PCORI’s Role in Supporting CER

Ayodola Anise, MHS
Program Officer, Addressing Disparities Program

December 8, 2014
Objectives

- Background on PCORI
- Our national priorities and research PCORI supports
- Focus on dissemination
- Upcoming awards and initiatives
- Addressing Disparities program snapshot
About PCORI
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.
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.
Our Focus on CER…

Comparative Clinical Effectiveness Research

- Patient-centered
- Answering questions that matter to patients and other clinical decision makers
- Comparisons of outcomes that matter to patients
Strategic Goals

Increase Quantity, Quality and Timeliness of Research Information

Speed the Implementation and Use of Evidence

Influence Research Funded by Others
Core Attributes Central to PCORI’s Mission

Patient & Stakeholder Engagement

- In all aspects of PCORI’s work (e.g., topic selection and research prioritization for funding announcements, merit review, evaluation)
- Research funded engages patients at every step (e.g., study design, implementation, and dissemination)

Emphasis on Patient-Centered CER

- Research questions and outcomes of projects are driven by patients, caregivers, and other stakeholders

PCORI Methodology Standards

- 47 minimal standards for conduct of research
- Standards across 11 broad categories (e.g., formulating research questions, patient-centeredness, handling missing data, heterogeneity of treatment effects)
Who Are Our Stakeholders?

PCORI Community

- Patient/Consumer
- Caregiver/Family Member of Patient
- Patient/Caregiver Advocacy Org
- Clinician
- Payer
- Industry
- Policy Maker
- Hospital/Health System
- Training Institution
- Purchaser
Our National Priorities and Research We Support
Our National Priorities for Research

Assessment of Prevention, Diagnosis, and Treatment Options

Improving Healthcare Systems

Communication & Dissemination Research

Addressing Disparities

Accelerating PCOR and Methodological Research
PCORI Funding Opportunities

1. “Broad” Funding Announcements
2. Targeted Funding Announcements
3. Pragmatic Clinical Studies
We Follow a Unique Proposal Review Process

Applications are reviewed against five criteria:

- Impact of the condition on the health of individuals/populations
- Potential for the study to improve healthcare and outcomes
- Technical merit
- Patient-centeredness
- Patient and stakeholder engagement

- Applications are reviewed by a panel of two scientists, one patient, and one other stakeholder.
- PCORI’s Board of Governors makes funding decisions based on merit review and staff recommendations.
We Require Patient-Centeredness and Patient and Stakeholder Engagement

**Patient-Centeredness**
- Does the project aim 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
We Work to Improve Research Methodology

In any study, methods matter. That’s why we’ve developed methodology standards that all research 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
Funded Projects as of September 2014

Total number of research projects awarded: **360**

Total funds awarded: **$671 million**

Number of states where we are funding research: **39 states** (plus DC & Quebec, Canada)
Snapshot of Funded Projects

As of September 30, 2014

Selected Conditions Studied

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Studies Funded</th>
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<tbody>
<tr>
<td>Mental/Behavioral Health</td>
<td>45</td>
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<tr>
<td>Cardiovascular Diseases</td>
<td>44</td>
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<tr>
<td>Cancer</td>
<td>36</td>
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<td>Endocrine System Disorders</td>
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<tr>
<td>Nervous System Disorders</td>
<td>21</td>
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<tr>
<td>Musculoskeletal Disorders</td>
<td>14</td>
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</table>

Selected Populations Studied

<table>
<thead>
<tr>
<th>Populations</th>
<th>Studies Funded</th>
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</thead>
<tbody>
<tr>
<td>Racial/Ethnic Minorities</td>
<td>130</td>
</tr>
<tr>
<td>Older Adults</td>
<td>90</td>
</tr>
<tr>
<td>Socioeconomic Status</td>
<td>87</td>
</tr>
<tr>
<td>Rural</td>
<td>64</td>
</tr>
<tr>
<td>Urban</td>
<td>46</td>
</tr>
<tr>
<td>Children</td>
<td>45</td>
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</table>
Peer Health Navigation: Reducing Disparities in Health Outcomes for the Seriously Mentally Ill

Engagement

- Relies on significant stakeholder involvement in the intervention development, project development and management, and in the plans for dissemination and implementation.

