Board of Governors Meeting

In-Person and via Teleconference/Webinar

March 2, 2020
12:30 PM – 5:30 PM MST

pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Josephine Briggs, MD

Interim Executive Director & Acting Chief Science Officer

Agenda

12:30 PM	**Call to Order and Welcome**
12:35-12:40	**Consider for Approval:** Consent Agenda
12:40–12:50	**Executive Director's Report**
12:50–1:05	**Consider for Acceptance:** 2019 Financial Audit Report
1:05–1:35	**Consider for Approval:** Cycle 2 2019 Slate of Broad Awards & Dissemination & Implementation
1:35-2:15	**Consider for Approval:** Phased Large Awards for Comparative Effectiveness Research (PLACER) PFA
2:30-2:50	**Consider for Approval:** Observational Analyses of Second-Line Pharmacological Agents in Type 2 Diabetes Mellitus PFA
2:50-3:20	**Consider for Approval:** PCORnet Rare Disease PFA
3:20-5:00	**PCORI's Community Health Worker Portfolio**
5:00-5:30	**Public Comment Period**
5:30	**Wrap up and Adjournment**

Consent Agenda Items

Christine Goertz, DC, PhD

Chairperson, Board of Governors

Board Vote

- That the Board approve:
  - Minutes from the January 28, 2020 Board meeting
  - Appointment of Catherine (Kate) Crespi-Chun, PhD as Co-Chair of the Advisory Panel on Clinical Trials to serve until August 31, 2021, or until a replacement is appointed
  - The proposed revised Award Project Budget Increase Policy

Board Vote

Call for a Motion to:	• **Approve** each of the Motions on the Consent Agenda
Call for the Motion to be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Voice Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Executive Director's Report

Josephine Briggs, MD

Interim Executive Director

David Hickam, MD, MPH
Program Director, Clinical Effectiveness and Decision Science

Please join us in thanking Dave for his many years of service to PCORI.

Dave joined PCORI in the fall of 2012 as one of our scientific program directors.

He also supported the Methodology Committee and has coordinated the expansion of the PCORI Methodology Standards to address the many challenging methodological issues in comparative effectiveness research.

FY2019 Independent Auditor's Report

Sharon Levine, MD

Chair, Governance Committee

Thomas J. Sneeringer, CPA

Partner, RSM US LLP

AUDITOR PRESENTATION

PCORI Board of Governors

March 2, 2020

FY2019 Independent Auditor's Report

PCORI received an unmodified opinion; the financial statements presented fairly, in all material respects, the financial position, the changes in its net assets, and its cash flows.

- There are no findings related to deficiencies in internal control over financial reporting.
- There are no findings related to compliance or other matters.

RSM

Statement of Activities

Statement of Activities	FY2019	FY2018
Revenue	$615,205,771	$506,485,458
Expenses	$390,494,397	$384,523,987
Realized and unrealized loss on investments	$ 2,904,912	$ (502,360)
Change in Net Assets	$227,616,286	$121,459,111

RSM

Statement of Financial Position

Statement of Financial Position	FY2019	FY2018
Assets	$1,376,285,798	$1,151,077,182
Liabilities	$ 86,885,031	$ 89,292,701
Net Assets	$1,289,400,767	$1,061,784,481

RSM

Board Vote

Call for a Motion to:	• **Accept** the FY2019 Audit Report
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 **Accept** the **FY2019 Audit Report** • Ask for votes in favor, opposed, and abstentions

Broad PFAs
Cycle 2 2019 Award Slate

Barbara McNeil, MD, PhD

Chair, Selection Committee

Josephine Briggs, MD

Interim Executive Director and

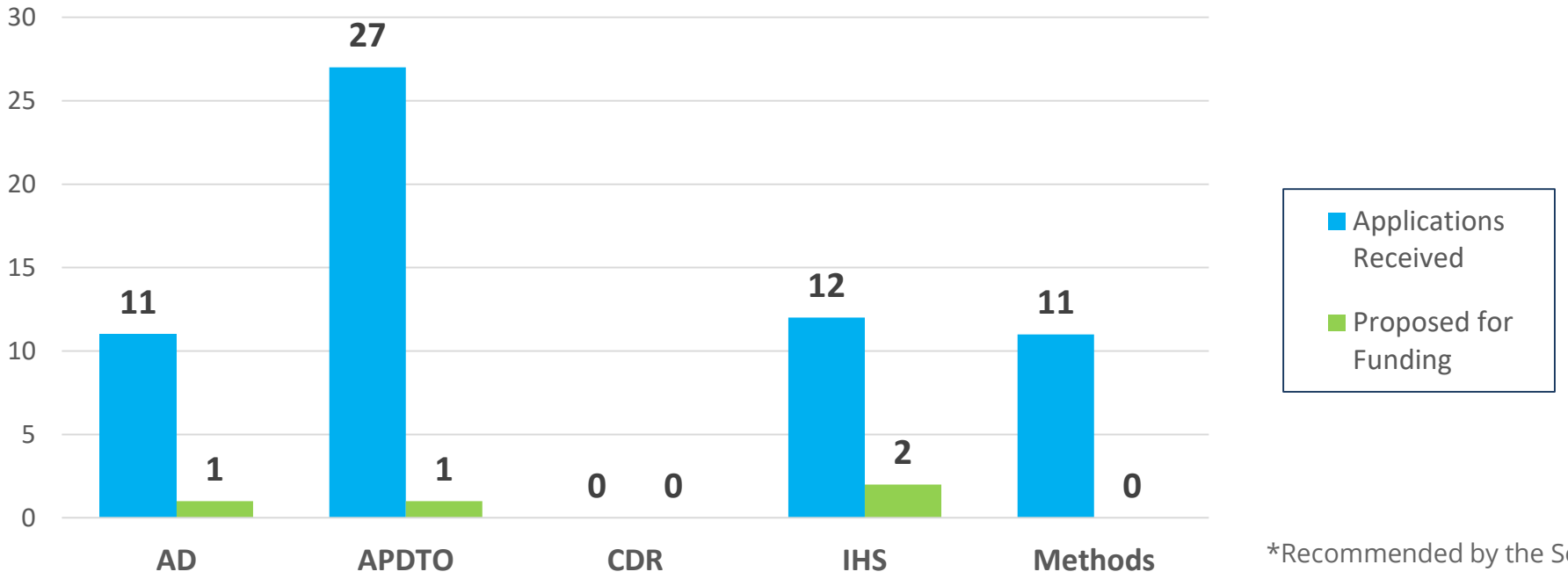
Acting Chief Science Officer

Cycle 2 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 2 2019 – Broad PFAs
Process Overview

- 140 Letters of Intent (LOIs) received
- 75 LOIs invited to submit a full application
- 62 applications were received
- The Selection Committee is proposing to fund 4 applications* out of 62 received applications



*Recommended by the Selection Committee on February 5, 2020

Cycle 2 2019 – Addressing Disparities
Slate of 1 Recommended Project

Project Title
Comparing Mobile Health Strategies to Improve Pre-exposure Prophylaxis Use (PrEP) for HIV Intervention

Resubmissions in bold

Cycle 2 2019 – Assessment of Prevention, Diagnosis, and Treatment Options

Slate of 1 Recommended Project

Project Title
Randomized Trial Comparing MRI-Targeted Transperineal vs Transrectal Prostate Biopsy

Resubmissions in bold

Cycle 2 2019 – Improving Healthcare Systems
Slate of 2 Recommended Projects

Project Title
Comparative Effectiveness of Perinatal Psychiatric Access Programs on Treatment Engagement
Using Mobile Integrated Health and Telehealth to Support Transitions of Care among Heart Failure Patients

Resubmissions in bold

Cycle 2 2019
Recommended Slate of 4 Projects

PFA	Amount Budgeted	Proposed Total Award*
Cycle 2 2019 Broad	$15M	$16.4M

*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 awards from the Cycle 2 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 2 2019 Award Slate

Lawrence Becker

Chair, Engagement, Dissemination, and Implementation Committee

Joanna Siegel, SM, ScD

Director, Dissemination and Implementation

Cycle 2 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

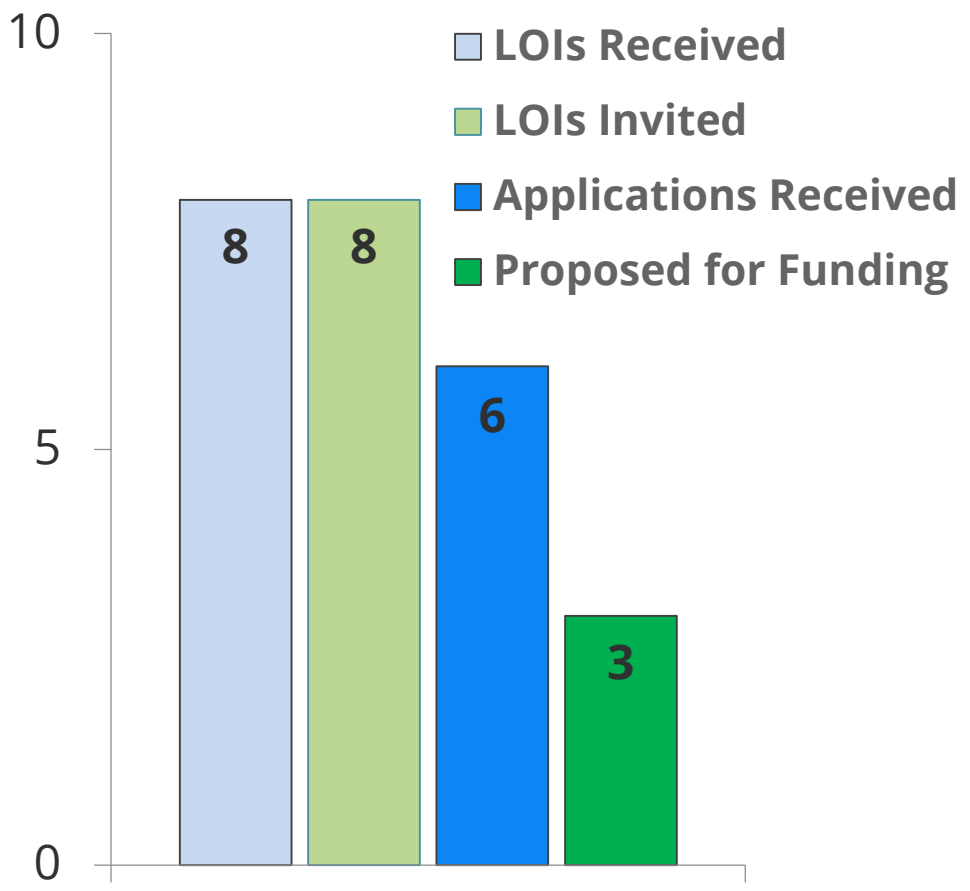
Cycle 2 2019 - Limited Competition Dissemination and Implementation PFA

