PCORI’s Role in Creating a Research Agenda to Reduce Disparities and Improve Patient-Centered Outcomes

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For Today

Overview of PCORI

The Addressing Disparities Program

The PCORI framework and review criteria
About PCORI

- An independent research institute authorized by Congress through the Affordable Care Act.
- Funds comparative clinical effectiveness research (CER) that engages patients and other stakeholders throughout the research process.
- Answers real-world questions about what works best for patients based on their circumstances and concerns.
We Have a Broad and Complex Mandate

“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...and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services...”

-- from Patient Protection and Affordable Care Act
Mandate includes: “….reducing practice variation and disparities”

IDENTIFYING RESEARCH PRIORITIES.—The Institute shall identify national priorities for research, taking into account factors of disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), gaps in evidence in terms of clinical outcomes, practice variations and health disparities in terms of delivery and outcomes of care…

-- from Patient Protection and Affordable Care Act
Our 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.
What is PCOR?

Patient-centered outcomes research (PCOR) helps people and their caregivers communicate and make informed healthcare decisions, allowing their voices to be heard in assessing the value of healthcare 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?
# Key Features of Our Funded Research

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
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<tbody>
<tr>
<td>Studies the benefits and harms of interventions and strategies delivered in real-world settings</td>
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<td>Compares at least two alternative approaches</td>
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<td>Adheres to PCORI’s Methodology Standards</td>
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<td>Is based on health outcomes that are meaningful to the patient population</td>
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<td>Engages patients and other stakeholders at every stage</td>
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<td>Is likely to improve current clinical practices</td>
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We Pay Particular Attention to...

<table>
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<tr>
<th>Conditions that heavily burden patients, families and/or the health care system</th>
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<td>Chronic or multiple chronic conditions</td>
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<td>Rare and understudied conditions</td>
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<td>Conditions for which outcomes vary across subpopulations</td>
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We Use Engagement as a Path to Rigorous Research

Advise Us on What PCORI Should Study

Review Proposals and Partner in Research

Tell Us How We’re Doing

Help Us Share the Findings
PCORI’s Planned Funding Patterns, 2014-19

<table>
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<tr>
<th>Year</th>
<th>Millions</th>
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<tr>
<td>2012</td>
<td>$31</td>
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<tr>
<td>2013</td>
<td>$303</td>
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<tr>
<td>2018</td>
<td>$200</td>
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<tr>
<td>2019</td>
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Research Commitments
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
Addressing Disparities Mission Statement

PCORI’s Vision, Mission, Strategic Plan

Program’s Mission Statement

To reduce disparities in healthcare outcomes and advance equity in health and healthcare.

Program’s Guiding Principle

To support comparative effectiveness research that will identify best options for reducing and eliminating disparities.
Addressing Disparities: Program Goals

Identify Research Questions
- **Identify** high-priority research questions relevant to reducing and eliminating disparities in healthcare outcomes

Fund Research
- **Fund** comparative effectiveness research with the highest potential to reduce and eliminate healthcare disparities

Disseminate Promising/Best Practices
- **Disseminate** and facilitate the adoption of promising/best practices to reduce and eliminate healthcare disparities
Addressing Disparities Advisory Panel helps guide the work of our program.
Addressing Disparities Program has committed $140 million in CER to reduce disparities (as of October 2014)

**Investigator Initiated Projects**
- 41 CER projects. $71.8 million
- Treatment Options for Uncontrolled Asthma: 8 CER trials. $23.2M
- Obesity treatment options in primary care for underserved populations. 2 comparative effectiveness research trials. $20 M
- Reducing Hypertension Disparities in collaboration with NHLBI/NINDS. Funding Announcement. Nov 2014. Up to 2 comparative effectiveness research trials. $25M

**Targeted Projects**
- First round of Pragmatic clinical trials, awards in January 2015
- In Development Stage (Perinatal Outcomes, Lower Extremity Amputations, and other topics)
Conceptual Framework & Driver Model
Anchors and Helps to Guide the Addressing Disparities Program
### Conceptual Framework - Barriers and Mediators of Equitable Healthcare

#### Barriers
- **Personal/Family**
  - Acceptability
  - Cultural
  - Language/literacy
  - Attitudes, beliefs
  - Preferences
  - Involvement in care
  - Health behavior
  - Education/income
- **Structural**
  - Availability of appointments
  - How organized
  - Transportation
- **Financial**
  - Insurance coverage
  - Reimbursement levels
  - Public support

#### Use of Services
- **Visits**
  - Primary care
  - Specialty
  - Emergency
- **Procedures**
  - Preventive
  - Diagnostic
  - Therapeutic

