Advisory Panel on Improving Healthcare Systems

March 31, 2017

8:30 a.m. – 4:00 p.m. EST

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- Chair Statement on COI and Confidentiality

Welcome & Introductions

Steve Clauser, PhD, MPA

Director, Healthcare Delivery and Disparities Research

IHS Advisory Panel Leadership

- Michael Dueñas, OD
  - IHS Advisory Panel Chair

- Timothy Daaleman, DO, MPH
  - IHS Advisory Panel Co-Chair

IHS Advisory Panel Members

- **Rebecca Aslakson, MD, PhD**
  Associate Professor, Johns Hopkins School of Medicine
- **Leah Backhus, MD, MPH**
  Associate Professor, Veterans Affairs and Stanford University
- **Ignatius Bau, JD**
- **Jim Bellows, PhD, MPH**
  Senior Director, Care Management Institute, Kaiser Permanente
- **David Bruhn, PharmD, MBA**
  Health Outcomes Liaison, National Accounts, GlaxoSmithKline
- **Bonnie Clipper, DNP, RN, MA, MBA, FACHE, CENP**
  Chief Clinical Officer, Cornerstone Hospital of Austin
- **Timothy Daaleman, DO, MPH**
  Professor of Family Medicine, University of North Carolina at Chapel Hill School of Medicine
- **Michael Dueñas, OD**
  Chief Public Health Officer, American Optometric Association
- **Lisa Freeman, BA**
  Independent Patient Safety Advocate and Consultant
- **John Galdo, PharmD, BCPS***
  Clinical Pharmacy Educator, Barney's Pharmacy
- **Ravi Govila, MD***
  Vice President, Medical Management and PPO, Blue Cross Blue Shield of Michigan
- **Joan Leon, BA**
  Retired Health Consultant
- **James Perrin, MD**
  Professor of Pediatrics, Harvard Medical School and Pediatrician, Massachusetts General Hospital Physician Organization
- **Carolyn Petersen, MS, MBI**
  Senior Editor, MayoClinic.org
- **Alexis Snyder, BA**
  Independent Contractor, Patient Family Advisor
- **Jamie Sullivan, MPH**
  Director of Public Policy, COPD Foundation
- **Craig Umscheid, MD, MS***
  Associate Professor of Medicine and Epidemiology, University of Pennsylvania Perelman School of Medicine
- **Mitzi Wasik, PharmD**
  Medical Stars Business Lead, Aetna
- **Nancy Yedlin, MPH**
  Vice President, Donaghue Foundation

Guests

- Cheryl Pegus, MD, MPH*
  - Addressing Disparities Advisory Panel Chair
- Elizabeth Jacobs, MD, MAPP, FACP
  - Addressing Disparities Advisory Panel Co-Chair
- Ray Dorsey, MD, MBA

  University of Rochester
  - PCORI Funded Investigator

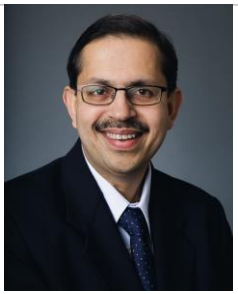
Improving Healthcare Systems Program Staff

Steven Clauser, PhD, MPA

Director

Els Houtsmuller, PhD

Associate Director



Neeraj Arora, PhD

Associate Director

Carly Parry, PhD, MSW

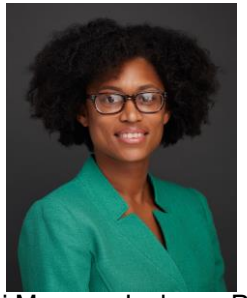
Sr. Program Officer

Penny Mohr, MA

Sr. Program Officer

Beth Kosiak, PhD

Program Officer



Gyasi Moscou-Jackson, PhD

Program Officer

Jeanne Murphy, PhD, CNM

Program Officer

Andrea Brandau, MPP

Program Officer

Stephanie Parver, MPH

Program Associate

Anum Lakhia, MPH

Program Associate

Jamie Trotter

Program Associate

Sindhura Gummi, MPH

Program Associate

Hannah Kampmeyer

Senior Admin Assistant

Aaron Shifreen

Program Assistant

Allie Olender

Program Assistant

Anushka Sindkar

Intern

Addressing Disparities Program Staff

Steven Clauser, PhD, MPA

Director

Cathy Gurgol, MS

Associate Director

Parag Aggarwal, PhD

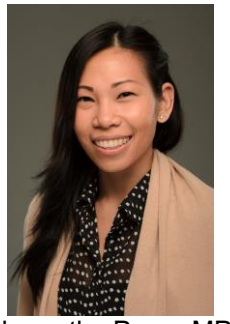
Sr. Program Officer

Mira Grieser, MHS

Program Officer

Ayodola Anise, MHS

Program Officer



Soknorntha Prum, MPH

Program Associate

Marisa Torres, MPH

Program Associate

Alyzza Dill, MPH

Program Associate

Julia Anderson, MPH, MEM

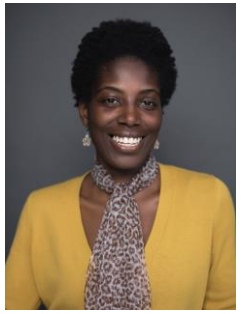
Program Associate

Kaitlynn Robinson-Ector, MPH

Program Associate

Dionna Attinson

Program Assistant



Tomica Singleton

Senior Admin Assistant

Agenda and Logistics for this Meeting

Steve Clauser, PhD, MPA

Director, Healthcare Delivery and Disparities Research

Program Updates

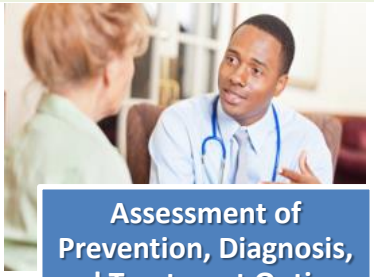
Steve Clauser, PhD, MPA

Director, Healthcare Delivery and Disparities Research

Overview of PCORI

PCORI's MISSION

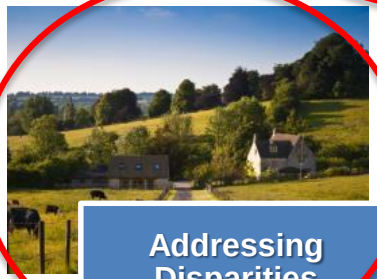
PCORI helps people make informed health care decisions, and improves health care delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from **research guided by patients, caregivers and the broader health care community.**



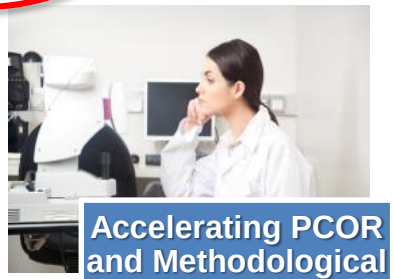
Assessment of Prevention, Diagnosis, and Treatment Options

Improving Healthcare Systems

Communication & Dissemination Research



Addressing Disparities

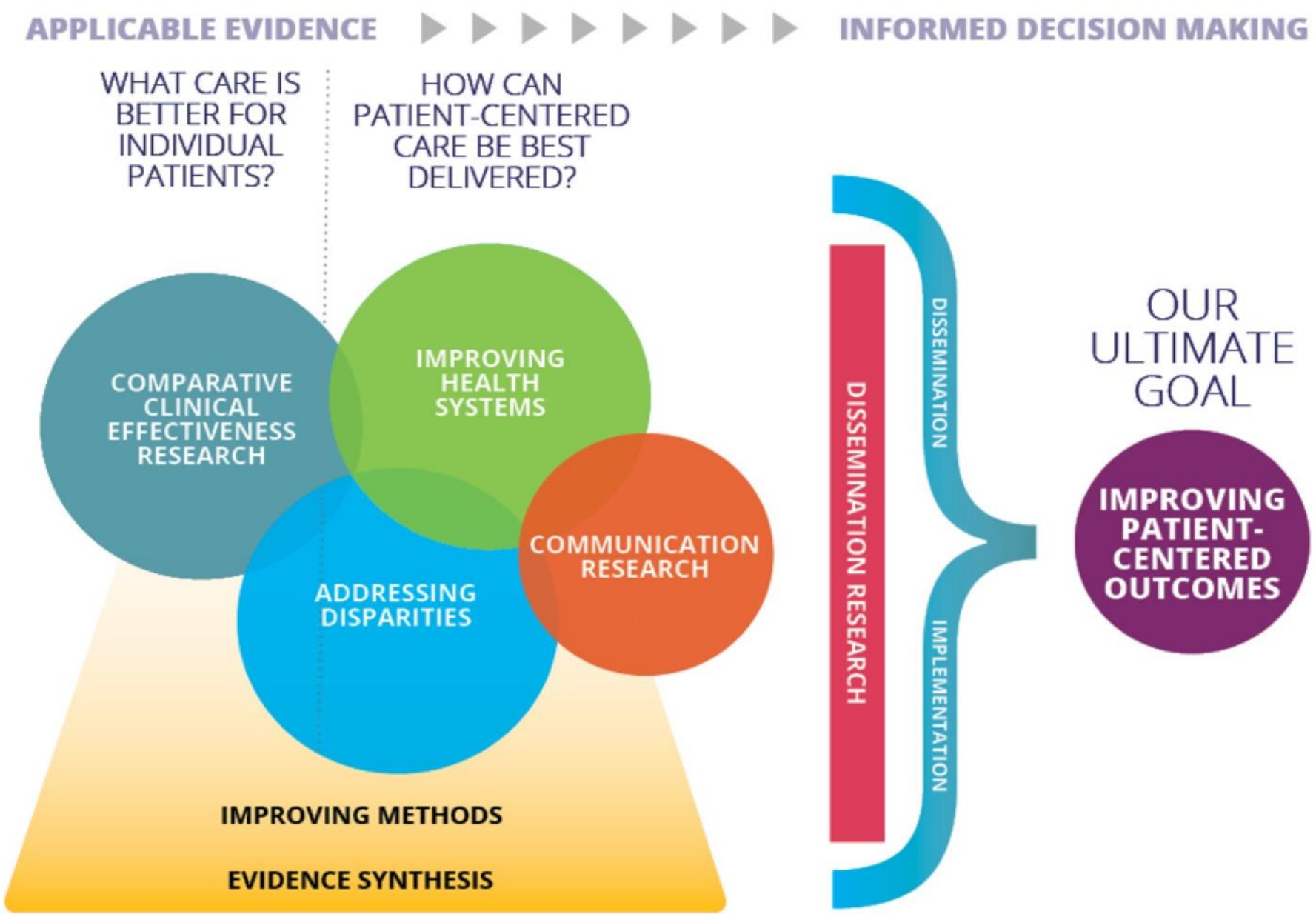


Accelerating PCOR and Methodological Research

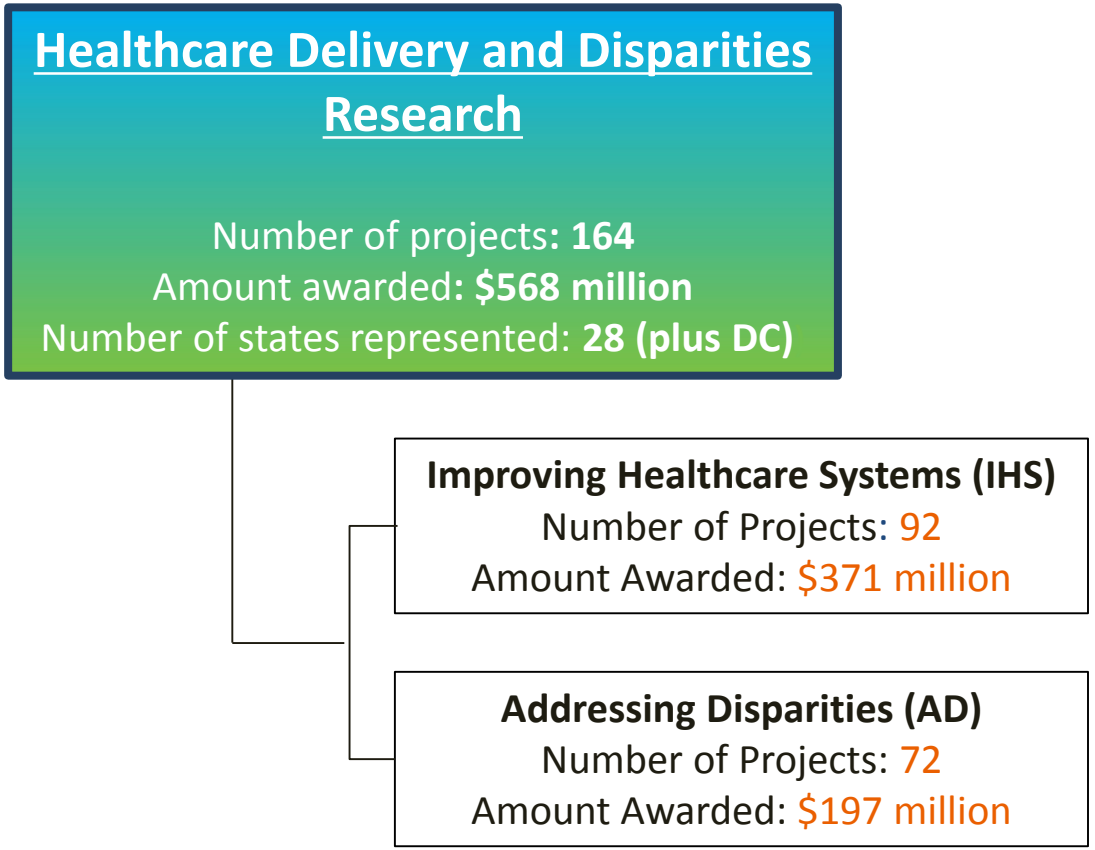
Addressing Disparities Goal Statement

To support comparative effectiveness research that will identify best options for reducing and **eliminating disparities.**