Process Overview

- 8 Letters of Intent (LOIs) submitted
- 8 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 3 applications out of the 6 received
- **Funding rate is 50 percent**



Cycle 2 2019 - Limited Competition Dissemination and Implementation PFA

Slate of 3 Recommended Projects

Project Title
Implementing Team-based Outpatient Palliative Care in Parkinson Foundation Centers of Excellence
Innovative Implementation of a Robust Executive Function Intervention Delivered in Schools
Learning Collaborative to Improve the Quality of Elective Orthopedic Surgery Decisions

Resubmissions in bold

Cycle 2 2019 - Limited Competition Dissemination and Implementation PFA

Slate of 3 Recommended Projects

PFA	Amount Budgeted [per Year]	Proposed Total Award*
Implementation of PCORI-Funded Patient-Centered Outcomes Research Results	$9.0M	$3.5M

Note: Budgeted amount is for up to 3 cycles per year; $2.6M awarded in Cycle 1 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 slate of awards from the Cycle 2 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

Phased Large Awards for Comparative Effectiveness Research (PLACER) PFA

Robert Zwolak, MD, PhD

Chair, Science Oversight Committee

Josephine Briggs, MD

Interim Executive Director and Acting Chief Science Officer

Anne Trontell, MD, MPH

Associate Program Director, Clinical Effectiveness and Decision Science

Opportunity and Background

This innovative mechanism is intended to remove roadblocks to funding highly important research questions of large scale and scope…. but which have risks in their readiness to "go live" with full execution in the absence of further development

- Support for a phased mechanism comes from multiple venues, including:
  - **Committees**: Methodology Committee, Science Oversight Committee
  - **Advisory Panels**: Advisory Panel on Clinical Trials
  - **PCORI Staff**: Direct Comparisons of Clinical Options (DCCO) Work Group, Targeted PFA evaluation and interviews with staff
  - **PCORI Applicant Survey**

Benefits of Phased Testing for Critical-Yet-Underdeveloped Research Studies

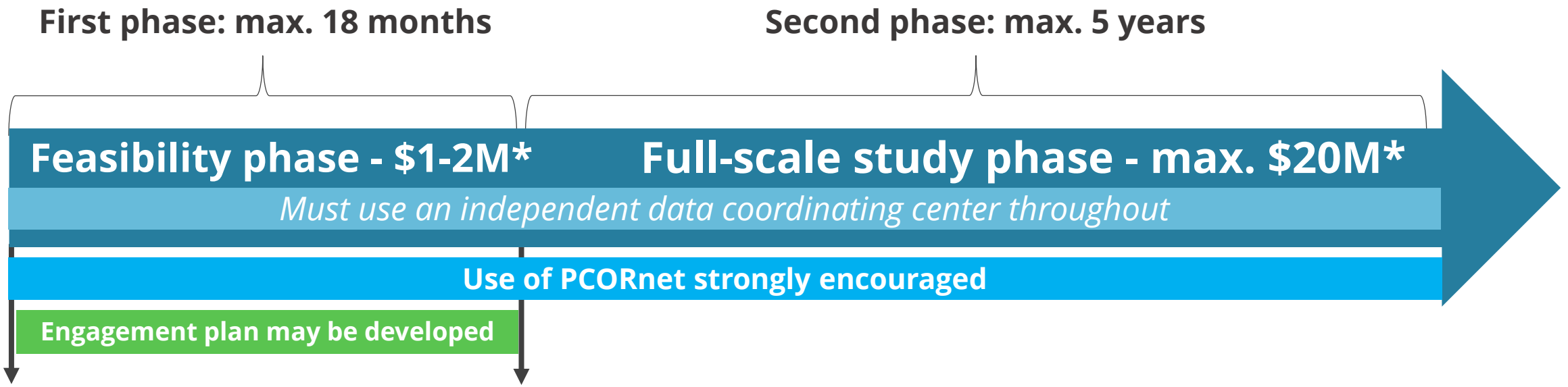
Phased testing will:

- Better support the development of robust **stakeholder engagement and question refinement**
- Allow **feasibility testing of interventions in diverse and challenging research settings** such as primary care
- Provide the opportunity to **test and assure effective study recruitment**
- Enable **development of a robust research design and study execution plan**
- **Limit risk** by fostering strong studies during feasibility phase and halting funding after feasibility phase if progress or feasibility are unacceptable

How is PLACER different from existing mechanisms?

- **PLACER is a new and distinctive addition** to the existing PCORI funding suite of Pragmatic Clinical Studies (PCS), Targeted studies, and Broad studies in:
  - Needing a larger scale and scope to answer a critical research question
  - Having residual uncertainties with non-trivial risks for full, up-front funding
  - Having sufficient evidence and stakeholder interest to warrant investment in further refinement before full-scale execution
- There will be variation in the "readiness" of the project for full execution and thus the areas for development during a feasibility phase, but all studies must provide **evidence of the importance of the research question** and **why it is appropriate for this level of funding**
- Studies must propose a comparative effectiveness question and randomized design

PLACER: Timeline and Requirements



Merit Review, SC & Board Approval

Go/No-Go Decision

Supporting information received ≥ 2 months before decision

***Direct costs for initial competition in Cycle 2 2020**

Independent Data Coordinating and Analytic Capacity

- The scope of PLACER awards will mandate the use of a data coordinating center (DCC) with independent study oversight functions which may include:
  - Well-defined outcome measures and statistical analysis plan
  - Development of data collection forms and tools
  - Assurance of data quality and completeness
  - Maintenance of randomization methods and randomization keys
  - Analysis of data and preparation for publication
  - Preparation of final data files for data sharing

- PCORI will vet all DCCs for quality and impartiality of their oversight function

PLACER: Application and Merit Review

Review will focus on the **full scope of the project, including the full budget and plans for both phases** with emphasis that

- **The research question** fully meets applicable PCORI Methodology RQ Standards
  - Results will inform a critical health decision for stakeholders needing compelling evidence
  - Research gap is documented by a current systematic review or evidence synthesis
  - A patient-centered question
  - Comparisons represent actual healthcare options which challenge stakeholders
- **Patient engagement has been demonstrated** in at least a preliminary fashion
  - Further development of patient and stakeholder engagement is expected in the feasibility phase

PLACER: Application, Merit Review, and Funding

- Merit review process will enhance the established process with more time devoted to individual application reviews
- The review panel will assure:
  - **Content expertise from ≥ 2 individuals**
  - **Statistical expertise**
  - **Trialists**
  - **Patients/stakeholders**
- Funding recommendations to the Selection Committee (SC) will emphasize:
  - The exceptional relevance and scope of the research question
  - Uncertainties in execution that justify a feasibility assessment

Oversight of Awarded PLACER Studies in Feasibility Phase

- PCORI oversight of milestone progress and criteria established at award
- Periodic progress reviews by an **External Advisory Panel (EAP)** with
  - Knowledge and experience of the priorities of PCORI and its stakeholders
  - Specific content/clinical expertise with the clinical condition
  - Methodologic/statistical expertise in the proposed research design
  - Perspectives of patients, providers, and other key stakeholders
  - No conflicts of interest
- EAP membership
  - Well-qualified members may come from merit review panel, advisory panel members, and Board recommendations

Go/No-Go Decision: Process

- Decision will be **based on pre-specified milestones and criteria**
  - Milestones = **core + study-specific milestones** negotiated with PCORI after award
  - **Criteria** will assess the merits of the full-scale study question, its feasibility & power
- Feasibility phase progress & any modifications to the initial full-scale study plan will receive an in-depth, critical review in advance of feasibility phase conclusion by
  - Senior PCORI staff including the PCORI Chief Science Officer
  - External Advisory Panel
- PCORI's Executive Director will make the final Go/No-Go decision based on the findings and recommendations of the in-depth review

Full-scale Study Execution: Milestones and Oversight

Milestones, external review, and indicators of elevated risk will be tracked closely using well-established PCORI contract control mechanisms

- Before full-scale study initiation, milestones will be updated or added using core and study-specific measures
- Tight PCORI oversight, remediation, and termination processes will operate as usual
  - Monthly enrollment reporting and check-ins with PCORI
  - Regular progress reports
  - Real-time tracking of milestones and deliverables
- EAP will review progress periodically

Requested Research Commitment

- Total requested for this PFA is $150M in total costs
- Estimated number of studies: Up to 5
- Maximum project duration (first and second phase): 7 years

Board Vote

Call for a Motion to:	• **Approve** the phased-funding model and development of Phased Large Awards for Comparative Effectiveness Research (PLACER) 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

BREAK

We will return in 15 minutes

Join the conversation on Twitter via @PCORI

Targeted PFA: Observational Analyses of Second-line Pharmacological Agents in Type 2 Diabetes Mellitus

Robert Zwolak, MD, PhD

Chair, Science Oversight Committee

Kim Bailey, MS

Senior Program Officer, Clinical Effectiveness and Decision Science

Second-line Pharmacological Agents in Type 2 Diabetes

- While metformin is the consensus first-line pharmacotherapy, guidelines provide less clarity regarding the choice of second-line treatments for those without established cardiovascular or kidney disease
- Many classes of drugs are used as second-line treatments, with mechanisms of action, risks, and benefits varying across the classes and within each class
  - Sulfonylureas
  - Thiazolidinediones
  - DPP-4 inhibitors
  - SGLT-2 inhibitors
  - GLP-1 receptor agonists
  - Insulin
- Few head-to-head comparisons of these drugs have been conducted

Second-line Pharmacological Agents in Type 2 Diabetes

- Historically, there has been a concern about the cardiovascular safety of drugs used to treat type 2 diabetes
- In response, the FDA began to require post-marketing studies to assess the cardiovascular safety of newly approved diabetes drugs in 2008
- Somewhat surprisingly, apparent cardiovascular benefit has now been demonstrated for 6 agents in 2 classes
  - SGLT2 inhibitors: empagliflozin and canagliflozin
  - GLP-1 receptor agonists: liraglutide, semaglutide, albiglutide, dulaglutide
- Importantly, these trials included patients with established cardiovascular disease and those at very high cardiovascular risk

Second-line Pharmacological Agents in Type 2 Diabetes

Question of interest:

What is the comparative effectiveness of older versus newer agents among individuals with type 2 diabetes at moderate cardiovascular risk?