Potential Impact

- Could change practice by identifying an intervention that reduces disparities in the utilization of health services for the seriously mentally ill.

Methods

- Research is conducted through a mixed methods approach.

Tests the effectiveness of a peer health navigation intervention in comparison to usual treatment patients with mental illness. The goal of the intervention is train clients to successfully engage and navigate the primary healthcare system as well as other needed health care services.

John Sinclair Brekke, PhD, MS
University of Southern California

Addressing Disparities Research Project, awarded September 2013
Evaluating the Impact of Patient-Centered Oncology Care

Engagement

• A broad multi-stakeholder advisory group will help define the Patient-Centered Oncology Care model.

Potential Impact

• Could change practice by addressing current gaps in cancer care and providing patients and clinicians with important information about what kind of care is possible.

Methods

• Research is completed through qualitative and quantitative analysis.

Tests and evaluates using the patient-centered medical home (PCMH) model of care for treating oncology patients. The goal is to examine whether the model improves patient experiences and quality of care, reduces events such as ED visits and hospital stays, and whether its adoption varies across practices.

Sarah Scholle, MPH, DPH
National Committee for Quality Assurance

Improving Healthcare Systems, awarded May 2013
Imperial County Asthma CER Project

Engagement

- Study is part of on-going partnership between an academic institute, an FQHC, a community-based organization with experience promoting asthma control, and a division of the state health department.

Potential Impact

- May help identify alternate settings to reach underserved populations and inform health policies for long-term asthma control.

Methods

- Research is conducted through 2x2 factorial (family and clinic) study nested in a community intervention.

Examines the impact of a family-clinic-community intervention on asthma control among Latino youth in a rural county along the U.S.-Mexico border.

John Elder, MPH, PhD
San Diego State University Research Foundation

Addressing Disparities Research Project, Targeted Asthma Portfolio, awarded December 2013
Focus on Dissemination
PCORI Evidence to Action Networks

PCORI is launching Evidence to Action Networks—learning networks with more engagement of end users.

Goals of networks are to:

- Engage awardees (researchers, patients, caregivers, and other stakeholders) and facilitate cross-learning between funded projects across PCORI.
- Link awardees with end users to enhance relevance of evidence and increase likelihood of uptake of findings.

Networks can be organized around:

- Health topic or condition
- Intervention
- Methodology
Upcoming Awards and Funding Opportunities
# Upcoming Awards and Funding Opportunities

## Fall Funding Cycle: Broad PFA
- Applications received in Nov 2014
- Merit Review in Feb 2015

## Spring Funding Cycle: Broad PFA
- Upcoming LOI Deadline: March 2015
- Application Deadline: May 2015 (by invitation only)

## Large Pragmatic Clinical Trials PFA
- LOI Deadline: Oct 2014
- Application Deadline: Feb 2015 (by invitation only)
Testing of Multi-Level Interventions to Improve Blood Pressure Control in Racial/Ethnic Minority, Low Socioeconomic Status, and/or Rural Populations

- Supported by the Hypertension Disparities Reduction Program Partnership, a research partnership between NHLBI, NINDS, and the Addressing Disparities program at the Patient-Centered Outcomes Research Institute (PCORI), with funds provided by PCORI to the NIH

- **Goal:** To solicit comprehensive comparative effectiveness studies testing multi-component interventions, with strong patient and stakeholder engagement, to reduce hypertension disparities among racial/ethnic minorities, and/or low socioeconomic status, and/or rural populations

- **Objective:** To fund up to two multi-component comparative effectiveness trials to assess the best strategies to achieve superior blood pressure control levels (>75%) among high-risk patients, including racial/ethnic minorities and/or low socioeconomic and/or rural populations