PCORI RESEARCH FRAMEWORK



Healthcare Delivery and Disparities Research (HDDR)



HDDR: Defined

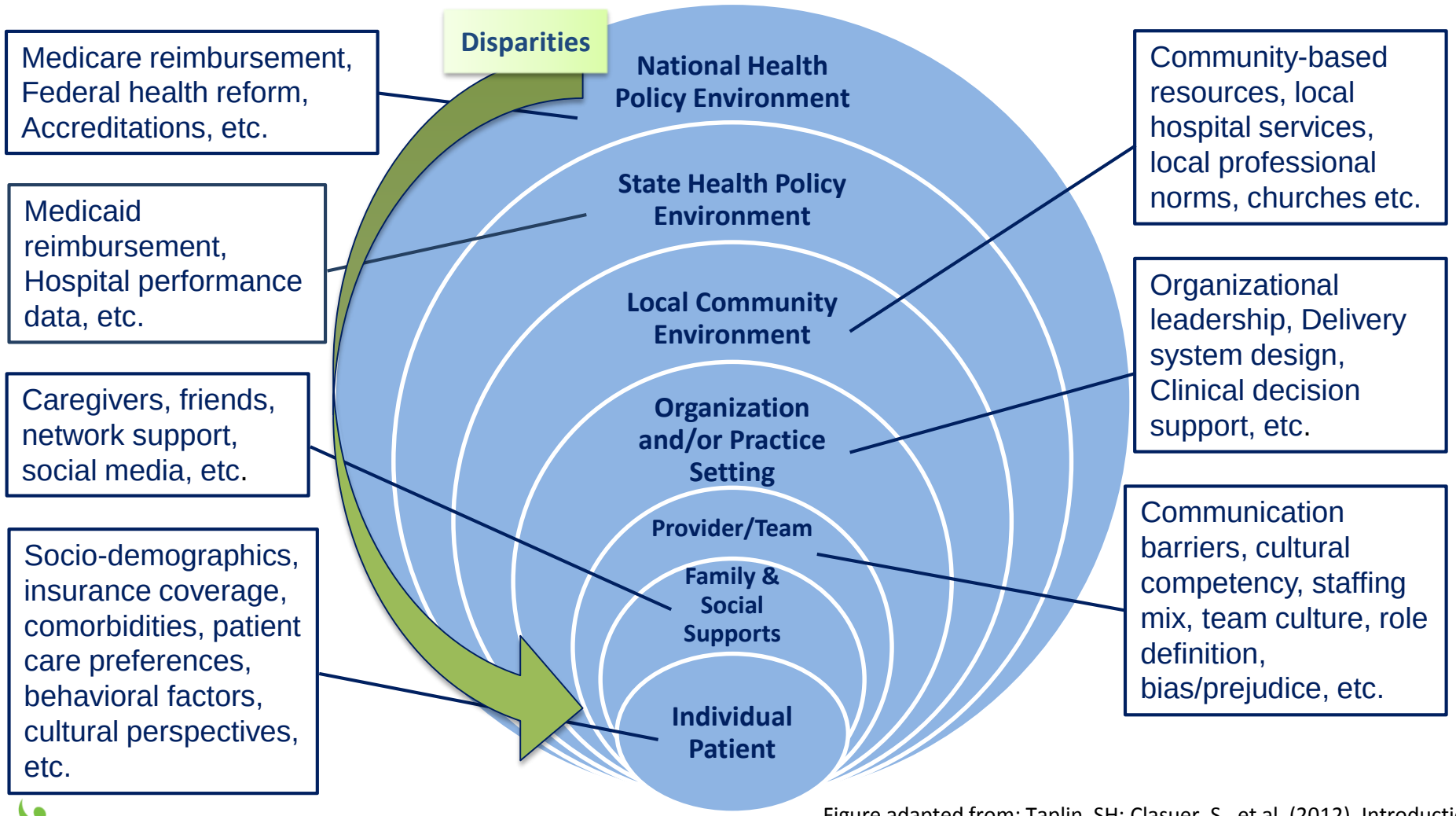
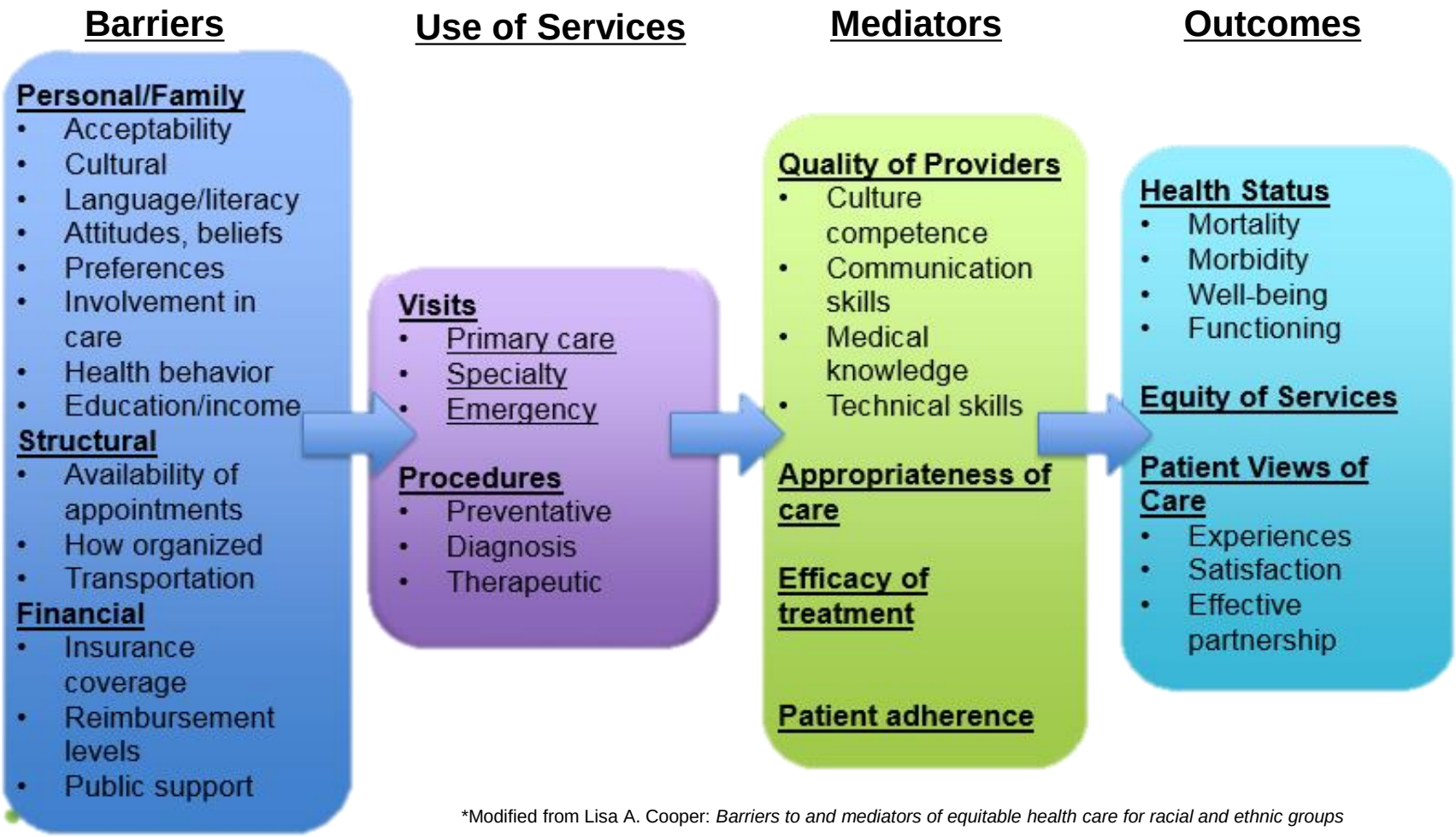


Figure adapted from: Taplin, SH; Clasuer, S., et al. (2012). Introduction: Understanding and Influencing Multilevel Factors across the Cancer Care Continuum. Journal of the National Cancer Institute, 44, 2-10.

IHS Studies Comparing Interventions by System Level

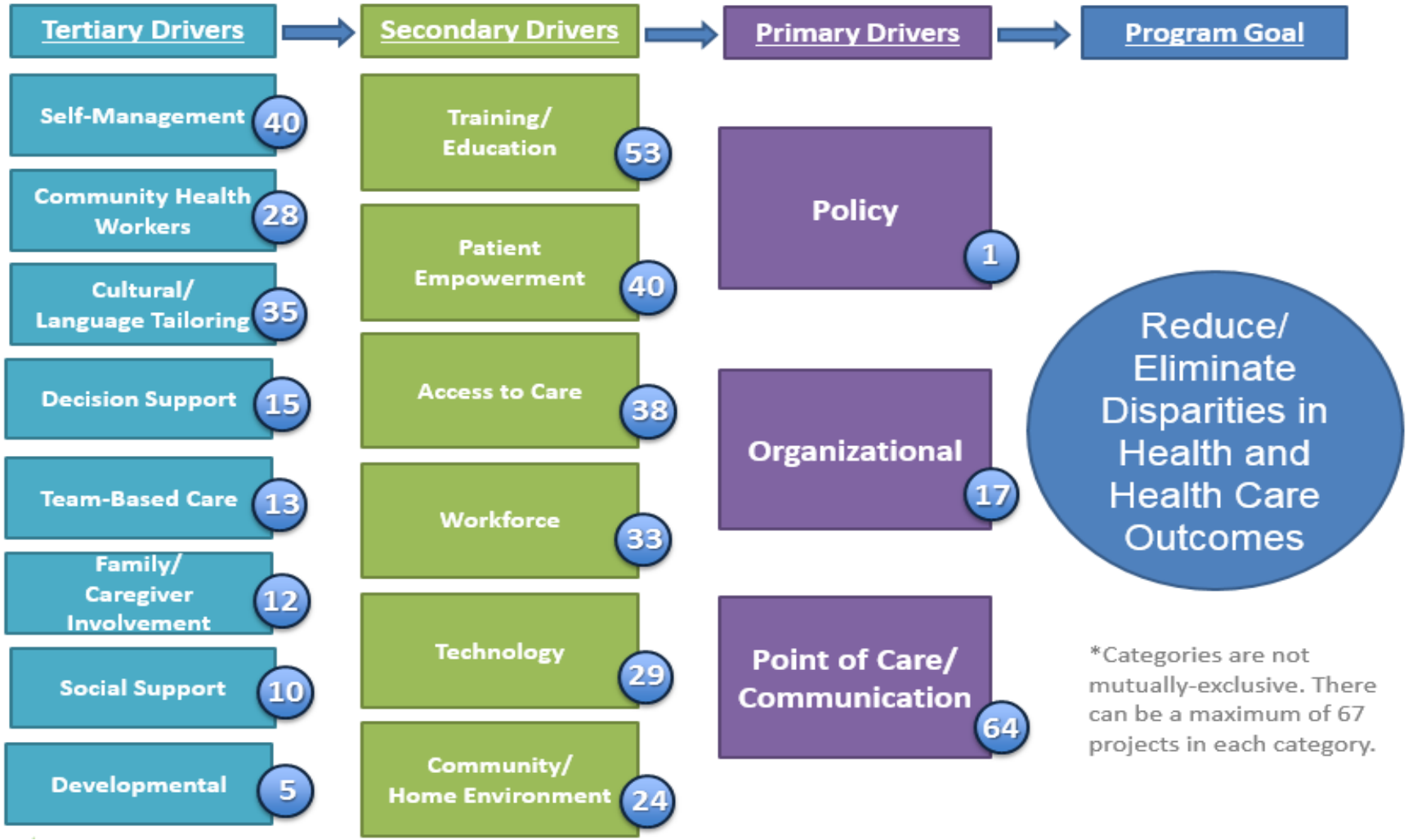
System Level	Examples of Comparisons in the IHS Portfolio
Individual Patient	Compares the use of an electronic asthma medication tracker to standard primary care (no tracker) for children with asthma and their parents and caregivers to improve quality of life, among other patient-centered outcomes.
Family and Social Supports	Compares the use of advance planning tools for access to community-based and in-home services for the frail elderly and their caregivers to an electronic educational intervention of available services and programs. Measures understanding and knowledge outcomes.
Provider/Team	Compares nursing home staff team-based training and palliative care delivery using an adapted NQF protocol to a standard nursing home palliative care protocol to improve EOL outcomes, such as pain, shortness of breath, in-hospital deaths, hospitalizations, and presence of advance directive
Organization and/or Practice Setting	Compares elements of patient-centered medical home (e.g., addition of a PCP in the context of regularly scheduled dialysis sessions and health promoters to help support patients and their caregivers) to traditional team-based specialty care for end-stage renal disease patients to improve utilization, quality of life and caregiver burden outcomes.
Local Community Environment	Compares an ED-to-home community health worker that links patients with community-based social-support (e.g., home-delivered meals) and medical follow-up, to care transition programs using written and verbal discharge instructions alone to improve utilization and quality of life outcomes.