Second-line Pharmacological Agents in Type 2 Diabetes

- Why observational analyses?
  - Investment of time and resources to conduct randomized controlled trial would be very large
  - Lack of certainty regarding comparators to select/durability of information for potential randomized trial
  - Observational analyses will provide much-needed information about the relative risks and benefits of these drugs and help to inform the design of a future trial

Second-line Pharmacological Agents in Type 2 Diabetes

Population	Adults with type 2 diabetes at moderate cardiovascular risk (~2-3% annual event rate) who require the addition of a second antihyperglycemic agent
Intervention/ Comparators	SGLT2 inhibitors, GLP-1 receptor agonists, sulfonylureas, and DPP-4 inhibitors (studies to look at individual agents in each class)
Outcomes	Cardiovascular outcomes to include non-fatal myocardial infarction, non-fatal stroke, cardiovascular death, revascularization, and hospitalization for heart failure; other endpoints of interest include adverse effects, renal function, changes in weight, and additional patient-centered outcomes (hypoglycemia, etc.)
Timing	Retrospective analyses inclusive of ≥4 years of follow-up data

Requested Research Commitment

- Total requested for this PFA is up to $20M in total costs
- Estimated number of studies: 2-3
- Maximum project duration: 3 years

Board Vote

Call for a Motion to:	• **Approve** the development of Observational Analyses of Second-Line Pharmacological Agents in Type 2 Diabetes 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

Targeted PFA: Conducting Rare Disease Research Using PCORnet®

Robert Zwolak, MD, PhD

Chair, Science Oversight Committee

Penny Mohr, MA

Senior Advisor, Emerging Technology and Delivery System Innovation Research Initiatives

Conducting Rare Disease Research Using PCORnet

- Signaling that PCORI give special attention to the conduct of rare disease research, PCORI's authorizing legislation mandated the establishment of a rare disease advisory panel.

- The ability to conduct robust rare disease comparative effectiveness research (CER) is often limited by small numbers

The vision behind this funding initiative: Harness the scale of PCORnet to enable improved comparative effectiveness research in rare disease

PCORnet as a Resource for Rare Disease Research

Scale

- Power in numbers so that studies are possible in rare conditions

Data

- Collected at point of care, reflective of patient experience within health system
- Collected from a variety of specialties and clinics
- Linkable with claims data and/or PROs for more complete picture of patient experience

Access

- To patients behind the data, allowing contact for study participation through ethically approved channels

Engagement

- Involvement of patients with lived experience to help develop patient-centered questions and studies

Prior PCORnet Work on Rare Disease

Rare Disease	CRN	Cohort (N)
Alpha-1-antitrypsin deficiency	ADVANCE	272
Sickle cell anemia	STAR/REACHnet	6316
Recurrent C. difficile colitis	CAPrICORN	516
Amyotrophic lateral sclerosis (ALS)	GPC	1079
Cystic fibrosis	INSIGHT	62
Duchenne muscular dystrophy	OneFlorida	1363
Idiopathic pulmonary fibrosis	PaTH	1056
Glomerular Disease	PEDsnet	1600
Pulmonary arterial hypertension	ARCH*	440
Osteogenesis imperfecta	LHSnet*	1590
Severe congenital heart disease	PORTAL*	985
Kawasaki disease	pSCANNER*	712

* Indicates former CRN

Advisory Panel on Rare Disease (RDAP) Priorities

- RDAP has a strong interest in use of PCORnet for rare disease research
- Particular interest in pediatric rare disease
- Some priority questions they identified include:
  - Retrospective evaluation of use patterns and presentation prior to diagnosis of rare disease;
  - Tracking of symptoms, clustering of symptoms, patterns of care after rare disease diagnosis
  - Mechanisms to improve case management, care coordination services
  - Transitions of care (across the lifespan, between primary and specialty care)
  - Monitoring and screening for rare disease complications post-diagnosis
- Have prioritized certain core outcomes that are important to them

Rare Disease Research Using PCORnet
PFA Target Population

- Standard definition - prevalence of fewer than 200,000 in the United States (NIH)
  - Operationally if included on lists maintained by:
    - NIH Office of Rare Disease Research;
    - Orphanet; or
    - FDA
  - Groupings of rare diseases with common characteristics may be desirable for addressing cross-cutting CER questions

Rare Disease Research using PCORnet
PFA Goals

Utilize PCORnet resources to perform an observational research study that will answer one or more important research questions about the care of patients with rare diseases

AND

Enhance the capabilities for the conduct of multi-site rare disease research by creating partnerships, methods, tools and linkages that will facilitate future comparative effectiveness studies

Complementarity with Other Initiatives

- NIH Rare Disease Registry Program
  - Provides the rare disease community guidance on how to set up and maintain patient registries
- National Organization for Rare Disorders Registry Program
  - Patient-initiated registries
  - Compilation of services that help in developing, launching and managing natural history studies
- NIH Rare Diseases Clinical Research Network
  - Consortia of patient groups and academic research centers working together to enhance clinical trial readiness and develop cures for rare disease
- The FDA Rare Disease Cures Accelerator-Data and Analytics Platform
  - Purpose is to accelerate the movement of new therapies from bench to bedside for rare diseases
    - Developing clinical trial networks
    - Data analytics platform (e.g., clinical trials, registry, patient-generated data) – not for prospective research
    - Developing Core Outcome Sets for rare disease

Research Requirements

- Limited competition – open to all network partners of PCORnet
- Conduct the study across multiple PCORnet Clinical Research Networks/Health Plan Research Networks (CRNs/HPRNs)
  - A minimum of two or more
- Partner with rare disease community with attention to representing the diversity of the population affected by the disease(s)
- Research must address compelling comparative questions about the treatment or management of rare disease

Requested Commitment

- Maximum project budget and duration: $5M in total cost; 3 years
- Estimated number of studies: 5
- Total requested for this PFA: $25M in total cost

Board Vote

Call for a Motion to:	• **Approve** the development of Conducting Rare Disease Research Using PCORnet 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

PCORI's Community Health Worker Portfolio

Steven Clauser, PhD, MPA
Program Director
Healthcare Delivery & Disparities Research

Cathy Gurgol, MS
Senior Program Officer
Healthcare Delivery & Disparities Research

Outline

- **Overview of PCORI's Community Health Worker (CHW) Portfolio**
  - Complexities in reducing health and healthcare disparities
  - Understanding the role of CHWs
  - Study spotlights across PCORI's CHW portfolio
- PCORI Awardee Panel Presentation
  - **Raj Shah, PhD and Kevin English, DrPh, University of New Mexico Health Sciences Center**
    - *Reducing Health Disparity in Chronic Kidney Disease in Zuni Indians*
    - *Home-Based Chronic Kidney Disease (CKD) Care in Native Americans of New Mexico: A Disruptive Innovation*
  - **Shreya Kangovi, MD, University of Pennsylvania and Keysha Brooker, MSW**
    - *Effectiveness of Collaborative Goal-Setting Versus IMPaCT Community Health Worker Support for Improving Chronic Disease Outcomes*
    - *Implementation of the IMPaCT Community Health Worker Intervention*
- Q&A
- Discussion

Addressing Health Disparities is Challenging

- **Disparities are widespread in the US healthcare system**
  - Institute of Medicine, *Unequal Treatment,* 2003
  - AHRQ Annual National Healthcare Quality & Disparities Report, 2003-2018
  - PCORI National Research Priorities, 2012
- **Addressing disparities is complex**
  - Coverage does not always ensure equal access to care
  - Access to care does not always produce the same quality of care
  - Quality of care does not always achieve equivalent health outcomes
- **Social determinants of health** and **cultural factors** contribute to health disparities and inequities in health and health care
  - Health systems have a role in addressing social needs and responding to contextual factors patients have

Definition of Community Health Workers

- **Community Health Worker (CHW):** "a frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served" (APHA)

- The CHW title is not standard. CHWs may also be called:
  - community health representative
  - promotores de salud
  - peer/patient navigator
  - other
- CHWs may practice in community settings and augment the health care system, liaise directly with health providers, or be members of the health care team

APHA. "Community Health Workers." Retrieved from https://www.apha.org/apha-communities/member-sections/community-health-workers.

Community Health Workers are a Recommended Strategy to Address Disparities

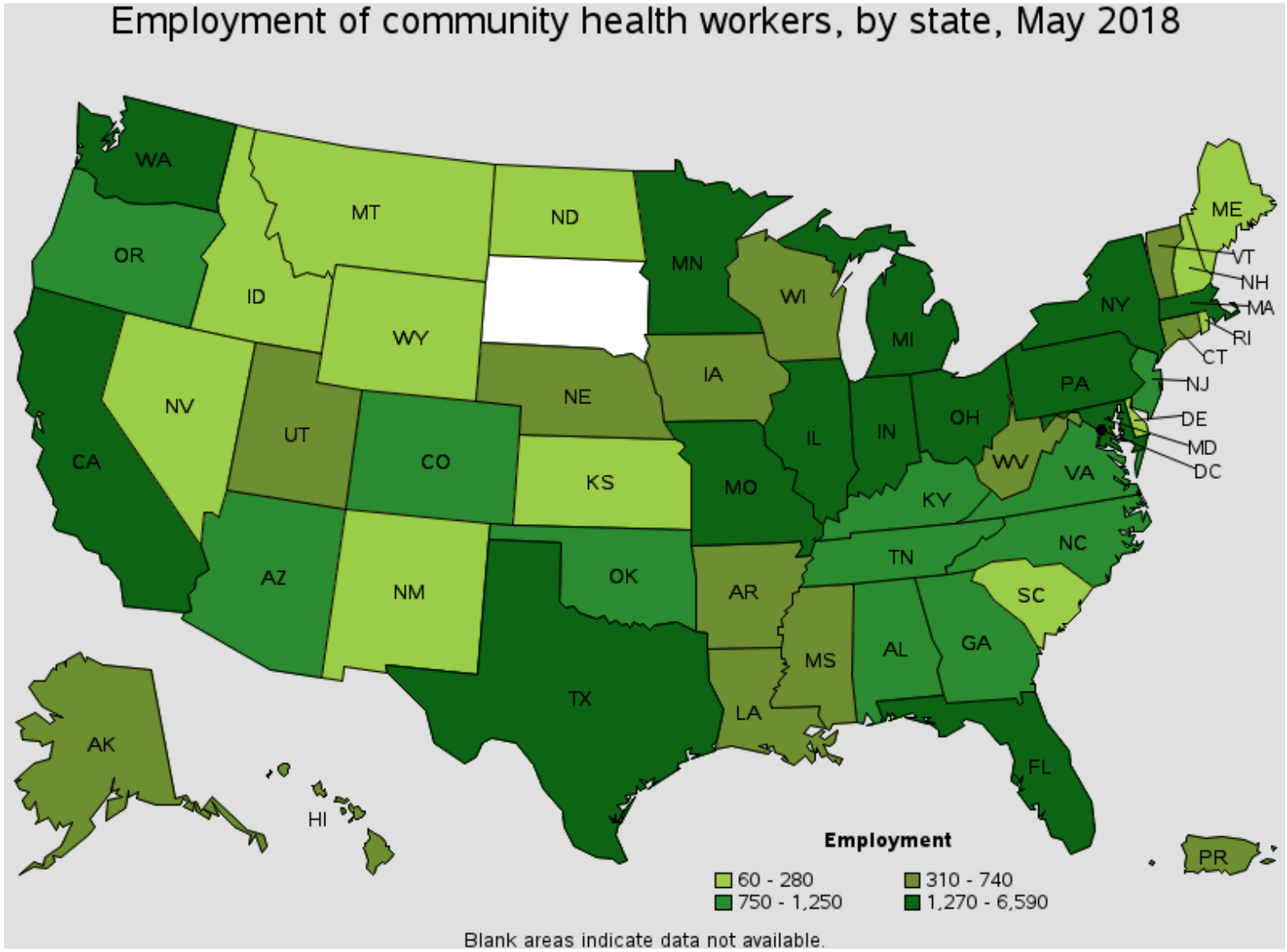
- **Recommendations in IOM Reports (e.g., *Unequal Treatment*, 2003)**
  - Increase care access by using CHWs as liaison between patient and provider
  - Incorporate CHWs on multi-disciplinary teams to address patient social factors that affect health and health care access
- **Legislation (e.g., Affordable Care Act)**
  - Grants to promote healthy behaviors among medically underserved populations through use of CHWs
  - Increased access to preventive health services under Medicaid (states may designate non-licensed providers to provide preventive services)
- **Systematic reviews support benefits of CHWs in addressing disparities**