- **Award Amount:** $25M for up to two trials
**Notice Number:** NOT-HL-14-238

<table>
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<tr>
<th>Key Dates</th>
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<tbody>
<tr>
<td>Notice of Intent Release Date</td>
<td>September 25, 2014</td>
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<tr>
<td>Estimated Publication Date of Announcement</td>
<td>December 2014</td>
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<tr>
<td>First Estimated Application Due Date</td>
<td>February 2015</td>
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<tr>
<td>Earliest Estimated Award Date</td>
<td>September 2015</td>
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<tr>
<td>Earliest Estimated Start Date</td>
<td>September 2015</td>
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Addressing Disparities
Program Snapshot
Addressing Disparities Program’s Mission Statement

PCORI’s Vision, Mission, Strategic Plan

Program’s Mission Statement
To **reduce disparities** in healthcare outcomes and **advance equity** in health and health care

Program’s Guiding Principle
To support comparative effectiveness research that will identify best options for **eliminating disparities**.
## Addressing Disparities: Program Goals

<table>
<thead>
<tr>
<th>Identify Research Questions</th>
<th>• <strong>Identify</strong> high-priority <em>research questions</em> relevant to reducing long-standing disparities in health care outcomes</th>
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</thead>
<tbody>
<tr>
<td>Fund Research</td>
<td>• <strong>Fund CER</strong> with the highest potential to reduce and eliminate health care disparities</td>
</tr>
<tr>
<td>Disseminate Best Practices</td>
<td>• <strong>Disseminate</strong> and facilitate the adoption of <em>best and promising practices</em> to reduce and eliminate health care disparities</td>
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Addressing Disparities Program
Current Status

Broad PFAs
6 cycles
• 41 projects totaling $95M

Targeted PFAs
2 cycles
• Treatment Options for Uncontrolled Asthma in African Americans and Hispanics/Latinos: 8 projects totaling $23.2M
• Obesity Treatment Options in Primary Care: 2 projects totaling $20M
Addressing Disparities Portfolio Snapshot

Populations

AD Target Populations

*Not mutually exclusive
Addressing Disparities Portfolio Snapshot
Research Areas

- Mental Health: 21%
- Oncology: 6%
- Infectious Diseases: 6%
- Sexual Health: 4%
- Substance Abuse: 2%
- Health Care Delivery Systems: 2%
- Trauma: 2%
- Disabilities: 2%
- Neurologic Disorders: 2%
- Smoking: 2%
- Respiratory Disease: 2%
- Neurologic Disorders: 2%
- Infectious Diseases: 2%
- Substance Abuse: 2%
- Sexual Health: 2%
- Health Care Delivery Systems: 2%
- Trauma: 2%
- Disabilities: 2%
- Neurologic Disorders: 2%
- Smoking: 2%
- Respiratory Disease: 2%

Chronic Conditions Portfolio

- Chronic Conditions: 17%
- Multiple Chronic Conditions: 13%
- CVD: 6%
- Diabetes: 4%
- Chronic Pain: 4%
- Kidney Disease: 4%
- Asthma: 17%
Addressing Disparities Program Driver Model

**Tertiary Drivers**
- Self-management
- Community Health Workers
- Cultural/language tailoring
- Decision Support
- Family/Caregiver Involvement
- Team-based Care
- Social Support
- Developmental

**Secondary Drivers**
- Access to Care
- Training/Education
- Workforce
- Patient Empowerment
- Technology
- Community/Home Environment

**Primary Drivers**
- Policy
- Organizational
- Point of Care/Communication

**Program Goal**
Reduce/Eliminate Disparities in Health Care Outcomes
Assessing Addressing Disparities Program Impact

Using Driver Model to

- Assess portfolio to identify and address gaps
- Assess portfolio for areas where we have funded a considerable amount of research and where other Evidence to Action Networks can be implemented

First Evidence to Action Network will focus on asthma

Assessing projects focused on community health workers to understand current research and gaps in funding
Addressing Disparities Upcoming Awards and Initiatives

2014-15 Pipeline

- Awaiting board approval: Perinatal care PFA
- In development: workgroup on interventions to reduce lower extremity amputations in minorities
Thank You

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