Advancing Behavioral Health Integration in Primary Care through Patient-Centered Comparative Effectiveness Research

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Harvard Catalyst Population Health Research Program
June 25, 2015
Roadmap

• Inside the Patient-Centered Outcomes Research Institute (PCORI)
• Engagement as a Tool to Enhance & Advance Research
• National Priorities, Research We Support, & PCORI Research Funding Opportunities
• Integration of Mental/Behavioral Health into Primary Care: PCORI’s Portfolio
• Q&A
Inside PCORI
Inoculation to PCORI Vocabulary
About PCORI

• An independent research institute authorized by Congress through the Patient Protection and Affordable Care Act.
• Funds comparative clinical effectiveness research (CER) that engages patients and other stakeholders throughout the research process.
• Seeks answers to real-world questions about what works best for patients based on their circumstances and concerns.
Our Mission and Strategic Goals

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

Our Strategic Goals:

- Increase quantity, quality, and timeliness of useful, trustworthy research information available to support health decisions
- Speed the implementation and use of patient-centered outcomes research evidence
- Influence research funded by others to be more patient-centered
Questions External to PCORI’s Mandate

- Cost effectiveness analyses
- Disease-processes and -causes
- Studies lacking comparative nature or foundation
- Efficacy trials
- Pilot studies
Who are Our Stakeholders?

- Payer
- Clinician
- Caregiver/Family Member
- Policy Maker
- Purchaser
- Patient/Consumer
- Hospital/Health System
- Industry
- Training Institution
- Patient/Caregiver Advocacy Organization
PCORI Is Creating a Paradigm Shift Toward Patient-centered Comparative Clinical Effectiveness Research

“I have a feeling we’re not in Kansas anymore, Toto.”
Engagement as a Tool to Enhance & Advance Research
PCORI Engagement Goals

- Build a patient-centered outcomes research (PCOR) community
- Engage the PCOR community in research
- Promote dissemination and implementation of PCOR findings
Engagement as a Path to Useful, High-Quality Research

- Proposal Review; Design and Conduct of Research
- Dissemination and Implementation of Results
- Evaluation
- Topic Selection and Research Prioritization
How We Promote Participation in Research

• **Engagement Awards**: Will build a PCOR-ready community of patients, stakeholders, and researchers

• **Pipeline to Proposal Awards**: will build a national community of patients and stakeholders who have the expertise and passion to participate in PCORI research, and create partnerships within that community that lead to high-quality research proposals.

* Not Research Awards
Engagement Award Support

• Engagement projects:

Knowledge Awards

• **Increase knowledge** about how consumers of healthcare information view, receive, and make use of PCOR and CER

Training & Development Awards

• **Build capacity** for participating in PCOR and CER and create ways to connect patients, caregivers, and other stakeholders with the research community

Dissemination Awards

• **Develop and strengthen channels** for disseminating and implementing PCOR and CER findings

• Meetings and conferences that align with PCORI’s Mission and Strategic Plan* and facilitate expansion of PCOR/CER

• Program budget $15.5 million (FY 2015)

• Awards up to 2 years in duration; $250,000 total costs

How We Promote Participation in Research: 
*Pipeline to Proposal Awards*

**Tier I**
Build relationships, develop infrastructure, and create channels for communication

**Tier II**
Mature partnerships, develop research infrastructure, and define research questions and priorities

**Tier III**
Develop and submit a patient-centered research proposal with equal participation from patients, stakeholders, and researchers

PCORI Funding Announcement or other CER funder
Improving Outcomes for Children with Mental Health Challenges and Their Families through Parent-to-Parent Peer Support, Jane Walker, MSW (Tier I)

• Background
  • Expansion of services starting in the mid-1980s led to creating more effective, community-based, and family-driven children’s mental health services.
  • There are over 100 family-run organizations offering parent-to-parent peer support.

• Gap to Address
  • Limited rigorous research to measure the effectiveness of parent peer support on clinical, functional, and service outcomes for children with mental health challenges and related family outcomes.

• Goal of Project:
  • Through the Family-Run Executive Directors Leadership Association (FREDLA), convene a stakeholder group of family leaders, researchers, and others stakeholders.
  • To design a multisite study to compare multilevel outcomes for children and families receiving parent peer support in addition to traditional mental health services with the outcomes for children and families receiving only traditional mental health services.
    • Reviewing promising family support models for further testing, identify potential study sites, and engage local partners in study design.
On Engagement: Quotes from PCORI Research Awardees

“We have assembled a diverse team of over 35 collaborators and stakeholders from academic medical centers, key state and city government agencies, community-based social and health service providers, payers and a non-profit hospital advocacy organization.”

“We’ve never done research this way before, but now I can’t imagine doing it differently.”

