The Power of Partnership in Research: Improving Healthcare Outcomes in Underserved Communities

August 1, 2013
About Us

An independent non-profit research organization authorized by Congress as part of the 2010 Patient Protection and Affordable Care Act (PPACA).

Committed to continuously seeking input from patients and a broad range of stakeholders to guide our work.
Our Mission and Vision

Mission
The Patient-Centered Outcomes Research Institute (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.

Vision
Patients and the public have the information they need to make decisions that reflect their desired health outcomes.
Our Board of Governors Represents the Entire Healthcare Community

PCORI Board of Governors, March 2012 in Baltimore, MD
Our Purpose – From the PPACA

“The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of medical treatments, services.

Our Core Duties

- Establish national research priorities
- Establish and carry out a research agenda
- Develop and update methodological standards
- Disseminate research findings
What is Patient-Centeredness?

Does the proposed research compare the effects of treatment options that matter to patients?
- Are these realistic choices faced by patients or other decision-makers?

Does the proposed research focus on outcomes of interest to patients and their caregivers?
- Outcomes of interest might include: health, health-related quality of life, functioning, symptoms, safety from medical harm, survival and satisfaction with care.
### National Priorities for Research and Research Agenda

1. **Assessment of Prevention, Diagnosis, and Treatment Options**
   - Comparisons of alternative clinical options to support personalized decision-making and self-care
   - Identifying patient differences in response to therapy
   - Studies of patient preferences for various outcomes

2. **Improving Healthcare Systems**
   - Improving support of patient self-management
   - Focusing on coordination of care for complex conditions and improving access to care
   - Comparing alternative strategies for workforce deployment

3. **Communication and Dissemination Research**
   - Understanding and enhancing shared decision-making
   - Alternative strategies for dissemination of evidence
   - Exploring opportunities to improve patient health literacy

4. **Addressing Disparities**
   - Understanding differences in effectiveness across groups
   - Understanding differences in preferences across groups
   - Reducing disparities through use of findings from PCOR

5. **Accelerating PCOR and Methodological Research**
   - Improving study designs and analytic methods of PCOR
   - Building and improving clinical data networks
   - Methods for training researchers, patients to participate in PCOR
   - Establishing methodology for the study of rare diseases
Our Major Funding Opportunities

PCORI Funding Announcements (PFAs)
- Assessment of Prevention, Diagnosis, and Treatment Options
- Improving Healthcare
- Communication and Dissemination
- Addressing Disparities
- Accelerating PCOR Research and Methodological Research

Improving Infrastructure for Conducting PCOR
- Clinical Data Research Networks (CDRN)
- Patient-Powered Research Networks (PPRN)

Targeted Funding Announcements
- Treatment options for African Americans and Hispanics/Latinos with uncontrolled asthma *(Letter of Intent due: 8/1/13)*
- Preventing injuries from falls in the elderly (in partnership with the National Institute on Aging)
- Treatment options for uterine fibroids
Our Review Criteria

National Research Priority Areas 1-4

- Impact of the condition on health of individuals and populations
- Potential for improving care and outcomes
- Technical merit
- Patient-centeredness
- Patient and stakeholder engagement

National Research Priority Area 5

- Impact on field of PCOR
- Potential for the study to improve PCOR methods
- Technical merit
- Patient-centeredness
- Patient and stakeholder engagement
Our Primary Research Portfolio

We will award more than $355 million in 2013 and upwards of $500 million in 2014.

The first cycle of our second year of funding opened May 15 and applications are due August 15.

Cycle III awards will be announced September 2013.
Research Infrastructure

Two funding announcements for up to $68 million to support development of a National Patient-Centered Clinical Research Network.