IOM Unequal Treatment (2002)

CHWs are Widespread and Rapidly Growing

Estimated **56,130** CHWs employed in the United States in 2018 (U.S. Bureau of Labor Statistics)

Position projected to grow 18.1% between 2016 and 2026 (Center for Health Workforce Studies)



U.S. Bureau of Labor Statistics. Retrieved from https://www.bls.gov/oes/2018/may/oes211094.htm

Evidence is Needed for Wider Adoption of CHWs

- How can healthcare organizations best incorporate the value of including CHWs on health care teams?
- What are the best approaches for tailoring evidence-based CHW interventions to address diverse underserved populations?
- What type of curriculum or training should be required for CHWs?
- What type of payment models provide the best evidence for improved health outcomes?
- Which models or intervention designs optimize CHWs in improving patient-centered outcomes?

Overview of PCORI's Community Health Worker Portfolio

The Portfolio Includes CHWs and Peers

- PCORI's CHW portfolio includes:
  - **CHWs** – trained lay workers who come from same or similar community as patients (shared life experiences)
  - **Peers** – trained lay workers who share a diagnosis and treatment experiences

PCORI's Investment in CHW Research

PCORI HAS AWARDED

$275 MILLION TO FUND **76** **CER studies**

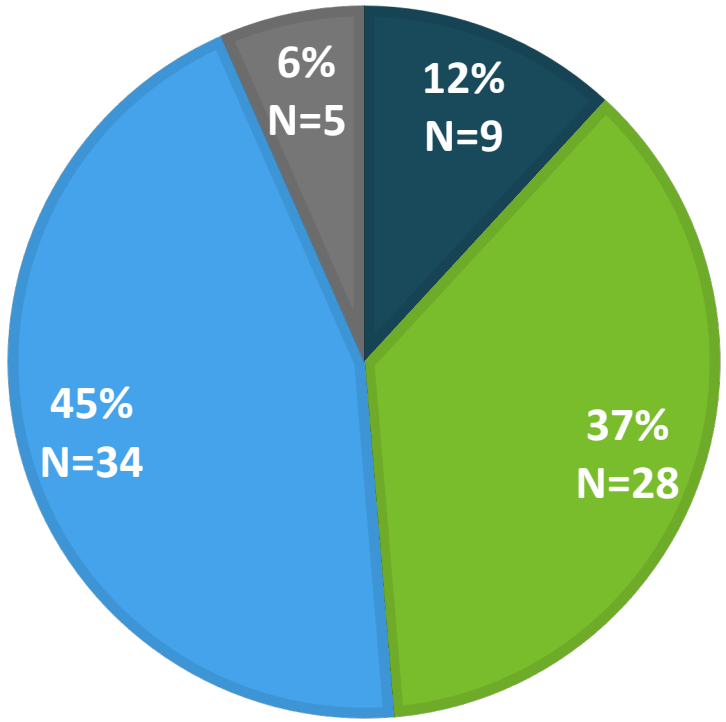
that include a CHW (53%) or peer (47%) in the intervention

In addition, PCORI has also awarded:

- 9 Engagement Awards: $2.1M
- 3 Dissemination & Implementation Awards: $3.9M

The CHW Portfolio Spans PCORI's National Priority Areas

PCORI's CHW Portfolio by National Priority Area (N=76 studies)

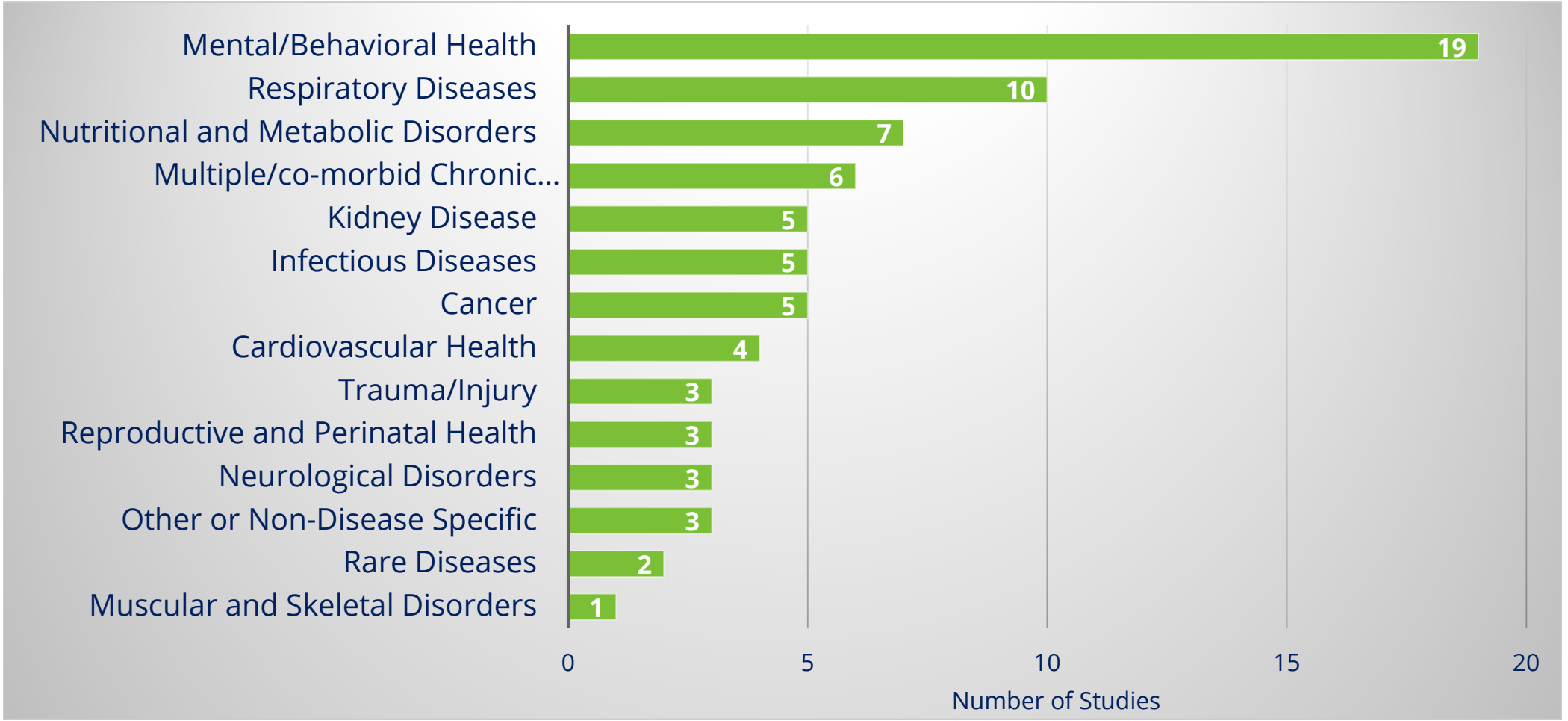


Key Portfolio Characteristics

- 95% (N=71) are randomized controlled trials
  - 35% (N=26) include large sample sizes (≥500 participants)
- Portfolio targets diverse populations most affected by health disparities, including racial and ethnic minorities, rural residents, individuals with low socioeconomic status, older adults, and women
- A wide range of stakeholders, including patients, clinicians, and health systems, are significantly engaged in the research process:
  - Selecting/refining interventions and/or comparators (89%)
  - Recruitment and retention of study participants (86%)
- Over two-thirds (68%) of studies have a patient or stakeholder co-investigator

The CHW Portfolio Includes a Range of Conditions

N=76 studies, categories are mutually exclusive



The CHW Portfolio Includes a Range of Outcomes

- **Health services utilization outcomes**
  - Access to care
  - Emergency department utilization
  - Hospital admission
  - Preventive services
- **Health behaviors outcomes**
  - Self-efficacy
  - Medication adherence
- **Clinical outcomes**
  - Disease risk factor reduction
  - Physiologic measures
  - Assessments of disease control
- **Care experience outcomes**
  - Satisfaction with care
  - Perceptions of care
  - Patient/provider interaction experiences
- **Health status and wellbeing outcomes**
  - Quality of life
  - General health/functioning

Study Spotlights From the Community Health Worker Addressing Disparities Portfolio

CHW Role in Improving Health & Reducing Disparities

Increasing Access to Care

Increase Access

- **Understand social factors that affect health and care access**
  - **Social support to address barriers to care**
  - **Cultural competence, language**
  - **Arranging appointments**

Peer Health Navigation: Reducing Disparities in Health Outcomes for the Seriously Mentally Ill. John Brekke, PhD, MS (Principal Investigator), University of Southern California

Integrated Care and Patient Navigators for Latinos with Serious Mental Illness. Patrick Corrigan, PsyD, MA (Principal Investigator), Illinois Institute of Technology

Results from Two Studies: Peer Navigators Can Increase Access for Patients with Serious Mental Illness

John Brekke, PhD, MS - University of Southern California &
Patrick Corrigan, PsyD, MA - Illinois Institute of Technology

Research Question	Compared to usual mental health care, do peer navigators **improve access** to appropriate care for **Hispanic patients with serious mental illness (SMI)?**
Peer Roles	• Healthcare system navigation • Participant education about healthcare system • Attend appointments with patient
Design	Randomized controlled trials; N=151; N=100
Key Findings	Peer navigation increased: • Appropriate health service use (primary outcome – Brekke and Corrigan) • Quality of life (secondary outcome – Corrigan) • Other health-related indices (e.g., chronic disease detection) (secondary outcome – Brekke)
References	• Kelly E, Duan L, Cohen H, et al. Integrating Behavioral Healthcare for Individuals with Serious Mental Illness: A Randomized Controlled Trial of a Peer Health Navigator Intervention. *Schizophr Res*. 2016 Oct 25. • Corrigan P, Sheehan L, Morris S, et al. The Impact of a Peer Navigator Program in Addressing the Health Needs of Latinos With Serious Mental Illness. *Psychiatr Serv*. 2017 Dec 15.

