PCORI Advisory Panel on Healthcare Delivery and Disparities Research

Winter 2019 Meeting

December 6, 2019

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Housekeeping

- Webinar is available to the public and being recorded
- Members of the public are invited to listen to this teleconference and view the webinar
- Meeting materials can be found on the PCORI website after the meeting
- Anyone may submit a comment through the webinar chat function, although no public comment period is scheduled
- Visit www.pcori.org/events for more information
- Statement on COIs and confidentiality

1.

Welcome and Introductions

Panel Leadership

- Nadine Barrett, PhD, MA, MS
  HDDR Advisory Panel Co-Chair

- Frank Wharam, MBCHB, MPH
  HDDR Advisory Panel Co-Chair

- Steve Clauser, PhD, MPA
  Director, Healthcare Delivery and Disparities Research Program

Returning HDDR Advisory Panel Members

- **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)
- **Cheryl Holly, EdD, MED, RN**
  Professor, Rutgers School of Nursing
- **Danielle Brooks, JD**
  Senior Consultant and Director of Patient Engagement, WiseThink Health Solutions; Founder & CEO, Bridges
- **Frank Wharam, MBCHB, MPH**
  Associate Professor, Harvard Pilgrim Health Care Institute
- **Kathy Phipps**
  Community Health Worker, Memorial Hermann Health System
- **Mary Grace Pagaduan, MPH**
  Independent Consultant, March of Dimes Foundation
- **Nadine Barrett, MA, MS, PhD**
  Director of the Office of Health Equity & Disparities, Duke Cancer Institute
- **Rachel Raia, MPH**
  Manager, Client Consulting, Blue Cross Blue Shield of Texas

*indicates panelist not in attendance

New HDDR Advisory Panel Members

- **Alicia Arbaje, PhD, MD, MPH**
  Associate Professor of Medicine and Director of Transitional Care Research, Johns Hopkins University
- **Ana Lopez, BSN, RN**
  Facing Our Risk of Cancer Empowered (FORCE)
- **Jane Kogan, PhD**
  Senior Director, University of Pittsburgh Medical Center, Center for High-Value Health Care
- **Jennifer Potter, MD**
  Professor, Beth Israel Deaconess Medical Center
- **Kathleen Kieran, MD, MSc, MME**
  Physician, Seattle Children's Hospital
- **Marissa D. Sanders, MPH, CPHRM**
  Manager, Quality Assessment, American Dental Association
- **Rainu Kaushal, MD, MPH**
  Professor of Healthcare Policy and Research, New York-Presbyterian Hospital
- **Thomas James, III, MD**
  Senior Medical Director, Highmark, Inc.
- **Xiaoduo Fan, MD**
  Associate Professor, Psychiatry, University of Massachusetts Medical School

*indicates panelist not in attendance

Healthcare Delivery and Disparities Research Staff

Steve Clauser, PhD, MPA
Program Director

Neeraj Arora, PhD
Associate Director

Els Houtsmuller, PhD
Associate Director

Penny Mohr, MA
Senior Advisor

Carly Parry, PhD, MSW
Senior Advisor

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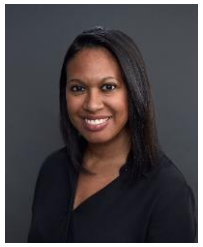
Juliette Price, MPH
Program Associate

Brendan Weintraub, MPH
Program Associate

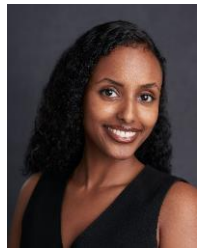
Sindhura Gummi, MPH
Sr. Program Associate



Candace Hall, MA
Program Associate

Tshema Nash, MPH
Program Associate

Aaron Shifreen
Program Associate



Metti Duressa
Program Assistant

Rachel Kotiah,
Sr. Administrative Assistant

Elizabeth Zofkie, MPH
Program Associate

Welcome New HDDR Staff

Juliette Price, MPH
Program Associate

Brendan Weintraub, MPH
Program Associate

Elizabeth Zofkie, MPH
Program Associate

2.

Agenda

Agenda

Morning

- 9:45 AM HDDR Program Updates
- 10:25 AM Break
- 10:35 AM HDDR Study Results Awardee Panel Presentations and Panel Discussion
- 12:00 PM Lunch

Agenda

Afternoon

- 1:00 PM Topic Exploration: *Maternal Morbidity and Mortality*
- 2:00 PM Break – Poster Presentations
- 2:30 PM Topic Exploration: *Suicide Prevention*
- 3:30 PM Complete Evaluations
- 3:45 PM Wrap-up

3.

Healthcare Delivery and Disparities Research Program Updates

Steve Clauser, PhD, MPA

Director, Healthcare Delivery and Disparities Research Program

HDDR Updates

- New Research Awards
- Research and Learning Networks
- In The Pipeline
- Update: Aging in Place Portfolio Analysis

New Research Awards

Current Portfolio

PCORI HAS AWARDED OVER

$925 MILLION TO FUND 220

COMPARATIVE EFFECTIVENESS STUDIES IN HEALTHCARE DELIVERY AND DISPARITIES RESEARCH.

AS OF OCTOBER 2019

Funding Mechanism	# of Projects
Broad	164
Pragmatic	20
Targeted	36

New Research Awards

Recent Awards

4 Improving Healthcare Systems Broad Awards

3 Addressing Disparities Broad Awards

*AWARDED August 2019 & November 2019

New Broad Awards:
Improving Healthcare Systems

Study Title	PI Name	Site
Innovative Care Model for Older Adults with Chronic Heart Failure(i-COACH): A Comparative Effectiveness Cinical Trial	Leanne Lefler	University of Arkansas Medical Sciences
Comparing Safety Planning + Follow-Up vs. Safety Planning Only for Suicide Prevention in EDs and Primary Care	Anna Radin	St. Luke's Health System, Idaho
Comparing Two Approaches to Care Coordination for High-Cost/High-Need Patients in Primary Care	Leif Solberg	Health Partners, Minneapolis, MN
Comparative Effectiveness of Unobserved vs In-Office Inductions for Medication Assisted Treatment	Linda Zittleman	University of Colorado Denver

New Broad Awards:
Addressing Disparities

Study Title	PI Name	Site
Comparative Effectiveness of Multi vs Single Intervention Allergen Reduction Strategies on Asthma Morbidity	Felicia Rabito	Tulane University of Louisiana
Care in the CCP Program vs. Care in the C4P Program vs. Care in Traditional Care Coordinator Program	David Meltzer	University of Chicago
Improving Communication and Healthcare Outcomes for Patients with Communication Disabilities: the INTERACT Trial	Megan Morris	University of Colorado Denver

Examining Our Portfolio

- **Recent Portfolio Presentations to the PCORI Board of Governors (BOG)**
  - Opioid Substance Use Disorder (June 18)
  - Multiple Sclerosis (July 23)
  - Mental Health (September 18)
- **Upcoming Presentations to the BOG**
  - Cancer (December 9)
- **Potential Future Presentations**
  - Community Health Workers
  - Rural Health
  - Care Transitions

Research and Learning Networks

Research and Learning Networks

- Asthma Evidence to Action Network (AE2AN)
- Transitional Care Evidence to Action Network (TCE2AN)
- Natural Experiments Network for Improved Prevention and Treatment for Patients with Type II Diabetes (NEN)
- Palliative Care Learning Network
- Telehealth Research Portfolio Synthesis Group

Telehealth Research Portfolio Synthesis Group

- PCORI hosted three telehealth webinars between March and May of this year targeting funded investigators. Topics included:
  - Addressing Disparities Through Telehealth
  - Examining Evidence Gaps in the Use of mHealth for Self-Management of Chronic Disease
  - Challenges in Addressing Large, Multi-site, Multi-state Pragmatic Trials in Telemedicine
- Manuscripts spearheaded by PCORI PIs and supported by PCORI staff are being completed in each of these three areas (anticipated completion early 2020). These will:
  - Highlight PCORI's investment in each of these sub-areas of telehealth
  - Address the unique challenges and solutions based on collective experience across several PCORI studies for #1 and #3
  - Showcase how PCORI's portfolio addresses gaps and identify future research needs for #2

Palliative Care Learning Network

- HDDR has created a learning network of nine multi-site palliative care CER studies that were funded in FY2017 for a total investment of ~$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 the projects; contribute to the field via joint presentations and publications
- 2019 Network activities:
  - Panel on challenges and opportunities in conducting large, multi-site palliative care trials: American Academy of Hospice and Palliative Medicine's (AAHPM) annual assembly, March 2019
  - PCORI funded supplement of the Journal of Palliative Medicine showcasing all nine study protocols published August 2019
  - 3rd annual in-person awardee meeting held September 2019
  - Ongoing conference calls facilitated by HDDR among investigators and project managers
- Progress of these studies will be summarized in an annual report early in 2020

Transitional Care Evidence to Action Network (TC E2AN)

- Final in-person meeting of the network September 17, 2019
- Shared results from Stakeholder Interviews with TC E2AN members
- Webinar on pragmatic trials and complex interventions (PCORI-wide webinar)
- Conducted review of evidence to date and created initial summary of findings of completed research projects—in process.
- Discussion is underway regarding a special issue highlighting the challenges of conducting this research.
- Added one study (PI: Leyenaar), focusing on transitions in ED; total of 26 studies in the portfolio

Training Programs

AHRQ/PCORI K12 Mentored Career Development Program

- 5-year, $40 million initiative
- Designed to produce the next generation of LHS researchers to conduct PCOR and implement results to improve quality of care and patient outcomes
- 11 LHS Centers of Excellence were funded (tart date: 9/30/2018)
- 45 scholars were recruited in year one, with an estimated 92 scholars to be trained over the 5-year period
- $800,000/year in total annual costs per project

In the Pipeline

Upcoming Awards

2019 Cycle 2 Broad PFA

- Addressing Disparities: Up to $8M funds available
- Improving Healthcare Systems: Up to $16M funds available
- PFA Posted: May 2019
- Awards to be Announced: **February 2020**

2019 Cycle 3 Broad PFA

- Addressing Disparities: Up to $4M funds available
- Improving Healthcare Systems: Up to $8M funds available
- PFA Posted: September 2019
- Awards to be Announced: **July 2020**

2019 PCORI Annual Meeting HDDR Highlights

Breakout Sessions. HDDR research awardees featured in several breakout sessions broadly focused on reducing burden of chronic conditions, promoting health equity, telehealth, PCOR approaches to prevention, shared decision making, improving outcomes in Medicaid patients, and implementation of research results.

Poster Presentations. Many HDDR research awardees and project partners presented posters highlighting project successes.

Pre-Meetings with Research Networks. The PCORI Transitional Care Network and the Palliative Care Learning Network awardees met in person to share updates and lessons learned.

2020 PCORI Annual Meeting: Save the Date

pcori ANNUAL MEETING

September 16-17, 2020

Crystal Gateway Marriott
Arlington, VA

Report Back
Assessment of Comparative Effectiveness Research Gaps to Promote Aging in Place

Sindhura Gummi, MPH
Senior Program Associate
Healthcare Delivery and Disparities Research Program

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Recap

- Our goal was to determine PCORI's investment in CER focused on aging in place among older adults
- We then created a conceptual framework on aging in place to guide our selection of studies for the portfolio
  - The advisory panel helped refine the framework including target populations, relevant interventions and key outcomes
- We then worked with a subset of panelists to finalize the list of studies to be included within our portfolio analysis
- We presented highlights from our portfolio at the Gerontological Society of America (GSA) on November 16th, 2019

HDDR Advisory Panel Feedback on Conceptual Model

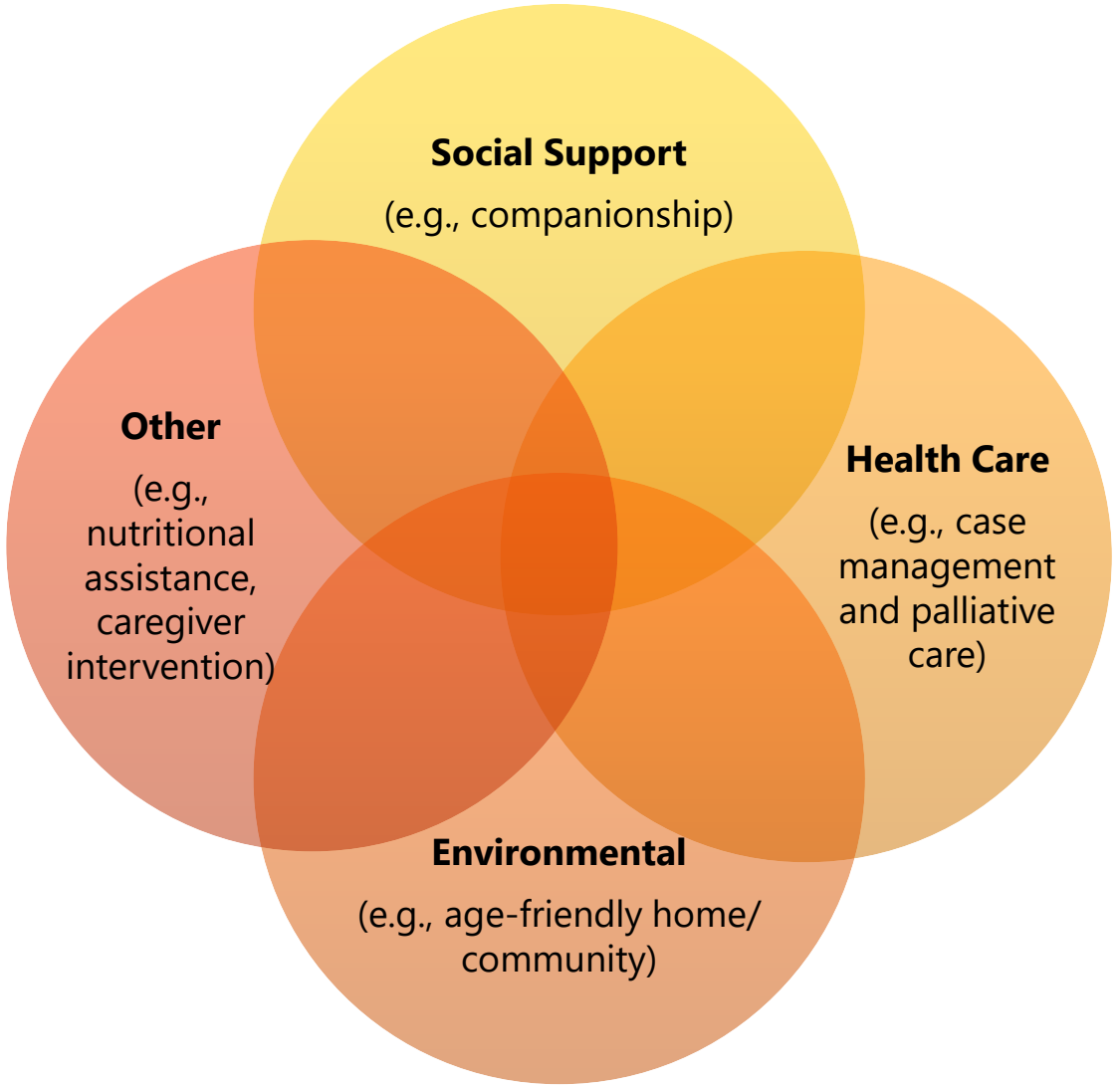
- Key themes:
  - Endorsed the importance of comparative effectiveness research focused on aging in place
  - Studies should focus on individuals 65+ years old, but should be flexible and include individuals 55+ years old who may be at risk of institutionalization
  - Interventions should be patient-centered and align with patients' needs and goals
  - Interventions go beyond environmental modifications and include social support, healthcare (inclusive of palliative care), and personal care services.
  - Interventions should include and affect caregiver outcomes (e.g., support and satisfaction)

PCORI's Aging in Place Conceptual Framework

Personal Characteristics

- Age (55+ years)
- Functional and cognitive status
- Availability of support
- Prior institutionalization
- Living arrangements (i.e., own home)
- Self-rated health status

