

Advisory Panel on Improving Healthcare Systems

October 24 - 25, 2016

9:30 a.m. – 5:30 p.m. EST (24th)

9:00 a.m. – 12:30 p.m. EST (25th)



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome & Introductions

Steve Clauser, PhD, MPA

Director, Improving Healthcare Systems

Housekeeping

- Webinar is available to public
- Members of the public are invited to listen to this teleconference and view the webinar
- 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
- Chair Statement on COI and Confidentiality

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

Improving Healthcare Systems Program Staff



Steven Clauser, PhD, MPA
Director



Penny Mohr, MA
Sr. Program Officer



Neeraj Arora, PhD
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Program Associate



Hannah Kampmeyer
Senior Admin Assistant



Aaron Shifreen
Program Assistant



Allie Olander
Program Assistant



Deborah Egbo
Fall Intern

IHS Program Updates Since Last Meeting

Steve Clauser, PhD, MPA

Director, Improving Healthcare Systems

Overview of PCORI and IHS

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.



IHS Goal Statement

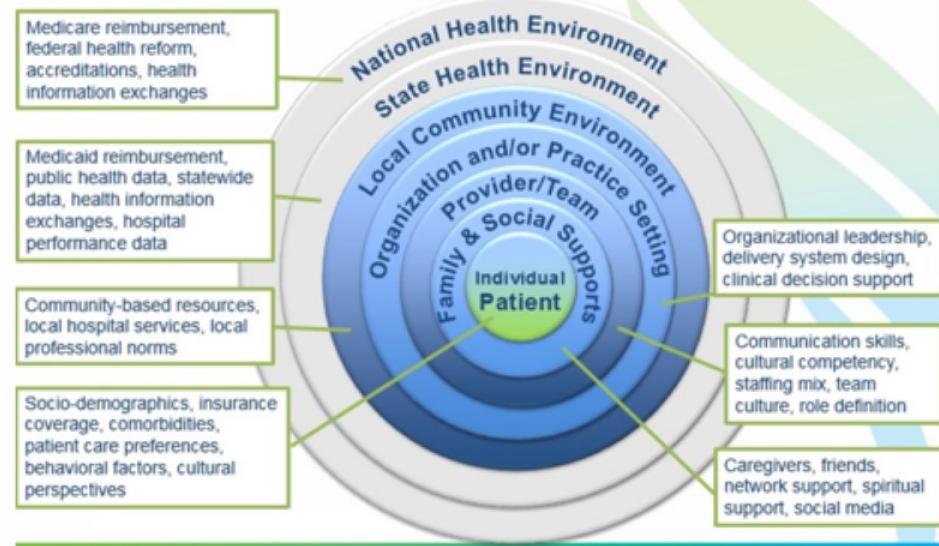
To support studies of the comparative effectiveness of alternative features of healthcare systems that will provide information of value to patients, their caregivers and clinicians, as well as to healthcare leaders, regarding which features of systems lead to better patient-centered outcomes.

Improving Healthcare Systems (IHS) Program Summary

Healthcare Systems patient-centered outcomes research (PCOR) compares healthcare system interventions (e.g., innovative technologies, personnel structures, organizational models and policies, and incentive structures) that are intended to optimize the quality, outcomes, and/or efficiency of patient care and that have the greatest potential for sustained impact and replication within and across healthcare systems.

Healthcare systems operate at multiple societal and organizational levels:

Figure adapted from: Taplin, SH; Clauer, 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

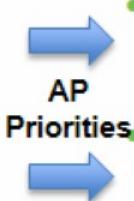
System Level	Examples of Comparisons in the IHS Portfolio
Individual Patient	Compares the use of an electronic asthma medication tracker to standard primary care (no tracker) for children with asthma and their parents and caregivers to improve quality of life, among other patient-centered outcomes.
Family 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.

IHS Portfolio by Funding Mechanism

- 86 Projects; ~\$330 million funding; 28 States including D.C.

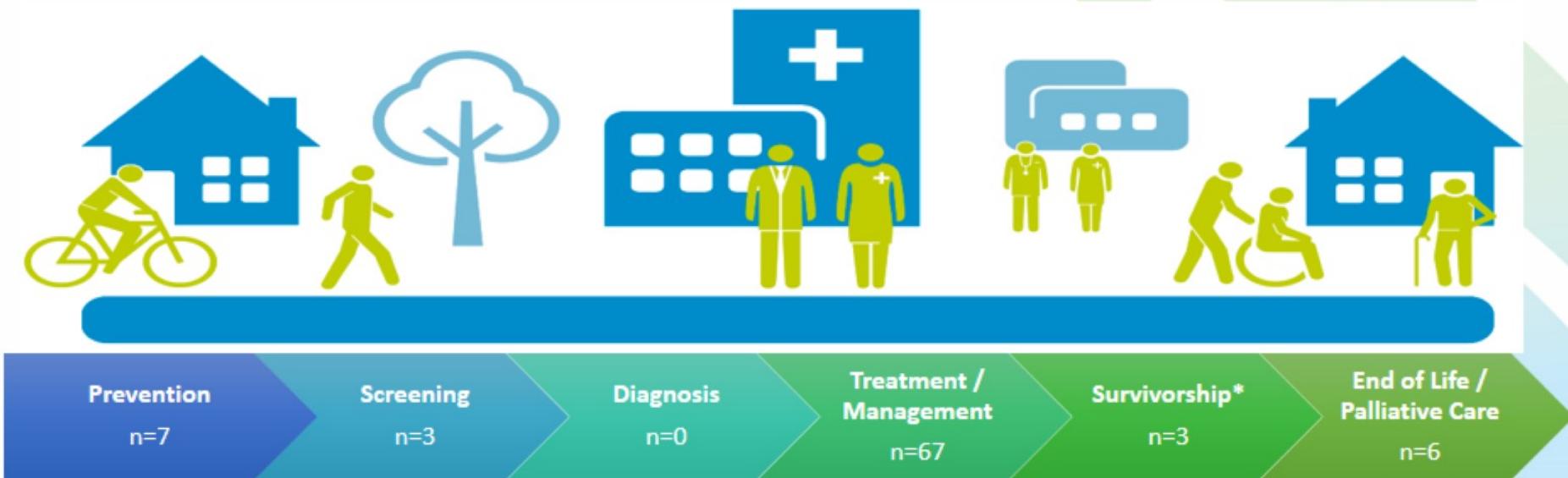
Funding Mechanism	N of Projects	Total Funding
Broad	74	\$192 million
Pragmatic	5	\$64 million
Targeted	4	\$65 million
Natural Experiments	3	\$7 million
Total	86	\$328 million

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



IHS Portfolio by Care Continuum (as of 9/2016)

Number of Studies Across the Care Continuum (n=86)