#### Mediators
- **Quality of Providers**
  - Cultural competence
  - Communication skills
  - Medical knowledge
  - Technical skills
  - Bias/stereotyping
- **Appropriateness of care**
- **Efficacy of treatment**
- **Patient adherence**

#### Outcomes
- **Health Status**
  - Mortality
  - Morbidity
  - Well-being
  - Functioning
- **Equity of Services**
- **Patient views of care**
  - Experiences
  - Satisfaction
  - Effective partnership

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**Citation:** Lisa A Cooper, et al. Designing and Evaluating Interventions to Eliminate Racial and Ethnic Disparities in Health Care *JGIM*, 2002
Addressing Disparities Driver Model

The model is an *evolving* tool used to

- Evaluate where we are
- Identify where we need to go
Addressing Disparities Program: Comparative Effectiveness Research Driver Model (n=39*)

**Tertiary Drivers**
- Self-Management: 19
- Community Health Workers: 17
- Cultural/Language Tailoring: 16
- Decision Support: 9
- Family/Caregiver Involvement: 7
- Team-Based Care: 6
- Social Support: 7
- Developmental: 4

**Secondary Drivers**
- Access to Care: 27
- Training/Education: 32
- Workforce: 21
- Patient Empowerment: 24
- Technology: 14
- Community/Home Environment: 14

**Primary Drivers**
- Policy: 0
- Organizational: 9
- Point of Care/Communication: 37

**Program Goal**
Reduce/Eliminate Disparities in Health Care Outcomes

*Categories are not mutually exclusive. There can be a maximum of 39 projects in each category.*
A Look Toward Portfolio Impact

Pre-Award and Strategic Planning

Post-Award and Portfolio Management

Assessment of Impact

We are here
Where Do We Go From Here?
Learning, Disseminating, and Implementing

- Engage patients and other end-users from start to finish (i.e., research topic generation → dissemination)

- Establish *communities* among PCORI-funded projects-
  EVIDENCE TO ACTION NETWORKS
  - Mechanism to foster cross-learning among project teams
  - Bring together the research community and end-users including patients, payers (e.g., AHIP), employers and purchasers (e.g., National Business Group on Health), clinicians, professional societies, policy makers, and training institutions.
PCORI Evidence to Action Networks (E2AN)

PCORI just launched our first Evidence to Action Network (E2AN) — learning networks with more engagement of end users.

Goals of networks are to:
- Engage awardees 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
- Methodology
How We Review Research Proposals

**Who:** Each proposal is reviewed by two scientists, a patient, and another stakeholder.

**What:** Reviewers critique and score applications, making recommendations that our Board of Governors and staff consider carefully in deciding which applications to approve.

**How:** We provide training so all participants are prepared and understand PCORI’s review criteria.

**When:** You can apply at any time to serve as reviewer.

Learn more [pcori.org/reviewers]

Contact us reviewers@pcori.org
How Are Applications Reviewed?

Applications are reviewed against five criteria:

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

- Applications are reviewed by a committee 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 have adopted 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
How Patient-Centeredness Compares with Patient Engagement

**Patient-Centeredness**

- A component of what PCORI is looking for in research applications
- 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 Engagement**

- Patients are partners in research, not merely subjects
- Active engagement between scientists, patients, and stakeholders
- Community, patient, and caregiver involvement already in existence or a well-thought out plan
The rubric is intended to provide guidance to applicants, merit reviewers, awardees, and engagement/program officers (for creating milestones and monitoring projects) regarding patient and family engagement in the conduct of research. It is divided into four segments:

I. Planning the Study
II. Conducting the Study
III. Disseminating the Study Results
IV. PCOR Engagement Principles
Engagement Officers

Engagement Officers, working closely with Program Officers, will support active portfolio management by:

- Helping Awardees to identify and outline engagement milestones during contract negotiation
- Participating in the Awardees' kick-off and interim phone calls as well as in separate calls with key patient and stakeholder partners
- Facilitating communication between Awardees to troubleshoot engagement challenges
- Gathering promising engagement practices from the portfolio to feature in webinars and for use in updating or expanding the Patient and Family Engagement Rubric
How We Promote Participation in Research

**Pilot Projects:** address a broad range of questions about **methods for engaging patients** in various aspects of the research and dissemination process.

**Matching Challenge:** two challenge winners created innovative ways to **connect patients and researchers as partners** in research.

**Engagement Awards:** Pipeline to Proposal Awards will build a national community of patients and stakeholders who have the expertise and passion to participate in PCORI research. Create partnerships between the community and academic institutions that lead to high-quality research proposals.
Thank you!
Find Us Online

www.pcori.org