Interventions and Services



Intermediate Outcomes

- Prevent or address functional decline
- Maintain wellbeing
- Maintain independence
- Caregiver outcomes (support and satisfaction)

Long-Term Goal

Remain in home/ community OR avoid residential care/nursing home placement

PCORI Portfolio Analysis:
Aging in Place for Older Adults

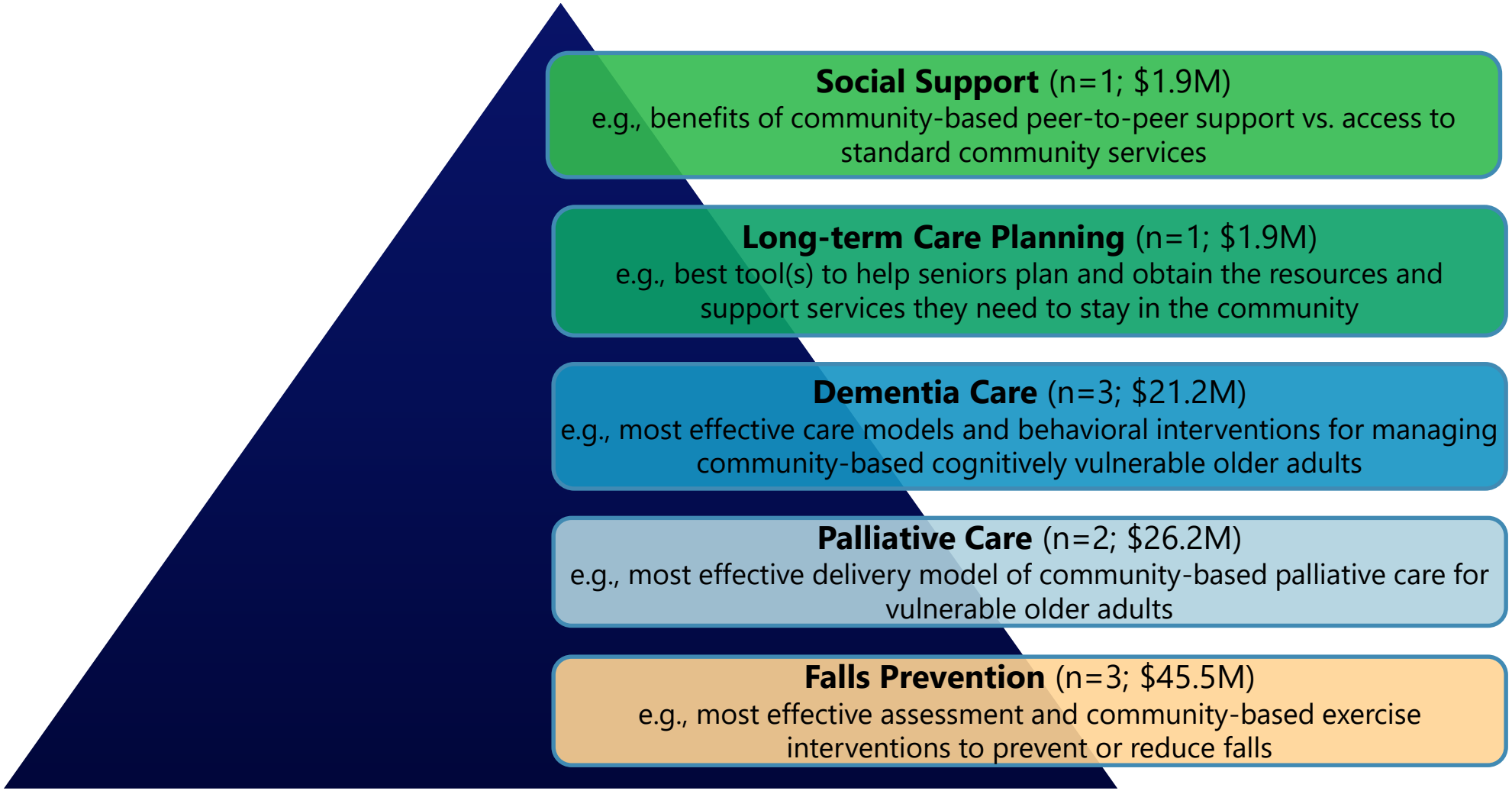
PCORI HAS AWARDED

$96.8 MILLION TO FUND **10**

COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH STUDIES RELATED TO AGING IN PLACE

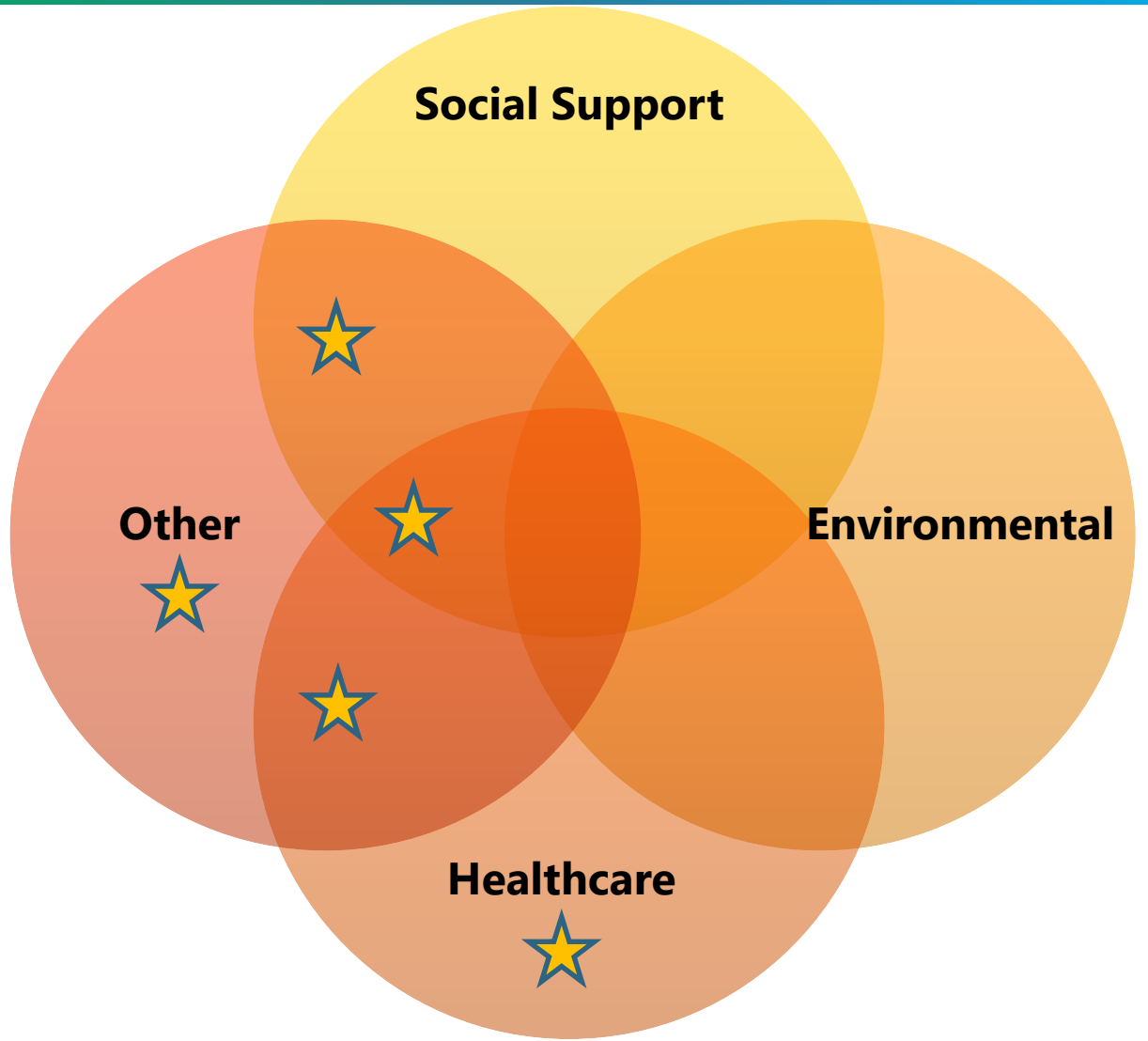
AS OF DECEMBER 2018

Topics Studied with Sample Decisional Dilemmas (N=10)

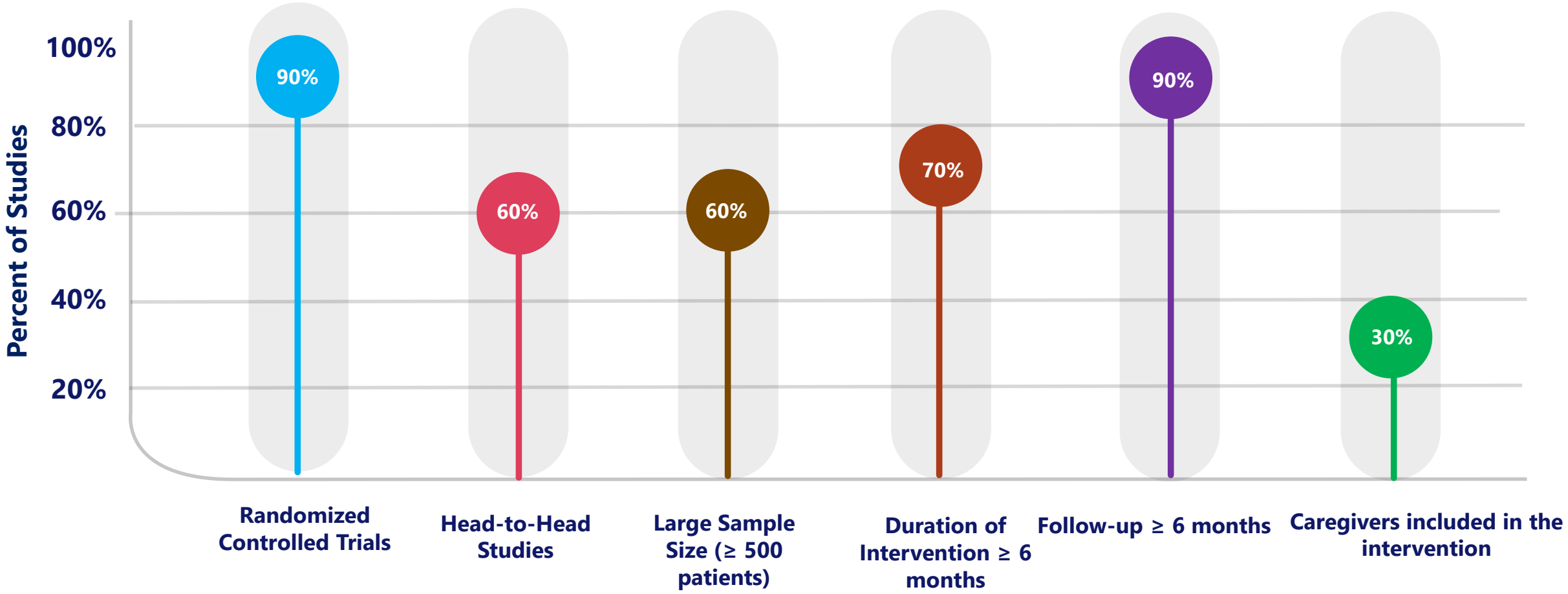


Interventions and Services Compared (n=10)

- Healthcare (n=3)
- Healthcare and Other (n=2)
- Healthcare and Social Support (n=1)
- Healthcare, Social Support, and Other (n=2)
- Social Support and Other (n=1)
- Other (n=1)



Key Portfolio CER Highlights* (N=10)



*As of November 2018

Outcomes

- Three (3) studies included a direct measure of long-term care or nursing home placement
- Most studies include some measure of function and wellbeing; many studies as a primary or secondary outcome
- Assessment of caregiver-related outcomes was limited

Summary

- PCORI has invested $208 million dollars in 10 comparative effectiveness research that will provide evidence to promote aging in place for older adults.
- PCORI's research portfolio is covering important decisional dilemmas
  - Comparative effectiveness research evidence gaps remain (i.e., environmental interventions, transportation and housing)
- There is a clear need for additional research on informal caregiver interventions and outcomes

Next Steps

- Incorporating updates to our conceptual framework
  - Policy
  - Personnel
- Continue to explore interest among the research and stakeholder community on comparative effectiveness research on the topic of aging in place
- Exploring caregiver related interventions that could be potential avenues for comparative effectiveness research

Acknowledgements

- **PCORI Staff**
  - Gyasi Moscou Jackson, PhD, MHS, RN
  - Neeraj K. Arora, PhD
  - Carly P. Khan, PhD, RN, MPH
  - Stephanie Parver, MPH, CPHQ
  - Lauren Davis
  - Steve B. Clauser, PhD, MPA

2018-2019 HDDR Advisory Panel

HDDR Advisory Panel Sub-Group

- Cheryl Holly, EdD, MED, RN
- Carmen Pace, MPA/HCA, BSN, RN
- Kathy Phipps
- Rachel Ria, MPH
- Alexis Snyder
- Nancy Yedlin, MPH

Morning Break

4.

HDDR Study Results Awardee Panel Presentations and Q&A

Awardee Panelist Presenters

A Patient-Centered Strategy for Improving Diabetes Prevention in Urban American Indians

- **Lisa Goldman-Rosas MD, PhD,** Assistant Professor, Department of Epidemiology and Population Health, Stanford School of Medicine
- **Jan J. Vasquez, MPH,** Community Based Research Coordinator, Stanford School of Medicine and Research Director, Pathways to American Indian and Alaska Native Wellness

A Comparative Effectiveness Trial of an Information Technology Enhanced Peer-Integrated Collaborative Care Intervention for US Trauma Care Systems

- **Douglas Zatzick, MD,** Professor, Department of Psychiatry and Behavioral Science, Harborview Medical Center, University of Washington School of Medicine
- **Peter W. Thomas, J.D.,** Principal, Powers Law Firm, Washington DC

Pathways to American Indian and Alaska Native Wellness: Comparative effectiveness of two approaches to diabetes prevention

Jan Vasquez, MPH; Lisa Goldman Rosas, PhD MPH

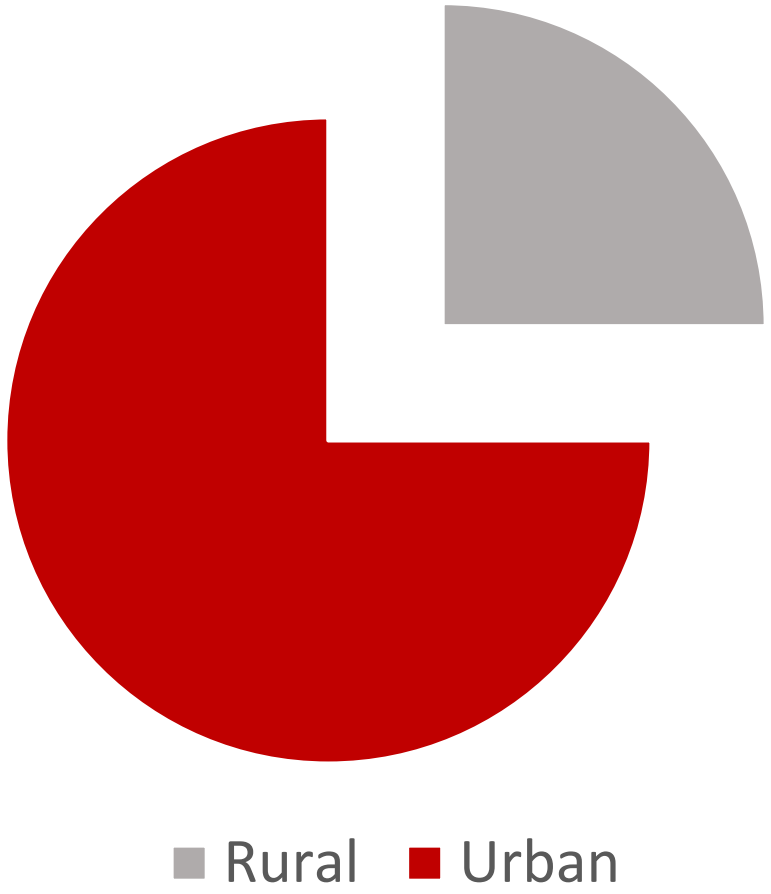
PCORI Healthcare Delivery and Disparities Advisory Panel