ENGAGEMENT AWARD PROJECT PROFILE

Dissemination of Lay Support to Address Health Needs of Patients with SMI

Objectives

- To **disseminate PCORI-funded CER evidence** related to **peer interventions** that address the **health needs of patients with SMI** to patients, lay intervention providers, professional providers and administrators

Activities

- Develop materials that summarize research findings in formats that are accessible to end-users, including patients and peer supporters
- Disseminate findings to stakeholders through a website, webinars, and conferences, promoted through stakeholder channels
- Evaluate dissemination efforts to yield insights about impact

Patrick Corrigan, PsyD, MA
Illinois Institute of Technology

Enhancing Care Quality

Enhance Quality

- **Improve disease self-efficacy and management**
  - **Increase treatment adherence**
- **Health system navigation and coordination**
- **Bridging community and health system**
  - **Provide education**

Increasing Colorectal Cancer Screening Among Hispanic Primary Care Patients. Ronald Myers, PhD (Principal Investigator), Thomas Jefferson University

Reducing Health Disparities in Appalachians with Multiple Cardiovascular Disease Risk Factors. Debra Moser, PhD, RN, FAAN (Principal Investigator), University of Kentucky

Tailored Decision and Navigation Support Can Address Colorectal Cancer Screening Disparities

Ronald Myers, PhD (2013) - Thomas Jefferson University

Research Question	Compared to mailed educational information, does active decision support with a patient navigator improve **colorectal cancer screening** rates among **Hispanic patients**?
CHW Roles	• Obtained referral for patient to preferred colonoscopy screen • Prepared patient for colonoscopy • Provided financial counseling/assistance as necessary
Design	Randomized controlled trial at 5 primary care practices; N=400
Key Findings	Telephonic decision and navigation support increased colorectal screening (78%) compared to mailed information (44%) (primary outcome).
References	• Myers RE, Stello B, Daskalakis C, et al. Decision Support and Navigation to Increase Colorectal Cancer Screening Among Hispanic Patients. Cancer *Epidemiol Biomarkers Prev*. 2018 Oct 17. • Myers RE, DiCarlo M, Romney M, et al. Using a Health System Learning Community Strategy to Address Cancer Disparities. *Learn Health Sys*. 2018 Sept 18.

Engagement Enhances Intervention

"Members reviewed .... materials in both English and Spanish, helped to **frame terminology in plain language that was culturally sensitive and literacy appropriate**.....[They] recommended making **financial counseling** support available to those individuals in need of such services in order to undergo screening and follow-up as needed. Importantly, this **service was routinely made available** to study participants as part of a pre-colonoscopy visit."

– Ronald Myers, PhD

Thomas Jefferson University

Quote from the Final Progress Report

Reducing Health Disparities in Appalachians with Multiple Cardiovascular Disease Risk Factors

Debra Moser, PhD, RN, FAAN – University of Kentucky

Research Question	Compared to usual care, does a self-care, risk-reduction intervention delivered by trained CHWs reduce **cardiovascular disease (CVD) risk factors** among **at-risk adults living in rural Appalachian Kentucky**?
CHW Roles	• Delivered group sessions on principles of self-care and CVD risk reduction; nutrition; physical activity; depression management; stress reduction; medication adherence and smoking cessation • Provide ongoing social support
Design	Randomized Controlled Trial; N=300
Key Findings	The CHW intervention reduced a number of CVD risk factors, including: • blood pressure, cholesterol, high-density lipoprotein, body mass index, smoking, depressive symptoms, and overall risk of heart disease (primary outcomes)
References	D Moser, M L Chung, F Feltner, et al. Reduction of Cardiovascular Disease Risk Factors in Rural, Medically Under-Served, Socioeconomically Distressed, High-Risk Individuals: A Randomized Controlled Trial. *European Heart Journal.* Volume 40, Issue Supplement_1. 2019 Oct 21.

Engagement Builds Trust and Increases Trial Accrual

"We do work in areas where people are **somewhat suspicious of outsiders who come in to do research**, and it would be impossible to do research in these communities without **engaging patients and stakeholders**. In addition, they clearly **understand the problems** that need work **in their communities**, and they understand the nuances of how to **recruit, intervene and retain participants**."

– Debra Moser, PhD, RN, FAAN

University of Kentucky

Quote from the Final Progress Report

Large PCORI Projects in Progress

- **Sickle Cell Disease:** Community Health Workers and Mobile Health for Emerging Adults Transitioning Sickle Cell Disease Care (PI: David Rubin, MD, MS; The Children's Hospital of Philadelphia)
- **High Blood Pressure:** Comparative Effectiveness of Health System vs. Multi-level Interventions to Reduce Hypertension Disparities (PI: Lisa Cooper, MD, MPH; Johns Hopkins University)
- **Serious Mental Illness:** Integrating Smoking Cessation Treatment for Smokers with Serious Mental Illness (PI: Eden Evins, MD, MPH; Massachusetts General Hospital)
- **Hepatitis C:** Patient-Centered Models of HCV Care for People Who Inject Drugs (PI: Alain Litwin, MD, MPH, MS; Clemson University)

Panel Presentations

Guest Speakers:

- Vallabh Shah, PhD, Professor, Department of Biochemistry and Molecular Biology and Internal Medicine, School of Medicine, University of New Mexico Health Sciences Center
- Kevin English, DrPH, Director, Albuquerque Area Southwest Tribal Epidemiology Center, Indian Health Board, Inc.
- Shreya Kangovi, MD, MSHP, Associate Professor, Medicine, Perelman School of Medicine
- Keysha Brooker, MSW, Penn Center for Community Health Workers

COMMUNITY HEALTH WORKER (CHW) ROLE IN REDUCING HEALTH DISPARITIES

PARADIGM CHANGE

PCORI Board of Governor's Meeting
Scottsdale, AZ
March 2nd, 2020

Raj Shah, PhD, MS, FASN

Kevin English, DrPH

University of New Mexico

Albuquerque Area Southwest Tribal Epidemiology Center (AASTEC)

National Native American Heritage Month
Zuni Pueblo with Dr Selby (PCORI Director)

CHWs are an important part of the answer…

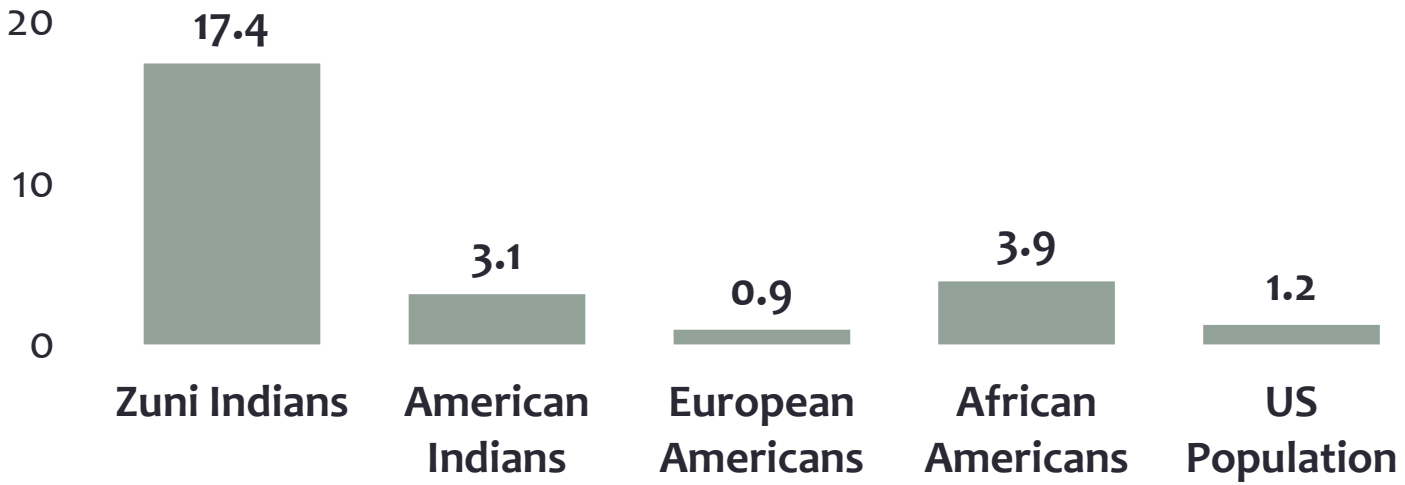
Frontline agents of change

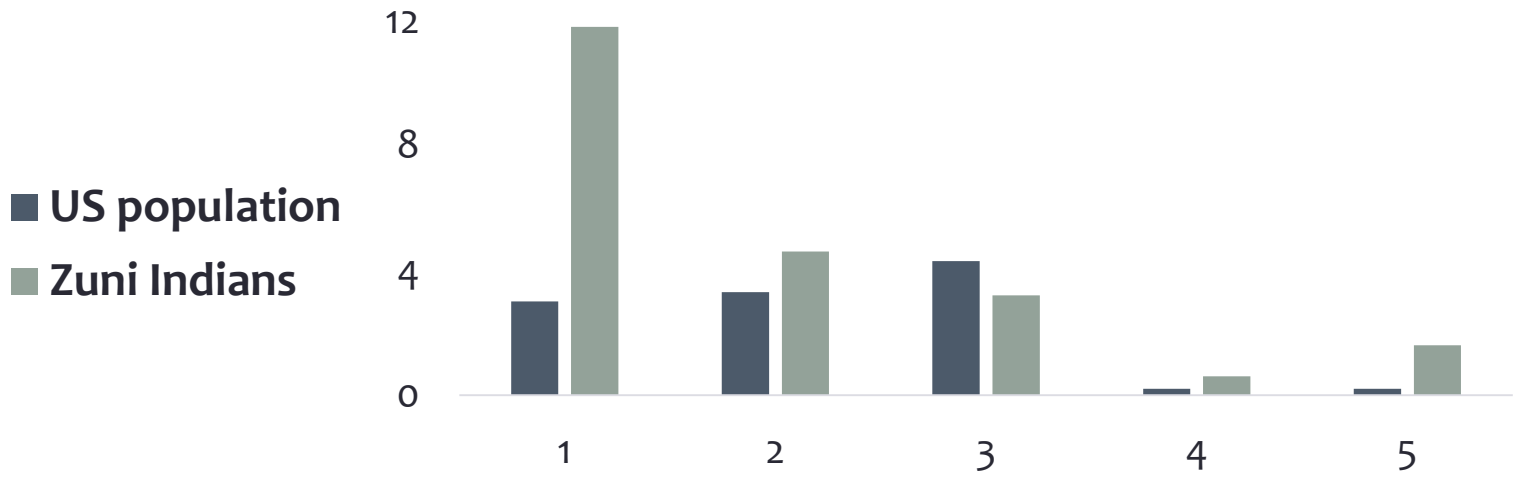
Continuous Patient and Provider Engagement Leading to Care Enhancement