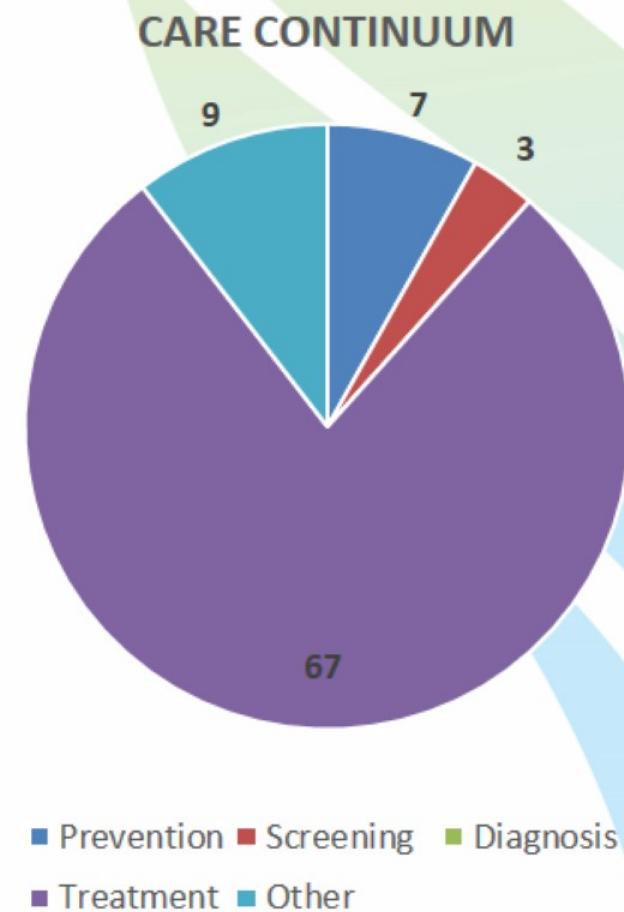


*Unique to cancer studies

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

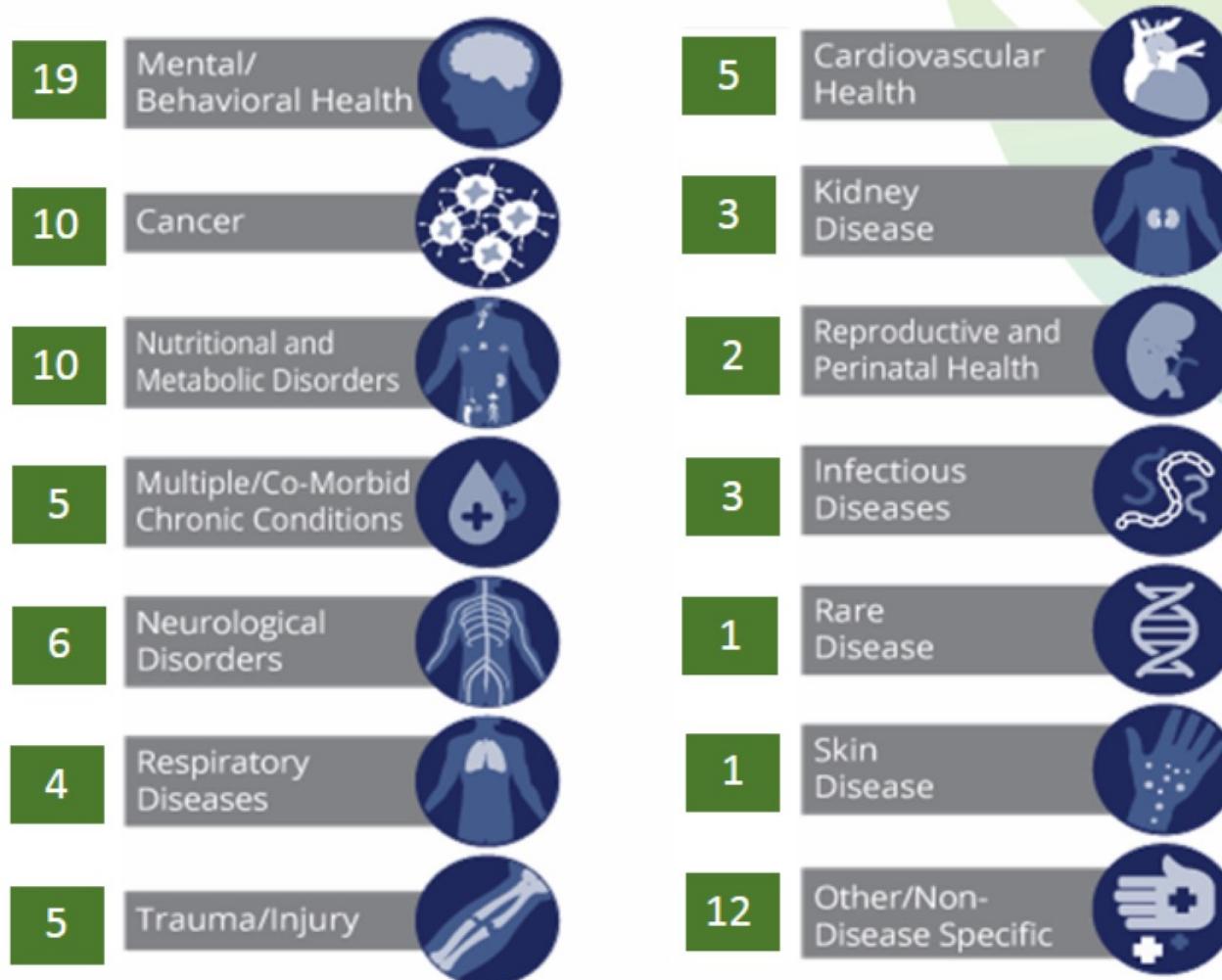
IHS Portfolio Overview (as of 9/2016)

Care Continuum	# projects	\$
Treatment	67	\$249,046,264
Prevention	7	\$52,213,815
Screening	3	\$6,967,421
Diagnosis	0	\$0
Other	9	\$20,241,642

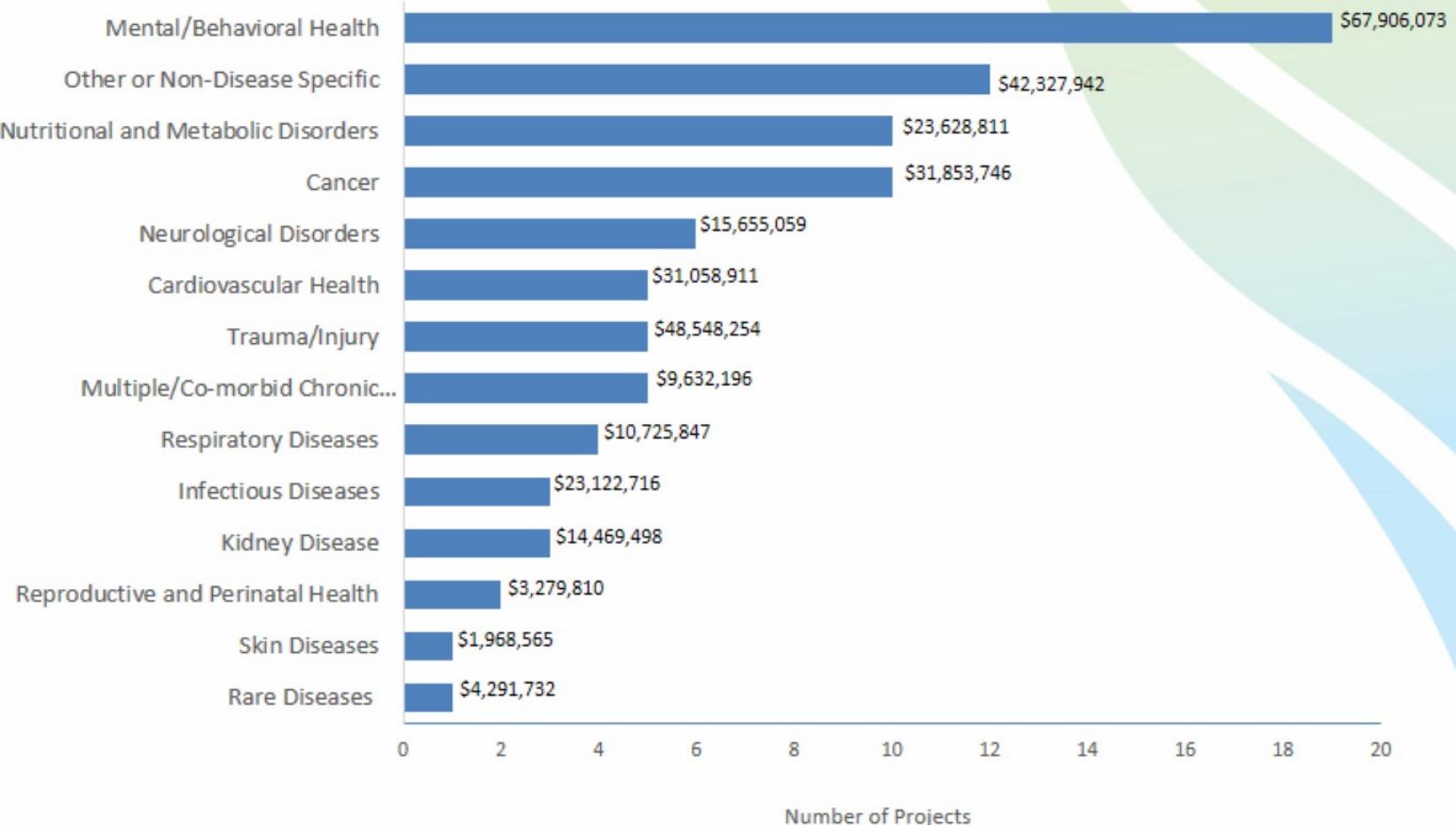


IHS Portfolio by Disease Focus (as of 9/2016)

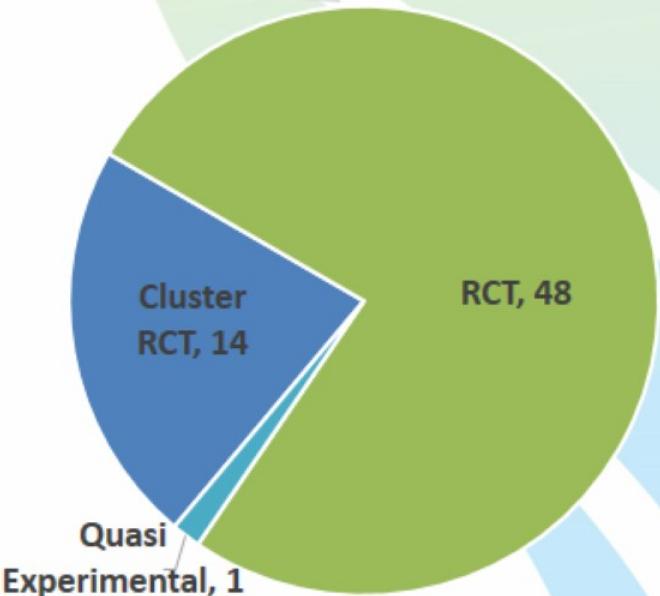
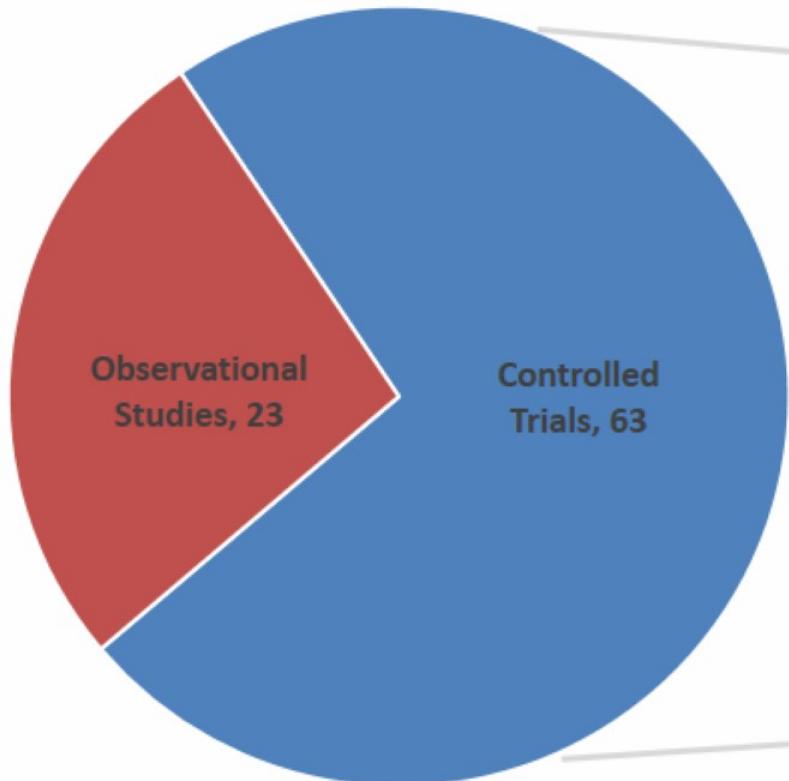
Primary Diseases (n=86)