Addressing Disparities Framework

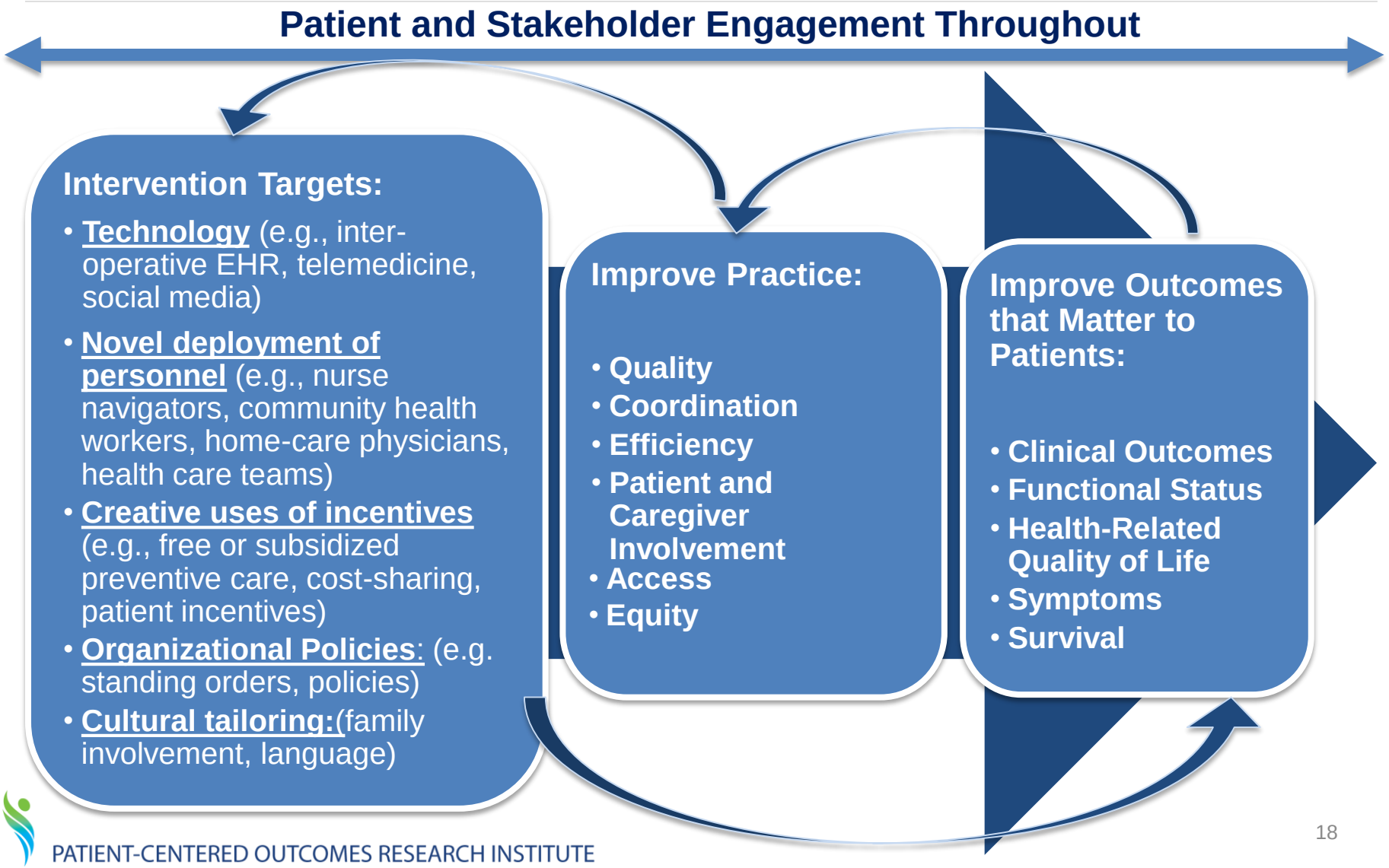


*Modified from Lisa A. Cooper: *Barriers to and mediators of equitable health care for racial and ethnic groups*

AD Driver Model



HDDR: Strategic Framework



New IHS Projects – Awarded Dec. 2016

Project Title	PI Name	Institution
Expanding Access to Home-based Palliative Care through Primary Care Medical Groups	Susan Enguidanos, PhD, MPH	University of Southern California
Comparing Patient-Centered Outcomes for Adults and Children with Asthma in High-Deductible Health Plans with and without Preventive Drug Lists	Alison Galbraith, MD, MPH	Harvard Pilgrim Health Care, Inc.
Ambulatory Cancer Care Electronic Symptom Self-Reporting (ACCESS) for Surgical Patients	Andrea Pusic, MD, MS	Memorial Sloan Kettering Cancer Center
Improving Patient-Centered Communication in Primary Care: A Cluster Randomized Controlled Trial of the Comparative Effectiveness of Three Interventions	Ming Tai-Seale, PhD, MPA	Palo Alto Medical Foundation Research Institute

New AD Projects – Awarded Dec. 2016

Project Title	PI Name	Institution
Improving Outcomes for Low-Income Mothers with Depression: A Comparative Effectiveness Trial of Two Brief Interventions in the Patient-Centered Medical Home	Michael Silverstein, MD, MPH	Boston Medical Center
Comparative Effectiveness of Diabetes Prevention Programs	Pearl McElfish, PhD, MS, MBA	University of Arkansas for Medical Sciences
Addressing Childhood Hearing Loss Disparities in an Alaska Native Population: A Community Randomized Trial	Philip Hofstetter, MA	Norton Sound Health Corporation
A Randomized-Controlled Trial to Compare the Reach, Effectiveness, and Maintenance of Two Family-Based Childhood Obesity Treatment Programs in a Medically Underserved Region	Jamie Zoellner, PhD	Virginia Polytechnic Institute and State University

New PCS Projects – Awarded March 2017

Project Title	PI Name	Institution
A Simple Large Trial of Patient-Centered Care for Opioid Use Disorders in Federally Qualified Healthcare Centers and Specialty Care Settings	David Gastfriend, MD	Treatment Research Institute
Improving Transition from Acute to Post-Acute Care following Traumatic Brain Injury*	Jeanne Hoffman, PhD	University of Washington

* Priority topic endorsed by IHS Advisory Panel

HDDR Portfolio by Funding Mechanism

- 164 Projects; ~$568 million funding; 28 States, plus D.C.

Funding Mechanism	N of IHS Projects	IHS Funding	N of AD Projects	AD Funding
Broad	78	$209 million	58	$107 million
Pragmatic	7	$90 million	2	$25 million
Targeted	4	$65 million	12	$65 million
Natural Experiments	3	$7 million	0	$0
Total	**92**	**$371 million**	**72**	**$197 million**

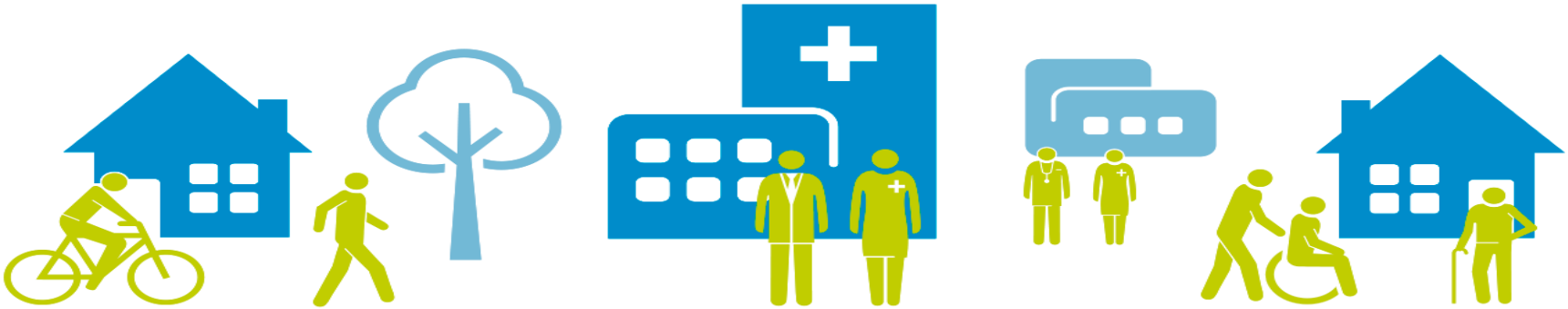
- **Broad**: Both small ($1.5M, 3 year) and large ($5M, 5 year) investigator-initiated studies; 2 cycles per year; competitive LOIs

AP Priorities

- **Pragmatic**: $10M, 5 year head-to-head comparisons in large, representative study populations and settings; PCORI, IOM, and AHRQ CER priorities; 2 cycles per year
- **Targeted:** Stakeholder driven priorities with the greatest specificity in research requirements; range from $5M - $30M; often collaborations with other funding organizations.

HDDR Portfolio by Care Continuum *(as of 3/2017)*

Number of Studies Across the Care Continuum (n=164)

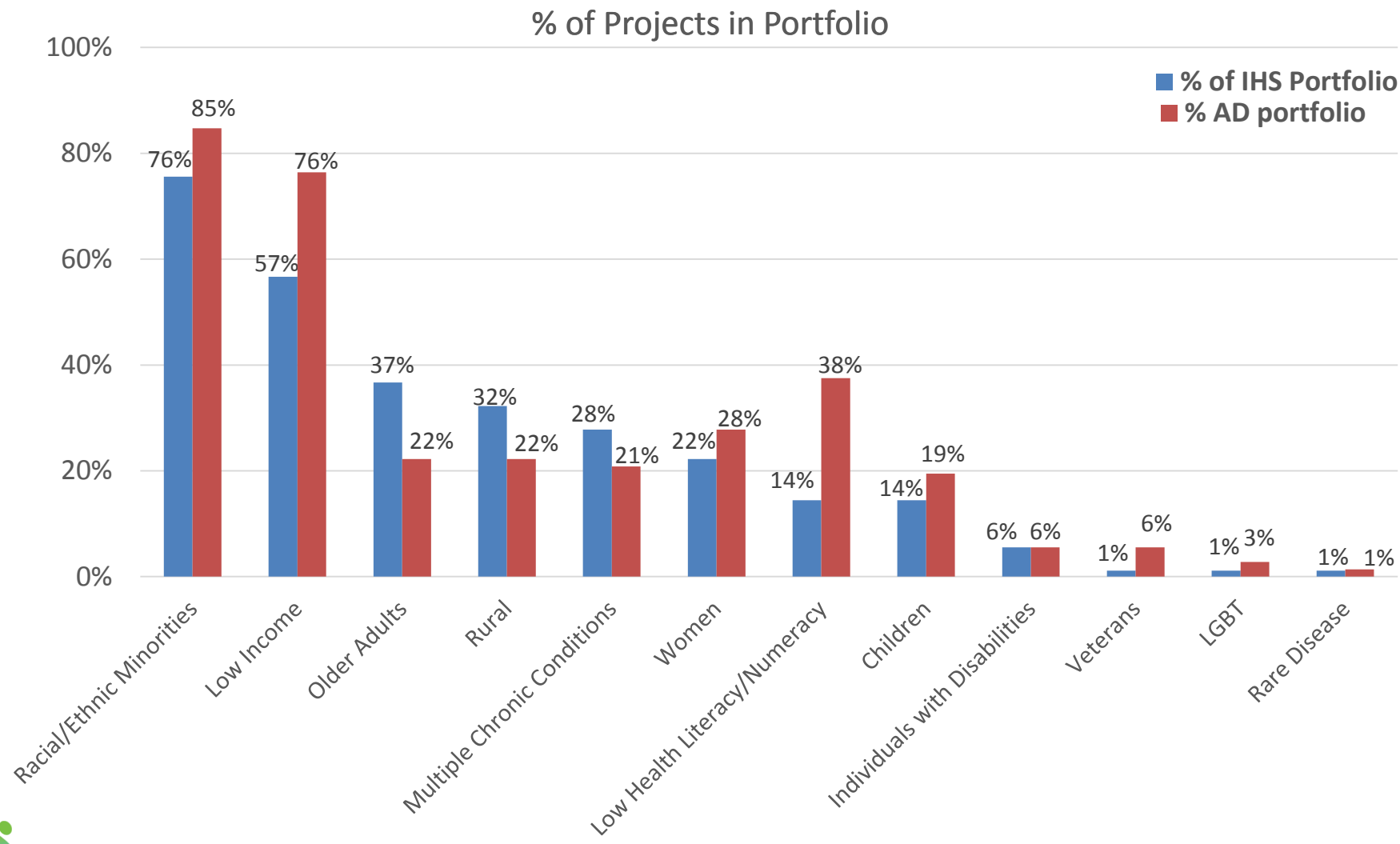


	Prevention	Screening	Diagnosis	Treatment / Management	Survivorship*	End of Life / Palliative Care
IHS:	n=7	n=3	n=0	n=72	n=3	n=7
AD:	n=7	n=4	n=0	n=59	n=0	n=0