- Clinical Data Research Networks (CDRN)
- Patient-Powered Research Networks (PPRN)

Key Dates:

- April 23, Funding Announcement Release Date
- June 14, Letters of Intent (LOI) Due
- **September 23, Application Deadline**
- December, Awards Announced
Building Research Infrastructure

Characteristics:

- A “network of networks”
- Two types of component networks: systems-generated and patient driven networks
- Active involvement of health care systems, of clinicians and of patients
- A commitment to establishing inter-operability and data sharing across networks and ready collaboration with the larger research community

Capabilities:

- Rich clinical data from electronic health records and other data sources stored in standardized, interoperable formats
- Capacity to conduct both observational studies and randomized trials embedded in clinical settings
- Rigorous practices for data security and confidentiality
- Appropriate IRB and human subjects oversight
- Utility for comparative clinical effectiveness, safety studies, surveillance, etiologic research, and potentially for pre-approval trials
National Patient-Centered Clinical Research Network: Our Vision

Steering Committee

Scientific Advisory Board
Special Expert Group

Coordinating Center Staff
Our First Targeted Research Topics

- Identified several high-priority, stakeholder-vetted topics for targeted funding announcements
- Jumpstarts our long-term topic generation and research prioritization effort
- Leverages stakeholder input from before we were created
- Allows us to build on our engagement work

- Treatment Options for Uterine Fibroids
- Preventing Injuries From Falls in the Elderly
- Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma
PCORI seeks to fund comparative effectiveness research that focuses on reducing adverse outcomes due to poorly controlled asthma in African-American and Hispanic/Latino individuals, populations, and subgroups.

We seek CER that tests interventions to improve clinician and patient adherence to guidelines produced by the National Asthma Education and Prevention Program of the National Heart, Lung, and Blood Institute.

- Research Priority Area: Addressing Disparities
- **LOI Deadline: Aug. 1, 2013**
- Funds Available: Up to $17 million
- Max. Project Period: 3 years
Building Our Research Portfolio: 2013 Funding Commitments

We will commit more than $355 million in research and infrastructure development funding in 2013

<table>
<thead>
<tr>
<th>Funding Stream</th>
<th>LOI Deadline</th>
<th>Application Deadline</th>
<th>Anticipated Award Date</th>
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Engagement as a Path to Rigorous Research

Advise Us On What PCORI Should Study
- What outcomes should be studied?
- What questions are most important?

Review Proposals & Partner in Research
- Review research proposals
- Participate in conducting research

Tell Us How We’re Doing
- How can we improve on what we are doing and how we are doing it?

Help Us Share Research Findings
- How do we best communicate important research findings?
Two Paths to Research Funding

**Investigator-Initiated**

1. PCORI issues broad funding announcements
2. Researchers partner with patients and stakeholders to generate questions
3. Researchers, stakeholders apply review criteria in their applications
4. Peer review prioritizes applications by level of alignment with criteria

**Patient/Other Stakeholder Initiated**

1. PCORI and stakeholders generate and prioritize questions based on review criteria
2. PCORI issues specific funding announcements for highest priority topics
3. Researchers partner with patients and stakeholders to develop proposals
4. Peer review prioritizes applications by level of alignment with criteria

**Diverse research portfolio answering key questions for patients and clinicians**
Tell us what PCORI Should Study

Submit your questions online:
www.pcori.org/questions

I want to know which diabetes treatment won’t slow me down?

How is my home and environment affecting my child’s asthma?

How do I help my employees stay healthy and productive?

How can I help my patients make better informed decisions?
Our First Advisory Panels

- Include clinicians, researchers, patients, and other experts with appropriate experience and knowledge to help us achieve our goals.

- Assure meaningful patient engagement in:
  - Research activities
  - Identifying research priorities and topics
  - Conducting randomized clinical trials
  - Performing special research studies
Review Research Proposals

PCORI invites professional and lay audiences to be reviewers of research applications.

Help us support research that will be both scientifically rigorous and truly patient-centered.

Learn more and apply online: pcori.org/get-involved/reviewers
What roles should patients and stakeholders play in research teams?