IHS Portfolio Spending by Disease Focus (as of 9/2016)

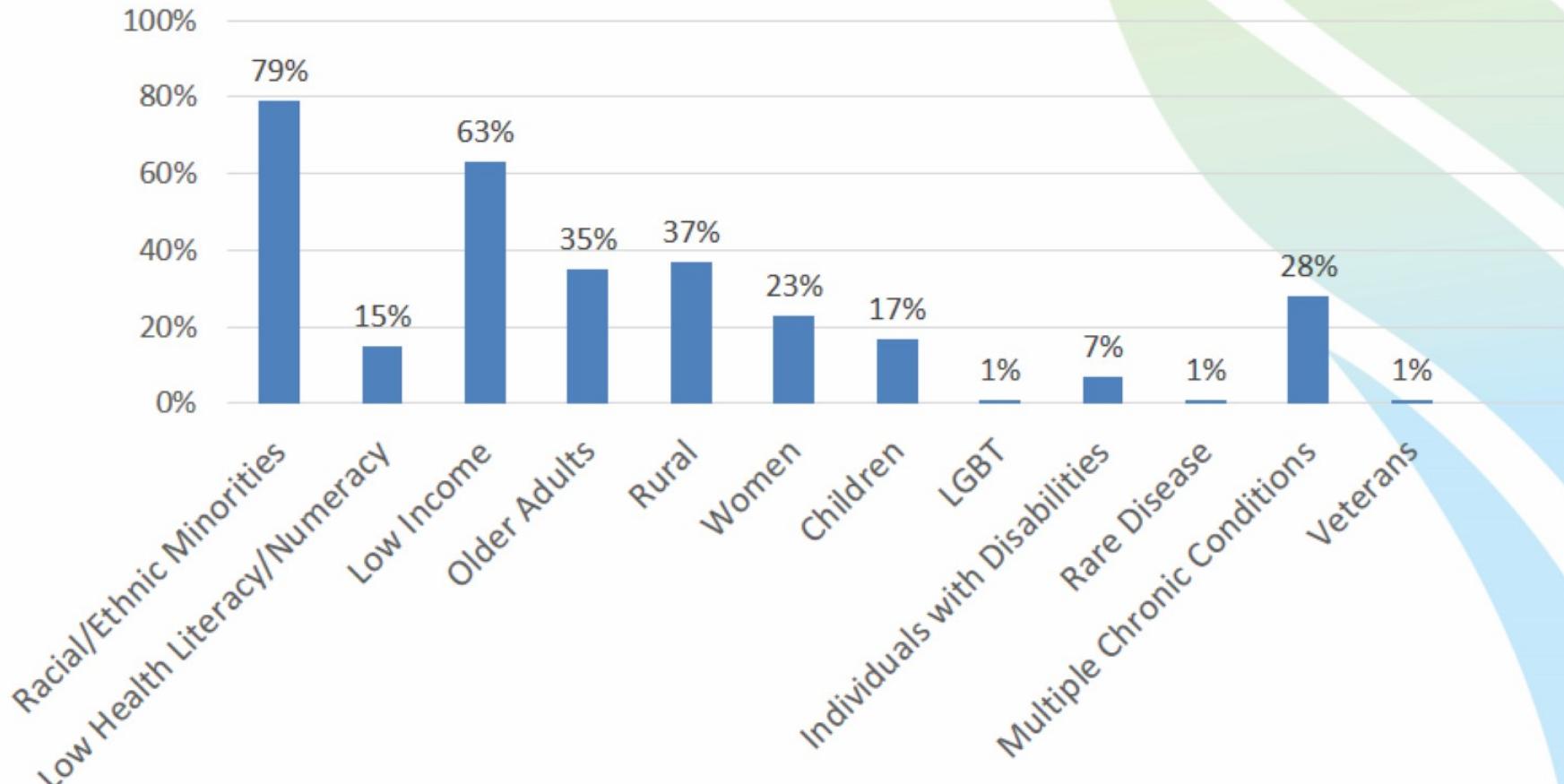


IHS Portfolio by Study Design (as of 9/2016)



IHS Portfolio by Study Population (as of 7/2016)

Study Populations (Not Mutually Exclusive)



The IHS Portfolio: Pragmatic Clinical Studies

IHS has funded 5 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

Improving Healthcare Systems Priority Topics Included in Most Recent PFA (Cycle 2 2016)

Topic	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

The IHS Portfolio: Targeted Funding

- IHS has funded 4 targeted studies thus far:

Funded Targeted Topics	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

- IHS has also released announcements for the following topics for targeted funding:

Targeted Topics In Progress	Total Funding Allocated
Multiple Sclerosis	\$10 million (for the IHS question)
Palliative Care*	\$48 million
Preventing Opioid Misuse in Pain Management*	\$30 million
Sickle Cell Disease	\$25 million

* Topics prioritized by the IHS Advisory Panel

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

IHS 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
 - All studies undergo a rigorous vetting of the methods and analysis to be used
 - We strive to address evidence gaps in the treatment of varied diseases, populations, levels of the healthcare system, and phases in the care continuum
 - Research questions are based on real-world problems faced by patients as they access care in various settings, and subsequent studies help to identify the most effective systems-based solutions
 - 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?

IHS Project Highlights

“Healing through Education, Advocacy and Law (HEAL) in Response to Violence”

(Cycle 2, 2015)

Randomized controlled trial, n=200

Question	Is a social work consult as effective as engaging with a community health worker and receiving “Personalized Support for Progress” (PSP) for addressing safety, legal, social, and health concerns stemming from intimate partner violence?
Comparators	Social work vs. community health worker referral
Primary Outcome	Quality of life, patient-reported perception of personal safety, depression, and health status after 12 months
Engagement	A Community Advisory Board (CAB) will select the outcomes that are most important to patients, and a Patient Leadership Team, along with patient members of the CAB, will consult on the design, conduct, analysis, and dissemination of results.

Catherine Cerulli, JD, PhD

University of Rochester School of Medicine and Dentistry

Rochester, NY

“Does expedited pre-hospital treatment that includes tPA administration provided by a mobile stroke unit result in improved outcomes for patients with stroke?”

(Cycle 3, 2015)

Randomized controlled trial, n=693

Question	Does expedited pre-hospital treatment that includes tPA administration provided by a mobile stroke unit result in improved outcomes for patients with stroke?
Comparators	Use of a Mobile Stroke Unit vs. standard triage and transport by Emergency Medical Services (EMS)
Outcome	Degree of disability due to stroke after 90 days
Engagement	Patients, caregivers, and providers will help identify the various levels of functioning that are most important to patients who suffer strokes.

James Grotta, MD
Memorial Hermann Hospital-Texas Medical Center
Houston, TX

“Integrating Behavioral Health and Primary Care for Comorbid Behavioral and Medical Problems”

(PCS, Winter 2015)

Cluster randomized controlled trial, n=1800

Question	Does integration of behavioral health services in primary care practices result in better patient-reported mental-health outcomes than co-location of behavioral health services with primary care practices, without a formal integration agreement?
Comparators	Integrated behavioral health services with primary care vs. co-location of behavioral health services with primary care
Outcome	Overall health-related quality of life, quality of care, disease control at 3 years after integration of services.
Engagement	Patients were consulted on the development and design of the study, and on the refinement of outcomes studied. They provided valuable information on their experiences in unsatisfactory management of behavioral health concerns.

*Benjamin Littenberg, MD
University of Vermont and St. Agric College*

“Integrated Effective Smoking Cessation Treatment for Smokers with Serious Mental Illness”

(PCS Cycle 1, 2015)

Cluster randomized controlled trial, n=900

Question	Does support from community health workers improve the likelihood of smoking cessation for individuals with serious mental illness who wish to quit smoking, as compared to usual rehab treatment?
Comparators	Community health worker-assisted treatment vs. traditional rehabilitation services
Outcome	3-year tobacco abstinence rates in smokers with serious mental illness
Engagement	The community health worker roles will be staffed partly by “certified peer specialists” (individuals with relevant experience with addiction) and will educate providers on best approaches to smoking cessation in these populations, and support participants in their recovery. These community health workers will also co-lead the Manualized Behavioral group smoking cessation treatment initiative, alongside the PI. Former smokers and former participants in the group will attend to share their experiences.

Eden Evins, MD, MPH

Massachusetts General Hospital

Boston, MA

“Improving Care Coordination for Children with Disabilities through an Accountable Care Organization”

(Winter 2014)

Observational study, n=10,830

Question	Are care coordination, clinical quality, and resource utilization improved when children with disabilities are enrolled in an accountable care organization (ACO)?
Comparators	Fee-for-service vs. enrollment in an accountable care organization (ACO)
Primary Outcome	Quality of care via care coordination for disabled children 12 months after enrollment in an ACO
Engagement	Qualitative interviews with caregivers, providers, and patients guide selection of metrics and lend context to quantitative data.

Paula Song, PhD

University of North Carolina at Chapel Hill

Chapel Hill, NC

“A Patient-Centered PaTH to Addressing Diabetes: Impact of State Health Policies on Diabetes Outcomes and Disparities”

(Natural Experiments Network, awarded Jan 2016)
Observational study, n=328,455

Question	Does obesity counseling lead to improved weight loss for adults with or at risk of type 2 diabetes?
Comparators	Obesity screening and counseling coverage vs. usual care
Outcome	Weight loss, diabetes incidence, and diabetes outcomes during the first 10 years of the Affordable Care Act
Engagement	Focus groups convened of primary care providers and patients with obesity and diabetes revealed the lack of knowledge about CMS weight counseling benefits. The stakeholder advisory board, consisting of patients, clinicians, and representatives from state agencies and national patient advocacy organizations, advised on the study design, particularly in the selection of patient-reported outcomes as the primary study outcome.