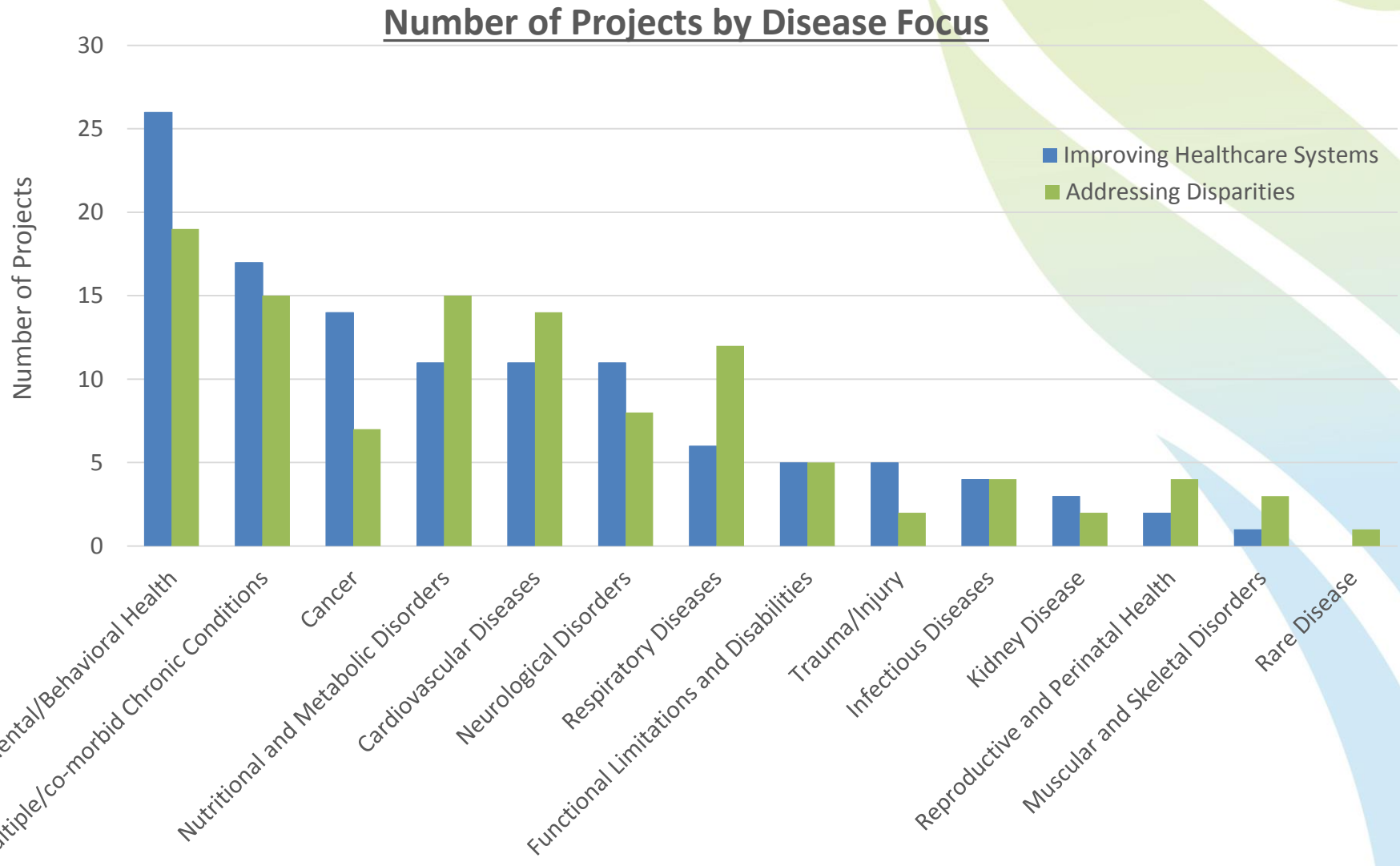
*Unique to cancer studies

The HDDR funded portfolio addresses multiple phases of the healthcare continuum, ranging from prevention, screening, and various phases of treatment, to survivorship and end of life.

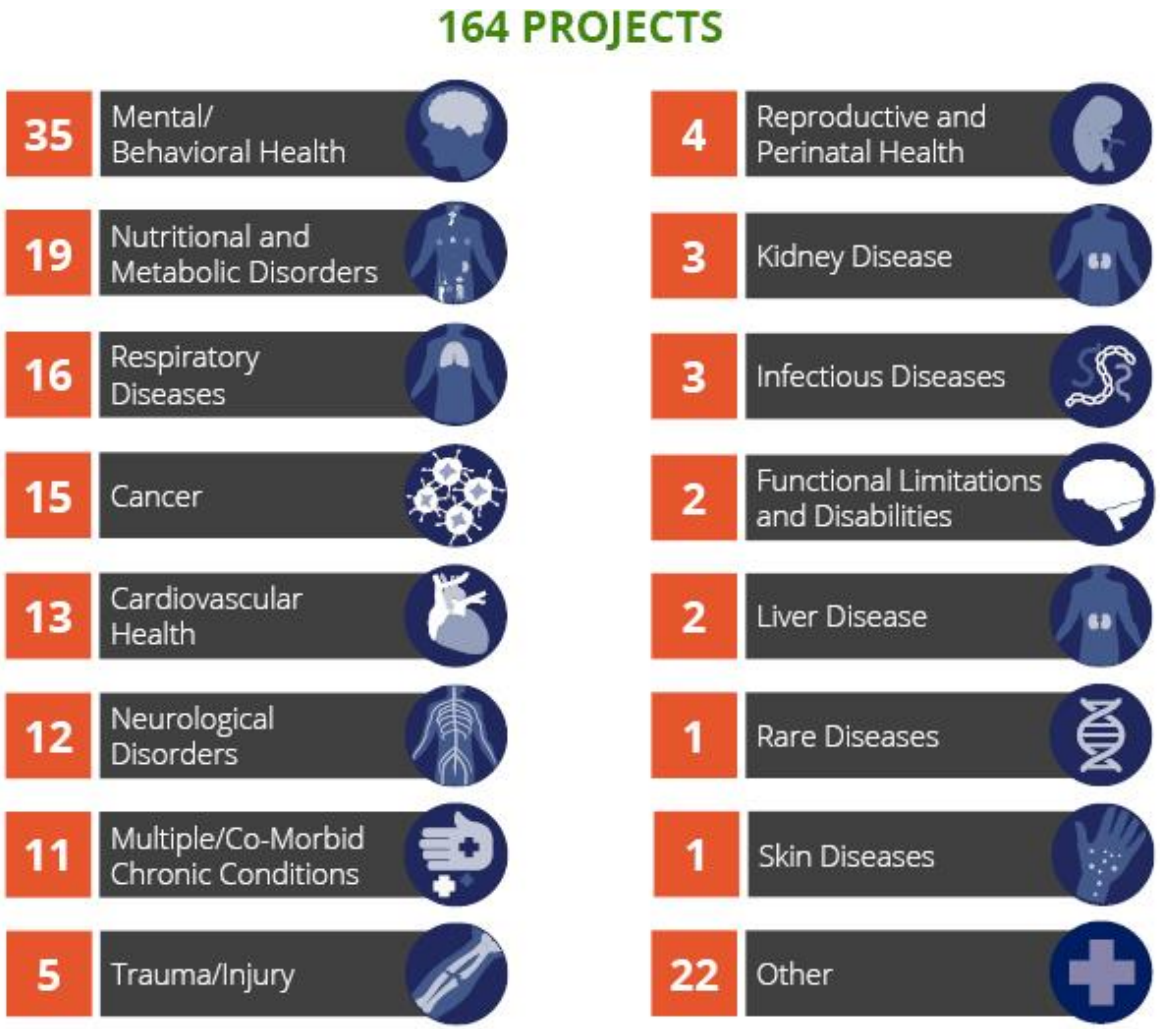
IHS & AD Portfolios by Study Population (as of 3/2017)



IHS & AD Portfolios by Disease Focus (as of 3/2017)

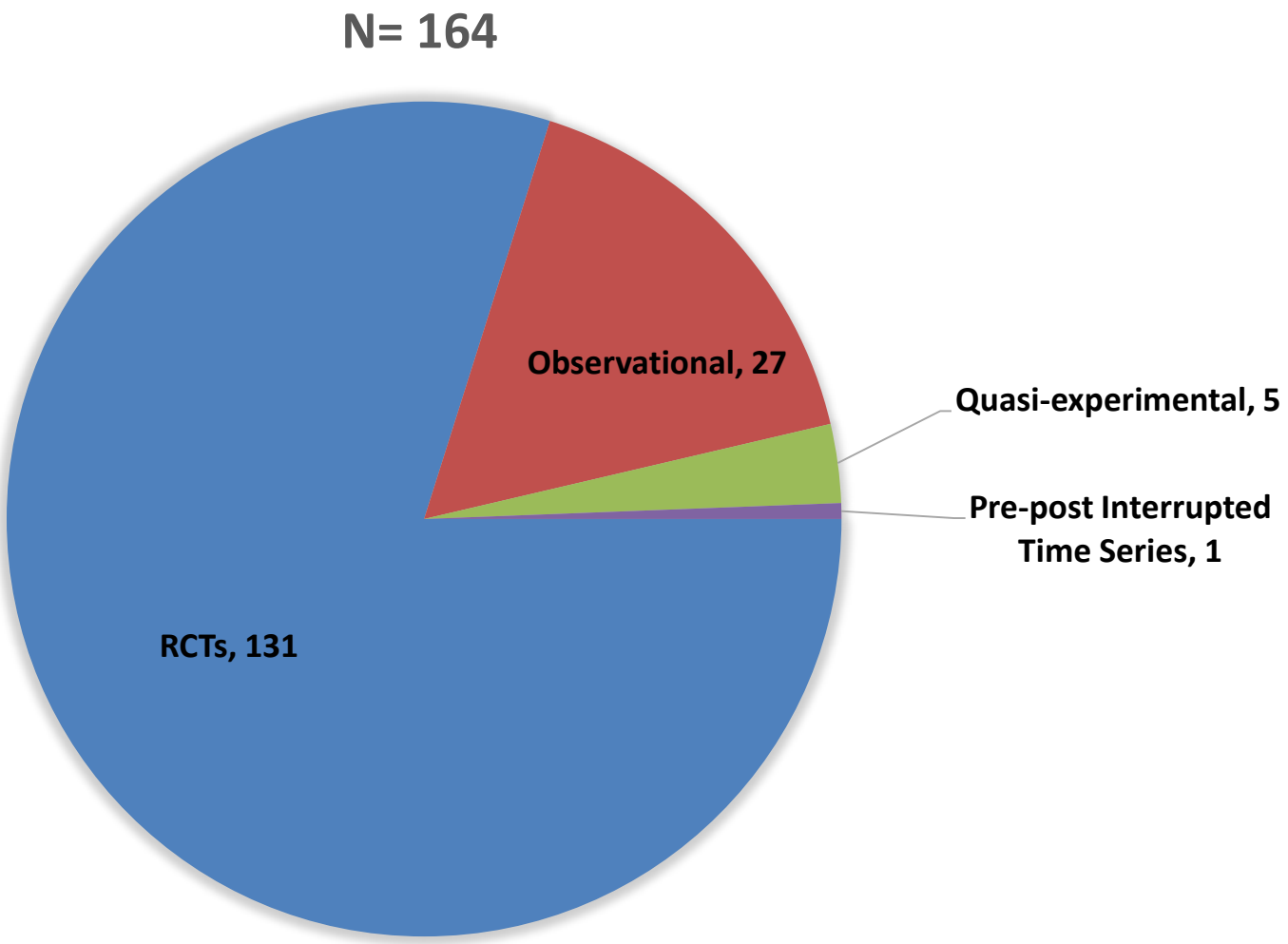


HDDR Portfolio by Primary Disease Focus



As of March 2017

HDDR Portfolio by Study Design (as of 3/2017)



HDDR Portfolio: Pragmatic Clinical Studies

IHS has funded 7 PCS studies thus far:

1. **"Integrating Behavioral Health and Primary Care"** – PI: Benjamin Littenberg, MD at University of Vermont and State Agricultural College **Integration of Mental Health and Primary Care Topic Prioritized April 2013**
2. **"Early Supported Discharge for Improving Functional Outcomes After Stroke"** – PI: Pamela Duncan, PhD, PT at Wake Forest University **Transitional Care Topic Prioritized April 2013**
3. **"A Pragmatic Trial to Improve Colony Stimulating Factor Use in Cancer"** – PI: Scott Ramsey, MD, PhD at Fred Hutchinson Cancer Research Center
4. **"Integrating Patient-Centered Exercise Coaching into Primary Care to Reduce Fragility Fracture"** – PI: Christopher Sciamanna, MD at Penn State U Hershey Medical Center
5. **"Dissemination of Effective Smoking Cessation Treatment to Smokers with Serious Mental Illness"** – PI: Eden Evins, MD, MPH at Massachusetts General Hospital
6. **"A Simple Large Trial of Patient-Centered Care for Opioid Use Disorders in Federally Qualified Healthcare Centers and Specialty Care Settings"** – PI: David Gastfriend, MD at Treatment Research Institute
7. **"Improving Transition from Acute to Post-Acute Care following Traumatic Brain Injury"** – PI: Jeanne Hoffman, PhD at University of Washington