The engagement of patients and stakeholders should include:

- Participation in formulation of research questions
- Defining essential characteristics of study participants, comparators, and outcomes
- Monitoring of study conduct and progress
- Dissemination of research results
Facilitating Patient Involvement in Research

Matching Initiative

Engagement Awards
Engagement Awards Program to Advance Patient-Centered Outcomes Research

Targeted funding to dozens of groups of patients and stakeholders to support the expansion of PCOR and implementation of its results

- Supporting projects to enhance knowledge of PCOR and its benefits
- Training to foster partnerships between patients, other healthcare stakeholders, and scientists that can lead to research projects
- Supporting efforts to implement results of the research in clinical practice

- $1.2 million
- Training program to build research capacity
- Fund a series of “Pipeline to Proposal” Awards

Engagement Awards
The PCORI Challenge

- Patient/researcher “matching” mechanism or system
- Connect potential partners interested in seeking funding for PCOR
- Concept or Prototype
- Managed by Health 2.0
The Winners!

Concept ($10,000)

“Act Together and Connect for Patient-Centered Outcomes Research (ACTONNECT)”

Research team lead: Marshfield Clinic Research Foundation, Marshfield, Wis.

Prototype ($40,000)

“WellSpringboard: A Prototype for Patient-Researcher Matching”

Research team: University of Michigan, Ann Arbor, MI.
Communicating Research Results

- Engage major patient organizations
- Establish partnerships with specialty organizations;
- Build working relationships with health plans;
- Develop partnerships with health systems;
- Connect with the National Patient-Centered Clinical Research Network;
- Publish findings in key journals; and
- Explore use of web services, social media, apps, etc.

PCORI's Blueprint for a Dissemination and Implementation Action Plan
The Case for Addressing the Implementation Gap

Optimal Healthcare Delivery

PCORI’s *Blueprint for Dissemination and Implementation* Targets the Gap

- Implementation Gap to Improve Practice
  - New Investments in Knowledge
  - Current Knowledge and Practice

Research + Practice
Developing the PCORI Dissemination and Implementation Action Plan

Process for Developing PCORI’s Blueprint for Dissemination and Implementation Action Plan

- Conduct Phone Calls
  - Collect preliminary information from roundtable participants
  - July 2013

- Host D & I Roundtable
  - Convene experts at D & I Roundtable to receive input which will inform RFP
  - July 2013

- Release RFP or RFPs
  - Using input from the roundtable, develop and release an RFP or a series of RFPs
  - August 2013

- Host D & I Workshop
  - Convene D & I Workshop to hear results of project(s)
  - February 2014

- Award RFP or RFPs
  - Award RFP or RFPs to finalists for development of background materials
  - February 2014

- FINAL: PCORI D & I Action Plan
  - Incorporate learning from workshop and develop PCORI Action Plan for Dissemination and Implementation
  - February 2014

- October 2013

PCORI's Blueprint for a Dissemination and Implementation Action Plan
Join us at www.pcori.org

info@pcori.org
ADDRESSING MENTAL HEALTH NEEDS OF RURAL AFRICAN AMERICANS

PCORI Engagement Panel

August 1, 2013
Academic & Community Team

- Greer Sullivan, MD, MSPH (PI)
- Mary Olson, D.Min (Community PI)
- Naomi Cottoms, MA
- Geoff Curran, PhD
- Ann Cheney, PhD
- Tiffany Haynes, PhD
- Keneshia Bryant, PhD, FNP
- Christina Reaves, MPH
- Elise Allee
- Faye Smith

Community Advisory Board

- Rev. George Barnes
- Linda Cole
- Melva Trask
- Gloria Scott
- Edlun Marshall
- Pamela Barnes Earnest
- Virgil Ward
The setting: Arkansas Delta

- Primarily rural with agriculture based economy

- Characterized by:
  - Poor economic conditions
  - Higher prevalence of chronic health conditions
  - Increased risk of early mortality
  - Poor access to quality health services

- Highest percentage of cities with predominately African-American populations
Mental Health in the Delta

- Poorer self-reported mental health
  - Increased levels of frequent mental distress (BFRSS)