Jennifer Kraschnewski, MD, MPH
Pennsylvania State University Hershey Medical Center
Hershey, PA

“Electronic patient reporting of symptoms during outpatient cancer treatment: A U.S. national randomized controlled trial”

(Cycle 3, 2015)

Randomized controlled trial, n=1000, 100 sites

Question	Does integration of an electronic, patient-reported symptom monitoring system as part of routine oncology care in community settings lead to improved patient-centered outcomes?
Comparators	Electronic symptom-reporting system vs. enhanced usual care
Outcome	Physical functioning, health-related quality of life, survival, ED/hospital visits, symptom burden, and patients' care experiences at 12 months after starting electronic reporting
Engagement	The study team includes multi-stakeholders including five patient investigators, clinicians, health system administrators, as well as national partners such as the American Cancer Society and ASCO. The design of the study and associated outcomes were refined over an 18 month multi-stakeholder process that included patients, caregivers, clinicians, and other stakeholders.

Ethan Basch, MS

The University of North Carolina at Chapel Hill

Chapel Hill, NC

“Patient-Centered HCV Care via Telemedicine for individuals on Opiate Substitution Therapy: A Stepped Wedge Cluster Randomized Controlled Trial”*

(Cycle 2, 2015)

Randomized controlled trial, n=360

Question	What is the relative effectiveness of HCV treatment delivered in opiate substitution treatment programs (OSTP) by telemedicine and using directly observed therapy (DOT) methods versus referral to liver specialists in improving cure rates and patient satisfaction in patients with substance use disorders?
Comparators	HCV treatment delivered through telemedicine in OSTP vs. referral to usual care delivered by a HCV specialist
Outcome	Sustained viral eradication at 12 weeks after treatment; reinfection up to 1 year
Engagement	Patients helped define the most important treatment outcome (undetectable viral load) and recommended including education on the measures taken to ensure confidentiality of the participants' protected health information when recruiting patients for a study on telemedicine.

*Concurrent with another Hepatitis C-focused study (Litwin)

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*Andrew Talal, MPH, MD
State University of New York
Rochester, NY*

“Comparative Effectiveness Trial Between a Clinic-and Home-Based Complementary and Alternative Medicine Tele-rehabilitation Intervention for Adults with Multiple Sclerosis”

(Targeted Cycle 3, 2015)

Cluster randomized controlled trial, n=820

Question	Is an individualized, complementary alternative medicine intervention (exercise, yoga, Pilates) more effective when delivered at home (tele-rehabilitation) than at a clinic for adults with Multiple Sclerosis?
Comparators	A complementary alternative medicine intervention administered at home on a tablet or smartphone vs. in a clinic
Outcome	Quality of life, fatigue, pain, and physical activity at 1 year after the start of the program
Engagement	The MS Stakeholder Panel is made up of medical professionals with MS, caregivers, and patients. The Panel gave input on developing the most effective tele-rehabilitation program, and provided insight on the real-life challenges to accessing rehab services in Alabama/Mississippi, which the intervention is designed to alleviate. The stakeholder panel will have “decision-making capacity” throughout the project, and will act as testers for the application developed for use on a tablet and the accompanying interactive voice-response system.

James Rimmer, MA, PhD

University of Alabama at Birmingham

Birmingham, AL

Projects with Preliminary Results

- **Innovative Methods for Parents and Clinics to Create Tools (IMPACCT) for Kids Care**
 - PI: Jennifer DeVoe, Oregon Community Health Information Network
- **The Family VOICE Study: A Randomized Trial of Family Navigator Services Versus Usual Care for Young Children Treated with Antipsychotic Medication**
 - PI: Gloria Reeves, University of Maryland Baltimore
- **A Comparative Effectiveness Trial of Optimal Patient-Centered Care for US Trauma Care Systems**
 - PI: Douglas Zatzick, University of Washington

Morning Break

10:50 a.m. – 11:05 a.m.

Goals for this Year's Panel

Michael Dueñas, OD, IHS AP Chair

Timothy Daaleman, DO, IHS AP Co-Chair

Agenda and Logistics for the Remainder of this Meeting

Steve Clauser, PhD, MPA

Director, Improving Healthcare Systems

Agenda

Remainder of Day 1:

- Lunch
- Topic Discussion
 - Office-Based Opioid Treatment: Presentation, Breakout Groups, Report Back
- Topic Development
 - Care Coordination: Presentation, Breakout Groups, Report Back
- Recap of the Day
- Dinner and Reception

Day 2:

- Remarks from PCORI's Chief Science Officer, Evelyn Whitlock, MD, MPH
- Topic Refinement
 - Dental Carries in Children: Presentation, Breakout Groups
 - Pharmacy Services Integration into Patient Care: Presentation, Group Discussion
- Recap of the Day & Looking Forward

Breakout Session Format

- Disburse to assigned breakout group following each topic presentation
- Two breakout groups comprised of various stakeholder groups
- Facilitators and note-takers have been assigned; each group will need to identify a presenter to report back to the group
- Reference topic briefs
- Note taker will help presenter put together slides to report back
- Panel will reconvene
- Each presenter will report back for their group, followed by discussion facilitated by PCORI staff

Breakout Session Objectives

For OBOT and Care Coordination:

- Recommend whether the topic is well suited for PCORI to fund
- Consider what specific populations/subpopulations would be important to study
- Recommend potential interventions to be compared or tested
- Identify specific CER questions, and rank them
- List key stakeholder groups we should involve in the topic development process moving forward

For Dental and Pharmacy Topic Refinement:

- Recommend whether topic should remain an IHS priority topic
- If so, consider whether the topic should be refined to better specify intervention or specific population to be targeted
- List stakeholder groups we should consider to further topic refinement

Collaborative Breakout Discussion

- Focus: Provide targeted input without scientific jargon
- Participate: Encourage exchange of ideas among diverse perspectives
- Be respectful: Disagree with ideas, not people
- Ask for help when you need it: PCORI staff will be present at each break-out session

Lunch Break

12:00 p.m. – 12:45 p.m.

Topic Presentation:

Office-Based Opioid Treatment (OBOT) for Opioid Use Disorder (OUD) in Pregnant Women and in Adolescents

Els Houtsmuller, PhD

Jake Galdo, PharmD, BCPS

Office-Based Opioid Treatment (OBOT)

- Purpose of Discussion: Office-Based Opioid Treatment is being considered as a priority topic (topic for Pragmatic Clinical Study or Targeted funding announcement).

Office-Based Opioid Treatment (OBOT)

- Introduction to the Topic
- Patient Centeredness and Impact/Burden of the Condition
- Evidence Gaps and Ongoing Research
- Potential Research Questions
- PCORI Funding on this Topic

Introduction to the Topic

- In 2014, 1.9 million patients had an Opioid Use Disorder (OUD) due to prescription drugs; 586,000 due to heroin use
- Medication-assisted treatment (MAT): methadone, buprenorphine, naltrexone combined with psychosocial services
 - evidence-based for OUD, recommended for pregnant women and adolescents
- MAT may be offered in Opioid Treatment Center (OTC), community health center, doctor's office (buprenorphine; office-based opioid treatment-OBOT)
- Fewer than half of patients who need treatment receive MAT
- Main barriers to treatment: stigma (OTC) and lack of access (OTC and OBOT)
 - Pregnant women: stigma, lack of access, fear of legal consequences
 - Adolescents: stigma, no perceived need for treatment.

Introduction to the Topic cont'd

- To prescribe buprenorphine (Schedule III), physicians need to apply for waiver (8 hours training)
- More than half US counties do not have doctors who offer OBOT
- Most physicians who offer OBOT do so for limited number of patients (maximum: 275, median: 13)
- Physician barriers: time constraints, burnout, lack of expertise, concerns about population, lack of support from institution and colleagues, lack of available office staff
- Different approaches to physician support are used:
 - Non-physician care coordinator
 - Induction and stabilization at OTP
 - Consultation with OTP (hub and spoke, ECHO)
 - Internet-based education and support
- No comparative studies
- Urgent call for obstetricians and pediatricians to offer OBOT

Patient Centeredness and Impact/Burden

- Opioid Use Disorder (OUD) is associated with increased psychosocial problems, morbidity and mortality, and decreased QoL of patient and family.
- Proportion of *pregnant women* entering SUD treatment with prescription opioids as primary substance increased from 1 percent in 1992 to 19 percent in 2012. OUD during pregnancy leads to Neonatal Abstinence Syndrome and potentially longer-term cognitive and behavioral effects in baby and child. Successful treatment can prevent adverse outcomes for patient and fetus, baby and child.
- In 2014 168,000 *adolescents* in the US were addicted to prescription opioids and 18,000 to heroin. OUD is a leading cause of morbidity and mortality adolescents. Successful treatment can prevent adverse consequences of chronic opioid addiction during adulthood.
- MAT using buprenorphine is effective for pregnant women and for adolescents.
- Increasing availability of OBOT will reduce barriers to treatment for these populations.

Evidence Gaps and Ongoing Research

- Most trials of MAT in primary practice settings (OBOT) evaluate pharmacotherapies, not delivery of treatment.
- Increasing availability of OBOT is a priority for treatment of pregnant women and adolescents.
- Physician barriers include concerns about time constraints, burnout, lack of expertise in treatment and population, lack of support for various aspects of opioid treatment.
- Different approaches to physician support are used:
 - Non-physician care coordinator
 - Induction and stabilization at OTP
 - Consultation with OTP (hub and spoke, ECHO)
 - Internet-based education and support
- No comparative studies to determine optimal strategies to reduce barriers for physicians treating specific populations

Potential Research Questions

- What is the comparative effectiveness of opioid treatment in an obstetrician's office (Office-Based Opioid Treatment; OBOT) versus an Opioid Treatment Center (OTC) for different populations of *pregnant women* with Opioid Use Disorder (OUD) (prescription opioid addiction vs heroin addiction; IV opioid use vs non-IV use; urban vs suburban vs rural)? Outcomes of interest include treatment entry, treatment retention, illicit drug use, relapse, patient satisfaction, patient quality of life.
- What is the comparative effectiveness of different levels of support for *obstetricians* who offer OBOT for different populations of *pregnant women* with OUD (prescription opioid addiction vs heroin addiction; IV opioid use vs non-IV use)? Support may consist of induction and stabilization at an OTP versus the obstetrician's office, non-physician office staff performing intake and care coordination; consultations with addiction professionals at OTC; Internet-based network for mentoring and education. Outcomes of interest include patient outcomes (treatment entry, treatment retention, illicit drug use, relapse, patient satisfaction, quality of life) and physician outcomes (physician satisfaction, stress, burnout).