HDDR Portfolio: Pragmatic Clinical Studies

PCS Priority Topics – IHS, Cycle 1 2017	Date Prioritized
Treatments for mild to moderate depression and anxiety	April 2013
Support services for infants and families/caregivers after discharge from the NICU	January 2015
Preventing dental caries in children in medically underserved areas	January 2015
Management of patients suffering from chronic, non-cancer pain	May 2014
Integrating pharmacists or pharmacy services into patient care	January 2015
Minimizing suicidality among adolescents	January 2015
Multidisciplinary rehab for Traumatic Brain Injuries	January 2015
Screening, brief intervention, and referral to treatment for adolescent alcohol abuse	November 2015

HDDR Portfolio: Pragmatic Clinical Studies

AD has funded 2 PCS studies thus far:

1. **"Integrated Versus Referral Care for Complex Psychiatric Disorders in Rural FQHCs"** – PI: John Fortney, PhD at University of Washington
2. **"Patient Empowered Strategy to Reduce Asthma Morbidity in Highly Impacted Populations (PESRAMHIP)"** – PI: Elliot Israel, MD at Brigham and Women's Hospital

PCS Priority Topics – AD, Cycle 1 2017	Date Prioritized
Multicomponent interventions to reduce initiation of tobacco and promote cessation of tobacco use among high-risk populations with known disparities	April 2014
Integration of mental and behavioral health services into the primary care of persons at risk for disparities in health care and outcomes	January 2014
Improving outcomes in mothers and babies at risk for disparities by comparing evidence-based models of perinatal care	April 2013
Clinical interventions to reduce non-traumatic lower extremity amputations in racial or ethnic minorities and low-income populations with diabetes	April 2013

HDDR Portfolio: Targeted Funding

Funded Targeted Topics - IHS	Total Funding Allocated
STRIDE / Falls Injury Prevention (Administered by NIA)	$30 million
Effectiveness of Transitional Care* (Project ACHIEVE)	$15.5 million
Managing Anti-Viral Therapy for Hepatitis C infected persons who inject drugs	$14 million
Treatment for Multiple Sclerosis	$6 million
Targeted Topics In Progress - IHS	**Total Funding Allocated**
Multiple Sclerosis	$10 million (IHS question)
Palliative Care*	$48 million
Preventing Opioid Misuse in Pain Management*	$30 million
Targeted Topics In Progress - AD	**Total Funding Allocated**
Management of care transitions for emerging adults with Sickle Cell	$25 million

* Topics prioritized by the IHS Advisory Panel

The AD Portfolio: Targeted Funding

Funded Targeted Studies	Total Funding Allocated
Comparative Effectiveness of Health System vs. Multi-level Interventions to Reduce Hypertension Disparities	$12 million
Collaboration to Improve Blood Pressure in the US Black Belt-Addressing the Triple Threat	$9.5 million
The Louisiana Trial to Reduce Obesity in Primary Care	$10 million
Midwestern Collaborative for Treating Obesity in Rural Primary Care	$10 million
Using Information Technology to Improve Access, Communication and Asthma in African American and Hispanic /Latino Adults	$2 million
Improving Asthma Outcomes Through Stress Management	$2 million
The Coordinated Healthcare Interventions for Childhood Asthma Gaps in Outcomes (CHICAGO) Trial	$4 million
Imperial County Asthma Comparative Effectiveness Research Project	$4 million
Clinic-Based vs. Home-Based Support to Improve Care and Outcomes for Older Asthmatics	$3 million
The Houston Home-based Integrated Intervention Targeting Better Asthma Control (HIIT-BAC) for African Americans	$2 million
Guidelines to Practice (G2P): Reducing Asthma Health Disparities through Guideline Implementation	$3 million
Preference and Effectiveness of Symptom-Based Adjustment of Inhaled Corticosteroid Therapy in African American Children	$2 million

The IHS Portfolio: Natural Experiments Network

First IHS Collaboration with PCORnet

- 3 Natural Experiments Network Projects:
  1. "The Impact of Medicaid Health Homes on patient with diabetes" – What is the comparative effectiveness of the Medicaid Health Home (HH) program to treatment as usual in reducing unnecessary hospitalizations and other health disparities for Medicaid patients with diabetes? ($2,250,000)
  2. "A Patient-Centered PaTH to Addressing Diabetes: Impact of State Health Policies on Diabetes Outcomes and Disparities" – What is the effectiveness of diabetes education and counseling in improving weight loss for adults either with or at high risk of type 2 diabetes? ($2,249,522)
  3. "Natural Experiments of the Impact of Population-targeted Health Policies to Prevent Diabetes and its Complications" – What is the comparative effectiveness of non-face-to-face care coordination services versus treatment as usual on diabetes outcomes for adults with type 2 diabetes and at least one other chronic condition? ($2,249,676)

The Natural Experiments Network is a multi-center network intended to:

- Test the comparative health impact of naturally occurring interventions
- Improve the methods and research infrastructure for natural experiments for clinical comparative effectiveness in public health

Topics Discussed at Last Meeting

- Medication Assisted Treatment for Opioid Use Disorder
- Care Models for High-Cost High-Need Patients
- Preventing Dental Caries in Children
- Pharmacy Services Integration into Patient Care

HDDR Portfolio: Concluding Thoughts

- We continue to develop a diverse, patient-centered portfolio.
  - All studies feature novel comparators or well-defined usual care practices, and aim to address decision dilemmas faced by patients, caregivers, clinicians, and/or healthcare system leaders
  - Research questions are based on real-world problems faced by patients as they access care in various settings
  - We strive to address evidence gaps in the treatment of varied diseases, populations, levels of the healthcare system, and phases in the care continuum
  - All studies undergo a rigorous vetting of the methods and analysis to be used
  - Engagement of patients, caregivers and other stakeholders throughout the research process is an integral element of all funded studies, which we believe is essential for real-world applicability and sustainability

Where do you see gaps and opportunities?

Morning Break

Awardee Presentation: *Using Technology to Deliver Multi-Disciplinary Care to Individuals with Parkinson's Disease in Their Homes*

Ray Dorsey, MD, MBA
University of Rochester

Training the Next Generation of PCOR Professionals to Lead Research Within Learning Health Systems

Carly Parry, PhD, MSW

Adapted from PCORI Board of Governor's meeting on January 24, 2017

Proposed PCORI-AHRQ Program for Training Researchers Based in Learning Health Systems

- PCORI would provide total of $30M to support up to 8 **institutional** training programs, each with multiple trainees over 5 years – some housed within or affiliated with PCORnet sites – administered by AHRQ through K12 traineeship mechanism
- PCORI contribution would be a major component of AHRQ's new, national multi-pronged approach to training LHS researchers:
  - LHS training within AHRQ's traditional NRSA training program
- Applicants may be academic institutions OR healthcare delivery systems with track records in systems-based research
- Target candidates include doctoral, post-doctoral scholars as well as masters level staff in leadership roles at participating health systems
- Program will combine didactic and experiential learning opportunities within research projects to ensure core competencies are mastered
- Affiliation with PCORnet mentioned as attractive feature, but not in any way required

Research in the Learning Health System

- Concept of researchers embedded within Learning Health Systems promoted by IOM beginning in 2012 and greatly advanced in PCORnet-IOM meetings with CEOs – 2014 and 2016
- Science, informatics, incentives, and culture are now aligned to make this feasible and necessary
- In-system experiences can generate new generalizable knowledge by systematically capturing and analyzing longitudinal data from the care experience
- Best practices can be identified from in-system research as well as external sources and embedded into care processes via HER and into system culture and program to improve outcomes
- Patients, families, and clinicians expected to be active participants in all elements of the research and training program

Training A New Type of Health Services Researcher for the LHS

- Current Training Models: Support skills development in knowledge generation by not the additional skills or experience necessary to work and succeed within LHSs
- Concept: To embed and train new researchers at the interface of research, informatics and clinical operations within PCORnet and other learning health systems
- Core Competencies: To construct and implement training for a set of core competencies to guide the development of training programs for learning health systems researchers

Draft Core Competencies

- **Domain 1: Systems Science:** *systems theory, how systems operate*
- **Domain 2: Research Questions and Standards of Scientific Evidence:** *Asking meaningful questions and evaluating scientific evidence*
- **Domain 3: Research Methods**
- **Domain 4: Informatics:** *using IT systems to improve patient and system outcomes*
- **Domain 5: Ethics of Research and Implementation in Health Systems:** *Ensuring that research done in health care settings adheres to the highest ethical standards*
- **Domain 6: Improvement and Implementation Science:** *Reducing inappropriate variation in outcomes; ensuring systematic uptake of research findings*
- **Doman 7: Engagement, Leadership, and Research Management:** *Engaging patients, clinicians and others in all aspects of the research process*

Program Specifications

- Encourage applications from PCORnet academic institutions and/or delivery systems as training programs or partnered sites
- Require strong coordinated infrastructure at each institution to support a combination of didactic and experiential training
- Demonstrate a focus on conducting PCOR that is relevant to host health systems and that can be rapidly implemented to improve quality of care and patient outcomes
- Include research projects designed with LHS partners and conducted within LHSs with system data
- Include training and hands-on experience working with health systems data and informatics

Program Specifications, continued

- Must focus on AHRQ-sponsored LHS training competencies or identify competencies their program will deploy, with justification
- Include evidence of support from host institutions and systems (direct or in-kind) and a long-term commitment to trainees
- Applicants should recruit trainees from other health systems thereby ensuring no more than 50% of trainees can come from the applicant institution

Recommendation for PCORI

- PCORI funding would support up to 8 institutional sites
- Anticipate 5-8 trainees per site over 5 years
  - Training duration 2-3 years
- Total of $6 million/year for 5 years = $30M
- Funding mechanism: MOU with AHRQ for K12
- PCORI would participate in the review process
- Board approval granted in January 2017 to support awards to begin summer of 2017

Benefits of this Joint Activity

- This funding announcement and partnership makes a clear statement that PCORI considers system-based research to be an essential, novel aspect of PCOR in the future
- It signals PCORI's interests and concerns for workforce training and supporting young investigators and helps to augment funding in the area of workforce training
- It builds on AHRQ's successful track-record in the are of workforce training and aligns our legislative mandate to contract with AHRQ when appropriate
- It has the potential to strengthen PCORnet by creating a cadre of young scientists familiar with PCORnet, the Common Data Model
- It provides a further incentive for health systems to value and work with PCORnet and PCORI

Questions?

Lunch Break

Meeting will resume at 1:00 p.m. EST

Topic Presentation:

Pharmacy Services Integration Into Patient Care

David Bruhn, PharmD, MBA

Mitzi Wasik, PharmD, BCPS

Penny Mohr, MA

Question in Pragmatic Clinical Studies Funding Announcement

- Compare the effectiveness of various strategies to better integrate pharmacists or pharmacy services in patient care on patient-centered outcomes (e.g., reduction in inappropriate medication use and polypharmacy, access to preventive vaccines (influenza, pneumonia), reduction in adverse events and hospital re-admissions, improved disease- or condition specific outcomes).

Refinement Process

- Subcommittee of the Improving Healthcare Systems Advisory Panel
  - David Bruhn, Mitzi Wasik, Jake Galdo
- Interviews with Key Informants
  - Academy of Managed Care Pharmacy
  - American Pharmacists Association
  - Pharmaceutical Care Management Association
  - Pharmacy Quality Alliance
- PCORI staff review of systematic reviews and recent literature
  - Stephanie Parver
  - Anushka Sindkar
  - Penny Mohr
- Findings presented today are preliminary

Research Questions

- **Question 1**: What are the comparative benefits and risks of different models of *Medication Therapy Management* in elderly patients with chronic disease (such as diabetes, COPD, CHF, or hypertension) to reduce negative clinical outcomes, and improve resource utilization, patient satisfaction/QOL, and medication concordance? In what types of patients is MTM most effective?
- **Question 2**: What are the comparative benefits and risks of different models of *integrating pharmacists into the care transitions* team in order to reduce adverse drug events, improve patient-centered outcomes and lower preventable emergency department visits and re-hospitalizations post hospital discharge among patients with multiple chronic co-morbidities?
- **Question 3**: What are the comparative benefits and risks of *using pharmacists to screen for substance use disorder and/or dispense naloxone* for patients who are opioid dependent SUD versus primary care physicians (usual care?)

Medication Therapy Management

- What are the comparative benefits and risks of different models of Medication Therapy Management (MTM)* in elderly patients with chronic disease (such as diabetes, COPD, CHF, or hypertension) to reduce negative clinical outcomes, and improve resource utilization, patient satisfaction/QOL, and medication concordance? In what types of patients is MTM most effective?

*Defined as "...a distinct service or group of services that optimize therapeutic outcomes for individual patients." It includes five core elements: medication therapy review, personal medication record, a med-cation related action plan, intervention and/or referral, and documentation and follow-up (Bluml 2005)

Why is this issue significant?