“We are very pleased with the level of engagement of our partners, and are grateful for the tremendous feedback and input that the [Stakeholder Engagement Core] members have provided. This has impacted our thinking in a number of key ways as we refine our proposed study design and intervention components.”
Patient and Stakeholder Engagement in Research

• PCORI encourages engagement of patients and other stakeholders at every stage of the research project
  • Planning the study
  • Conducting the study
  • Disseminating study results

• PCORI encourages creativity and innovation in engagement

• Spectrum of engagement for patient and stakeholder partners: focus groups to advisory committees to co-principal investigators

• Engagement should fit the project aims and objectives
Patient Engagement in Research

https://youtu.be/vtj-DfXMG4Y
Our National Priorities, Research We Support, and PCORI Research Funding Opportunities
Our National Priorities for Research

Assessment of Prevention, Diagnosis, and Treatment Options

Research that:

• Compares the effectiveness and safety of alternative prevention, diagnosis, and treatment options
• Determines which ones work best for different people with a particular health problem
Our National Priorities for Research

Assessment of Prevention, Diagnosis, and Treatment Options

Improving Healthcare Systems

Research that:

• Compares health system–level approaches to improving access

• Supports patient self-care, innovative use of health information technology, care coordination for complex conditions, and effective workforce deployment
Our National Priorities for Research

Assessment of Prevention, Diagnosis, and Treatment Options

Improving Healthcare Systems

Communication and Dissemination Research

Research on:

• Providing information produced by CER
• Empowering people to ask for and use the information
• Supporting shared decision making between patients and their providers
Our National Priorities for Research

Assessment of Prevention, Diagnosis, and Treatment Options

Improving Healthcare Systems

Communication and Dissemination Research

Addressing Disparities

Research on:

- Best prevention, diagnosis, or treatment strategies/options to reduce or eliminate disparities

- Target populations at risk for disparities: racial/ethnic minorities; rural populations; low literacy, numeracy, and LEP populations; populations with special healthcare needs (disabilities); LGBTQ populations; low income groups
Our National Priorities for Research

Assessment of Prevention, Diagnosis, and Treatment Options

Improving Healthcare Systems

Communication and Dissemination Research

Addressing Disparities

Accelerating Patient-Centered Outcomes Research and Methodological Research

Research on:

- Building data infrastructure
- Improving analytic methods
- Training researchers, patients, and other stakeholders to participate in this research
We Also Work to Improve Research Methodology

In any study, methods matter. That’s why we’ve developed methodology standards that patient-centered CER should follow, at a minimum.

Methodology Standards: 11 Broad Categories

- Formulating Research Questions
- Patient-Centeredness
- Data Integrity and Rigorous Analyses
- Preventing/Handling Missing Data
- Heterogeneity of Treatment Effects
- Data Networks
- Data Registries
- Adaptive and Bayesian Trial Designs
- Causal Inference
- Studies of Diagnostic Tests
- Systematic Reviews
Support for Researchers Nationwide

Number of research projects: 400

Amount awarded: $868.6 million

Number of states where we are funding research: 39 (plus the District of Columbia)

As of May 5, 2015
Portfolio Analysis: Primary Condition

Where are funded projects concentrated?

38 Cancer
38 Mental/Behavioral Health
23 Cardiovascular Health
18 Neurological Disorders
17 Respiratory Diseases
17 Nutritional and Metabolic Disorders
17 Rare Disease

Where is the most funding (in millions)?

$108.9 Cancer
$70.6 Trauma/Injury
$68.4 Mental/Behavioral Health
$64.9 Cardiovascular Health
$48.7 Nutritional and Metabolic Disorders
$44.1 Rare Disease
$43.2 Respiratory Diseases

As of May 5, 2015
PCORI Research Funding Opportunities

1. Broad Funding Announcements
2. Targeted Funding Announcements
3. Pragmatic Clinical Studies Funding Announcements
Overview:

• Aim is to fund investigator-initiated projects
• Funding announcements available for each of PCORI’s 5 programs/national priority areas
• PFA’s include details about programmatic priorities

Available Funds and Duration*:

• Total funds available range from $8 million to $32 million
• Up to $5 million in total direct costs per project
• Projects should be completed within 3-5 years

Upcoming Cycles (Cycle 2 2015):

• LOI’s due: July 29
• Invited applications due: Nov 3

* Review each program PFA for specific details
Targeted PCORI Funding Announcement

Overview:
• Aim is to fund PCORI-initiated projects, where PCORI details the CER question of interest, patient population, outcomes, study design
• PFAs are released as targeted topics are identified
• Potential topics being discussed include:
  • Long-Term Use of Opioids for Chronic Pain
  • Treatment of Chronic Low-Back Pain
  • Systems Interventions to Improve the Management of Chronic Musculoskeletal Pain
  • Treatment of Major Depressive Disorder
  • Use of New Oral Anticoagulants
  • Immunotherapy Options for the Treatment of Asthma