Washington DC, December 6, 2019

PCORI award number/project ID: AD-1306-02172
ClinicalTrials.gov registry identifying number: NCT02266576

Background

6.8 million American Indians/Alaska Natives

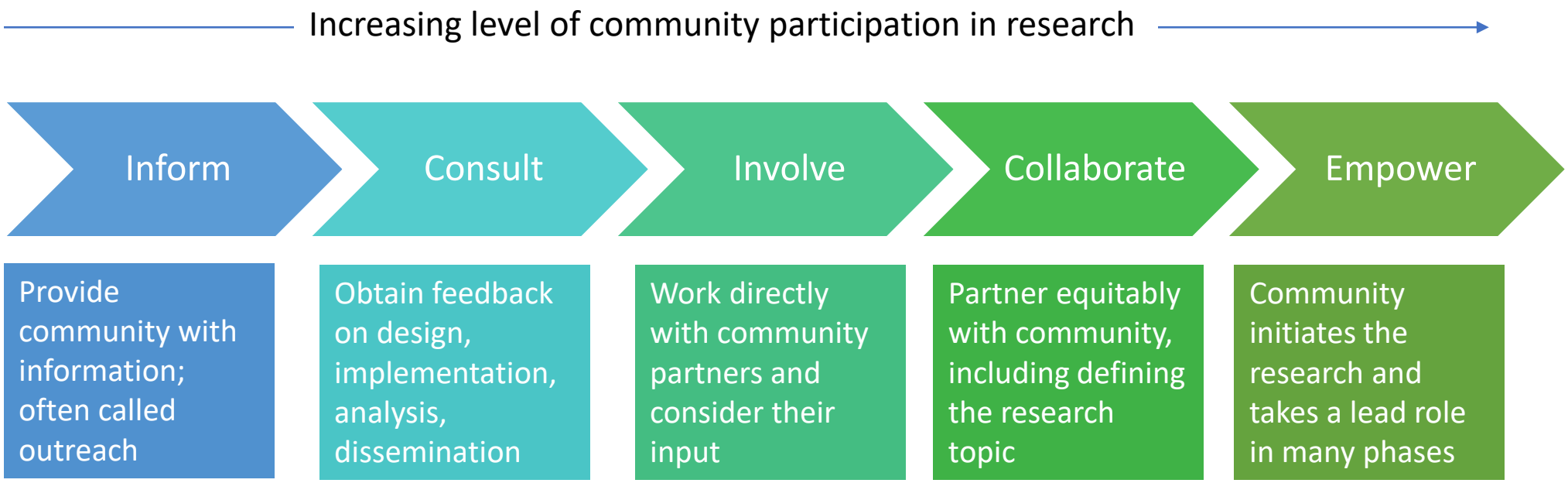


AIAN adults are twice as likely to be diagnosed with diabetes compared to non-Hispanic whites

+

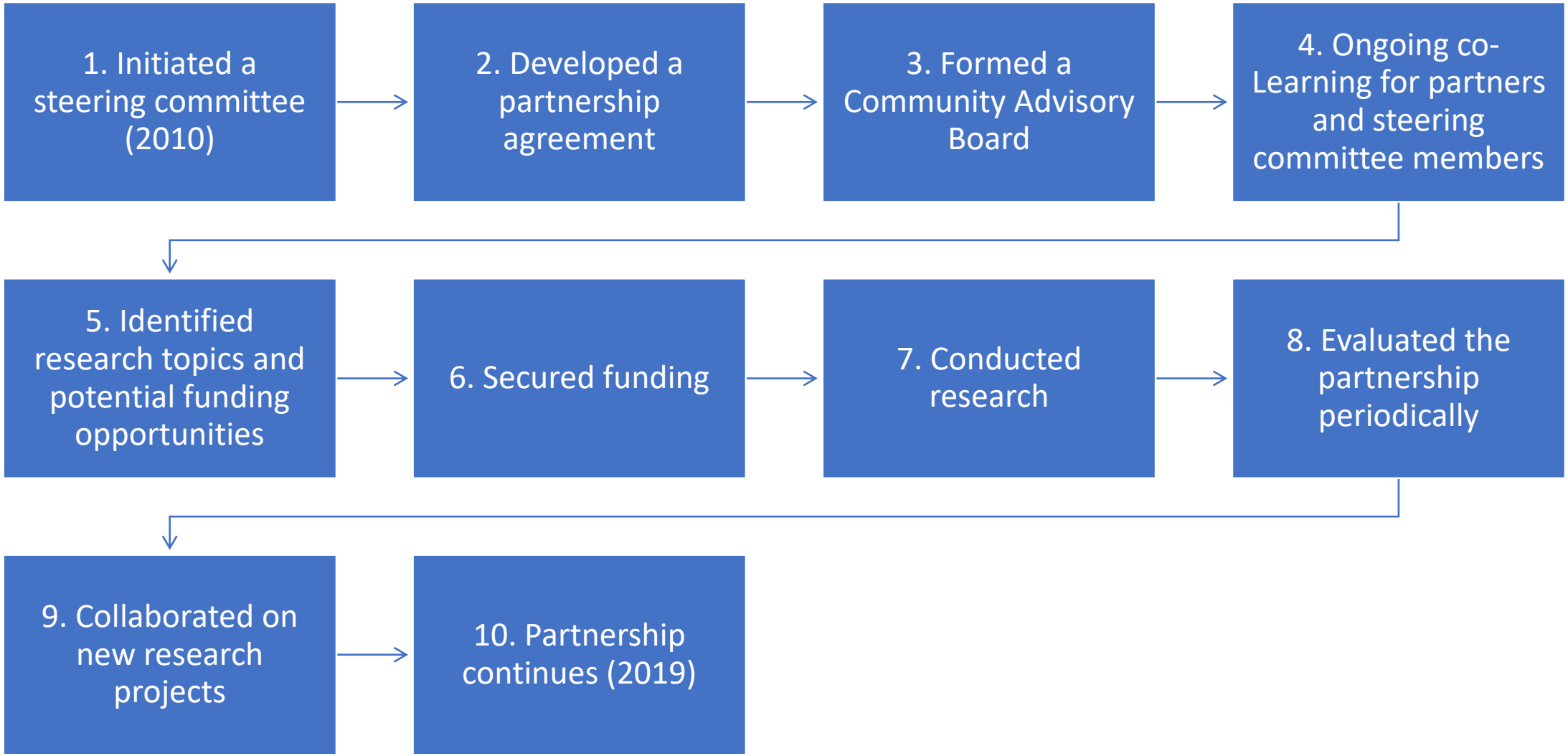
Historical trauma identified by the community as leading to diabetes and hindering prevention efforts

Background: Spectrum of engagement



Adapted from CDC, Principles of community engagement, 2nd ed. 2011

Formation of a partnership between Stanford & Pathways to American Indian and Alaska Native Wellness (PAAW)



American Indian Community Action Board

2014

2019

Patient/stakeholder engagement

Comparative effectiveness trial design

204 adults:

- Self-identified indigenous to the Americas
- BMI 30+
- +1 non-weight related criteria of metabolic syndrome

Standard DPP

Enhanced DPP

- Follow-up of 12 months
- Dual outcomes: BMI, quality of life (SF-12)

Rosas LG, Vasquez JJ, Naderi R, Jeffery N, Hedlin H, Qin F, LaFromboise T, Megginson N, Pasqua C, Flores O, McClinton-Brown R, Evans J, Stafford RS. Contemporary Clinical Trials. 2016

Enhanced DPP

- 16 week behavioral lifestyle intervention + enhancements:
  - Talking circles
  - Photovoice
  - Digital storytelling
  - Mental health support

Recruitment

Referred via outreach (n=1,326)

Nonresponsive (n=237); not interested (n=158); not contacted due to meeting target (n=23)

Initial screening (n=908)

Refused clinical screening (n=122); ineligible (n=257); eligible but not interested (n=133); MD review pending (n=46)

Clinical screening (n=35)

Ineligible (n=72); No show (n=40); Eligible but not interested (n=8); MD review pending (n=17)

Baseline visit (n=213)

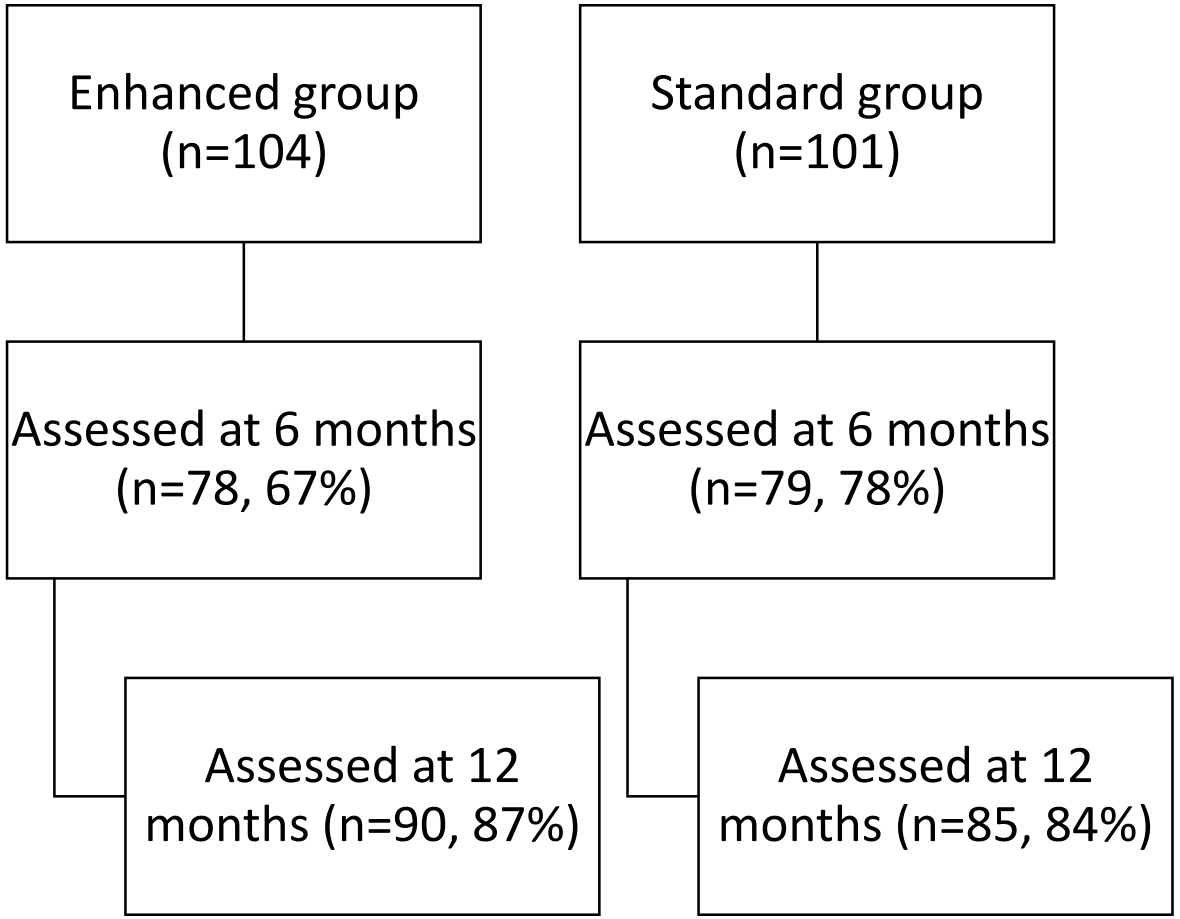
Eligible but not interested (n=6)

Randomized (n=207)

Excluded due to safety concern (n=2)

Retention


TIMPANY CENTER
SAN JOSÉ STATE UNIVERSITY
730 EMPEY WAY


Enhanced group (n=104)
Standard group (n=101)
Assessed at 6 months (n=78, 67%)
Assessed at 6 months (n=79, 78%)
Assessed at 12 months (n=90, 87%)
Assessed at 12 months (n=85, 84%)