- There is significant harm associated with medication errors, polypharmacy and lack of concordance with prescribed therapies:
- Elderly patients are particularly susceptible to medication problems due to polypharmacy. In 2002, more than half of people aged 65+ were taking 5 or more medications, and 20% were taking 10 or more (Kaufman et al. 2002)
- Significant costs could be avoided by addressing issues related to inappropriate pharmaceutical use (IMS Institute for Healthcare Informatics, 2013) :
  - Lack of concordance ($105.4 billion)
  - Medication errors ($20 billion)
  - Mismanaged poly pharmacy ($1.3 billion)
- There is stakeholder interest. Recommended as a priority topic by the Academy of Managed Care Pharmacy and at a 2016 PCORI Pharmacy Benefit Roundtable. Also of interest to American Pharmacists Association, Pharmacy Quality Alliance, and Pharmaceutical Care Management Association.

What is the evidence gap?

- MTM is in widespread use in the Medicare population, but there is a lack of evidence about which models are most effective, and little is known about which populations would benefit most.
- MTM studies are hindered by poor methodology, the heterogeneity of study populations and the variation in the strategies studied (Viswanathan 2015).
- As most MTM research has been conducted in the private insurance setting, there is a need to assess the benefit of MTM for other populations, such as elderly patients with complex conditions. (Perloth 2013)
- Specifically, there is insufficient research on the effect MTM on patient satisfaction, health resource utilization, and role in achieving goals of care (Nkansah 2010)
- More research is needed on mechanisms to better engage patients in programs and sustain their long term interest in medication management (Viswanathan 2015)

Potential comparative models

- No clear evidence-based models of MTM;
- Stakeholder interviews suggested comparing:
  - MTM with collaborative practice agreements versus those without (Kiel, 2005);
  - Variations in pharmacists' scope of practice within collaborative practice agreements (e.g., allowing pharmacists to make referrals within more integrated models);
  - Evaluation of specific components of MTM (e.g., allowing access to more complete healthcare data);
  - Mode of service (e.g., telephone versus co-located in patient-centered medical homes)

Likelihood of Implementation and Timeliness

- What is the likelihood of implementation?
  - There are strict eligibility criteria for patients to receive MTM services in their Part D drug plan and no reimbursement for services. This makes it difficult for health plans and community pharmacies to invest in developing MTM programs.
  - Physicians have been resistant into entering into collaborative practice agreements
  - Medicaid programs have greater flexibility in the design of their MTM programs (eligibility, service model) and could be a better environment to develop innovative, effective MTM programs.
- Why is this research timely?
  - It may not be. CMS has launched a 5-year Part D Enhanced Medication Therapy Management Model initiative that will test innovative models of care. This will not be complete until 2021.
  - For this initiative, MTM standard service definitions and code sets are being developed that will facilitate future research.

Discussion

- Is this topic compelling enough to warrant further investigation and refinement? If so, how should the question be refined?
- Do the potential barriers to research seem surmountable?
- Do the potential barriers to adoption of effective models seem surmountable?

Pharmacists Integration into Care Transitions

- What are the comparative benefits and risks of different models of integrating pharmacists into the care transitions team in order to reduce adverse drug events, improve patient-centered outcomes and lower preventable emergency department visits and re-hospitalizations post hospital discharge among patients with multiple chronic co-morbidities?

Why is this issue significant?

- The failure to adequately attend to care transitions increases Medicare's annual spending by $12 billion as 75 percent of 30-day readmissions are preventable (MedPAC 2007).
- Two-thirds of these readmissions are costly drug-related events (IOM, 2006).
- Up to 50 percent of medication errors and 20 percent of adverse drug events have been associated with a lack of communication during care transitions (Resar 2012).
- The Joint Commission's National Patient Safety Goals for ambulatory care include reconciliation of a patient's medication list during care transitions—and the Joint Commission has prioritized work to reduce hospital readmissions (Joint Commission 2006)
- American Pharmacists Association see this as a priority area for research

What is the evidence gap?

- Though there are a number of studies on the role of pharmacists in care transition to prevent poor patient outcomes, they are generally underpowered, have a high risk of bias, and provide insufficient evidence to make any conclusions about the most effective models of integrating pharmacists into care transitions (Thomas, et al. 2014)
- Additional research is needed to better understand the most effective models of pharmacist-assisted care transitions, as well as the settings and populations in which these strategies can be most beneficial.

Models of pharmacist integration in care transitions

- Face-to-face pharmacist-assisted discharge counseling to review medication list, provide patient/caregiver teaching, and resolve any medication issues prior to discharge (Trang 2015)
- Post-discharge follow-up calls to the patient from the pharmacist, at various intervals (Budiman 2016)
- Provider-to-pharmacist follow-up post-discharge to confirm medication lists, face-to-face or via telephone (Kilcup 2013)
- Pharmacist as a member of the care transitions team, providing services prior to discharge (Koehler 2009)
- Use of a care coordinator (case manager, advanced practice nurse, or similar) as a conduit between the hospital and the patient's community pharmacy, and between the patient and caregiver (Walker 2009)

Likelihood of Implementation and Timeliness

- What is the likelihood of implementation?
  - Hospitals, health plans, healthcare quality advocates, and ACOs are interested in programs to reduce re-admissions.
  - Though medication reconciliation at discharge has been shown to reduce re-admissions, a significant amount of work remains to most effectively integrate pharmacists into the current work flow of discharging and transitioning patients out of acute care (Mekonnen et al. 2016)
  - Health plans, providers, and insurers will need to see considerable evidence on the efficacy of adding pharmacists to the care transitions team before investing in these programs
- Why should PCORI fund research in this area right now?
  - There are some evidence-based models of integrating pharmacists into the care transition, but there are no good comparative studies
  - Such research would complement PCORI's active transitions in care portfolio

Discussion

- Is this topic compelling enough to warrant further investigation and refinement? If so, how should the question be refined?

- Which models of care are seem compelling enough to warrant further investigation and refinement?

Afternoon Break

TC E2AN Transitional Care Evidence to Action Network

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Transitional Care Evidence-to-Action Network (TC-E2AN)

IHS Advisory Panel Meeting

March 31, 2017

Carly Parry, PhD, MSW--Senior Program Officer, IHS

Introduction and Context: The Transitional Care Evidence to Action Network (TC-E2AN)

- Purpose and Structure of the Transitional Care Evidence to Action Network
- Overview of the Studies
- Activities to Date
- Current Activities and

  Next Steps

Transitional Care Evidence to Action Network: A Strategy for Bridging the Gap

- **Organized around** strategic portfolio area: **"Transitional Care"**
- **Developed area**, primed for CER and impact
- **Fit with PCORI's foci** on patient-centeredness, contextual factors (beyond rehospitalization→ patient experience)
- **Impact**: changing the dynamic of the evidence conversation to groups or clusters of studies, portfolios.

PCORI's Transitional Care Evidence to Action Network

Organized around strategic portfolio area: **"Transitional care"**

- **Facilitate engagement among awardees and cross-learning between projects** studying transitional care to leverage the significant investment made to date and strengthen the impact of the individual projects
- **Promote collaboration among awardees to enhance their in-progress work** by sharing best practices, measures, tools, opportunities, etc.
- **Engage key stakeholders/end-users, facilitate exchanges between awardee teams and these groups** to convey the relevance of the findings

PCORI's Transitional Care Evidence to Action Network

- **20 PCORI awardee teams: ~$69M**
- E2AN members accelerate research & its impact:
  - Identify common **challenges**, **strategies**
  - Highlight **lessons learned & best practices**
  - Identify useful (common) measures/tools
  - Maximize utility of **patient engagement** throughout the research process
  - Synthesize **portfolio contributions** in a manner that is actionable and relevant to end users

PCORI's Transitional Care Evidence to Action Network

- PCORI has made a **$69M** investment in **20 projects** in Transitional Care in 16 states
  - 1 Project (Williams **$15.0M**) funded through an IHS topic-specific PFA
  - 1 Project (Duncan **$14.2M**) funded as an IHS Pragmatic Clinical Study
  - 18 projects (**$39.7M**) funded via the Broads mechanism
    - 14: Improving Healthcare Systems
    - 2: Addressing Disparities
    - 1: Assessment of Prevention, Diagnosis and Treatment Options
    - 1: Improving Methods for Conducting PCOR

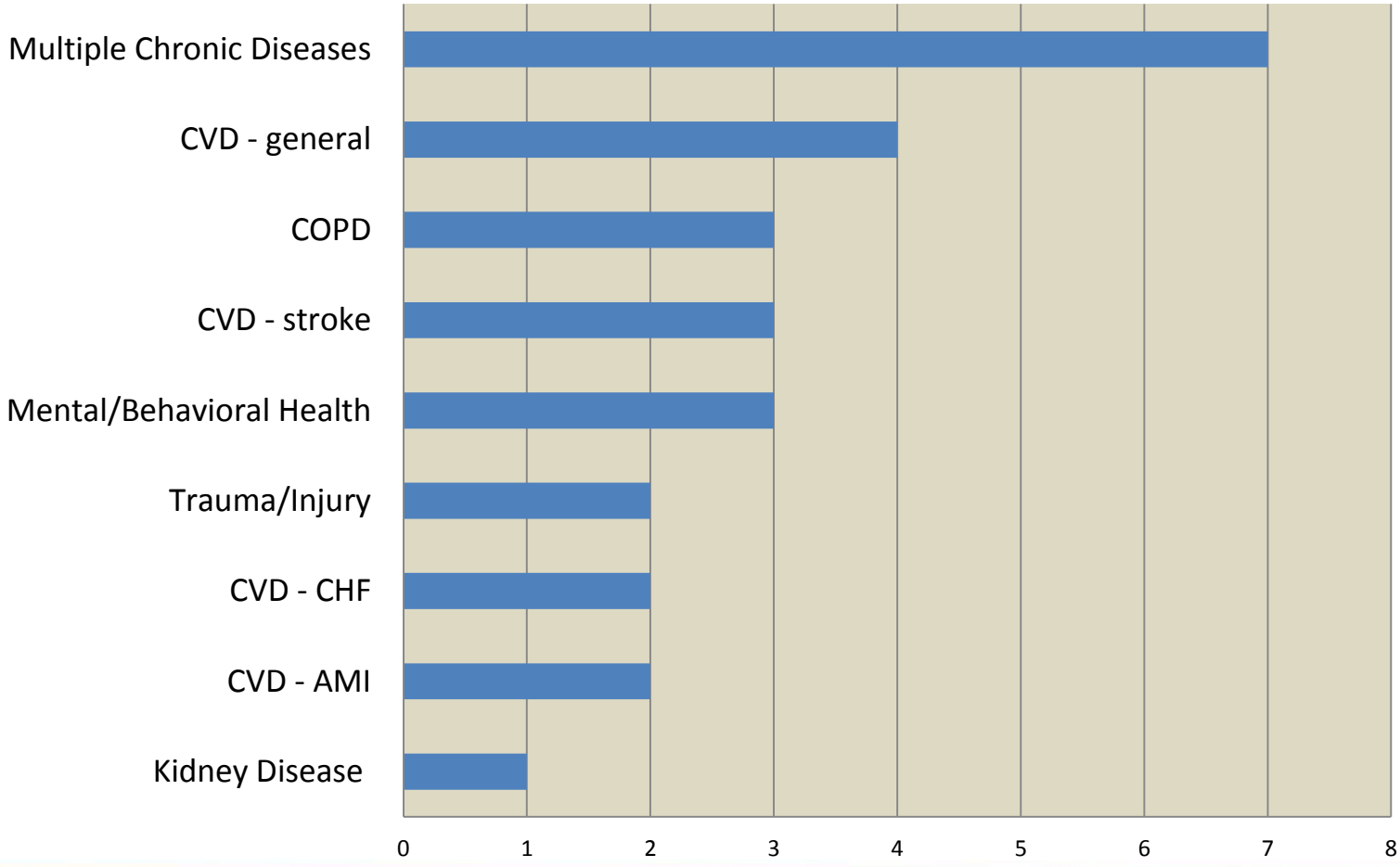
PCORI's Existing Transitional Care Evidence to Action Network

Project Characteristics

- 20 patient-centered CER studies*
  - 12 RCTs (patient level)
  - 1 interrupted time series
  - 2 cluster randomized
  - 2 quasi experimental
  - 2 stepped wedge
  - 2 observational
- 2 studies focus on children, while the remainder focus on adults (all ages)
- Interventions are all multi-component and include:
  - Rehabilitation
  - Counseling
  - Community health workers
  - Peer support
  - Care coordination
  - Self-management
  - Technology (patient portals)
  - Clinician/patient education
- Interventions take place in the hospital, ambulatory, ED, community, virtual, and home settings

Number of Awards by Disease/Condition

(N=20 studies; studies may include multiple diseases/conditions)



Gaps Network Fills

Characterization:

- Many efficacious studies conducted >10 years ago
- Primarily **hospital-focused**, less evidence re: role of primary care teams during care transitions
- Dearth of high-quality evidence in MH or surgical populations

Evidence gaps identified:

- Extent/for whom post-discharge home visits are necessary component of TC interventions
- Which strategies should be employed to improve safety and reduce post-discharge adverse events
- No patient population within which transitional care interventions are uniformly successful. Suggests role of contextual factors…