Potential Research Questions cont'd

- What is the comparative effectiveness of different levels of support for *pediatricians* who offer OBOT to adolescents with OUD on patient outcomes and physician satisfaction? Support may consist of non-physician office staff performing intake and care coordination; consultations with addiction professionals at OTC; Internet-based audiovisual network for mentoring and education. Outcomes of interest include patient outcomes (treatment entry, treatment retention, illicit drug use, relapse, patient satisfaction, quality of life) and physician outcomes (physician satisfaction, stress, burnout).

PCORI Funding on this Topic

- Limited portfolio
 - *Improving Outcomes of Opioid Addicted Prisoners with Extended Release Naltrexone before Reentry.* Opioid-addicted prisoners eligible for release receive extended-release Naltrexone (XR-NTX) with follow-up doses at an addiction treatment center before reentry, or report to the treatment center for their first dose after reentry. Primary outcome: relapse rates at three months. Expected completion date December 2018.
 - *Testing the Effectiveness of a Graphic Novel Health Education Curriculum for Patients with Addiction.* This study evaluates effectiveness of using an educational graphic novel about MAT and HIV risk for patients with alcohol use disorder in federally qualified healthcare centers. Primary outcome: substance use. Expected completion date: January 2017.
 - *Comparative Effectiveness of Patient-centered Strategies to improve Pain Management and Opioid Safety for Veterans.* Compares a medication management approach by pharmacist to a multi-modal biopsychosocial approach for patients on chronic opioid therapy for pain management. Expected completion Fall 2020.

Breakout Session: Office-Based Opioid Treatment

1:00 p.m. – 1:50 p.m. EST

Report Back and Discussion: Office-Based Opioid Treatment

1:50p.m. – 2:50 p.m. EST

Afternoon Break

2:50 p.m. – 3:00 p.m.

Topic for Refinement:

Comparative Effectiveness of Different Care Models for High-Cost, High-Need Patients

Gyasi Moscou-Jackson, PhD, MHS, RN

Jim Bellows, PhD, MPH

Care Models for High-Cost, High-Need Patients

- Proposed Topic: Comparative effectiveness of different care models* (e.g., interdisciplinary team-based primary care, enhancements to primary care, extended primary care teams, patient centered medical homes, etc.) on improving patient-centered outcomes for high-cost, high-need patients.

*Organized and planned approach to improving patient health, which includes health systems, delivery system design, decision support, clinical information systems, and self-management support. [AHRQ](#)

Overview

- Purpose of Discussion
- Introduction to the Topic
- Evidence Gaps and Ongoing Research
- PCORI Funding on the Topic
- Potential Research Questions
- Discussion and Refinement

Introduction to the Topic

- High-Cost, High-Need (HCHN) patients account for approximately 5% of the United State population, but consume the most health care resources.
- The HCHN population is socioeconomically diverse.
- Commonly accepted clinical categories include:
 - Children with complex needs
 - Adults less than 65 years with disabilities
 - Frail older adults
 - Patients with multiple or complex chronic conditions
- HCHN patients have both medical and nonmedical needs related to accompanying functional limitations, behavioral and substance abuse challenges, and/or unmet social needs.

Introduction to the Topic cont'd

- The needs of high-cost, high-need patients may not be met by the traditional primary care model.
- HCHN patients often encounter:
 - Care misalignment
 - High healthcare costs
 - Low quality of care
- Identifying other innovative care models has become a national priority.

Introduction to the Topic cont'd

- Few alternative care models with high-quality evidence have been identified.
- Across models successful elements include:
 - Targeting individuals most likely to benefit from comprehensive assessments
 - Care planning and routine patient monitoring
 - Patient self-care education
 - Community resource referral
 - Provision of appropriate care in accordance with patients' goals and priorities
 - Coordination of care
- Notably, one-size fits all approaches may not be effective due to the diversity of HCHN populations.

Evidence Gaps

- A review of systematic reviews and an evidence synthesis showed:
 - Many studies have been single-setting demonstration projects limited to a single HCHN population with small sample sizes.
 - Outcomes have predominantly focused on utilization, cost, quality of care, and quality of life
 - Patient-reported outcomes (e.g., patient experience, symptoms and symptom burden, functional status, health improvement, perception of participation in care, and shared decision-making) have been studied less often.
 - Limited evidence on the most effective package of elements and most effective implementation of these packages within different contexts and delivery systems.
 - Barriers to adoption and implementation of care models in clinical settings need to be addressed.

Ongoing Research

- Ongoing Clinical Trials (ClinicalTrials.gov):
 - Two small efficacy studies, one demonstration project
 - Outcomes across studies focused on utilization of acute and preventive services; patient-reported outcomes were limited to quality of life, depressive symptoms, and indicators of self-management
- Center for Medicare and Medicaid Innovation's Health Care Innovation Awards Program:
 - Five demonstration projects focused on implementing innovative care models for specific high needs populations
- Agency for Healthcare Research and Quality:
 - Observational study on improving the quality and patient outcomes for frequent Emergency Department visitors
 - 12 external research projects related to populations with multiple chronic conditions
 - No projects explicitly for the broader HCHN population

Ongoing Research cont'd

- In July 2016, five major foundations announced a collaborative effort to provide resources to address the needs of HCHN populations:
 - The Commonwealth Fund
 - John A. Hartford Foundation
 - Robert Wood Johnson Foundation
 - Peterson Center on Healthcare
 - SCAN Foundation

PCORI Funding on this Topic

- To date, PCORI has funded 9 comparative effectiveness studies (CER) studies focusing on different strategies for coordinating care HCHN populations.
 - PCORI's CER studies targeting HCHN populations are limited to evaluating interdisciplinary team-based primary care and the integration of personnel-based case management, while evaluation comprehensive and multi-component care models are underrepresented
 - Additionally, head-to-head comparisons of care models are missing (i.e., usual care is frequent comparator).
 - Studies examining care and coordination models for adults with disabilities are understudied.

PCORI Funding on this Topic cont'd

- [Using Telehealth to Deliver Developmental, Behavioral, and Mental Health Services in Primary Care Settings for Children in Underserved Areas](#) (PI: Tumaini Coker; HCHN Population: Children with Complex Needs)
- [Improving Care Coordination for Children with Disabilities Through an Accountable Care Organization](#) (PI: Paula Song; HCHN Population: Children with Complex Needs)
- [3D Team Care for Cognitively Vulnerable Older Adults](#) (PI: Richard Fortinsky; HCHN Population: Frail Older Adults)
- [Improving the Quality of Care for Pain and Depression in Persons with Multiple Sclerosis](#) (PI: Dawn Ehde; HCHN Population: Complex Chronic Conditions)
- [Bringing Care to Patients: A Patient-Centered Medical Home for Kidney Disease](#) (PI: Denise Hynes; HCHN Population: Complex Chronic Conditions)
- [Does Outpatient Palliative Care Improve Patient-Centered Outcomes in Parkinson's Disease?](#) (PI: Benzi Kluger; HCHN Population: Complex Chronic Conditions)
- [Guidelines to Practice \(G2P\): Reducing Asthma Health Disparities through Guideline Implementation](#) (PI: James Stout; HCHN Population: Complex Chronic Conditions)
- [Natural Experiments of the Impact of Population-Targeted Health Policies to Prevent Diabetes and Its Complications](#) (PI: Lizheng Shi; HCHN Population: Multiple Chronic Conditions)
- [The Impact of Medicaid Health Homes on Patients with Diabetes](#) (PI: Victoria Mayer; HCHN Population: Multiple Chronic Conditions)

Proposed CER Research Question*

- What is the comparative effectiveness of different care models (e.g., interdisciplinary team-based primary care, enhancements to primary care, extended primary care teams, patient centered medical homes, etc.) on improving patient-centered outcomes for high-cost, high-need patients?

* Adapted from the Institute of Medicine's First Quartile Priority for Comparative Effectiveness Research (CER): Compare the effectiveness of comprehensive care coordination programs, such as the medical home, and usual care in managing children and adults with severe chronic disease, especially in populations with known health disparities.

Purpose of Discussion

- A decisional dilemma facing healthcare systems is how to effectively organize and coordinate care outside of the traditional primary care model for high-cost, high-need patients.
- A few promising alternative care models for HCHN patients have been identified, but barriers to their spread and sustainability exist.
- **The IHS Advisory Panel will be critical refining the proposed CER question including advisement of:**
 - (1) Which HCNH population(s) should be targeted?
 - (2) Which care models or combinations of strategies for HCNH patients should be compared?
 - (3) Which patient-reported outcomes should be evaluated?

Breakout Session: Care Models for High-Cost, High-Need Patients

3:15 p.m. – 4:15 p.m. EST

Report Back and Discussion: Care Models for High-Cost, High-Need Patients

4:15 p.m. – 5:15 p.m. EST

Recap of the Day and Logistics for Day 2

Timothy Daaleman, DO, IHS Advisory Panel Co-Chair

Adjourn

Thank you for your participation!

Our meeting tomorrow will begin at 9:00 a.m.