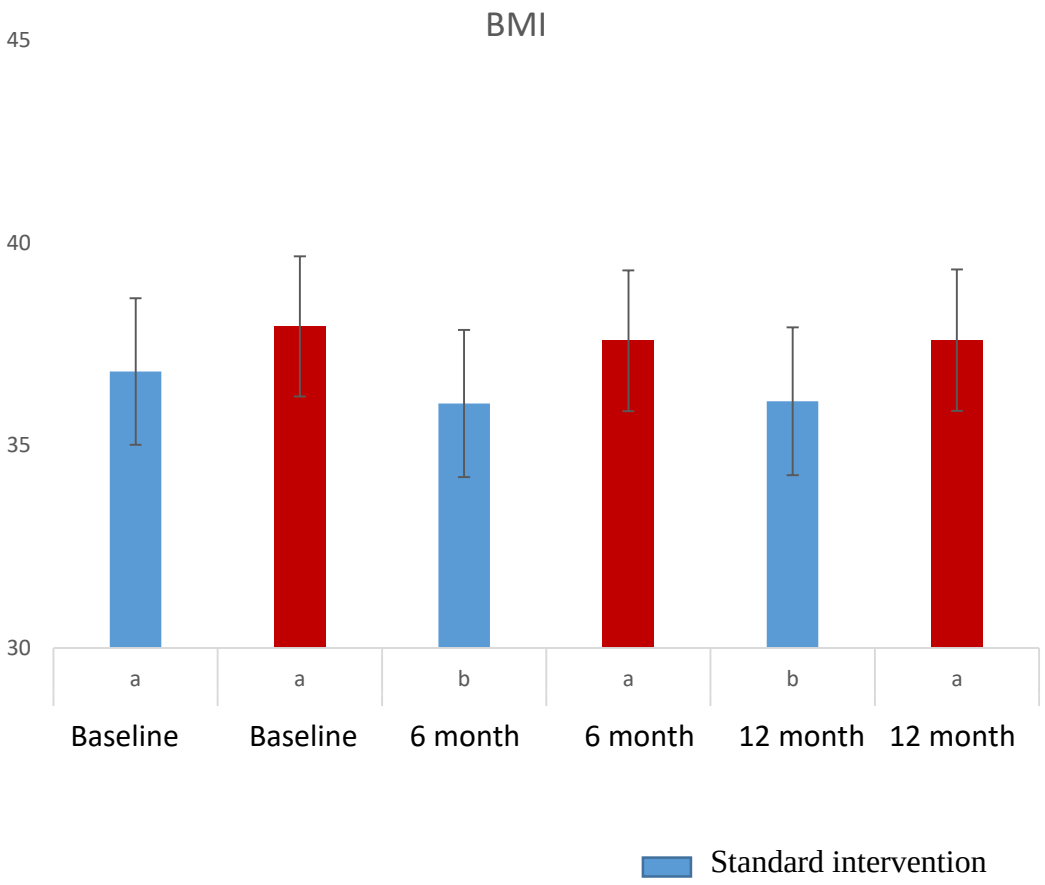
Baseline characteristics: Demographics

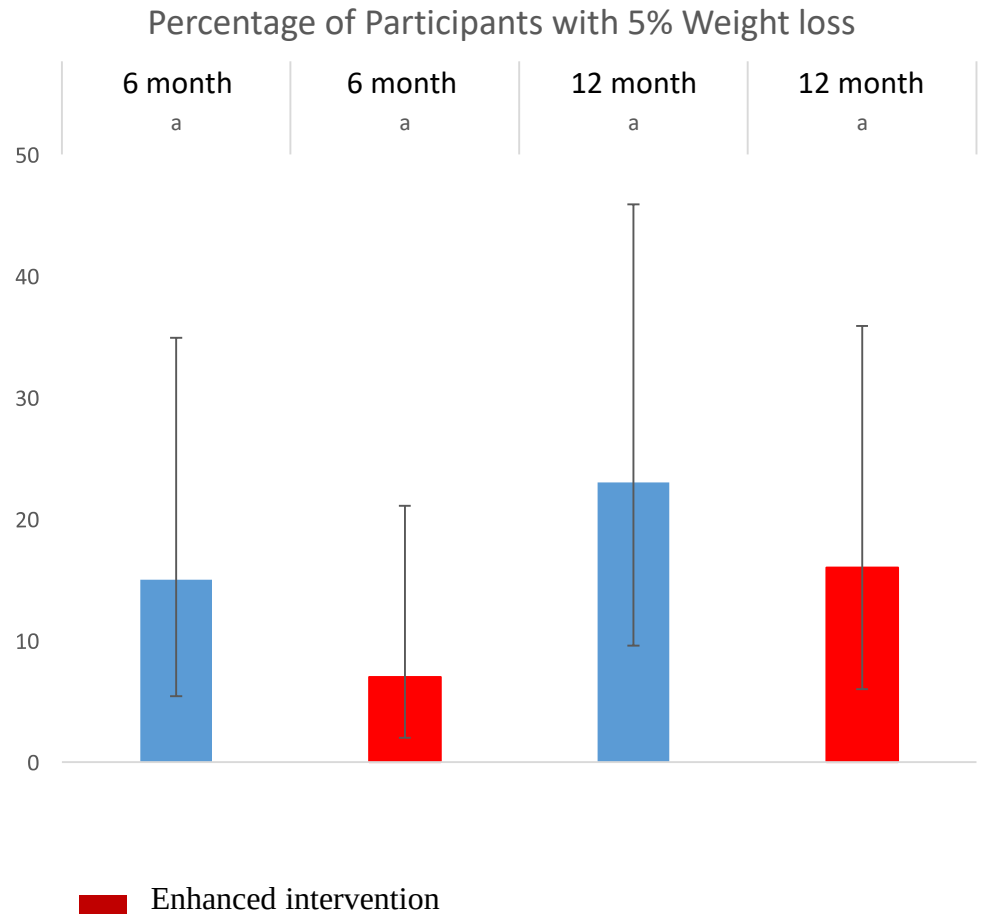
Characteristic	Overall	Enhanced	Standard
	N=207	N=105	N=102
Age, years (mean, SD)	52.1± 13.3	52.1± 13.8	51.9 ±12.8
Female (%)	79	79	78
Race/ethnicity (%)			
Indigenous from US/Canada	45	50	41
Indigenous from Latin America	30	29	31
Multi-race	25	22	27
Latino (%)	54	54	53
Education (%)			
< high school	13	16	11
High school	21	19	23
Some college	44	45	43
College	13	11	14
> College	9	9	10
Food insecure (%)	42	39	44

Baseline characteristics: Clinical and behavioral

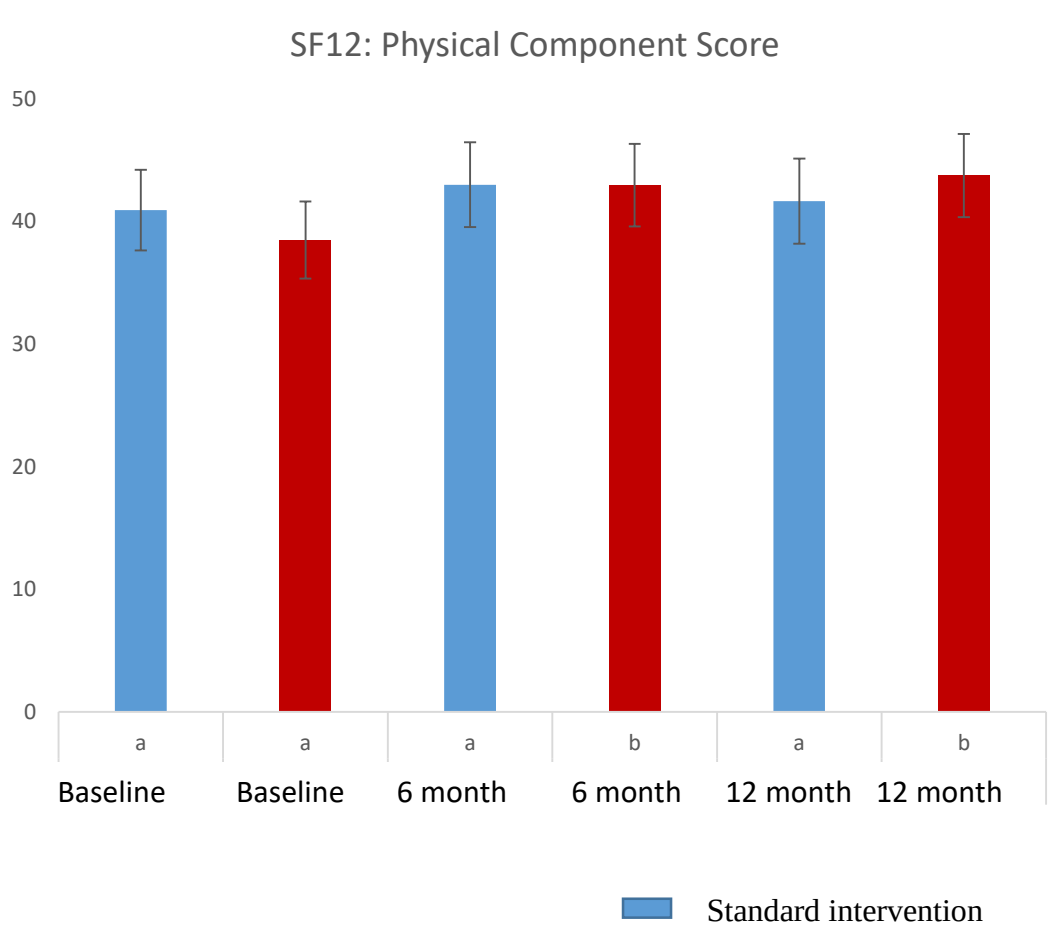
Characteristic	Overall	Enhanced	Standard
	N=207	N=105	N=102
BMI (mean, SD)	37.3 ±6.2	37.7± 6.7	36.9± 5.6
Fasting glucose (mean, SD)	100.7±10.7	101.2±10.9	100.1±10.5
Depression (% CESD>16)	34	31	37
Hazardous drinking (%)	14	12	15
Healthy food tertiles (%)			
1	36	34	37
2	44	45	42
3	21	21	21
Physical activity (%)			
< 500 MET-mins/week	52	54	50
500-1000 MET-mins/week	20	19	21
> 1000 MET-mins/week	28	27	29

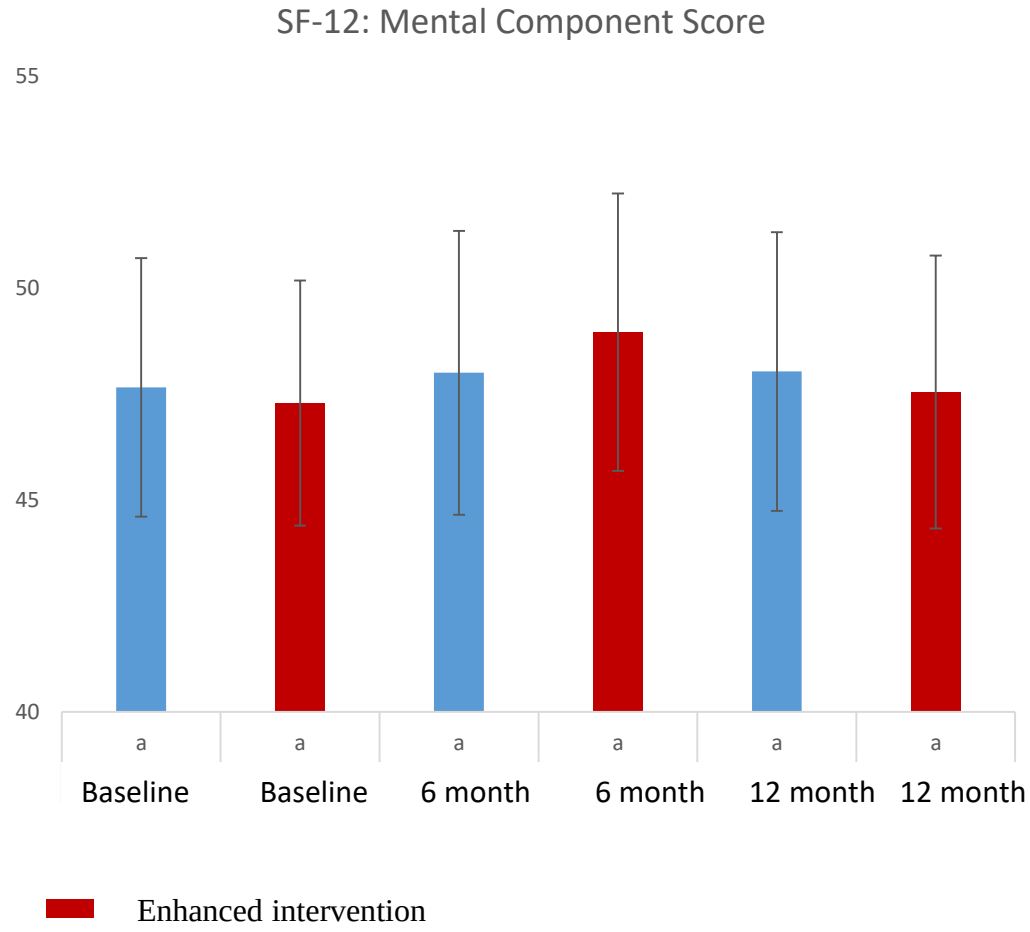
Primary outcomes: Weight





Primary outcomes: Quality of life

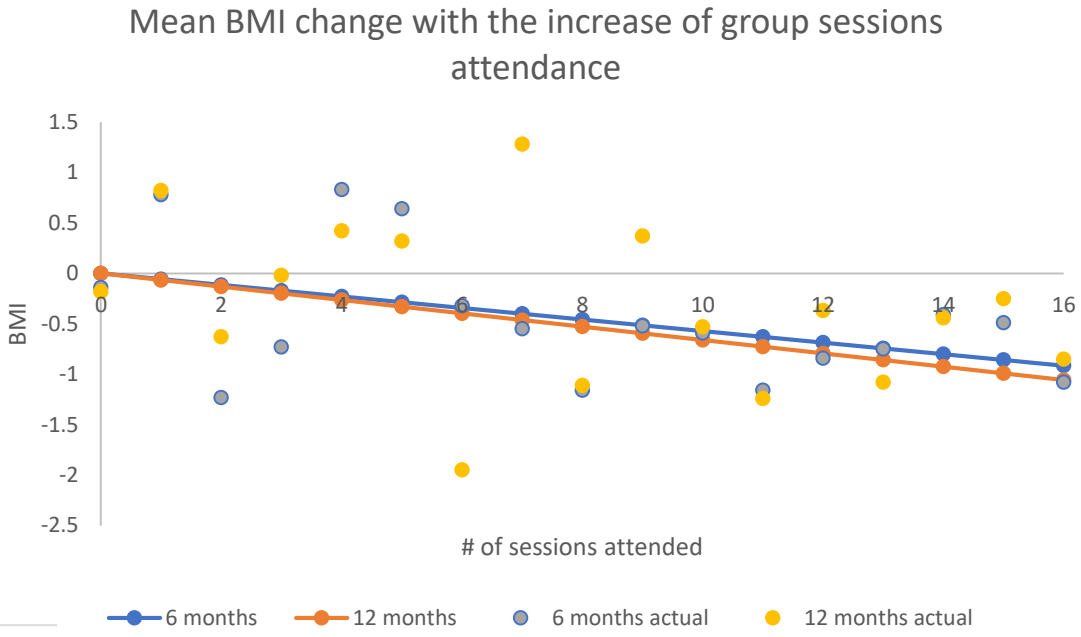


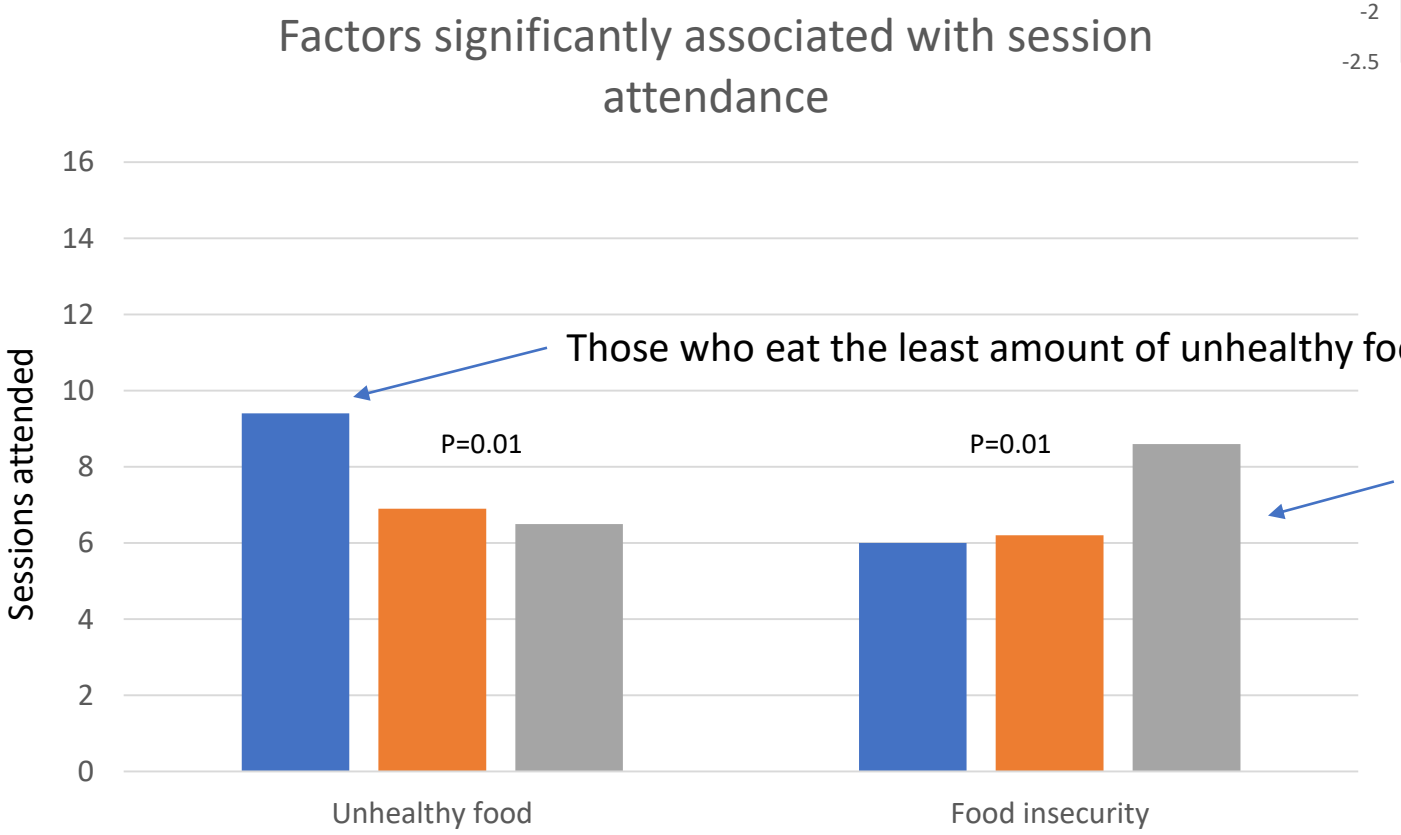


Standard intervention

Enhanced intervention

Session attendance





Those who eat the least amount of unhealthy food at baseline attend the most sessions