- Poorer mental health outcomes
  - Increased burden of disability
  - Increased mortality
  - Poorer management of chronic physical health

- Underuse of mental health services
Two Different Ways to Obtain Community Perspectives

**DHSR Methods**
- Focus Groups
  - Researcher identifies stakeholders
  - Researcher creates interview guide
  - More traditional research method

**Tri County’s Methods**
- Deliberative Democracy
  - Allows community to self-identify as stakeholders or citizens
  - Community creates the frame
  - Method utilized by Tri-County

**Hypotheses**
Differences in:
- Content of findings
- Degree of empowerment
Mental Health vs. Emotional Wellness

No one is going to talk to you about mental health. When people hear mental health they think of crazy. Ain’t nobody going to talk to you about being crazy. I ain’t crazy, I don’t know how to help you help crazy people.

If you want my expertise, you have to ask me about things I know about.

CAB member
Where are we now?

• Completed 6 Focus Groups (n=50)
  • Faith community
  • College students and administrators
  • Patients
  • Providers

• Completed 6 Community Forums (n=86)
  • Lay community “citizens”
  • Service organization leaders
  • Political leaders
Where are we now?

Preliminary analysis

- Stigma and low mental health literacy major barriers to care

- Importance of “reaching people where they are”
  - Community based services vs. clinic based

- Importance of community support in prevention, treatment, and recovery
  - Provide education and support
  - Address contextual causes that affect emotional wellness
Where are we going?

Potential Outcomes/Interventions

- Mental Health Awareness Campaign
- Peer Based Mental Health Services
- Stigma Reduction Campaigns

Dissemination of results

- Community Forums
- Scientific Peer Reviewed Journals
- Scientific Conferences
ADDRESSING MENTAL HEALTH NEEDS OF RURAL AFRICAN AMERICANS

PCORI Engagement Panel

August 1, 2013
Getting to a Patient-Centered Comparative Effectiveness Research Question

Susan Hildebrandt, MA
Director, Stakeholder Engagement
Memphis, Tennessee
August 1, 2013
Patient-Centered Outcomes Research (PCOR) helps people and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options.

“Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”

“What are my options and what are the potential benefits and harms of those options?”

“What can I do to improve the outcomes that are most important to me?”

“How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?”
How PCORI Defines Comparative Effectiveness Research (CER)

- Compares two or more health and healthcare choices faced by patients, caregivers, clinicians, and healthcare organizations.
- Seeks to answer a medical research question for which there is not sufficient evidence or there is contradicting information.
- Is likely to provide evidence that can reduce uncertainty, support decision making, change practice, and improve patients’ health outcomes.
- Studies a issue or condition that is highly prevalent or places a heavy burden on patients, their families and the healthcare system.
The Simplest Explanation

Treatment A

Treatment B
The Simplest Explanation

Treatment A
- Preferences
- Characteristics
- Risks
- Side Effects

Treatment B
- Preferences
- Characteristics
- Risks
- Side Effects
Getting to the Comparative Question

**Health Question**

- Am I taking the right blood pressure medication?

**CER Question**

- What are the side effects and benefits of different blood pressure medications?

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**Health Question**

- My elderly mother has dementia. Should I place her in a nursing home?

**CER Question**

- What are comparative benefits and risks of nursing home, assisted living and home-based care for elderly patients with dementia?
Questions Outside our Scope of Work

Cost Effectiveness: PCORI will consider the measurement of factors that may differentially affect patients’ adherence to the alternatives such as out-of-pocket costs, but cannot fund studies related to cost effectiveness, costs of treatments or interventions.

Medical Billing: PCORI cannot fund studies about an individual’s insurance coverage or about coverage decisions from third party payers.