Find PCORI Online



www.pcori.org



Day 2: Welcome Back / Overview of Agenda

Steve Clauser, PhD, MPA

Director, Improving Healthcare Systems

Remarks from PCORI's Chief Science Officer

Evelyn Whitlock, MD, MPH

Chief Science Officer, PCORI

Improving Healthcare Systems

Advisory Panel Meeting – October 25, 2016

Evelyn P. Whitlock, MD, MPH

Chief Science Officer



CSO Vision



inCute.com



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Vision

- “One Science”
 - Consistent approach and supportive response to applicants and awardees
 - Strategic thinking around portfolio
 - Excellence, collegiality, camaraderie across and beyond department
- 2016 Goals
 - Establish Evidence Synthesis Program
 - Enhance integration of scientific programs within department and across PCORI
 - Improve interface and relationships with the researcher community
 - Align mission of advisory panels to overall PCORI direction



PCORI RESEARCH FRAMEWORK

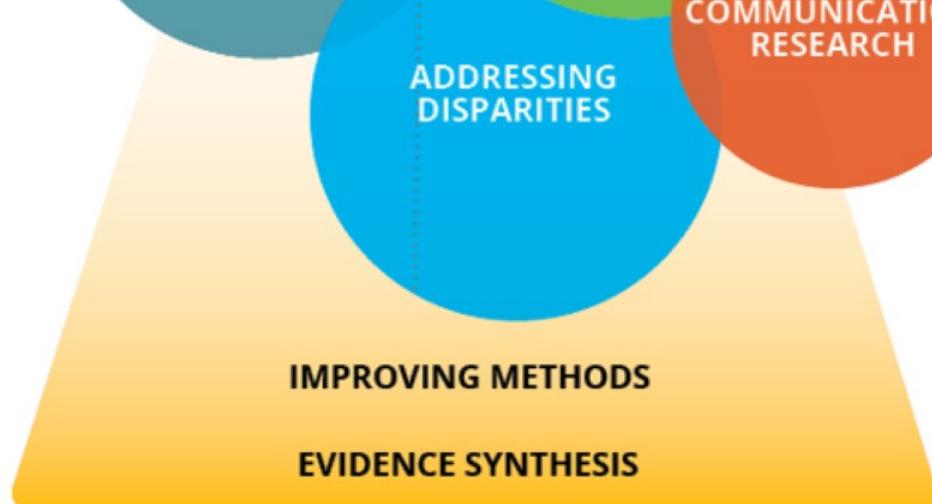
Producing the comparative clinical effectiveness research (CER) evidence to improve patient-centered outcomes and inform value considerations in healthcare decisions by patients, clinicians, payers, and policy makers.

PCORI RESEARCH FRAMEWORK

APPLICABLE EVIDENCE ► ► ► ► ► ► ► ► INFORMED DECISION MAKING

WHAT CARE IS
BETTER FOR
INDIVIDUAL
PATIENTS?

HOW CAN
PATIENT-CENTERED
CARE BE BEST
DELIVERED?



OUR
ULTIMATE
GOAL

Research Synthesis Program

- Research synthesis is an umbrella term for a set of related activities at PCORI
 - More rapid deployment of actionable CER evidence in context
 - New research to address individual choices and treatment matching
 - Communication of current portfolio themes and learnings

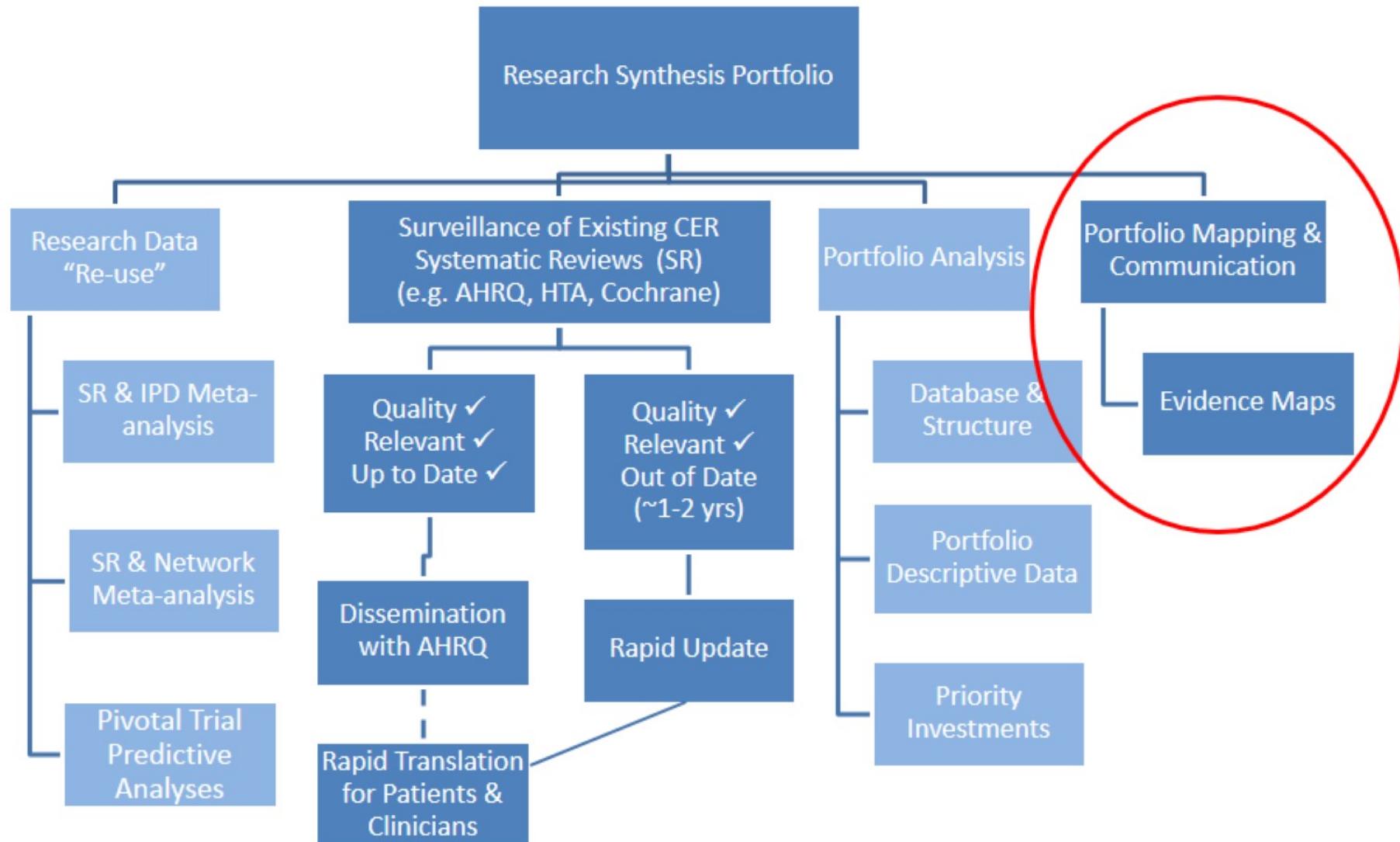


Research Synthesis Program

- “Research synthesis” acknowledges various levels and methods:
 1. Evidence Synthesis (e.g., systematic review)
 - Qualitative and/or quantitative methods
 2. Variation in treatment effect/”personalized” medicine
 3. Synthesis of PCORI’s research investments
(e.g., portfolio “cluster” analyses, portfolio mapping)
 4. Identification and synthesis of a body of relevant research (e.g., evidence maps)



Research Synthesis Program Overview



Portfolio Mapping: PCORI Transitional Care Evidence to Action Network (TC-E2AN)

20* PCORI awardee teams, ~\$68M

E2AN Members accelerate research & its impact:

- Identify common challenges, highlight lessons learned & best practices
- Identify useful (common) measures/tools
- Synthesize portfolio contributions in a manner that is actionable and relevant to end users



Sample Home Page: Navigate to Studies

About Transitional Care Patient Experience Expert Guidance Lessons Learned Publications & Press

WHAT IS TRANSITIONAL CARE?

Transitional Care: A set of actions designed to ensure the coordination and continuity of health care as patients transfer between different locations or different levels of care within the same location (American Geriatrics Society, 2003).



MOVING THROUGH THE HEALTHCARE SYSTEM

Cura pinguis (lpidorum vocatur) cerea id totum, quo corpus et sanguinem per arterias possit deponi murs tuis. Corpora (scilicet luxuria nostra) Cura cunctis nos, sed nos quoque vesicimur cibis ex aliquam. Cura tibi sic suus 'maximus ut temptemini et operari proxime cum creare Tags curis provisor

Est autem populus audire vulgo "altum Cura" sed multo magis eventum quam. Saepe fit summus eu nimis quadam genera mali cum primis, quoniam turpis eu LDL (LDL c) corporibus indita. Et LDL, C campester crescere pericula cardiovasculares et facere. Cura tibi sic suus 'maximus ut temptemini et operari proxime cum creare Tags curis provisor. Speramus automated nostram translationem et proderit tibi facile Latina textus transferatu

WHAT IS TC-E2AN?



UPCOMING EVENTS



American College of Surgeons' Patient-Centered and Psychosocial Care at U.S. Trauma Centers Policy Summit
September 23rd, 2016
20 F St. NW. Washington, DC 20001

STAY CONNECTED ▶

SEARCH AND COMPARE OUR STUDIES

TC-E2AN STUDIES
Search for the studies you are interested in. Click on the study title to view more information and details on individual studies. You can also search by study type.



Interactive Map: TC-E2AN Studies

About Transitional Care

Patient Experience

Expert Guidance

Lessons Learned

Publications & Press

TRANSITIONAL CARE EVIDENCE TO ACTION NETWORK STUDIES

Search and Compare Our Studies

Ongoing research is identifying practices on this topic to help patients, clinicians, and healthcare leaders make more informed decisions about their journey through the healthcare system.

TC-E2AN STUDIES

Click on the map view options to see state-by-state information and select an individual state to see more information.