Those who are food secure attend the most sessions

Lessons learned: clinical trial

- Enhanced intervention was not superior to standard intervention:
  - Weight loss was similar as in other racial/ethnic minority groups
  - Historical trauma may not be important for diabetes prevention above other factors
  - Participation in the ‘enhancements’ was low

- Successes of both arms included:
  - Addressing social determinants like transportation was important
  - Offering a welcoming space for physical activity
  - Group setting and trained facilitator were key

Evaluation methods

- Adapted a tool developed by Schultz et al. 2002 that assesses each members' views on:
  - Purpose of the partnership
  - Group dynamics and characteristics (leadership and participation, expressing opinions, addressing conflict, decision making, problem solving, trust, organization)
  - Intermediate measures of partnership effectiveness (accomplishments and impact, satisfaction, group cohesion, empowerment)
- Stanford Office of Community Engagement staff:
  - Conducted key-informant interviews with each member of the American Indian Community Action Board and the research team (20-30 mins each)
  - Summarized key findings
  - Presented findings back to group
  - Facilitated discussion on how to evolve based on
- Conducted evaluations in 2012, 2015, and 2018
- Findings from each evaluation are summarized according to:
  - Members' views on the purpose of the partnership
  - Other key findings
  - How the partnership evolved as a result of the evaluation

Evaluation #1 (2012)

- **Purpose of American Indian Community Action Board:**
  - Integrate the diverse cultures and histories of American Indian groups in Santa Clara County in health-related research
  - Understand why previous experiences with academia were perceived as negative
  - Appreciate American Indian attitudes and perceptions around diabetes prevention
- **Key Findings:**
  - Board members expressed desire for more of a voice in determining agenda items for meetings
  - Stanford provided key resources and facilitation to support the partnership
  - Overlapping goals promoted synergy for the partnership
  - Co-learning was key for success
  - Focusing on urban American Indian culture should set the foundation for all core activities
- **Results of evaluation:**
  - Developed protocol to include board members' contributions to meeting agendas
  - Continued co-learning activities at every meeting
  - Planned community events to promote the partnership in the community

Evaluation #2 (2015)

- **Purpose of American Indian Community Action Board:**
  - To guide research for our American Indian community
  - Studying how diabetes impacts our community
  - A voice for American Indians
  - Improving the health of American Indians
- **Key Findings:**
  - Group cohesion was high
  - Desired greater emphasis on spirituality/culture (spirituality, traditional food education)
  - Noted lack of transparency in decision making
  - Favored greater focus on social determinants of health
- **Results of evaluation:**
  - Established meeting structure that incorporated spirituality and culture
  - Shared clinical trial budget with steering committee to increase transparency
  - Incorporated multiple strategies to address social determinants during the clinical trial

Evaluation #3 (2018)

- **Purpose of American Indian Community Action Board:**
  - Focus attention on health issues that are important and relevant to the community at large
  - Respect and integrate American Indian culture and rituals into meetings
  - Deliberate, debate, and work to determine future directions

Key Findings:

- Enjoyed spending time with each other, trust each other, and are comfortable freely sharing their opinions
- A high level of trust exists between Board members and Stanford research staff
- Not clear on how to best leverage this academic partnership for collaboration on new projects and/or community activities
- Helps members feel more connected to San Jose and to local diverse Native communities
- Enjoy and appreciate diversity of Native history, culture, among the different tribes residing in the Santa Clara Valley

Evolution of Partnership:

- Increased opportunities for socialization between PAAW members and Stanford researchers
- Took on increasingly complex research topics
- Continue to integrate American Indian culture and tradition into meetings

Lessons Learned: Partnership evaluation

- Provided an opportunity to systematically assess members' views of the partnership
- Critical for achieving balance of power
- Having an external (yet known) group conduct the evaluation facilitated benefits
- Can be strategically times for key partnership inflection points (initiating, collaborating/sustaining, maintaining)

TC E2AN Transitional Care Evidence to Action Network

pcori

Trauma Survivors Outcomes & Support (TSOS) PCORI Studies: Harnessing Stakeholder Driven Science & the E2AN to Impact National Acute Care Policy

Doug Zatzick, MD & Peter Thomas, JD

Trauma Survivors Outcomes & Support (TSOS) Co-Principal Investigators

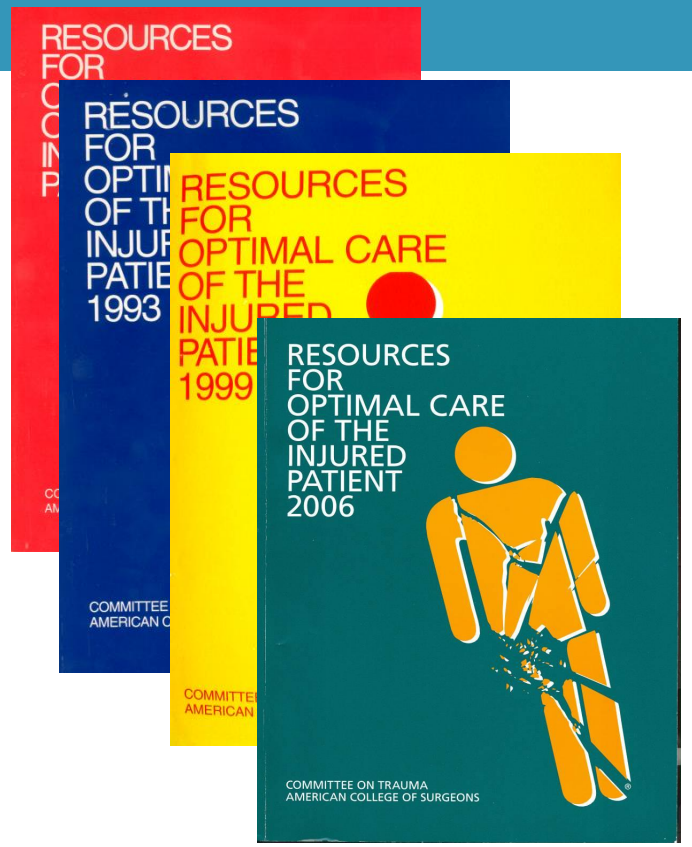
Supported by PCORI Contracts IH-1304-6319 & IHS-2017C1-6151

Overview: Two Decades of Scientific & Policy Related Work on Patient-Centered Care Transitions for US Trauma Care Systems

- 2001-2010 Patient-centered psychometric concerns assessment
- 2011 1st ACS/COT policy summit, no PCORI
- 2013-2016 TSOS PCORI Trial 1.0 within E2AN
- 2016 2nd ACS/COT policy Summit, with PCORI
- 2018-TSOS PCORI 2.0
- 2019 ACS/COT patient-centered care transitions policy statement: CER data is key and so is dissemination and implementation context

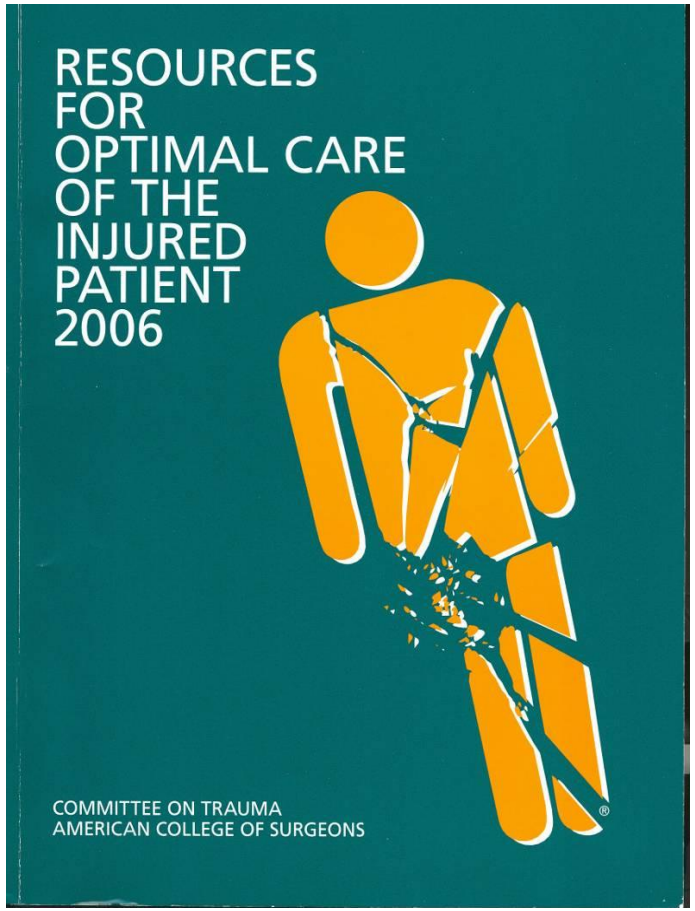
TSOS PCORI Timeline

American College of Surgeons
Committee on Trauma "Make it Happen"
Regulatory Policy



- Literature reviewed and expert opinion obtained
- Requirements developed
- Verification site visits by College ensure requirements are implemented
- Resource guide updated regularly

May 2011 Policy Summit & Patient Voice



- Comparative effectiveness trial data driven
- Universal Alcohol Mandate
- PTSD Guidelines Introduced
- No Patient-centered data: No policy statement

TSOS PCORI Study 1.0 Hypotheses

- Injured patients who have the opportunity to engage in a continuing helping relationship that addresses their posttraumatic concerns will demonstrate reduction in the number and severity of concerns as well as improvements in PTSD, depression and physical function when compared to patients who receive usual care

Posttraumatic Concerns

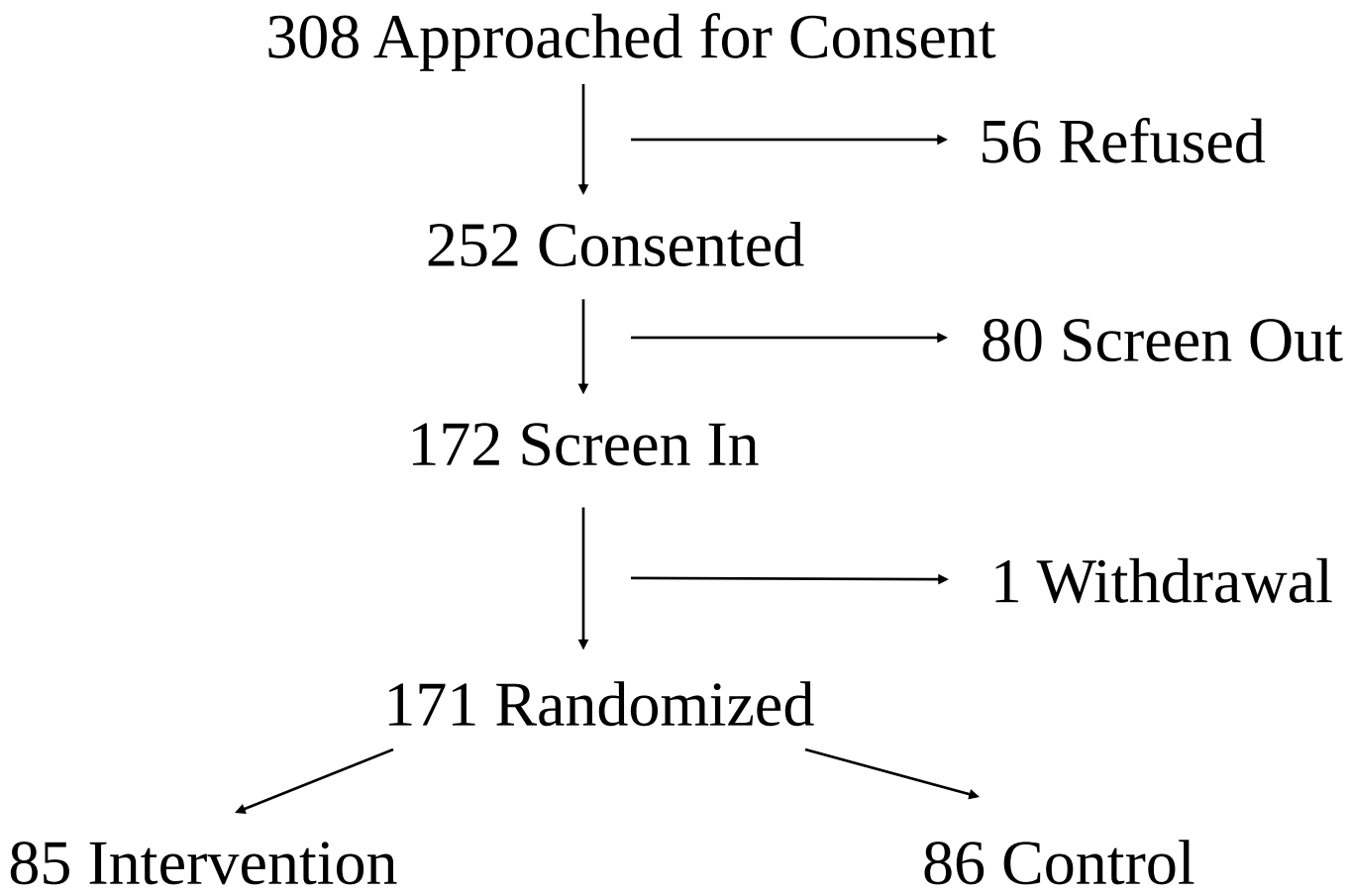
- Population-based sampling
- “Of all the things that have happened to you since your injury what concerns you the most?”
- “On a scale of 1-5, 1 is not at all concerned and 5 is very concerning. How concerning is this to you?”

Ms. A

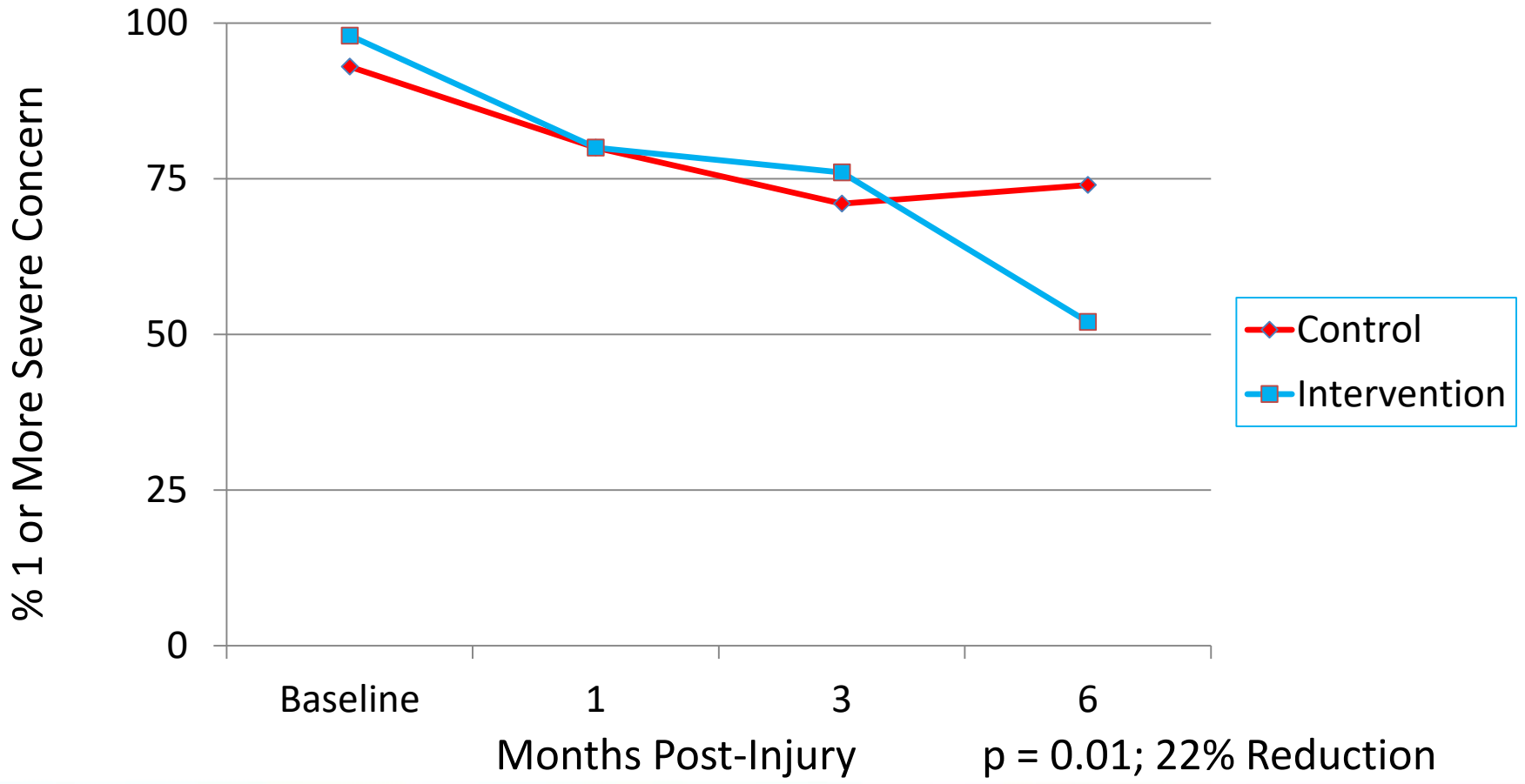
- “What is my biggest concern? The number of surgeries I still have to have. I am pretty concerned about going into the operating room again and again.”