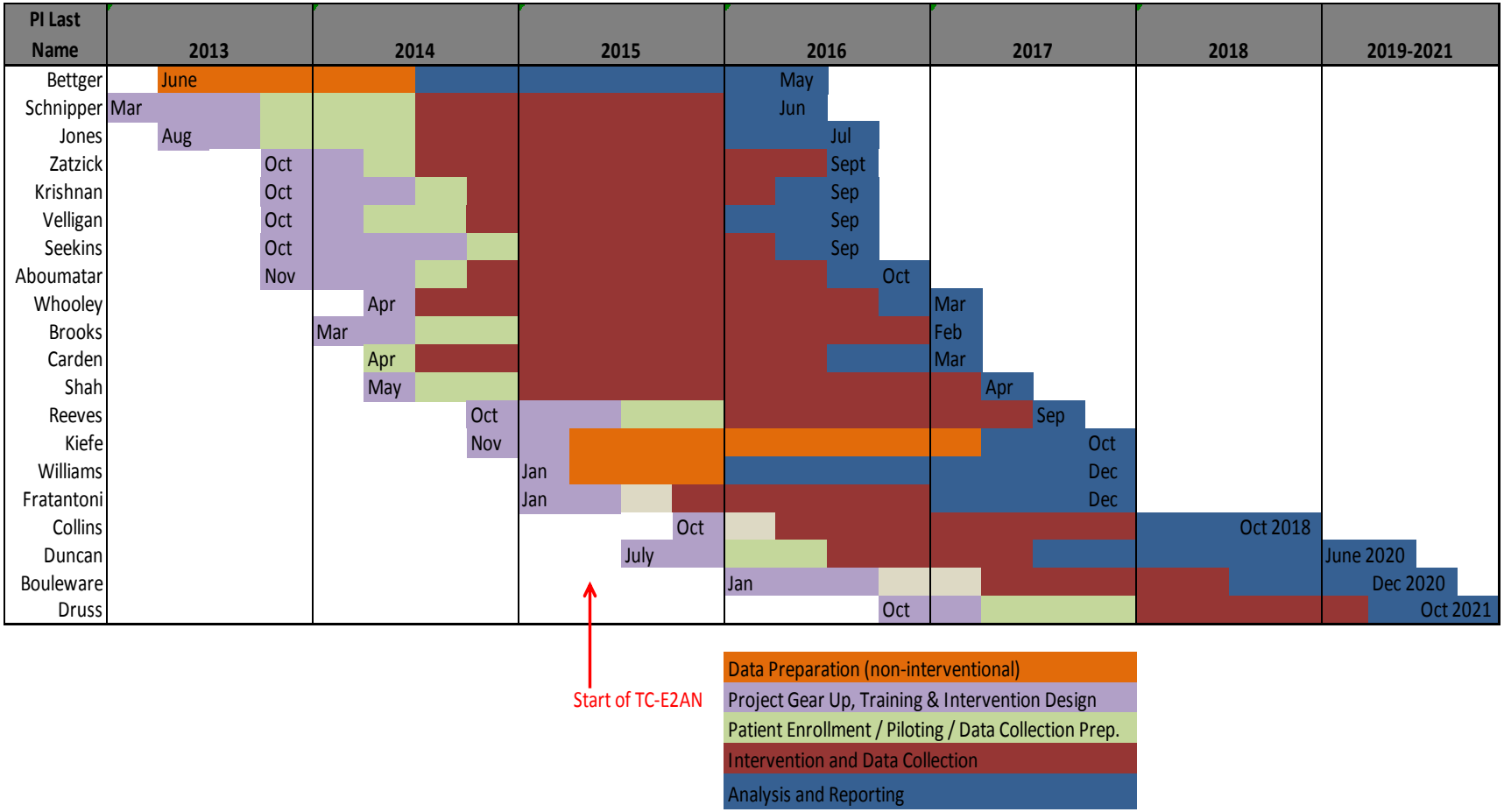
Kansagara D, Chiovaro JC, et al. Transitions of care from hospital to home: a summary of systematic evidence reviews and recommendations for transitional care in the Veterans Health Administration. VA-ESP Project #05-225; 2014.

Contextual Factors

- Target population
- Patient and caregiver capacity for/engagement in self-care
- Intervention setting/s
- Provider authority and self-efficacy
- Technology environment
- Community resources (rehab facilities)
- External policy, incentives, pressure to implement
- Fee for service vs. Integrated delivery environment

Leppin AL, Gionfriddo MR, Kessler M, et al. Preventing 30-day hospital readmissions: a systematic review and meta-analysis of randomized trials. *JAMA Intern Med*. 2014 July; 174(7): 1095–1107.
Albert NM. A systematic review of transitional-care strategies to reduce rehospitalization in patients with heart failure. *Heart Lung.* 2016 Mar-Apr;45(2):100-13.

Duration and Overlap of Studies



Shift in Network Focus

***Away from Dissemination and Implementation**

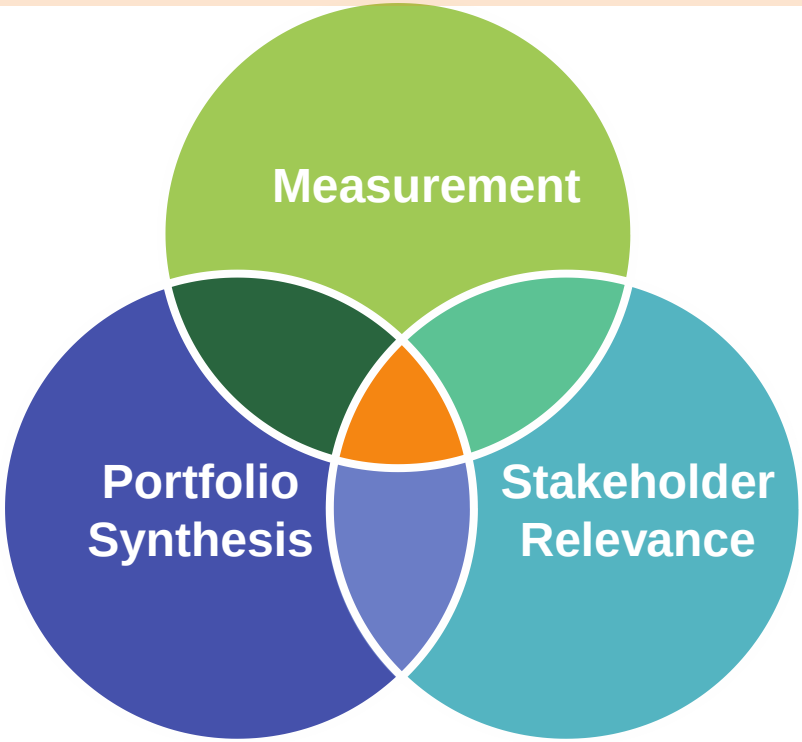
***Toward Portfolio Communication**

- **Changes to affinity groups**
- **New ways to communicate about the portfolio in progress: evidence mapping, website, video work**

TC-E2AN Affinity Groups

Patient and Stakeholder Engagement

TC-E2AN Overarching Goal: Connect investigators across projects to facilitate collaborative learning and problem solving, accelerate the research process, and maximize the impact of investments in TC services to support the overarching goals of improving patient-centered outcomes, engaging patients and other stakeholders, and communicating value

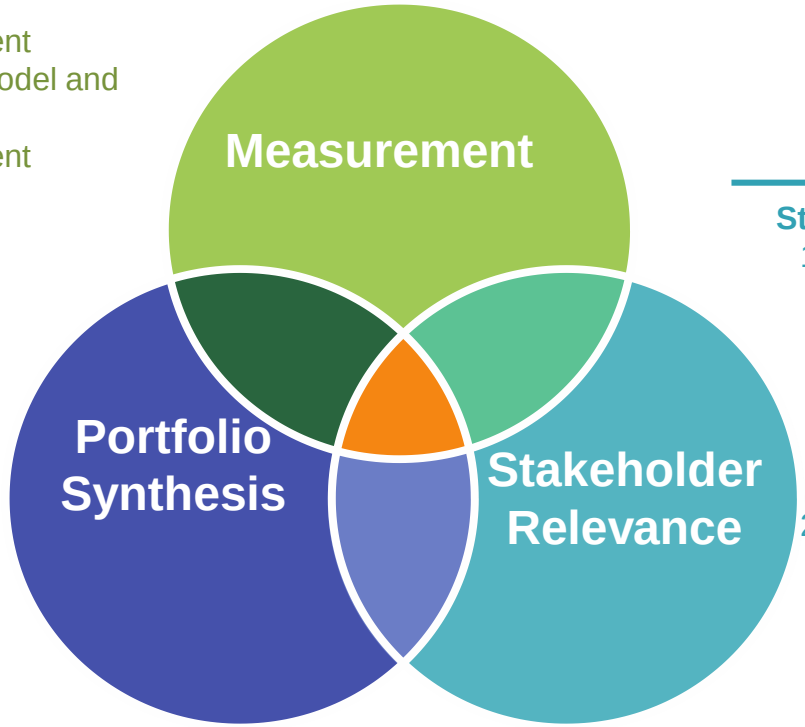


Overview of the Goals of the TC-E2AN Affinity Groups

Patient and Stakeholder Engagement

Measurement:

1) Map measures to conceptual model and end-user metrics; and
2) Identify any gaps in measurement
3) Map measures to conceptual model and end-user metrics; and
4) Identify any gaps in measurement



Portfolio synthesis:

1) Contextualize the transitional care studies in the literature and practice context
2) Synthesize the contributions of these studies including patient centered outcomes, stakeholder engagement strategies, subpopulation analyses, and unique study characteristics
3) Develop a searchable interactive web-based platform

Stakeholder relevance:

1) Gather information from TC-E2AN awardees and key stakeholders regarding best practices for promoting implement-ability and sustainability of evidence-based transitional care services; and
2) Deliver a summary of common approaches, effective D&I strategies, and key factors that influence implement-ability and sustainability

Activities to Date

Panel Presentations

- 8th Annual Conference on the Science of Dissemination & Implementation (12/2015)
- Health Care Systems Research Network (HCSRN) Annual Meeting (4/2016)
- IPFCC International Conference on PFCC Poster (7/2016)
- 2016 Advancing the Science of Community Engaged Research Conference Learning Lab (8/2016)
- American College of Surgeons Policy Summit (9/2016)
  - Hosted by the Zatzick team featuring Julie Gassaway (Jones' team)

Activities to Date (cont.)

TC-E2AN Working Meeting (Nov. 16-17, 2016)

- Network input on:
  - Research synthesis, website=portfolio communication
  - Lessons learned
  - Writing Opportunities
  - Conceptual Model

Activities to Date (cont.)

TC-E2AN Working Meeting (Nov. 16-17, 2016) (cont.)

- Sustainability and translation fishbowl with AHIP and Doris Lotz
- Video filming for Website Phase 1 (challenges, innovations)
- Highlighted work of 4 awardee teams (various stages)
- Brainstorm D&I and Eng. opportunities
- Journey mapping exercise for patient partner→ engagement AG

Activities to Date (cont.)
TC-E2AN Panel at the Annual Meeting

Led by Carly Parry, highlighting 2 awardee teams: PI and Patient Stakeholder (Zatzick and Thomas, Carden and Rosini)

Current Activities and Next Steps

1. TC Portfolio Synthesis and Communication
   - Research synthesis, portfolio synthesis, evidence mapping and data visualization, communication incubator
2. Website
   - Video, Lessons Learned, For Patients, Portfolio work
3. Measurement
   - Conceptual Mapping
   - Mapping to metrics that matter

Purpose

- Visualize Transitional Care (TC) evidence landscape/gaps, showcasing PCORI contributions to TC evidence

TC Portfolio Synthesis and Communication

- Various levels and methods:
  1. Evidence Synthesis (e.g., synthesis of systematic reviews)

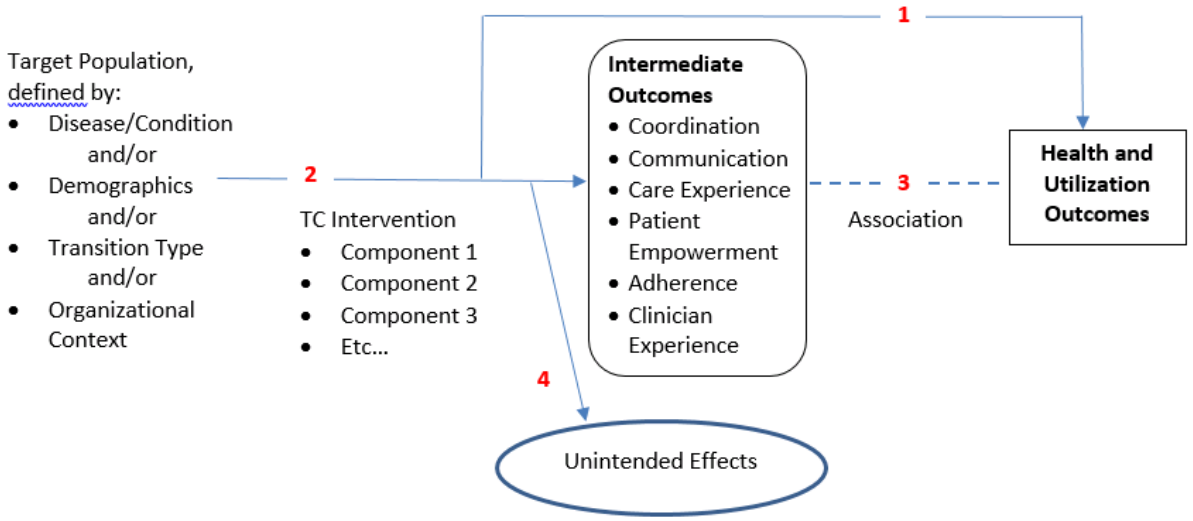
     Qualitative and/or quantitative methods
  2. Synthesis of PCORI's research investments (e.g., portfolio "cluster" analyses, portfolio mapping)
  3. Identification and communication of a body of relevant research (e.g., evidence maps)

Process Evidence Synthesis

Develop analytic framework

- Determine criteria, search terms, abstraction database to track articles and key elements of eligible syntheses
- Conduct broad search of peer-reviewed literature
- Identify evidence syntheses that meet criteria
- Abstract, analyze data and develop evidence map

Analytic Framework



Key Questions:

1 – Is there direct evidence that the TC Intervention, or some of its components, improves health and utilization outcomes for this target population?
2 – Is there direct evidence that the TC Intervention, or some of its components, improves intermediate outcomes for this target population?
3 – Are intermediate outcomes reliably associated with health and utilization outcomes for this target population?
4 – Does the TC Intervention result in unintended effects for this target population?