Known CHW Service Outcomes:

- Improved access to health care
- Increased health and screening
- Better understanding between community members and the health and social service system
- Enhanced communication between community members and health providers
- Increased use of health care services
- Improved adherence to health recommendations
- Reduced need for emergency and specialty services

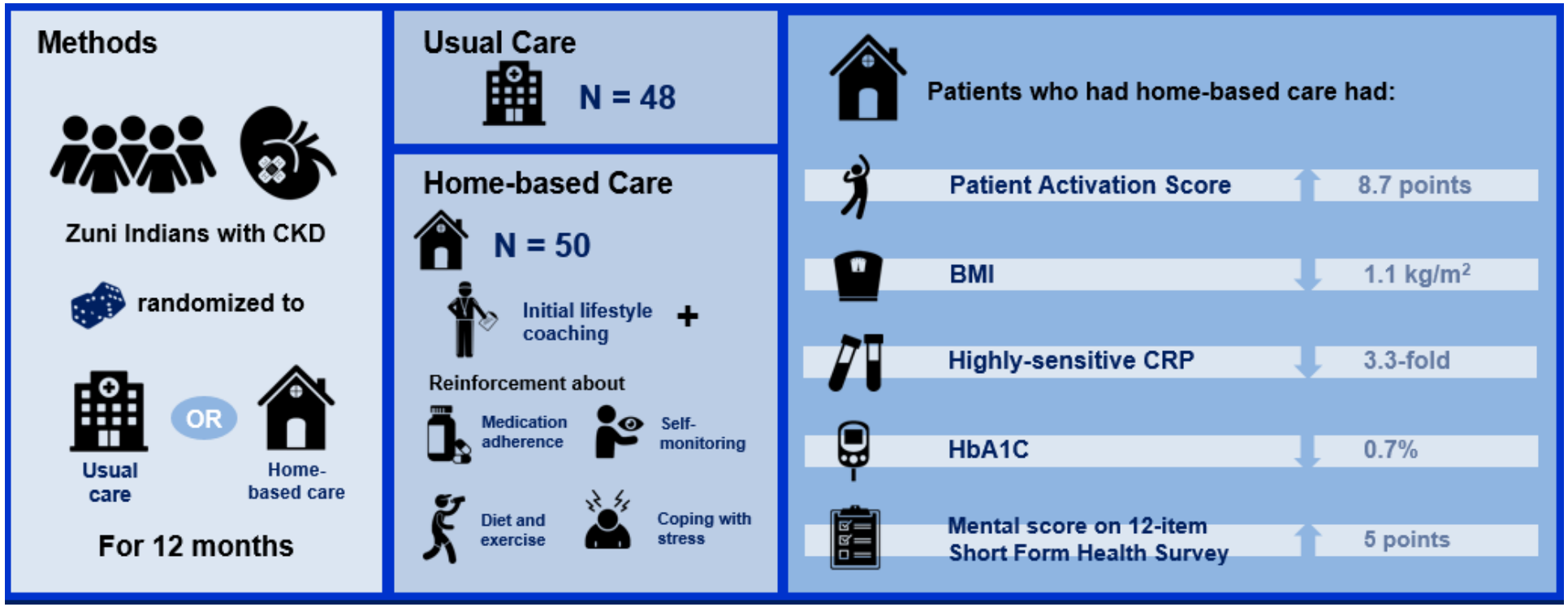
Highest Rate of Kidney Failure





Moving Knowledge Instead of Patients & Providers Approach in Delivering Kidney Care – Preserving vs Replacing

• CHR Delivered • Patient Preferences • POC Testing
• Telemedicine • Text Messaging



Conclusion: A home-based CHW–delivered intervention improves participants' activation in their own health and healthcare and may reduce risk factors for CKD in a rural disadvantaged population

Health Action 2020
Our Nation's Health in the Balance
SUSTAINING

FAMILIESUSA.ORG

FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

Making Community Health Workers (CHWs) Fundamental: New Research Strengthens the Case for State Policymakers to Include CHWs in Care Delivery Teams

FAMILIESUSA.ORG

FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

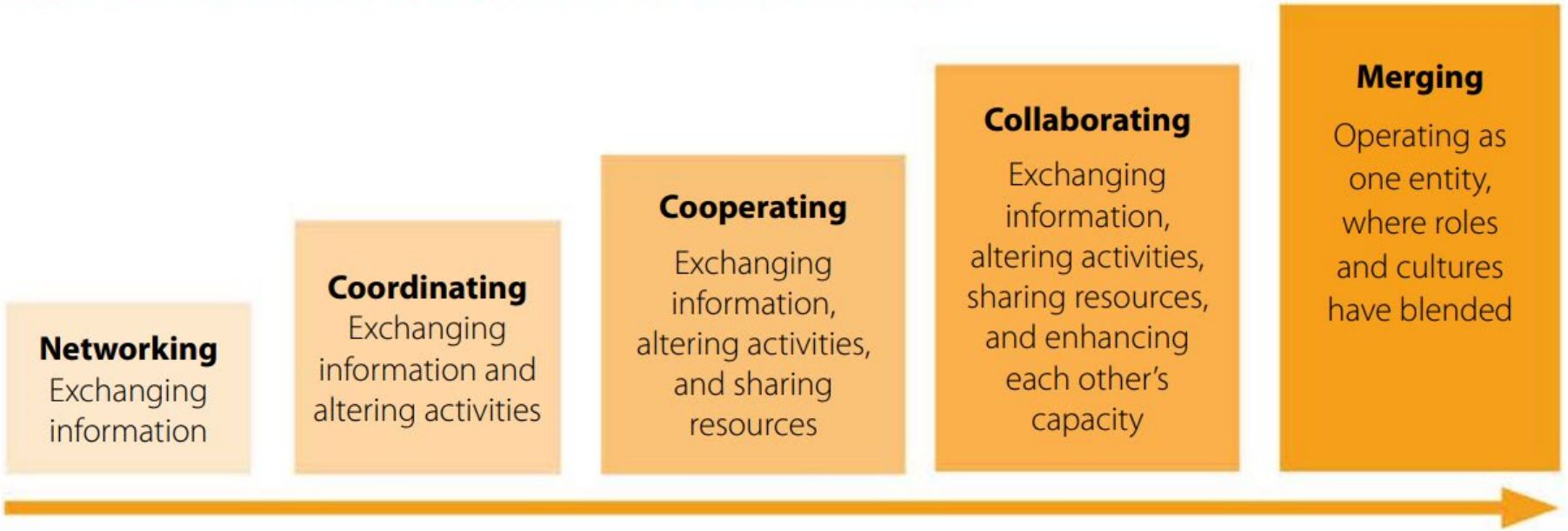
Spotlight on Success: New Mexico Community Health Representative Program Reduces Risk of Chronic Kidney Disease for Rural Zuni Indians

BENEFITS OF CHW APPROACH

- Trusted by target population
- Familiar with culture/language
- Understand sensitivities of certain health conditions
- Can leverage influence of peer/social support in health care decision making
- Familiar with local health care system
- Support community-clinical linkages, i.e., "*bridging*" function

Community-Clinical Linkages

Figure 2. Continuum of a Community-Clinical Linkage



Adapted from Himmelman AT. *Collaboration for a Change: Definitions, Decision-Making Models, Roles, and Collaboration Process Guide.*

LESSONS LEARNED & SUCCESSFUL STRATEGIES for WORKING WITH CHRS

Every bridge necessitates a solid foundation, consistent support, and sufficient resources.

- Recognize their Dual Role (*community member & provider*)
- Integrate into Local Health Care System
- Implement Concomitant System-Level Improvements
- Continuous Capacity Development

CAPACITY DEVELOPMENT RECOMMENDATIONS

- Multiple trainings, over time
- Extend beyond a unilateral, disease-specific emphasis
- Experiential learning approaches
- Language groups
- Field trips
- Survivor stories
- Student-to-teacher transition period
  - —Teach back opportunities back home
  - —Disseminate teaching materials
  - —Culturally appropriate educational materials

CHW Workshop Series Evaluation

RESULTS							
COLORECTAL HEALTH WORKSHOP PRE-POST TEST EVALUATION DATA							
Participants	Scale	Scale Items	N	Possible Range	Mean (Pre-Test)	Mean (Post-Test)	Significance
All Participants	Knowledge	15	19	0–15	8.9	11.3	.000*
	CHR Attitudes/Beliefs CRC Role (Norms/Intentions/Self-Efficacy)	19	19	0–95	77.2	83.3	.005*
	Self-Efficacy Only	11	19	0–55	43.6	47.5	.009*
Attended all 3 CRC workshops	Knowledge	15	9	0–15	9.7	11.9	.012*
	CHR Attitudes/Beliefs CRC Role (Norms/Intentions/Self-Efficacy)	19	9	0–95	79.6	88.0	.024*
	Self-Efficacy Only	11	9	0–55	45.4	50.9	.022*
Attended only 1 or 2 CRC Workshops	Knowledge	15	10	0–15	8.3	10.7	.002*
	CHR Attitudes/Beliefs CRC Role (Norms/Intentions/Self-Efficacy)	19	10	0–95	75.0	79.1	.125
	Self-Efficacy Only	11	10	0–55	41.9	44.4	.227
*p<0.05							

SESSION 1

WHAT IS

TRIBAL HOME BASED KIDNEY CARE PROJECT

PREVENTION: The project focuses on healthy ways of life that will help protect ourselves, our families and our communities from kidney disease.

HOME VISITS: Your participation will include brief home visits with a community health worker every 2 weeks scheduled at your convenience.

KNOWLEDGE: Sessions will focus on topics such as kidney function, managing blood pressure and diabetes, nutrition, tips for staying active and healthy, understanding medical tests and medications, and talking to health care providers about our kidneys.

FAMILY: We encourage any family members who are interested, to also participate in these visits.