- Concern Severity: “I would say a 5. And the ability for them to actually fix it, I am worried that I am going to have ongoing problems.”

Patient Flow

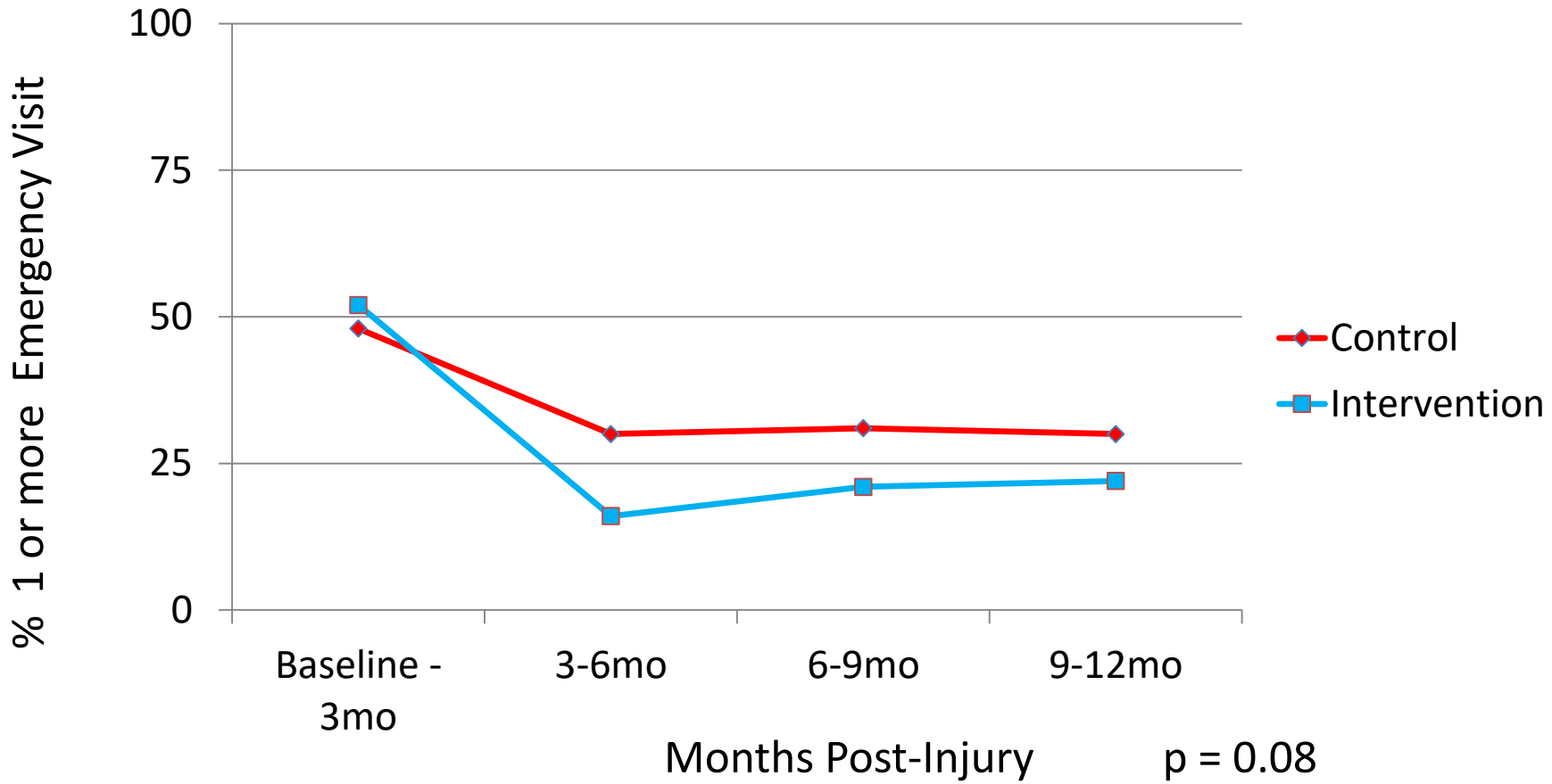


Results: Percent One or More Severe Concern (N = 171)



p = 0.01; 22% Reduction

Results: One or More Emergency Department Visit (N = 171)



Results: Clinically and Statistically Significant Intervention Effects

- Patient posttraumatic concerns
- Population-level emergency department utilization

Results: No Significant Intervention Effects

- PTSD
- Depression
- Suicide
- Alcohol use problems
- Drug use problems
- Physical function

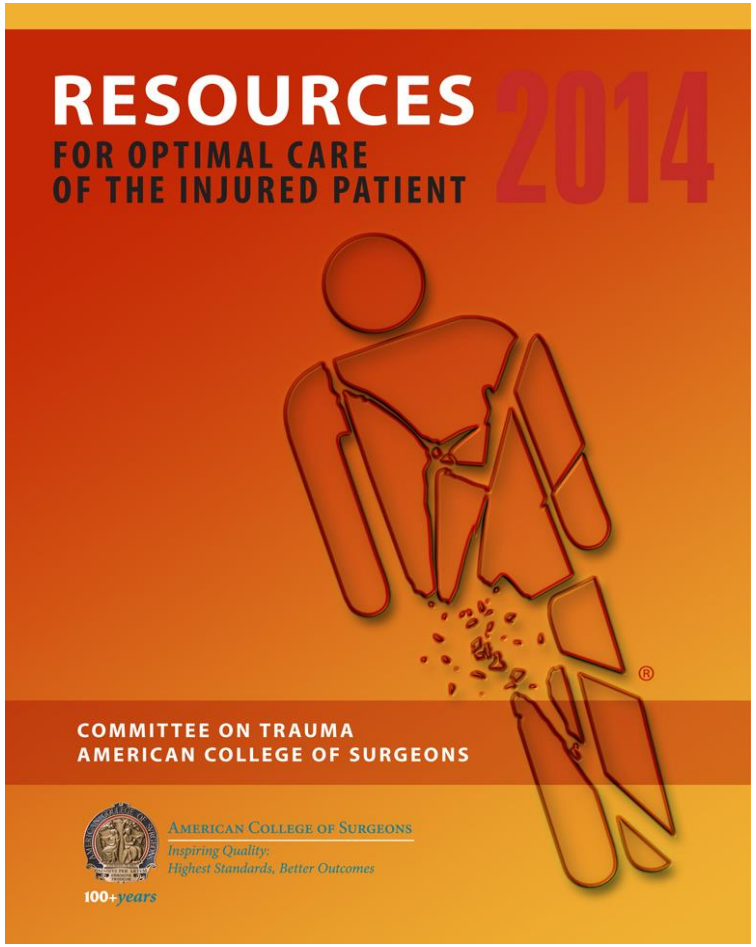
TSOS PCORI Project 2.0

- Comparative Effectiveness Trial
- 424 Patients Randomized
- Two Arms
  - Trauma team notification of distress / mental health consult
  - Peer-integrated collaborative care intervention / IT enhanced
    - Peer meets injured patients by bedside & provides care transition
    - IT enhancements include care plans and alerts in EHR linked ED records
- Outcomes
  - EDIE emergency department utilization primary outcome
  - Patient concern severity
  - PTSD symptoms & functional recovery

TSOS PCORI Project 2.0

- Patient Co-PI leads stakeholder group
- First call January 2018
  - Stakeholder input on consent form, baseline & 12 month follow-up interviews
- Phase I: Generation of peer intervention model
  - American Trauma Society peer program
  - Study team innovations such as peer recruitment after intervention completion
- Phase II: Peer case presentations to Patient Co-PI & other patient stakeholders during monthly calls

September 2016 Policy Summit: It Takes a Network…



- PCORI included summit
- Summit was not removed as PCORI D & I approaches evolved
- Again data driven
- Patient-centered care focus
- 3 clinical trials reviewed
- Patients led off discussion

PCORI E2AN Published Comparative Effectiveness Trials: Mixed Results

Effects of Peer Mentoring on Self-Efficacy and Hospital Readmission After Inpatient Rehabilitation of Individuals With Spinal Cord Injury: A Randomized Controlled Trial

Julie Gassaway, MS, RN, Michael L. Jones, PhD, FACRM, W. Mark Sweatman, PhD, Minna Hong, BS, Peter Anziano, Karen DeVault

From the Virginia C. Crawford Research Institute, Shepherd Center, Atlanta, GA.

Abstract

Objective: To investigate the effect of intensive peer mentoring on patient-reported outcomes of self-efficacy and unplanned hospital readmissions for persons with spinal cord injury/disease (SCI/D) within the first 6 months after discharge from inpatient rehabilitation.

Design: Randomized controlled trial.

Setting: Nonprofit inpatient rehabilitation hospital specializing in care of persons with SCI/D and brain injury.

Participants: Patients (N=158) admitted to the SCI/D rehabilitation program whose discharge location was a community setting. Participants (51% with paraplegia and 49% with tetraplegia) were 73% white and 77% men, with a mean age of 38 years.

Interventions: Participants in the experimental group received initial consult/introduction with a peer support program liaison and were assigned a peer mentor, who met with the participant weekly throughout the inpatient stay and made weekly contact by phone, e-mail, or in person for 90 days postdischarge. Participants also were encouraged to participate in regularly scheduled peer support activities. Nonexperimental group participants were introduced to peer support and provided services only on request.

Main Outcome Measures: General Self-efficacy Scale (adapted to SCI/D), project-developed community integration self-efficacy scale, and patient-reported unplanned rehospitalizations.

Results: Growth rate for self-efficacy in the first 6 months postdischarge was significantly higher for experimental group participants than nonexperimental group participants. Experimental group participants also had significantly fewer unplanned hospital days.

Conclusions: This study provides evidence that individuals receiving intensive peer mentoring during and after rehabilitation for SCI/D demonstrate greater gains in self-efficacy over time and have fewer days of unplanned rehospitalization in the first 180 days postdischarge. More research is needed to examine the long-term effects of this intervention on health care utilization and the relation between improved health and patient-reported quality of life outcomes.

Archives of Physical Medicine and Rehabilitation 2017;98:1526-34

Patient-Centered Care Transitions After Injury Hospitalization: A Comparative Effectiveness Trial

Douglas Zatzick, Joan Russo, Peter Thomas, Doyanne Darnell, Harry Teter, Leah Ingraham, Lauren K. Whiteside, Jin Wang, Roxanne Guiney, Lea Parker, Kirsten Sandgren, Margot Kelly Hedrick, Erik G. Van Eaton, and Gregory Jurkovich

Objective: The investigation aimed to compare two approaches to the delivery of care for hospitalized injury survivors, a patient-centered care transition intervention versus enhanced usual care. *Method*: This pragmatic comparative effectiveness trial randomized 171 acutely injured trauma survivors with three or more early postinjury concerns and high levels of emotional distress to intervention (I; $n = 85$) and enhanced usual care control (C; $n = 86$) conditions. The care transition intervention components included care management that elicited and targeted improvement in patients' post-injury concerns, 24/7 study team cell phone accessibility, and stepped-up care. Post-traumatic concerns, symptomatic distress, functional status, and statewide emergency department (ED) service utilization were assessed at baseline and over the course of the 12 months after injury. Regression analyses assessed intervention and control group outcome differences over time. *Results*: Over 80% patient follow-up was attained at each time point. Intervention patients demonstrated clinically and statistically significant reductions in the percentage of any severe postinjury concerns expressed when compared to controls longitudinally (Wald chi-square = 11.29, $p = 0.01$) and at the six-month study time point (C = 74%, I = 53%; Fisher's exact test, $p = 0.02$). Comparisons of ED utilization data yielded clinically significant cross-sectional differences (one or more three- to six-month ED visits; C = 30.2%, I = 16.5%, [relative risk

Palinkas & Zatzick 2018: Policy Relevant Pragmatic Comparative Effectiveness Trial Methods

Table 2 American College of Surgeons policy and implementation process summary matrix

Implementation process	Alcohol screening and intervention requirement	PTSD screening and intervention/ referral practice guideline	Possible patient-centered care informational section addition to guideline	No mandate or guideline
Reach	Implied that screening should be available for all patients; unclear whether verification site visits check on this or if this data is available within trauma registries	Not addressed	Not addressed	Not addressed
Effectiveness	Pragmatic trial literature including DO-SBIS study supports	Pragmatic trial literature supports	Some initial clinical trials, but insufficient for requirement or practice guideline not addressed	Insufficient literature Not addressed
Adoption Likely Adopter Groups	Early, Middle & Late Adopters required	Early Adopters likely to uptake	Early Adopters could explore uptake	No adoption likely
Adoption Centers familiar with topic (e.g., alcohol, PTSD)	Mandate enforces familiarity with issue	Guideline suggests familiarity with issue	Informational section introduces/disseminates patient-centered care	Familiarity optional
Implementation Centers required to implement procedure	Mandate requires; verification site visit confirms	Guideline only suggests appropriate practice, no implementation required	Informational section only introduces idea; no implementation required	No requirements
Implementation & Maintenance Adequate staffing and resources allocated	Not addressed; mandate does allow on-site providers to lobby institution for additional staffing and resources	Not addressed; Practice guideline does allow on-site providers to lobby institution for additional staffing and resources	Not addressed; Informational section does allow on-site providers to lobby institution for additional staffing and resources	No requirements
Implementation & Maintenance High quality procedures implemented and maintained	Not addressed unless specifically required by mandate; on-site providers may be aware of issues related to the variable quality of screening and intervention procedures delivered	Not addressed; on-site providers may be aware of issues related to the variable quality of screening and intervention procedures delivered	Not addressed; on-site providers may be aware of issues related to quality	No requirements

Awardee Panel

Discussion and Q&A

Lunch

12:00-1:00 PM

**Webinar will resume at 1:10 PM*

6.