[1] Based on the approach to reviewing evidence used by the USPSTF. See section 3.2 on page 20 of the USPSTF Procedure Manual for an explanation of this type of Analytic Framework at https://www.uspreventiveservicestaskforce.org/Home/GetFile/6/7/procedure-manual_2016_v2/pdf.

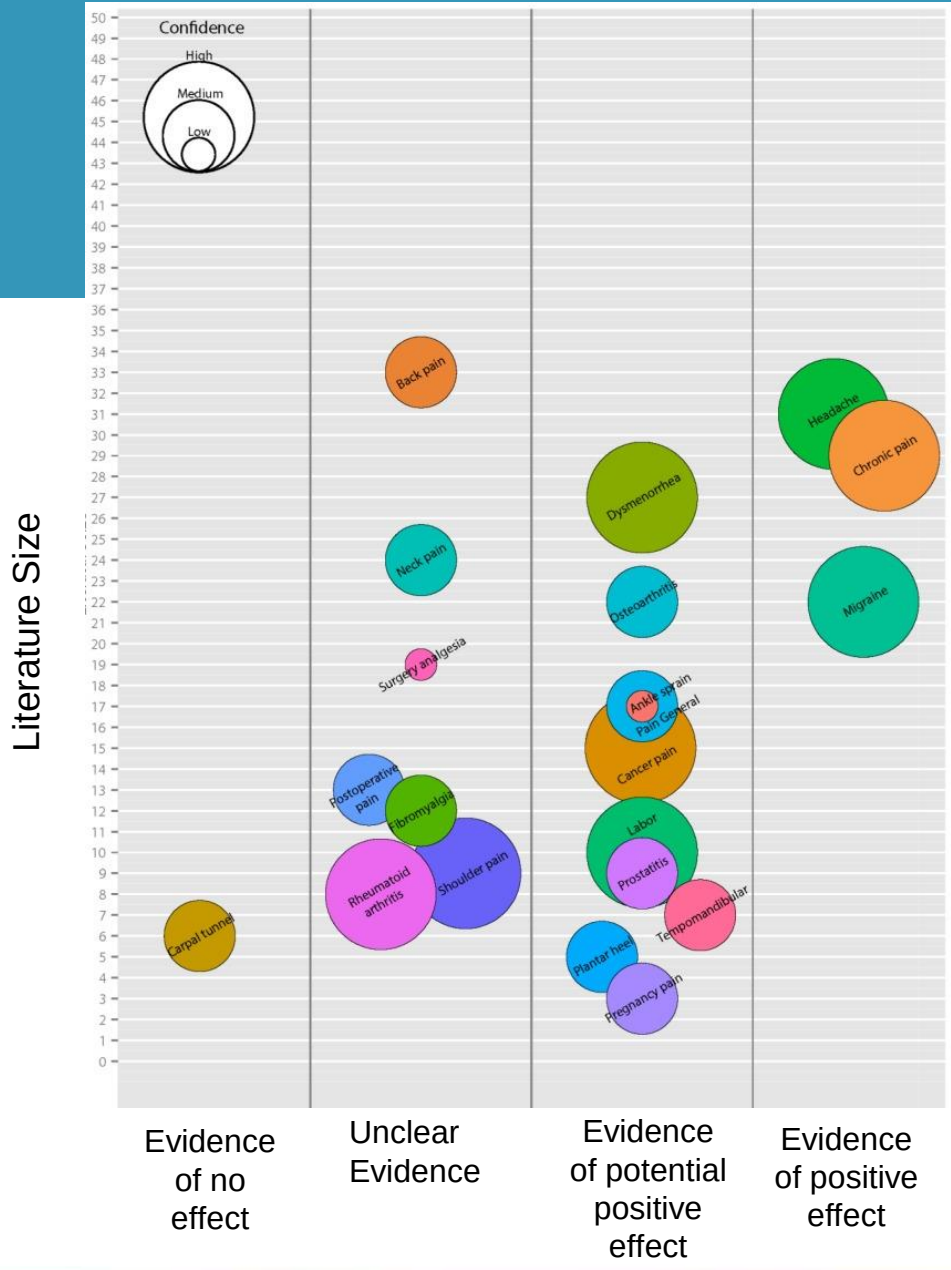
Process PCORI portfolio

- Inventory portfolio
- Categorize studies
  - Transition type
  - Interventions
  - Outcomes
- Analyze and map to evidence map

Sample Evidence Map:

Effects of Acupuncture for Pain

This shows a summary of 59 systematic reviews on the effect of acupuncture on pain



Source: http://www.ncbi.nlm.nih.gov/books/NBK185071/

TC-E2AN Website and Video

- Version 1.0 of the site undergoing final design refinements and review

- Version 2.0 in planning stage
  - User testing
  - Additional content
  - Enhanced features

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Transitional Care Evidence to Action Network

ABOUT TRANSITIONAL CARE | OUR SCIENCE | THE NETWORK | LESSONS LEARNED | EVENTS & PUBLICATIONS | FOR PATIENTS

During transitions between healthcare settings (e.g., hospitals, long-term care facilities, home) or providers (e.g. primary care, specialists), patients and their families may experience fragmented, poor-quality care, which can lead to unsatisfactory outcomes. To address this problem, PCORI has invested $69 million in research to understand which approaches work best to improve transitional care.

Through its Transitional Care Evidence to Action Network (TC-E2AN), PCORI links 20 PCORI-funded research teams to facilitate collaborative learning and share lessons learned in conducting patient-centered research on transitional care. The overarching goal of the Network is to produce actionable and relevant evidence to indicate which approaches to transitional care are most effective in specific populations, and ultimately to improve delivery of transitional care services.

The PCORI Approach to Transitional Care

Why Study Transitional Care

The videos above discuss how PCORI-supported projects address transitional care challenges in ways other research has not, and why transitional care is an important area to study.

About Transitional Care

Poor transitions of care between settings—such as from a hospital to home or a nursing

The Network

PCORI supports the Transitional Care Evidence to Action Network to connect PCORI-funded

TC E2AN

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pcori Transitional Care Evidence to Action Network

PCORI supports the Transitional Care Evidence to Action Network to connect PCORI-funded research teams studying transitional care.

PCORI launched the Transitional Care Evidence to Action Network (TC-E2AN) in 2015 to support and connect PCORI-funded research teams studying transitional care. The Network seeks to facilitate collaboration and share lessons learned about conducting patient-centered research in transitional care.

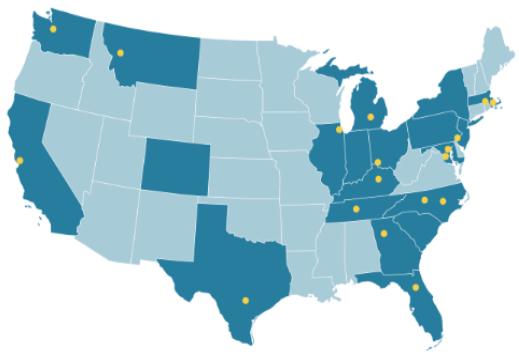
The 20 projects currently composing the TC-E2AN are comparing which approaches work best to reduce readmissions and improve patient experience and a wide range of outcomes important to patients and other healthcare stakeholders. The overarching goal of the Network is to cultivate a body of evidence on transitional care that is actionable and relevant to patients, families, clinicians, healthcare delivery systems, and payers.

The Network includes projects funded under the following PCORI National Priorities for Research:

- Improving Healthcare Systems
- Addressing Disparities
- Accelerating Patient-Centered Outcomes Research and Methodological Research
- Assessment of Prevention, Diagnosis, and Treatment Options

These projects are located across 15 states and the District of Columbia.

Locations of Studies in the Transitional Care Evidence to Action Network



Indicates locations of TC-E2AN study investigators; shaded states indicate study locations.

Using webinars, in-person meetings, collaborative projects, and other approaches, TC-E2AN is designed to:

- **Facilitate** engagement and collaboration among PCORI awardees studying transitional care to enhance work in progress and assure that work is relevant to key stakeholders and end users.
- **Engage** awardee teams and facilitate cross-learning between them.
- **Link** awardees with end users to enhance relevance of evidence and increase the likelihood of uptake of findings.

Network Members & Projects

Find studies by health condition, population, setting, or intervention strategy by selecting a category.

- An Integrative Multilevel Study for Improving Patient-Centered Care Delivery Among Patients with Chronic Obstructive Pulmonary Disease
  Hanan J. Aboumatar, MD, MPH, Johns Hopkins University, Study Location: Maryland
- Comparative Effectiveness of Rehabilitation Services for Survivors of an Acute Ischemic Stroke
  Janet Prvu Bettger, ScD, Duke University, Study Location: Nationwide
- Putting Patients at the Center of Kidney Care Transitions
  Leigh E. Boulware, MD, MPH, Duke University, Study Location: New Jersey, Pennsylvania
- Specialized Community Disease Management to Reduce Substance Use and Hospital Readmissions
  Adam Brooks, PhD, Treatment Research Institute, Inc., Study Location: Pennsylvania
- An Emergency Department-to-Home Intervention to Improve Quality of Life and Reduce Hospital Use
  Donna Lynne Carden, MD, University of Florida, Study Location: Florida

pcori. Transitional Care Evidence to Action Network

ABOUT TRANSITIONAL CARE | OUR SCIENCE | THE NETWORK | LESSONS LEARNED | EVENTS & PUBLICATIONS | FOR PATIENTS

PCORI funds research comparing which approaches work best to optimize care delivery as patients move between clinicians and care settings.

Research We Support

PCORI's research in transitional care generates evidence that will help patients and their families, clinicians, payers, and policymakers make better-informed decisions about which transitional care services are most effective, given patients' needs and circumstances.

$69 Million Awarded | **20** Funded Projects | **15** States with Research Funded

To date, PCORI has funded 20 transitional care projects ($69 million) across 15 states and the District of Columbia. These target a range of diseases and conditions (e.g., stroke, heart disease), patient populations (e.g., Medicare beneficiaries, rural-dwelling patients, children), and settings (e.g., hospital, emergency department, home). Funded between 2013 and 2016, these studies are at varying stages of research.

Explore Our Studies

Learn more about the studies in our transitional care research portfolio.

- Explore the transitional care studies by title or location; or
- Find studies by health condition, population, setting, or intervention strategy by selecting a category below.

Primary Condition/Disease | Patient Population | Care Setting | Intervention Components

Learn more about the key terms on this page

PCORI-Funded Transitional Care Projects

Specialized Community Disease Management to Reduce Substance Use and Hospital Readmissions

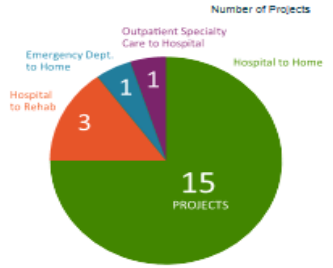
Tests a 90-day program of home visits and telephone calls by trained social workers and peers for patients with medical and substance abuse disorders following a hospitalization.

Go to project profile

What We've Funded

Awards by Funding Type

Awards by Patient Transition Setting



Conditions Studied

In Millions

Cardiovascular Health	$22.2
Non-Disease Specific	$18.9
Mental/Behavioral Health	$11.3
Multiple Chronic Conditions	$5.6
Kidney Disease	$5.6
Trauma/Injury	$3.2
COPD	$2.1

Populations Studied

Number of Projects

General Population	12
Medicare Beneficiaries	3
Children	2
Low Socioeconomic Status	1
Rural	1
Veterans	1

Measurement

- Catalogue measures used on TC-E2AN studies based on conceptual framework
- Catalogue core measures used and classify what does/does not work in context
- Identify measurement gaps (e.g., acceptability, feasibility)

Questions?

Recap of the Meeting & Looking Forward

Timothy Daaleman, DO, MPH

IHS Advisory Panel Co-Chair

Concluding Remarks

Steve Clauser, PhD, MPA

Director, Healthcare Delivery and Disparities Research

Adjourn

Thank you for your participation!

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