Available Funds and Duration*:
• Total funds available TBD
• Total direct costs per project TBD
• Projects should be completed within 3-5 years

Upcoming Cycle(s):
• TBD

* Review PFA for specific details.
Pragmatic Clinical Studies PCORI Funding Announcement

Overview:

• Compares two of more options for prevention, diagnosis, treatment, or management of a disease or symptom
•Addresses critical clinical choices faced by patients, caregivers, clinicians, and systems
•Often conducted in a clinical setting that is as close as possible to a real world setting
•The methodological approach (including study design, outcome measures, and follow-up) is as simple as possible without sacrificing scientific rigor
•Responsive to PCORI priority topics, AHRQ Future Research Needs Projects, and IOM 100 priority topics for CER

Available Funds and Duration:

• A total of $90 million (direct and indirect) for this cycle
• Up to $10 million in total direct costs per project
• Projects should be completed within 5 years

Upcoming Cycle (Cycle 3 2015):

• LOIs Due: Nov. 12, 2015
• Invited Applications Due: Feb. 16, 2016
We Fund Research That…

Meets these criteria:

1: **Impact of the condition on health of individuals and populations**

   Is associated with a *significant burden in the US population* (prevalence, mortality, morbidity, individual suffering, or loss of productivity)

2: **Potential for the study to improve health care and outcomes**

   Has the potential to lead to *meaningful improvement in the quality and efficiency of care* and to improvements in outcomes important to patients

3: **Technical merit**

   Has a research design of sufficient technical merit to ensure that the *study goals will be met*

4: **Patient-centeredness**

   Focuses on questions relevant to *outcomes of interest to patients and caregivers*

5: **Patient and stakeholder engagement**

   Includes patients and other healthcare stakeholders as *partners in every stage of the research*
We Fund Research That…

What we mean by…

“Patient-centeredness”

• The project aims to answer questions or examine outcomes that matter to patients within the context of patient preferences
• Research questions and outcomes should reflect what is important to patients and caregivers

“Patient and stakeholder engagement”

• Patients are partners in research, not just “subjects”
• Active and meaningful engagement between scientists, patients, and other stakeholders
• Community, patient, and caregiver involvement already in existence or a well-thought-out plan
Integration of Mental/Behavioral Health into Primary Care: PCORI’s Portfolio
PCORI’s Interest in Integration of Mental/Behavioral Health into Primary Care

• Developed topic briefs to understand:
  • Research gaps
  • Relevance to patient-centered outcomes
  • Likelihood that CER in this area could improve patient-centered outcomes and care
• 2 PCORI Advisory Panels reviewed the topic briefs and prioritized the topic highly
  • Addressing Disparities Advisory Panel
  • Assessment of Prevention, Diagnosis, and Treatment Options Advisory Panel
• Topics have been placed in our Pragmatic Clinical Studies PCORI Funding Announcement
PCORI’s Interest in Integration of Mental/Behavioral Health into Primary Care (cont.)

• Integration of mental and behavioral health services into the primary care of the general population
  • Compare the effectiveness of evidence-based approaches to providing accessible mental health care for adults in the workforce through integration with other medical practice or other programs (such as Employee Assistance Programs) to improve patient-centered and workforce outcomes (e.g., morbidity, health-related quality of life, productivity, absenteeism, presenteeism, and return-to-work).

• Integration of mental and behavioral health services into the primary care of persons at risk for disparities in health care and outcomes
  • Compare the effectiveness of care models that integrate mental and behavioral health care, including substance abuse treatment, into the primary care provided by community health centers and other relevant settings, with the goal of reducing disparities in care (e.g., access to mental and behavioral health services and the diagnosis and treatment of mental and behavioral health conditions) and improving health outcomes among underserved populations, including racial/ethnic minorities, low-income individuals, and rural populations.
PCORI’s Interest in Integration of Mental/Behavioral Health into Primary Care (cont.)

• PCORI’s funding
  • 48 projects across PCORI address mental/behavioral health broadly
    • 5 Pipeline to Proposal Awards
    • 2 Engagement Awards
    • 3 Pilot Project Awards
    • 38 Research Projects Awards
  • 7 research project awards address the integration of mental/behavioral health in primary care
Considerations for Applying to PCORI for Research Funding

• Know what we have and have not funded
• Review our funding announcements
• Ensure existing strong research, patient and stakeholder partnerships or have a solid plan in place to build partnerships
• Highlight the research gap you are addressing
• Identify the best comparators
  • Compare two or more interventions
  • Results should inform decisions of patients and providers and other stakeholders
• Identify patient-centered outcomes
• Develop a strong statistical and analysis plan
• Talk to a PCORI Program Officer
Thank You

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Questions about PCORI Research and Program Awards

Engagement Awards – ea@pcori.org
Pipeline to Proposal Awards – p2p@pcori.org
Research Awards – pfa@pcori.org