Maternal Morbidity and Mortality

Maternal Morbidity and Mortality

Identifying Research Priorities

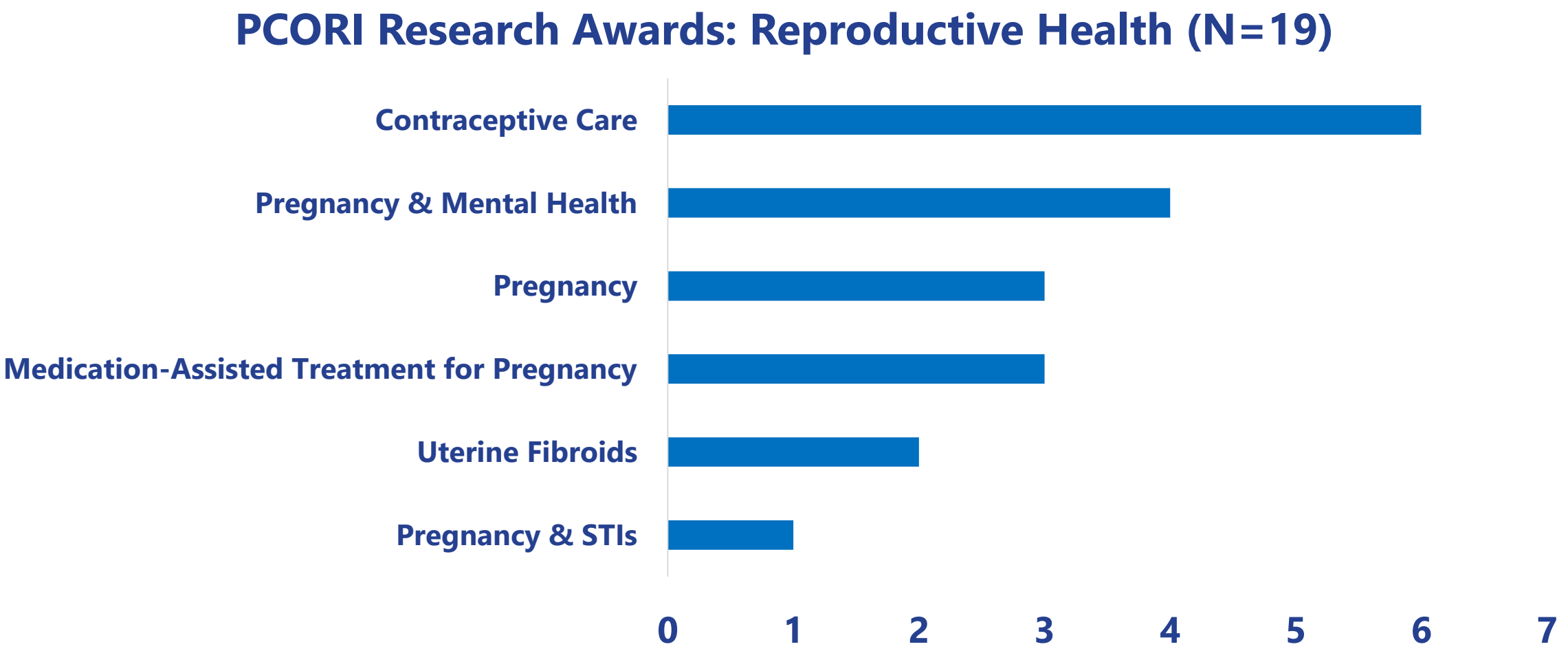
Cathy Gurgol, Sr. Program Officer

pcori
PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

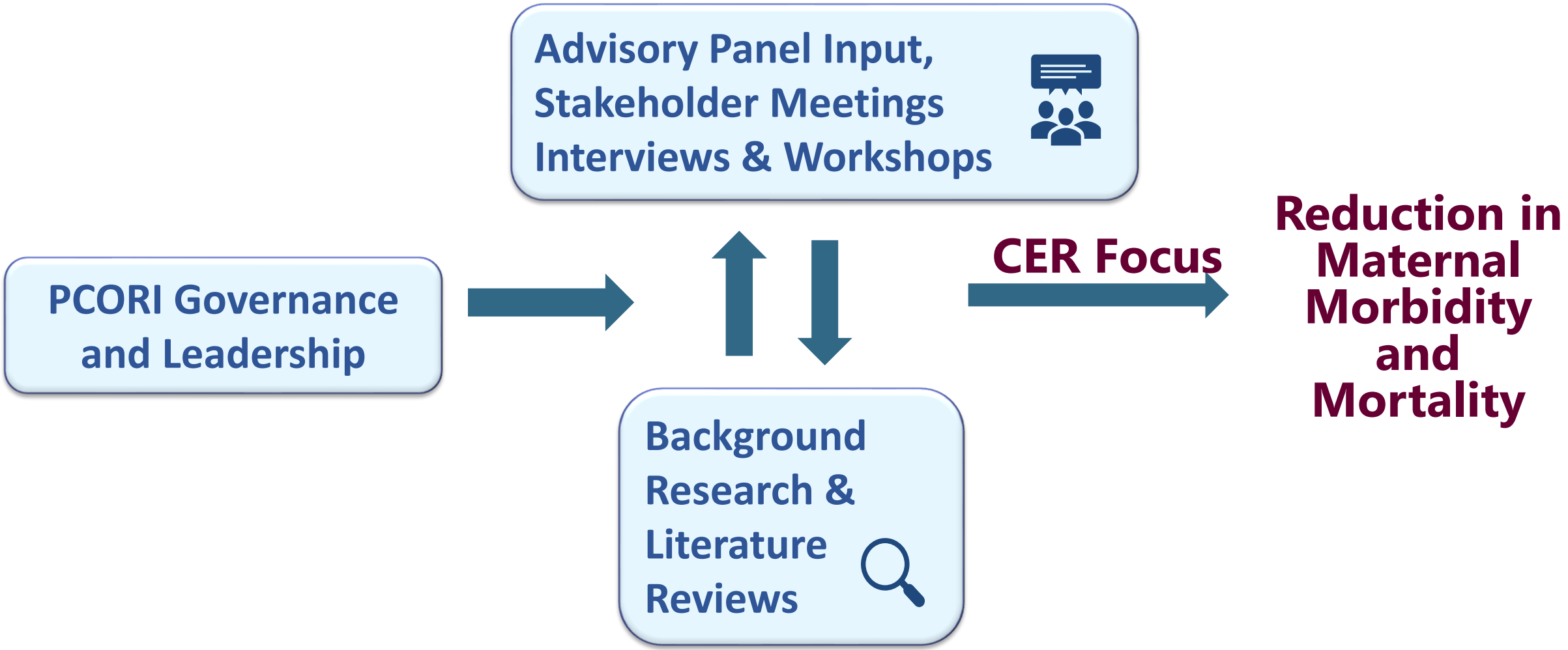
Maternal Morbidity and Mortality Topic Development

- The United States consistently ranks near the bottom among high-income countries on measures of perinatal outcomes
- Based on reports of poor outcomes and disparities; as well as much stakeholder input, PCORI is interested in contributing to evidence around healthcare decision-making regarding Maternal Morbidity and Mortality
- PCORI has previously identified Maternal Morbidity and Mortality as a priority topic in funding announcements; issued targeted funding for medication-assisted treatment for pregnant women with opioid use disorder
- PCORI has a growing research portfolio focused on reproductive health

PCORI Portfolio on Reproductive Health



Maternal Morbidity & Mortality Topic Development
PCORI's Stakeholder-Driven Process for CER

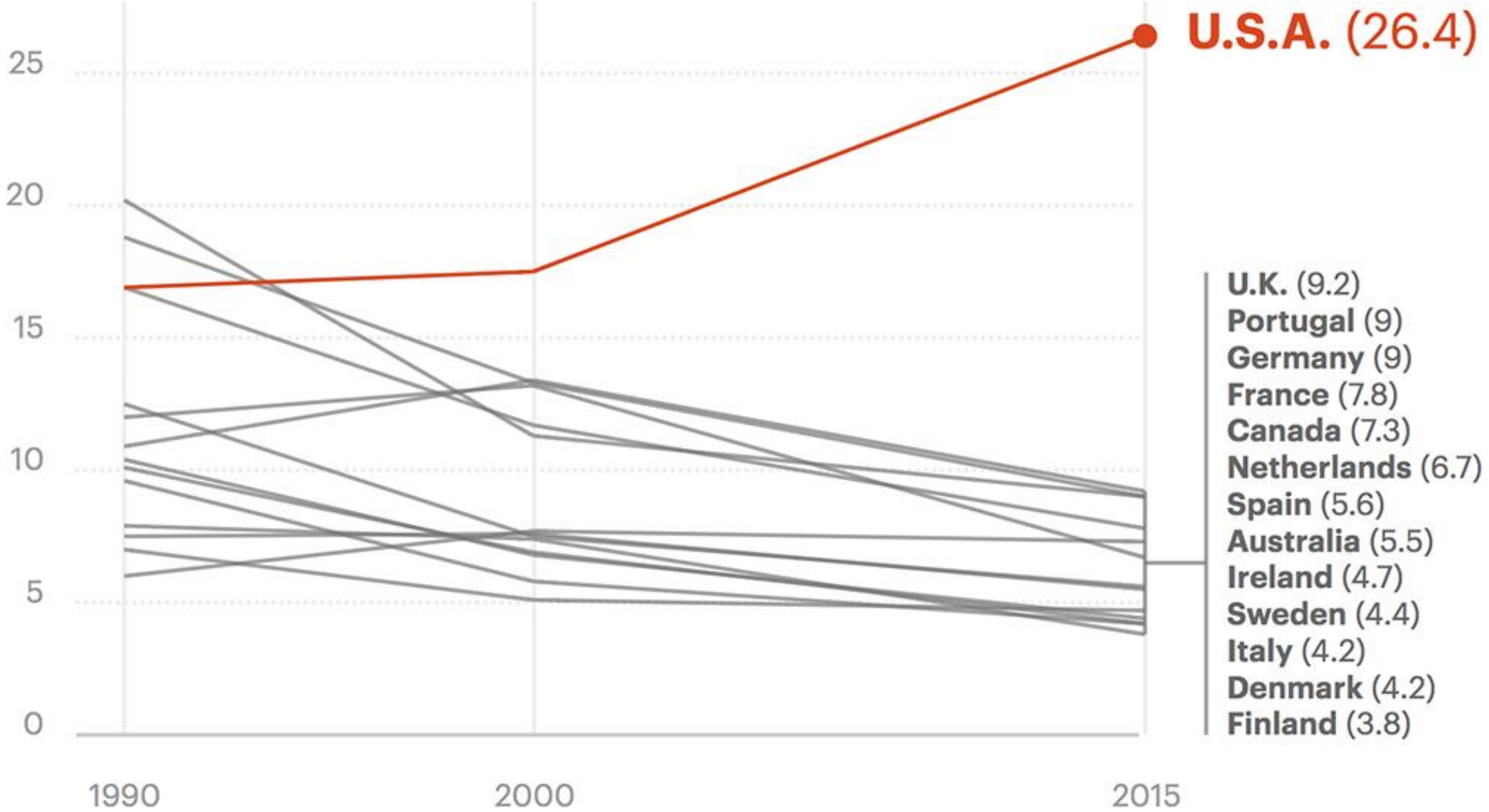


Background and Disparities: Maternal Morbidity and Mortality

- 700 women die from pregnancy-related complications yearly in the US
  - Black women are 3 to 4 times more likely than white women to die from pregnancy-related complications
  - Mortality rate is also higher for Native Americans/Native Alaskans, Asians/Pacific Islanders and for certain subgroups of Hispanic women

- For every death, >100 women experience severe maternal morbidity (SMM)
  - Black women are two times more likely to experience SMM than white women
  - Native American women also have elevated morbidity
  - Black women are more likely to experience comorbid illnesses and pregnancy complications
  - Adverse perinatal outcomes, including infant death, are more common among Black than white women

Maternal Mortality Rates 1990-2015: per 100,000 live births



"Global, regional, and national levels of maternal mortality, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015," *The Lancet*.

Background: Maternal Morbidity and Mortality

- 60% of pregnancy-related deaths could be prevented for all subgroups: Hispanic, Non-Hispanic Black and Non-Hispanic White

- **Timing of deaths**
  - 31% during pregnancy
  - 36% during delivery-day 6
  - 33% 1 week-1 year after delivery

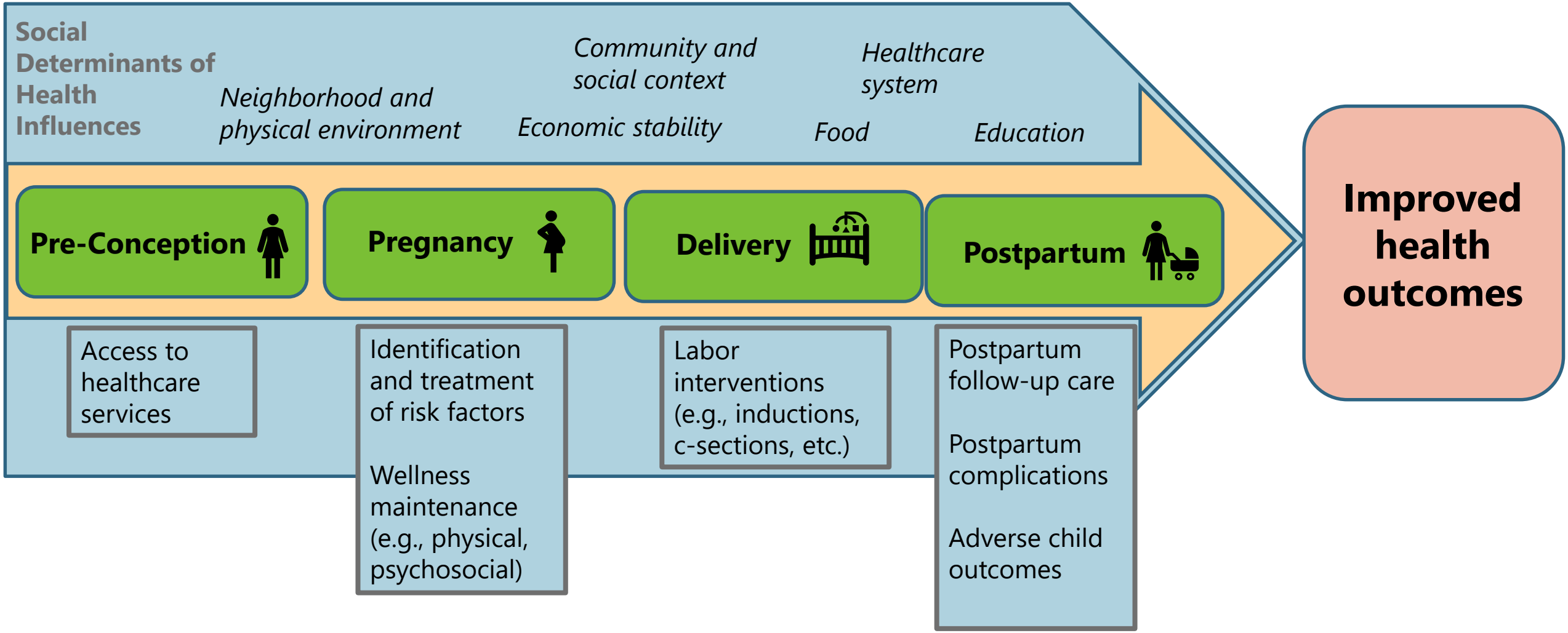
Background: Maternal Morbidity and Mortality

- **Causes of death**:
  - **Heart disease and stroke** cause most deaths overall
  - **Obstetric emergencies**, e.g., hemorrhage and amniotic fluid embolism, cause most deaths at delivery
  - **Hemorrhage, hypertension, infection -** most common the week post delivery
  - **Cardiomyopathy** causes most deaths 1 week to 1 year after delivery
  - **Drug-related**
  - **Suicide**

Background: Maternal Morbidity and Mortality

- **Barriers to Care and Drivers of Disparities**:
  - Patient factors (lack of knowledge of warning signs)
  - Provider factors (missed or delayed diagnoses, no continuity of care, attitudes and bias)
  - Health facility factors (lack of appropriate personnel/services; inconvenient locations, no transportation, poor quality of care)
  - Community factors (unstable housing, geographic location, other social determinants)
  - Systems factors (poor care coordination, inadequate access, discrimination)

Reducing Maternal Morbidity and Mortality: more than just pregnancy and delivery



Strategies to Overcome Barriers

- Patient-Level
  - Awareness of and communication about symptoms of complications
  - Communication about pregnancy history anytime medical care is received in the year after delivery

- Provider-Level
  - Effective communication with patients about warning signs
  - Use of strategies to address concerns/morbidities
  - Use of tools to flag warning signs early so women receive timely treatment

Strategies to Overcome Barriers

- Hospital System-Level
  - Standardize coordination of care and response to emergencies
  - Improve delivery of quality prenatal and postpartum care
  - Co-location of nurse/midwife practice and medical practice
  - Train non-obstetric providers to consider recent pregnancy history
  - Train providers on effective communication; maternal health disparities

Strategies to Overcome Barriers

- Community and Policy-Level
  - Address access to care and other social determinants
    - Telehealth – remote monitoring for perinatal visits; remote mental health care when appropriate
    - Addressing social needs – transportation, childcare, interpreter services
    - Improving health coverage – increasing Medicaid coverage post delivery
    - State policies for improving access – e.g., Massachusetts MCPAP for Moms

Discussion

- Potential for CER that Reduces Mortality and Morbidity:
  - **Strategies**
    - Patient and provider (e.g., tailored approaches to care coordination / delivery of care; patient-centered communication)
    - Health system (e.g., training providers on disparities, cultural competency, implementation of care models)
    - Community/policy (e.g., Natural experiments & policy evaluations (e.g., access to care models))
  - **Outcomes**
    - Pre- and post-natal maternal outcomes (e.g., satisfaction with care, Preterm labor, morbidity, labor characteristics mortality, depression, postpartum follow-up care)
    - Child outcomes (e.g., Birthweight, Neonatal infection, morbidity, NICU admission/hospital readmission/ED visit)
  - **Populations** (e.g., low income, racial/ethnic minority groups, rural)

Thank you!