CHECK-UPS: Every 3 months, there will also be simple blood sugar and urine tests to check your kidneys (these can be done at your home or in the clinic).

TOGETHERNESS: All community members participating in the Tribal Home Based Kidney Care project will come together for a group session four times during the year.

SHARING: Your will receive text messages from time to time to share new information and wellness tips.

HONORING: Following each quarterly group session and check-up you will receive a gift card to honor your time and commitment to this project.

WHEN FOUND EARLY,

KIDNEY DISEASE CAN BE TREATED TO SLOW ITS PROGRESSION AND PREVENT MORE SERIOUS DISEASE

KEY POINTS

- The kidney's main job is to filter blood and produce urine.
- Kidney disease, when found early, can be treated to slow its progression and prevent more serious disease and other complications.
- The goal of the Tribal Home-Based Kidney Care Project is to learn ways to help protect ourselves, our families and our communities from kidney disease.

Sources: Adapted from publically available information the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Indian Health Service and the National Kidney Foundation

TRIBAL HOME BASED KIDNEY CARE PROJECT

AN INTRODUCTION

ACTIVITY

REFLECTION:

- In your opinion, what are some healthy practices displayed in the pictures on this page?
- What teachings have been passed on to you to be well and live a healthy life?

TIME YOUR EXERCISING RIGHT!

WHEN SHOULD I EXERCISE?

Try to schedule your exercise into your normal day. Here are some ideas about when to exercise:

- Wait one hour after a large meal
- Avoid the very hot times of the day
- Morning or evening seems to be the best time for exercising
- Do not exercise less than an hour before bedtime

WHEN SHOULD I STOP EXERCISING?

- If you feel very tired
- If you are short of breath
- If you feel chest pain
- If you feel irregular or rapid heart beats
- If you feel sick to your stomach
- If you get leg cramps
- If you feel dizzy or light-headed

KEY POINTS

- Exercise is an important way to help manage your kidney disease.
- Talk with your health care provider to find the type of exercise that works best for you.
- Three days a week is the minimum requirement to achieve the benefits of your exercise.
- Be patient, don't push too hard, some exercise is better than none.

Sources: National Kidney Foundation, Inc.

TRIBAL HOME BASED KIDNEY CARE PROJECT

STAYING FIT

WITH CHRONIC KIDNEY DISEASE

Physical fitness is very important in today's world.
Everyone is enjoying the benefits of greater strength and feeling better. Exercise keeps your body strong and healthy.

Can I take part in moderate to vigorous physical activity?

Yes. People who follow an exercise program are stronger and have more energy.

How does exercise benefit me?

With exercise, it becomes easier to get around, do your necessary tasks and still have some energy left over for other activities you enjoy.

Do I need to see my doctor before starting exercise?

Yes. Before beginning any exercise program, be sure to check with your doctor.

IN ADDITION TO INCREASED ENERGY, OTHER BENEFITS FROM EXERCISE MAY INCLUDE:

- Improved muscle physical functioning
- Better blood pressure control
- Improved muscle strength
- Lowered level of blood fats (cholesterol and triglycerides)
- Better sleep
- Better control of body weight
- Reduce stress

CONTACT

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PCORI and community health workers: an agenda for transformation

Keysha Brooker, CHW MSW
Senior CHW, Certified IMPaCT Trainer
Penn Center for Community Health Workers

Shreya Kangovi, MD MS
Associate Professor and Executive Director,
Penn Center for Community Health Workers
Twitter @ShreyaKangovi

Social Determinants of Health

A new investigational agent

Clinical trials

Improved of mental health

Improved of access to primary care

Improved of quality

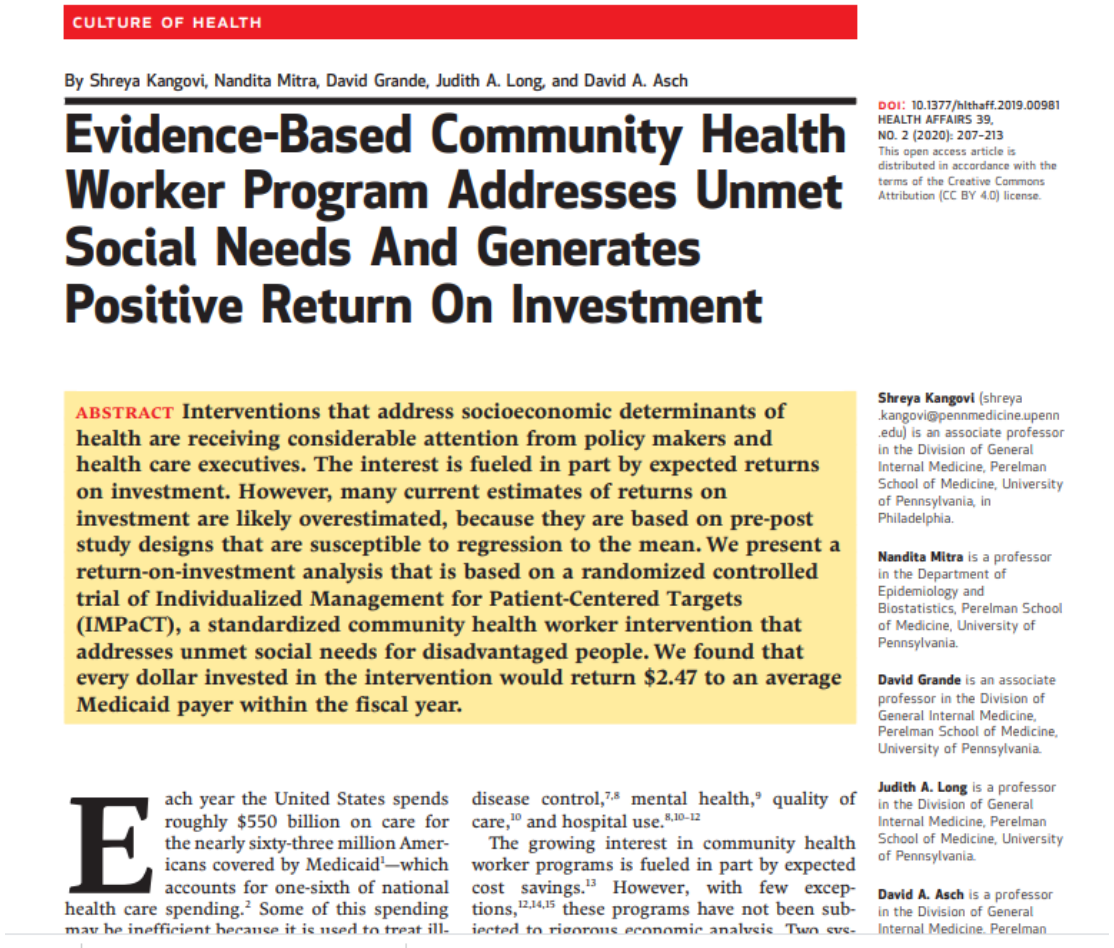
Lower
HbA1c
BMI
Smoking
Blood pressure

Reduced hospital days

AJPH A PUBLICATION OF THE AMERICAN PUBLIC HEALTH ASSOCIATION

JAMA The Journal of the American Medical Association

Savings for taxpayers



CULTURE OF HEALTH

By Shreya Kangovi, Nandita Mitra, David Grande, Judith A. Long, and David A. Asch

Evidence-Based Community Health Worker Program Addresses Unmet Social Needs And Generates Positive Return On Investment

DOI: 10.1377/hlthaff.2019.00981
HEALTH AFFAIRS 39,
NO. 2 (2020): 207–213

ABSTRACT **Interventions that address socioeconomic determinants of health are receiving considerable attention from policy makers and health care executives. The interest is fueled in part by expected returns on investment. However, many current estimates of returns on investment are likely overestimated, because they are based on pre-post study designs that are susceptible to regression to the mean. We present a return-on-investment analysis that is based on a randomized controlled trial of Individualized Management for Patient-Centered Targets (IMPaCT), a standardized community health worker intervention that addresses unmet social needs for disadvantaged people. We found that every dollar invested in the intervention would return $2.47 to an average Medicaid payer within the fiscal year.**

Shreya Kangovi (shreya.kangovi@pennmedicine.upenn.edu) is an associate professor in the Division of General Internal Medicine, Perelman School of Medicine, University of Pennsylvania, in Philadelphia.

Nandita Mitra is a professor in the Department of Epidemiology and Biostatistics, Perelman School of Medicine, University of Pennsylvania.

David Grande is an associate professor in the Division of General Internal Medicine, Perelman School of Medicine, University of Pennsylvania.

Judith A. Long is a professor in the Division of General Internal Medicine, Perelman School of Medicine, University of Pennsylvania.

David A. Asch is a professor in the Division of General Internal Medicine, Perelman

Each year the United States spends roughly $550 billion on care for the nearly sixty-three million Americans covered by Medicaid[1]—which accounts for one-sixth of national health care spending.[2] Some of this spending may be inefficient because it is used to treat ill-

disease control,[7,8] mental health,[9] quality of care,[10] and hospital use.[8,10–12]

The growing interest in community health worker programs is fueled in part by expected cost savings.[13] However, with few exceptions,[12,14,15] these programs have not been subjected to rigorous economic analysis. Two sys-