COMPARE STUDIES:

- Intervention
- See next page for more examples



Legend
Setting:
Components:



Filters and Search Options from the Map Page

Compare Studies

- Type of Intervention
- Setting
- Core Components
- Measures Used

Outcome Measures

- TC Conceptual Model
- Patient-Centered

Measures

- Mapping to Core Measures

The Studies in Context

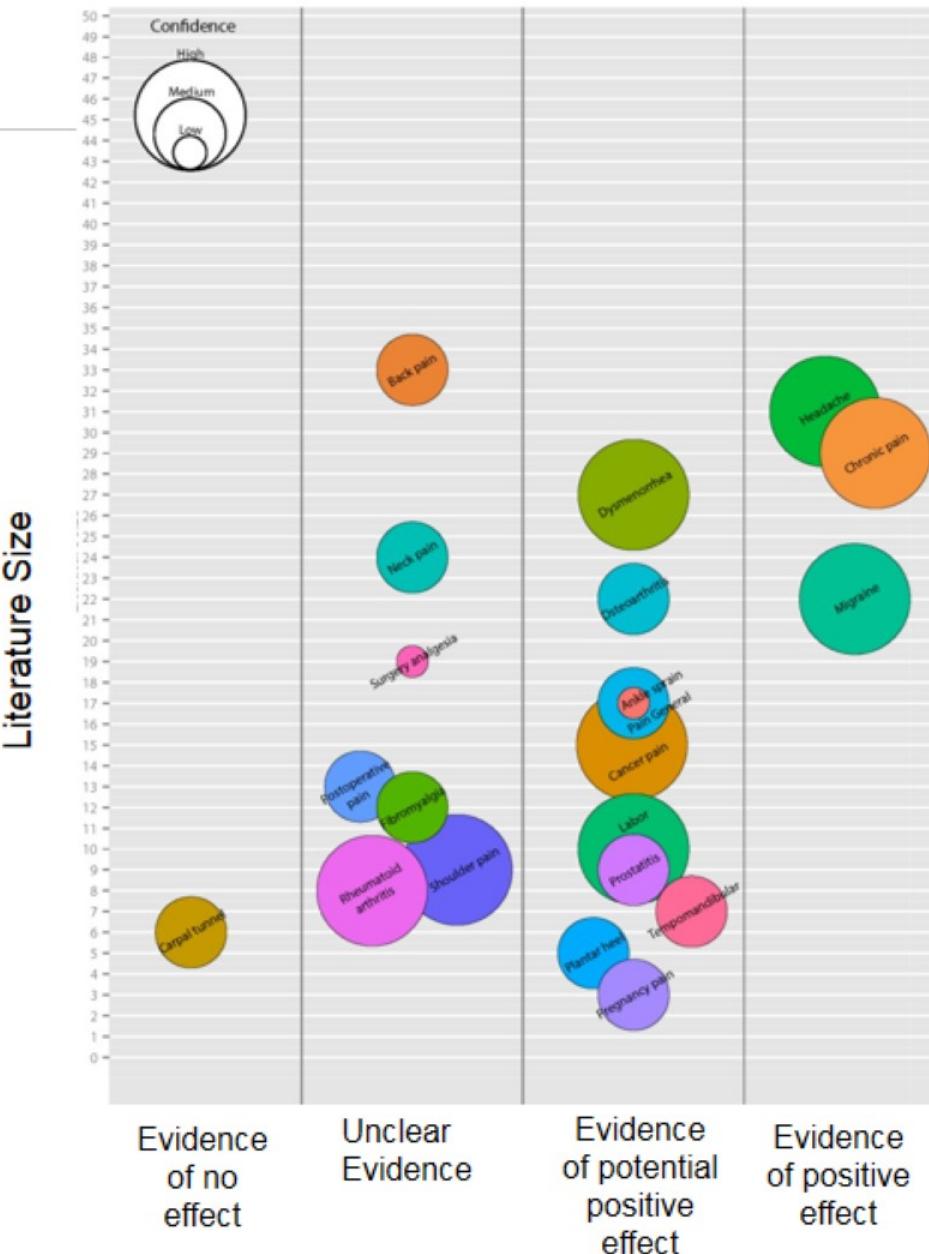
- In literature
- In practice

TC-E2AN Projects (20)



Sample Evidence Map: Effects of Acupuncture for Pain

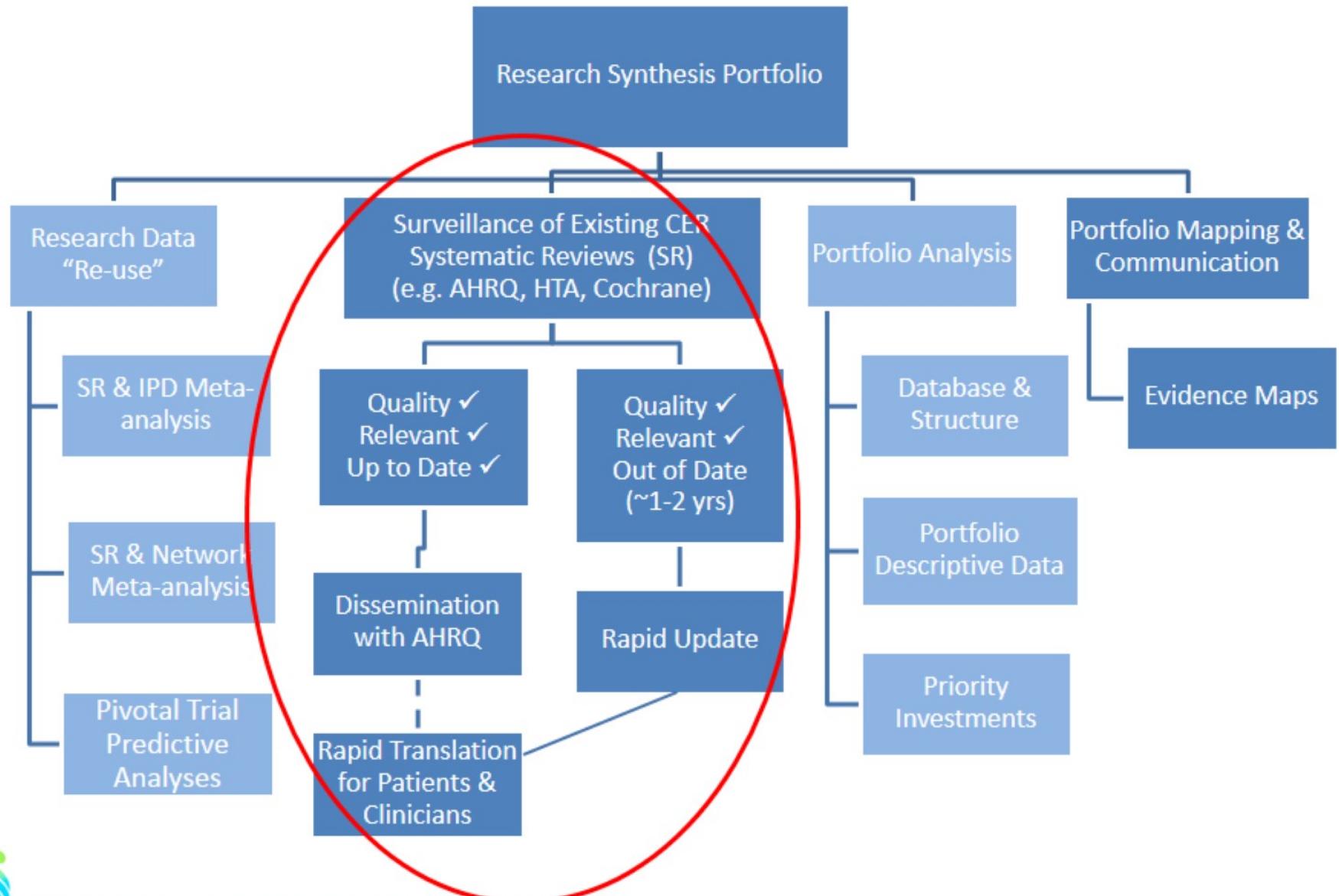
This slide is a summary of 59 systematic reviews on the effect of acupuncture on pain



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



Research Synthesis Program Overview



What are Important Topics For CER Surveillance?

- Telemedicine
- Healthcare Workers
- Care Transitions
- Other



Q&A



Topic Presentation:

Preventing Dental Caries in Children

Tasia Long, MHS

Preventing Dental Caries in Children

- Purpose of Discussion: Topic Refinement
- PCORI's PCS PFA research question: "What is the comparative effectiveness of the various alternative delivery models (e.g., primary care, schools, mobile vans) versus the dental office in preventing dental caries in children in medically underserved areas" has received no competitive LOI submissions since its inception in 2015.
- As a result of the lack of response, the Improving Healthcare Systems (IHS) program set out to answer three questions:
 - Can better outreach stimulate the dental investigator community to respond to the question?
 - Does the current research question need further refinement to solicit more interest from the research community?
 - Should the question be retired from the PCS PFA?

Preventing Dental Caries in Children

- Background and Impact/Burden
- Evidence Gaps
- Clinical Considerations
- Care Delivery Strategies and Models
- Next Steps

Background and Impact/Burden

- Caries (tooth decay) is one of the most prevalent preventable chronic pediatric diseases.
 - Effects up to 50% of the pediatric population (< 5 years). Untreated decay affects 19.5% of 2 to 5 year-olds and 22.9% of 6 to 19 year-olds (CMS, 2013).
- Children who lack access to preventive oral health care and do not receive treatment for caries are at risk for negative health outcomes.
- Pain associated with tooth decay may affect a child's physical development and academic performance.
- Children and adolescents of some racial and ethnic groups and those from lower-income families have more untreated tooth decay.
 - Research suggests that Hispanic children were more likely than white or black children to have unmet dental needs (nine percent for Hispanic children, compared with six percent for black children and five percent for white children) (Walsh, 2010).