Discussion

- Potential for CER that Reduces Mortality and Morbidity:
  - Patient and provider strategies
    - Incentives
    - Telehealth
    - Tailored approaches to care coordination / delivery of care; patient-centered communication
    - Awareness of symptoms and communication with providers
  - Health system strategies
    - Standardizing response protocols,
    - Training providers on disparities, cultural competency, availability of interpreter services, language-concordant care, shared decision making
    - Implementation of care models
  - Community/policy
    - Natural experiments & policy evaluations (e.g., access to care models)

Afternoon Break/ Poster Presentations

[2:00-2:30 PM]

**Webinar will resume at 2:30pm*

7.

Suicide Prevention

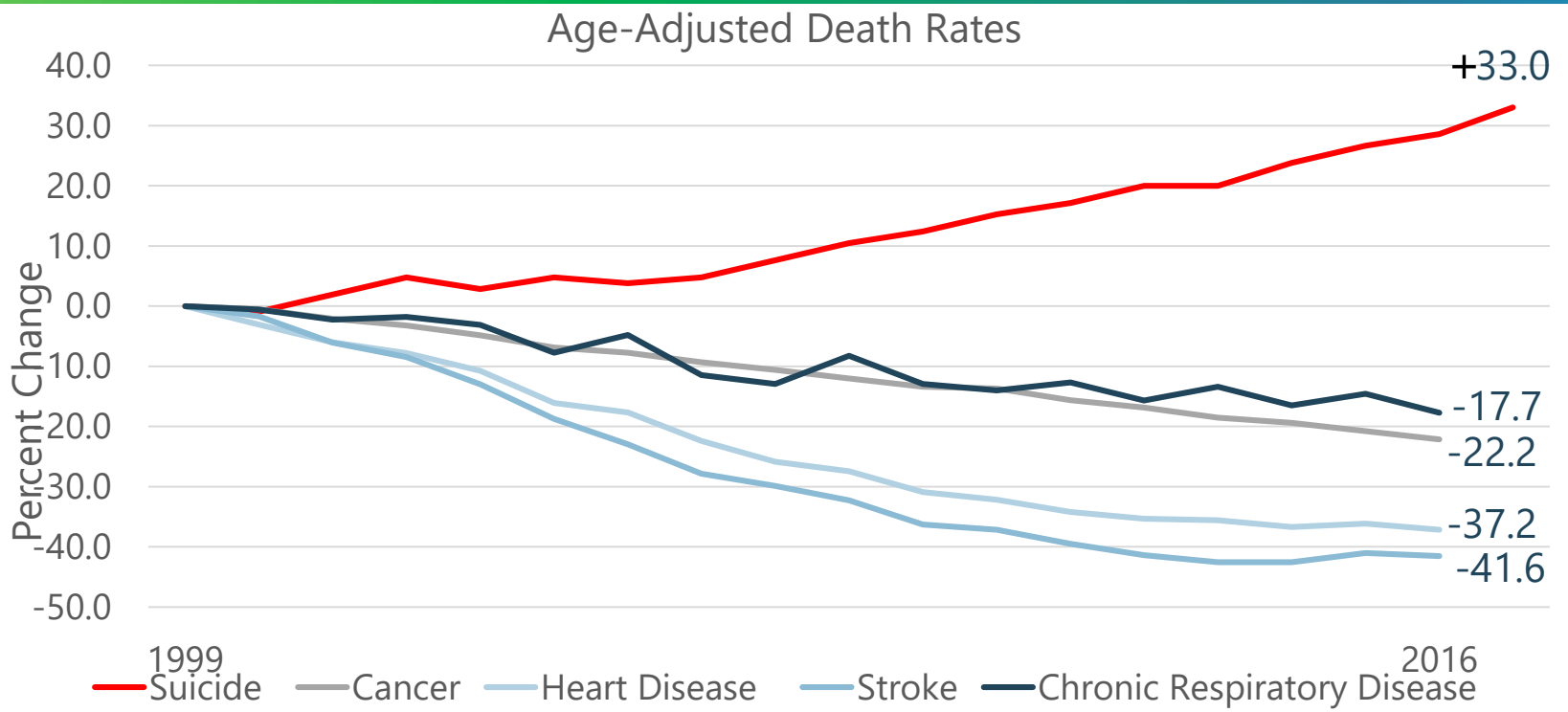
Suicide Prevention
Topic Development for targeted PFA

Els Houtsmuller, Associate Director
Cathy Gurgol, Senior Program Officer

Suicide Prevention Topic Development

Els Houtsmuller, Associate Director
Cathy Gurgol, Senior Program Officer

Suicide Prevention Background



- Suicide rates in the US have increased by 33% (10.5 to 14.0 per 100,000) since 1999
- In 2017, > 47,000 individuals in the U.S. died by suicide; suicide was the second leading cause of death for ages 10-34, and fourth for ages 35-54
  - Firearms most common method (almost 50%)

Systematic Reviews

Beauchaine et al. (2019) Nonsuicidal Self-Injury and Suicidal Behaviors in Girls: The Case for Targeted Prevention in Preadolescence. Clin Psychol Sci.7(4):643-667.

D'Anci et al. (2019) Treatments for the Prevention and Management of Suicide: A Systematic Review. Ann Intern Med. 171(5):334-342.

Costanza et al. (2019). The Meaning in Life in Suicidal Patients:The Presence and the Search for Constructs. A Systematic Review. Medicina (Kaunas). 11;55(8).

Grimmond et al. (2019) A qualitative systematic review of experiences and perceptions of youth suicide. PLoS One 12;14(6)

Hanratty (2019) A systematic review of efficacy of Collaborative Assessment and Management of Suicidality (CAMS) in managing suicide risk and deliberate self-harm in adult populations. Australas Psychiatry. 11:1039856219848832.

Hatchel et al. (2019) Suicidal Thoughts and Behaviors Among LGBTQ Youth: Meta-Analyses and a Systematic Review. Arch Suicide Res; 10:1-37.

Hobson et al. (2019) Mobile Health for First Nations Populations: Systematic Review. JMIR Mhealth Uhealth 7:7(10)

Hofstra et al. (2019) Effectiveness of suicide prevention interventions: A systematic review and meta-analysis. Gen Hosp Psychiatry. Epub ahead of print.

Iyengar et al (2018) A Further Look at Therapeutic Interventions for Suicide Attempts and Self-Harm in Adolescents: An Updated Systematic Review of Randomized Controlled Trials. Front. Psychiatry 9:583.

McCabe et al. (2018) Effectiveness of brief psychological interventions for suicidal presentations: a systematic review. BMC Psychiatry. 3;18(1):120

Pistone et al. (2019) The effects of educational interventions on suicide: A systematic review and meta-analysis. Int J Soc Psychiatry. 65(5):399-412.

Robinson et al. (2018) What Works in Youth Suicide Prevention? A Systematic Review and Meta-Analysis. EClinicalMedicine. 28;4-5:52-91

PCORI Suicide Prevention Portfolio

A Multi-Site Study to Compare the Outcomes of Psychiatric Treatment of Suicidal Adolescents in Different Treatment Settings

- Comparators: Inpatient psychiatric treatment vs. intensive outpatient psychiatric treatment; N=1000
- End date: July 2025

The SPARC Trial: Comparing Safety Planning Plus Structured Follow-Up from a Suicide Prevention Hotline (SP+SFU) to Usual Care (Safety Planning without Follow-Up) for Suicide Prevention Among Adult & Adolescent Recipients of Care in Emergency Departments & Primary Care Settings

- Comparators: Safety planning vs. safety planning + structured follow-up; N=1460
- End date: May 2024

Suicide Prevention: Research Area of Interest – Broad Funding Announcement 2019

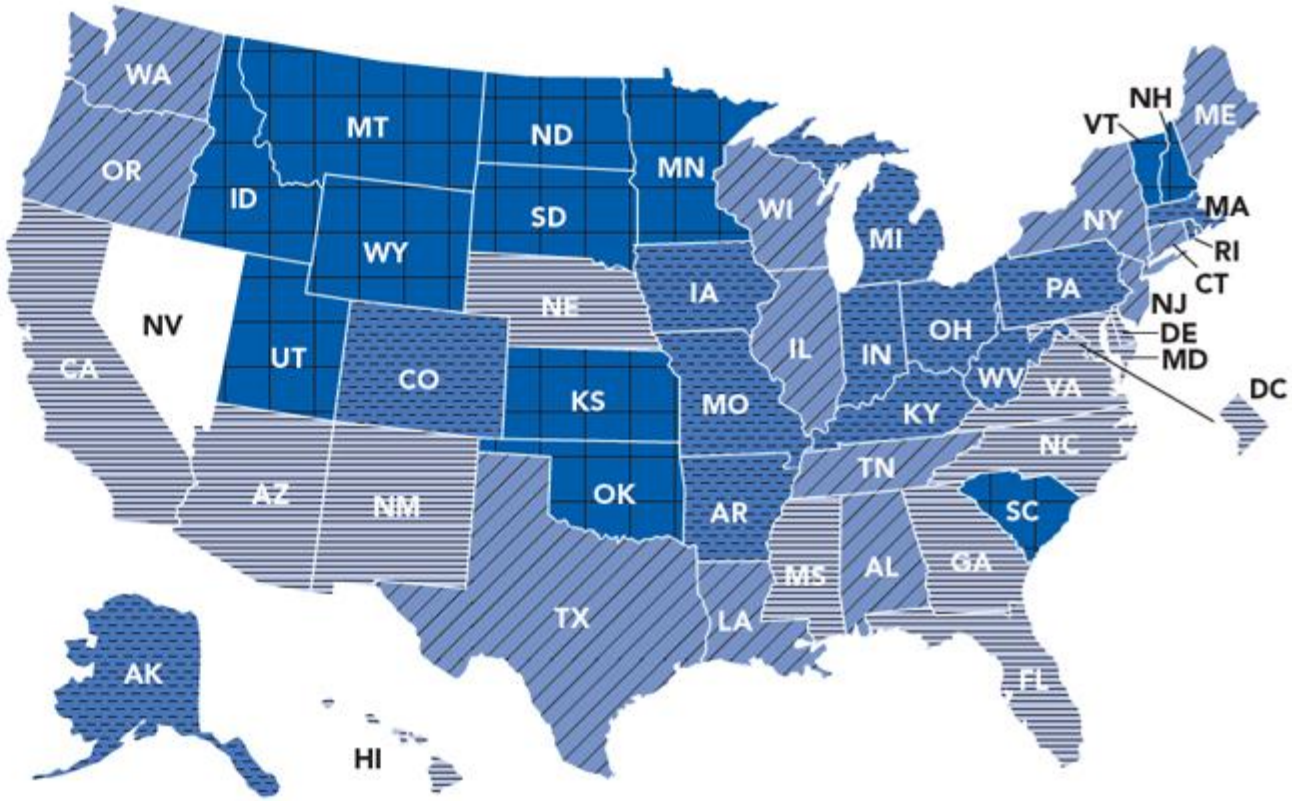
- Solicited applications that compare effectiveness of different prevention/treatment models, interventions and/or settings for patients at increased risk for suicide, released in Cycle 3 2019
  - Compare effectiveness of
    - Brief interventions to address acute suicidality
    - Psychological treatments to manage suicidal ideation and prevent suicidal crises for patients with suicidal ideation
    - Models of urgent care for patients with suicidality, such as urgent care clinics, emergency departments, psychiatric urgent care clinics, and psychiatric emergency departments
- Applications to be submitted Jan. 14, 2020

Suicide Prevention Background

Suicide rates vary by gender identity, race/ethnicity, age, state with higher rates in rural areas

Men
Transgender communities
American Indian/Native Alaskan; non-Hispanic White

Increasing rates for
Black teenagers



Suicide Prevention

- Crisis Settings

- Brief Interventions to address acute risk

- Treatments to prevent crisis

- Identification of people at risk

Suicide Prevention Crisis Settings

- Patients in crisis typically taken to Emergency Departments
  - Strong concern from patient community (traumatic experience)

- Psych EDs/Psych Urgent Care Clinics - Free-standing, not-for-profit clinics
  - Increasing in number due to strong face validity, patient concerns ED

- Mobile Crisis Unit - Community-based, component of larger model

Comparable effectiveness of crisis care settings for patients with suicidality?

Suicide Prevention Brief Interventions

- Patients considered at risk may receive a Brief Intervention in provider's office, ED, other
  - Safety Planning
  - Safety Planning plus Reasons for Living Planning
  - Motivational Interviewing
  - Teachable Moment Brief Intervention
  - Attempted Suicide Short Intervention Program

    - Which BIs, combinations of BIs, work best for which patients?

- Efficacy of BIs for specific populations unknown

    - Tailored interventions for specific populations?

Suicide Prevention Treatments

- Treatment focuses on preventing suicidal crisis, improving coping skills, reducing suicidality, depression. Evidence-based treatments are available:
  - Suicide-specific Cognitive Behavioral Treatment
  - Dialectical Behavior Therapy
  - Mentalization-Based Therapy
  - Collaborative Assessment and Management of Suicidality
  - Medications: lithium; antipsychotics, especially clozapine; ketamine; SSRIs

Comparative effectiveness, tailored interventions

- Patient retention in treatment remains challenge ('average 1.5 sessions' following identification)

Tailored interventions to increase patient engagement in care

Suicide Prevention Treatments

- Peer Respite programs
  - Voluntary short-term overnight programs
  - Offer community-based, non-clinical crisis support
  - People with lived experience)
  - Goal is to prevent psychiatric crisis

Endorsed by patients; preliminary reports positive outcomes; risks?

Observational study?

Suicide Prevention Identification

- 80% of people who die by suicide had contact with a provider in last year; nearly half in last month
- However, prediction of suicide remains challenging
  - Some known risk factors (e.g., previous attempt, serious mental illness) do not predict time-specific risk for individuals
  - Validated screening instruments 'of little clinical value'

- Machine learning (ML) models (EHR info, risk factors); appear more promising and are in use (e.g., Kaiser, VA)
  - Are ML approaches associated with improved identification, outcomes?
- Patients may also be identified by trained 'gatekeepers' (school, work, church); receive training to recognize suicidality; training increases gatekeepers' knowledge of suicidality
  - Do gatekeepers improve identification, outcomes?

Suicide Prevention

Discussion

Questions

Tailored interventions for target populations?

Which outcomes?

- Suicidal ideation
- Engagement in care
- Coping skills
- Quality of life

Study design?

Survey

Wrap Up and Next Steps

Nadine Barrett, MA, MS, PhD
HDDR Advisory Panel Co-Chair

Frank Wharam, MBCHB, MPH
HDDR Advisory Panel Co-Chair

Steve Clauser, PhD, MPA
Director, Healthcare Delivery and Disparities Research Program

Meeting Adjourned