IMPaCT®

Job Announcement

COMMUNITY HEALTH WORKER

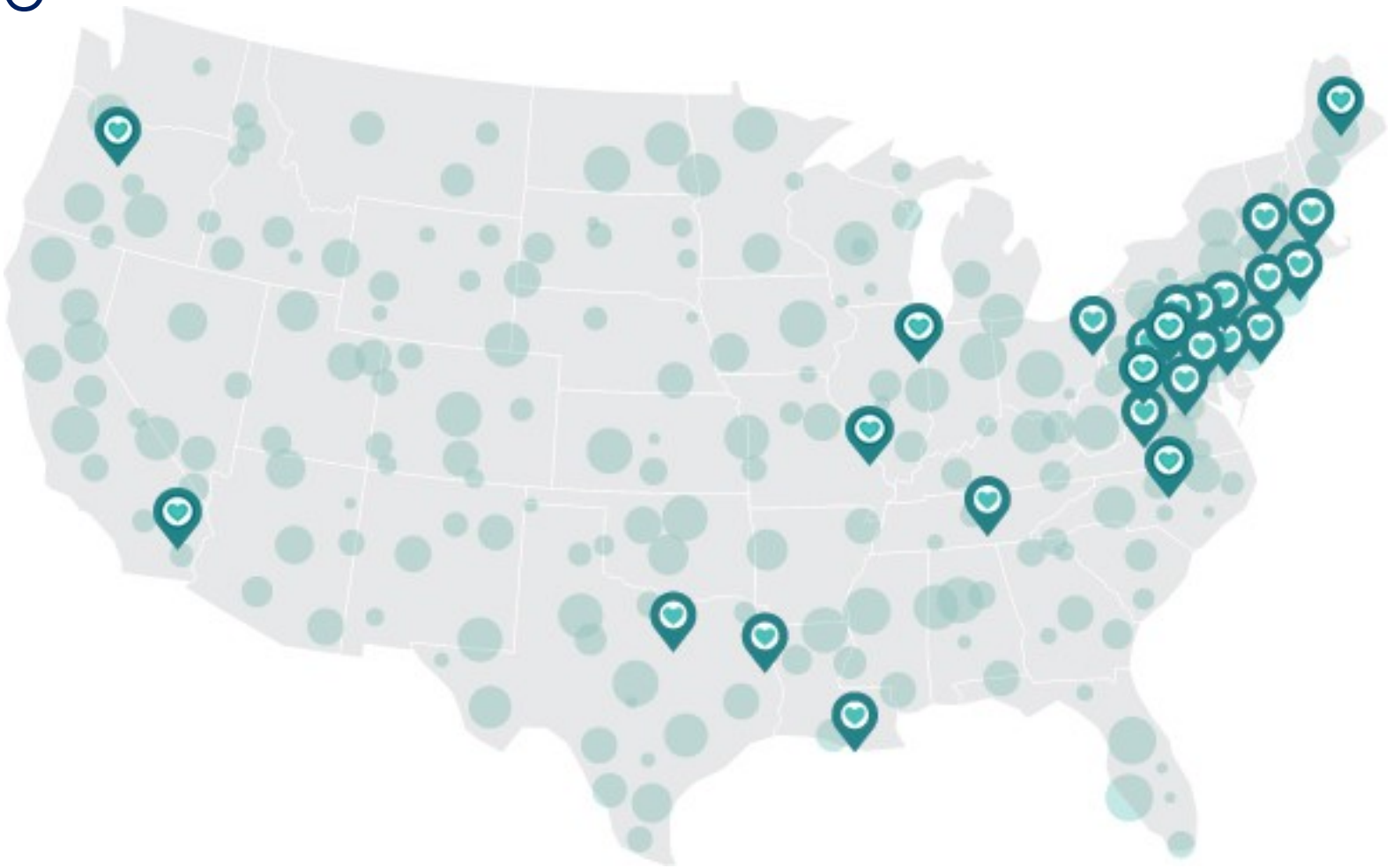
ARE YOU A TRUSTED MEMBER OF YOUR COMMUNITY?

QUALIFICATIONS

Rapid growth…
limited effectiveness

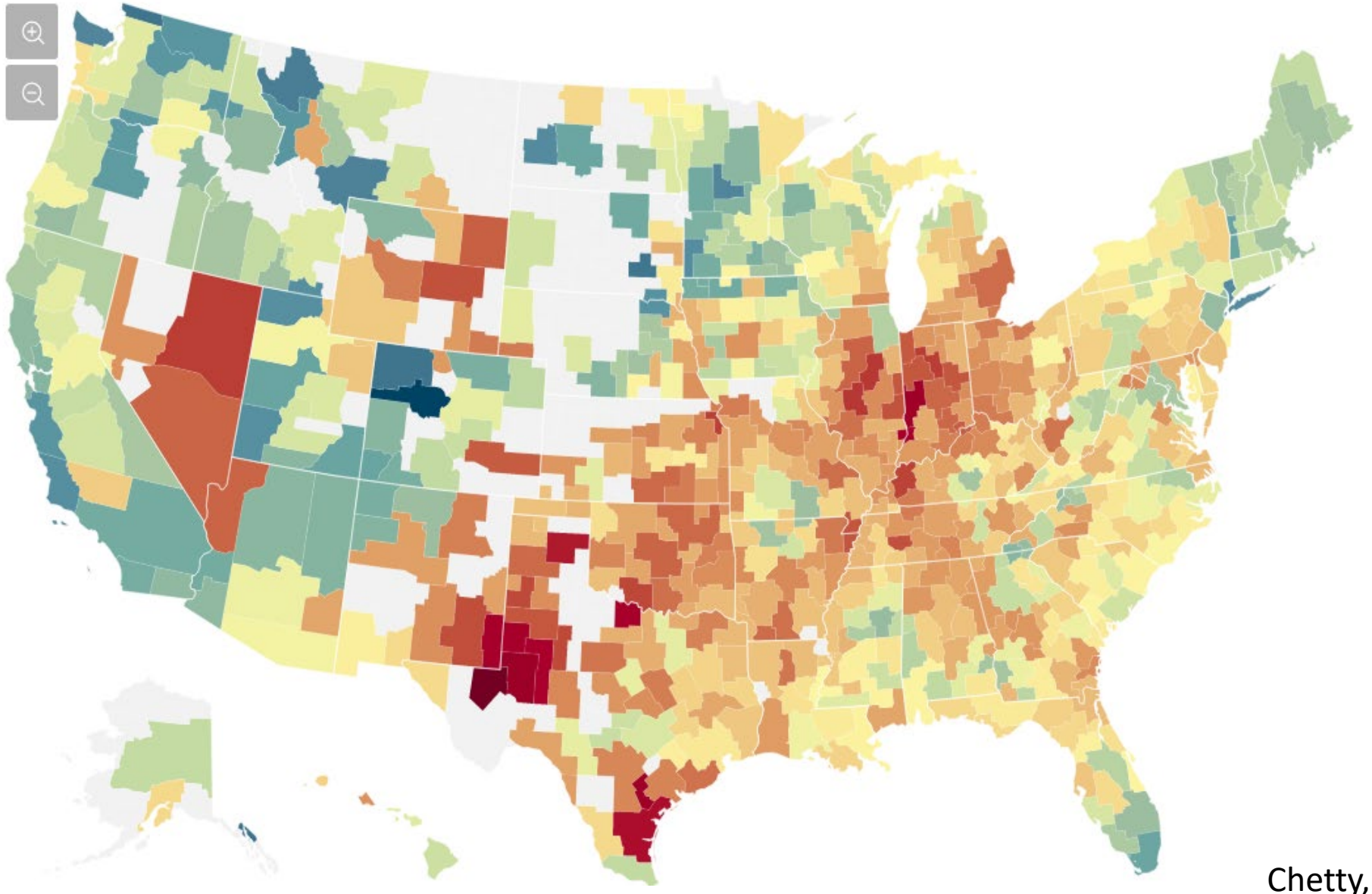
Research Practice Gap

IMPaCT around the country



PCORI-funded implementation project

- 4,625 patients
- 6 states: NY, DE, TN, VA, OR, NC
- Tailoring and hands-on technical assistance
- Fidelity, leadership, core components → What works, what doesn't

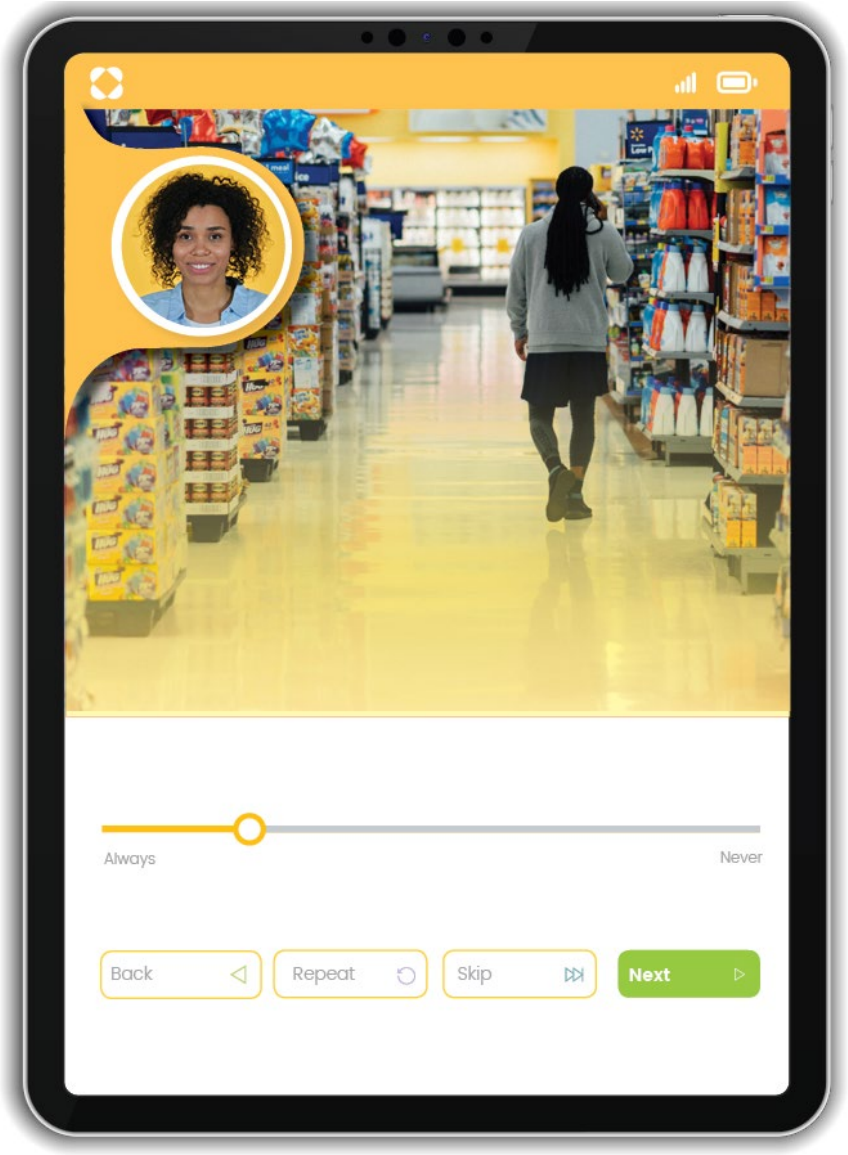


Chetty, JAMA 2016

A new pipeline

CHWs:
where does PCORI go from here

- Comparative effectiveness of different:
  - Program components
  - Policies to promote CHW adoption and quality
  - Enabling technology



Thank You!

chw.upenn.edu/

Discussion: Suggestions for Future CHW Research

- Address important public health problems, such as maternal health
- Target additional populations that experience disparities (e.g., rural, LGBTQ)
- Peer support for caregivers in the home (e.g., mothers with children who are seriously ill or have disabilities)
- Different payment and delivery models that incentivize CHWs to address social needs to improve health outcomes
- Dissemination and Implementation projects on sustainability and scalability of effective CHW interventions

Public Comment Period

Jean Slutsky, PA, MSPH

Chief Engagement and Dissemination Officer

Wrap Up and Adjournment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