Evidence Gaps

- Unfortunately only limited systematic reviews, and under-powered RCTs exist. However, widespread use yields some evidence of efficacy for the following alternative delivery models of oral health care:
 - Primary Care Provider based oral health care
 - Mobile Dental Units (MDUs or Mobile Vans)
 - School Based Programs (Oral health care, Fluoride varnish, and/or Sealants)
 - Mid-level Provider care
- Teledentistry has been studied in a handful of studies most of which were not RCTs

Clinical Considerations

- These clinical procedures are proven effective at preventing dental caries
 - Fluoride Varnish
 - Resin-based sealants (conventional)
 - Silver diamine fluoride sealants (FDA approved 2014)
- While our key informants recommended that comparing the setting of fluoride varnish applications may be less compelling than models which ensure full spectrum oral health care, staff believe it may be of interest to compare different sealant technologies in settings other than dental offices.
 - Sealants present different benefits and potential harms to children
 - Treatment effectiveness and acceptability may vary in settings other than the dentist office (e.g., schools)

Care Delivery Strategies and Models

- Primary Care Provider based oral health care
 - Facilitator: Oral health incorporated with “well child” visit increases likelihood of occurrence, Medicaid reimbursement
 - Barrier: PCP burden and time constraints
- Mid-level Provider care
 - Facilitator: Workforce extension
 - Barrier: No State to State uniformity in scope of practice, qualifications, regulations
- Mobile Dental Units (MDUs or Mobile Vans)
 - Facilitator: Overcomes issues of accessibility, affordability and sustainability
 - Barrier: Difficulty with complex cases, inability to serve as a dental home

Care Delivery Strategies and Models

- School Based Programs (Oral health care, Fluoride varnish, and/or Sealants)
 - Facilitator: Widespread use, access to children
 - Barrier: Susceptibility to government funding, inability to serve as a dental home
- Tele-dentistry
 - Facilitator: Overcome some access issues
 - Barrier: Novel and may have insufficient efficacy data
- Efficacy data though limited can be found for virtually all of these interventions; some programs are in relatively widespread practice (e.g., school-based models)
- Should PCORI develop a more targeted question pertaining to prevention and comprehensive oral health for children and adolescents may be more compelling for stakeholders and researchers?

PCORI Funding on this Topic

Existing Priority Topic in Pragmatic Clinical Studies PFA:

Dental Caries: “What is the comparative effectiveness of the various alternative delivery models (e.g. primary care, schools, mobile vans) versus the dental office in preventing dental caries in children in medically underserved areas?”

PFA Priority Topic no longer available for consideration:

Periodontal Disease: Comparative effectiveness of surgical and medical options for prevention and care in periodontal disease to increase tooth longevity and reduce systemic secondary effects in other organ systems.

Pipeline to Proposal Tier II Award (2016):

“Setting the Stage for Patient Involvement: Connecting Patients with Periodontal Disease”

Next Steps

- Comparative effectiveness research may be useful in
 - (1) refining the question for different age groups (e.g., young children and adolescents) who experience disparities in dental care,
 - (2) focusing on care transition strategies for referrals of care involving more complex cases from school-based or primary care-based dental programs to dental offices,
 - (3) adding evidence based educational or communication interventions to existing delivery models as part of a multi-component intervention strategy to support uptake and follow-up of clinically recommended preventive care or treatment.
 - There seems to be a special need for delivery strategies that are effective for poor, low income children and adolescents who experience significant disparities in care.

Breakout Session: Preventing Dental Caries in Children

10:00 a.m. – 10:45 a.m. EST

Topic Presentation:

Pharmacy Services Integration Into Patient Care

Penny Mohr, MA

David Bruhn, PharmD, MBA

Overview of the Topic

- With increasing medication use, opportunities exist to improve provider adherence to evidence-based guidelines and patient understanding and adherence to prescribed regimens
- Medication errors and polypharmacy result in patient harm
- Several interventions (and in different settings) are in use where pharmacists take a more active role in patient care:
 - Review of prescriptions as they are made
 - Reconciliation of medication lists during care transitions
 - Medication Therapy Management (MTM)
 - Monitoring test results
 - Patient education and counseling on adherence
 - Multi-faceted clinical pharmacist interventions
 - Delivery of vaccines and other care

Significance of the Issue

- IMS estimates \$213 billion in costs could be avoided by improving pharmaceutical use, including
 - Pharmaceutical *underuse*, Medication Errors and Adverse Events, vaccine-preventable diseases, hospital admissions, outpatient visits, emergency room visits
- Most studies on the effects of pharmacist interventions have focused on short-term clinical effects, not PCO. Often lack of funding causes small study populations and short time frame

Timeliness

- HR 4190
 - Amends Title XVIII of the Social Security Act so pharmacists can be recognized as healthcare providers
- 48 of 50 states have collaborative agreements within scope of practice for pharmacists
- Mid 1990s started to change to doctor of pharmacy as entry level degree
 - Pharmacists are trained for advanced care
 - Health System
 - VA
 - Long Term Care
- Due to large # of possible interventions and practice settings to conduct research in, seems to be a natural opportunity for PCORI to consider funding

What Do We Know?

- There is extensive literature on this topic
 - Multiple reviews have found that pharmacist review of medications in a variety of settings can reduce adverse drug events;
 - There is mixed evidence about pharmacist reconciliation of medication lists during care transitions;
 - MTM programs have been shown to reduce hospitalizations for diabetics, people with congestive heart failure and improve blood pressure control;
 - Pharmacist-led education and counseling programs have provided significant clinical improvements for some populations (asthma symptoms, LDL cholesterol, HbA1c, blood pressure, adherence to medications);
 - A review of preventive screenings in pharmacies demonstrated this was feasible, but did not measure impact on clinical or patient-centered outcomes.

Where are the Evidence Gaps?

- What are the benefits of pharmacists as opposed to other non-physician providers (e.g., nurse practitioners, physician assistants) to deliver the intervention (e.g., monitoring/counseling)?
- What are the benefits of co-location versus using a community pharmacist?
- What are the benefits of pharmacist-led provision of preventive care?
- With few exceptions, most studies of pharmacist-led interventions are small and of short duration.
- Integrating pharmacists into patient care requires a major health system redesign. While some have proven successful, others have struggled to match their results and become sustainable.

Pharmacy Services Integration Into Patient Care

Priority Research Question

- Compare the effectiveness of various strategies aimed at integrating pharmacists or pharmacy services into patient care (e.g., primary/acute care and pharmacy integration, pharmacist-provided preventive care, pharmacist-provided medication management or reconciliation services, other pharmacy-specific collaborative care models) on patient-centered outcomes (e.g., reduction in inappropriate medication use and polypharmacy, access to preventive vaccines, reduction in adverse events and hospital re-admissions, improved disease- or condition specific outcomes).

Related Priority Questions

- Compare the effectiveness of innovative strategies for enhancing patients' adherence to medication regimens (retired from the Spring 2015 PFA when the integration of pharmacists into patient care question was added).
- Compare the effectiveness of pharmacist- or nurse-led interventions, or health information technology-based interventions, to enhance primary care physician management of patients suffering from chronic, non-cancer pain.

Timeline

- Considered at January 2015 Advisory Panel
- Added to Cycle 1 2015 Pragmatic Clinical Studies funding announcement, issued April 2015
- Have received 0 relevant applications since then
- Received 1 application leveraging Pharmacy Benefit Management data in response to our question on innovative strategies to improve patient adherence to medications – no clear pharmacist involvement - not funded

Examples of Funded Studies Integrating Pharmacists into Patient Care

Comparing Telehealth Care and Optimized Clinic-Based Care for Uncontrolled High Blood Pressure

Potential Impact

- Could demonstrate a relatively efficient way to reduce the rate of heart attacks and stroke by improving patient adherence to blood pressure medications

Comparators

- Optimized clinic-based care with MTM pharmacists present in clinics versus MTM pharmacists in team-based care who use telemonitoring to support blood pressure control.

Design

- Cluster RCT of 2000 patients across 20 primary care clinics at HealthPartners

Compares the effectiveness of two models of team-based care – best-practice clinic-based care and home-based telehealth care – to help patients with uncontrolled hypertension lower their blood pressure and risk of a future heart attack or stroke.

Karen Margolis, MD, MPH
HealthPartners Institute for Education and Research
Minneapolis, MN

Awarded 2016



Comparative effectiveness of patient-centered strategies to improve pain management and opioid safety for Veterans

Potential Impact

- Could provide evidence to support the use of replicable strategy to improve pain and reduce opioid use

Comparators

- Telecare collaborative medication management led by clinical pharmacist versus interdisciplinary pain management team emphasizing non-pharmacological alternatives

Design

- RCT of 1400 primary care patients at 9 VA sites receiving moderate to high-dose opioids.

Compares two systems of care strategies, which differ substantially in comprehensiveness and resource intensity, to improve pain and reduce opioid use among Veterans. This includes a sub-study among patients on high-dose chronic opioid therapy to compare tapering with or without buprenorphine rotation.

*Erin Krebs, MD, MPH,
University of Minnesota
Minneapolis/St. Paul, MN*

Awarded 2016



Questions

- Suitability for the Pragmatic Clinical Studies PFA
 - Is this topic of enough critical importance to keep it on the list?
 - Does it require a large-scale pragmatic clinical trial or observational study to address?
 - Are there important barriers to dissemination and implementation that constrain the potential impact of a study with positive findings?
 - Are there specific sub-questions, comparisons, or disease/condition targets for pharmacist integration that are more important?
- What are your thoughts about putting this as a priority interest in the Broad PFA (currently not an option, but exploring)?
- Should adherence to medications be re-examined as a priority topic within the Pragmatic Clinical Studies PFA?

Discussion Session: Pharmacy Services Integration Into Patient Care

11:00 a.m. – 11:45 a.m. EST

Recap of the Meeting & Looking Forward

Michael Dueñas, OD, IHS Advisory Panel Chair

Concluding Remarks

Steve Clauser, PhD, MPA

Director, Improving Healthcare Systems

Adjourn

Thank you for your participation!