Disease-processes and causes: PCORI cannot funding studies that pertain to risk factors, origin and mechanisms of diseases.
We Are Pleased to Present…

Reducing Disparities with Literacy-Adapted Psychosocial Treatments for Chronic Pain: A Comparative Trial

- PFA Cycle I: Addressing Disparities
- Beverly Thorn, PhD
  - Principal Investigator
  - University of Alabama – Tuscaloosa
- Toya Burton, DC, MPH
  - Community Partner
  - Whatley Health Services
Patient-Centered Research: What Does It Look Like?

Beverly E. Thorn, Ph.D., ABPP  
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Toya T. Burton, D.C., MPH  
_Tburton@WhatleyHealth.org_  
Aug. 1, 2013  
PCORI Regional Workshop  
The Power of Partnership in Research: Improving Healthcare Outcomes in Underserved Communities  
Memphis, TN
More specifically, how did we get to where we are?
Examined PCORI Patient-centered Principles

- Help patients and providers **make more informed health care decisions**.
- Facilitate patient, consumer, and caregiver **voices to be heard**.
- Include opportunities for co-learning and reciprocal transfer of expertise among researchers, patients, and caregivers.
- Collaborate: patients, caregivers, and researchers partner to develop the research question
Clinical Relevance + Translational and “Real-World” Application of Product

Work in the Field
(not Just in Academic Research Centers)

Cognitive-Behavioral Chronic Pain Trial Among Rural Minorities and non-Minorities


• This research was supported by the National Institute on Nursing Research and NIMH
Solicited Patient Input

- Key informant interviews – targeted individual patients following initial treatment phase (followed by refinement of questions and materials)
- Focus groups of individuals with chronic pain (but not given the group treatment) after adapting materials and treatment approach
- Qualitative interviews of patients following completions of adapted treatment approach (followed by more refinement prior to PCORI prop.)
Hearing the Patient Voice


Original Reports

A Qualitative Analysis of a Randomized Controlled Trial Comparing a Cognitive-Behavioral Treatment With Education

Melissa A. Day, Beverly E. Thorn, and Shweta Kapoor

The Department of Psychology, The University of Alabama, Tuscaloosa, Alabama.
Our Patient-Centered Research Questions

If I have chronic pain....

1) “What are my options for treating my pain, and what are the benefits and harms of those options?”

2) “What can I do to improve my pain, interference due to pain, and my feelings of depression?”
How Did We Translate Them Into These Testable Research Questions?

1. In patients with chronic pain receiving care at a FQHC does participation in a health literacy–adapted psychosocial treatment group improve their self-reported pain intensity and interference in physical functioning when compared with a group receiving standard medical care?

2. In these patients, does participation in a Cognitive Behavioral pain management group improve depressive symptoms better than a Pain Education group?
To Determine Our Testable Research Questions:

• Met individually with willing practitioners
• Developed a small (pre-proposal) advisory board made up of former group members (patients) and practitioners
• Listened for possible stumbling blocks:
  – feasibility – will they attend?
  – cultural sensitivity – can we ask about depression?
  – Ethics – is it ethical to have a no-treatment control group?
Established Relationships with Community Collaborators
The “Practitioner” as Research Partner

Two-year clinical relationship with researcher helped with:

• Trust issues around patient care
• Confidence in researchers’ patient-centered questions
• Increased our comfort with offering feedback
• Increased willingness to introduce researchers to other key health care providers.
Practitioners Concerns

• Help patients rely less on pain medications & focus more on chronic disease self-management

• Certain clinics with the greater needs based on greatest substance dependency
  – Poses research design problem
  – Compromised by including another site with mixed population and few drug issues
Practitioners Concerns

• What will you do for the control group (medical treatment as usual)
Practitioner Concerns

• What will you do for our Spanish-speaking patients?
What does Engaging in this kind of research Mean to WHS as Stakeholder?

• Largest collaboration so far
• Prompted desire to get more expertise via training
• Hopeful about changing the clinic culture
• Hoping to reduce provider burden, especially regarding need to prescribing medications
In Conclusion

- Patient-centeredness
- Applies to real world
- (hopeful) Reduced practitioner burden
- (planned) Sustainability