostering collaboration among Centers?
 - How much should be directed and how much should be at the Centers' discretion?
- How can under-resourced communities be engaged in the initiative?
- What organizations or individuals should we solicit feedback from?

Survey



Wrap-Up and Next Steps

Alicia Arbaje & Jane Kogan
HDDR Advisory Panel Co-Chairs

Steve Clauser
Director, Healthcare Delivery and
Disparities Research Program



Meeting Adjourned
