Support for Research that Matters to Ordinary People

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February 27, 2014
Sources of Research Support

- NIH
- AHRQ
- Private foundations
- Industry
- Patient-Centered Outcomes Research Institute
- Others
PCORI

An independent, non-profit, research funding organization authorized as part of the 2010 Patient Protection and Affordable Care Act (PPACA)
How PCORI is Funded

The Patient-Centered Outcomes Research Trust Fund (PCORTF), created by the PPACA, receives income from:

- U.S. Treasury
- Medicare, private health insurance plans and self-insured plans.

80% of PCORTF goes to PCORI (~$3.5 billion through September 30, 2019).

20% goes to HHS to support dissemination and research capacity-building, 80% of which is transferred to AHRQ.
PCORI’s Vision and Mission

Vision:
Patients and others have the information they need to make decisions that reflect their desired health outcomes.

Mission:
To support patient-centered outcomes research (PCOR) that:
• Is guided by patients, caregivers and other stakeholders that represent the health care community
• Produces high-integrity, evidence-based information that helps people make informed health care decisions
• Improves health care and health-related outcomes that patients care about.
Board of Governors

Appointed by the U.S. Comptroller General, PCORI’s Board of Governors includes:

• Three **patient** representatives
• Five **clinician** representatives
• Three private **payer** representatives
• Three representatives of the pharmaceutical, device and diagnostic **industries**
• One representative of the quality improvement/health service **research** field
• Two representatives of federal or state **government**, at least one from a federal health program
• The directors of the **NIH** and **AHRQ**.
Board of Governors Represents the Entire Health Care Community

PCORI Board of Governors
Methodology Committee

Appointed by the U.S. Comptroller General to develop and advance the science and methodology of patient-centered outcomes research (PCOR). Its 17 members are experts in:

• Health services research
• Clinical research
• Clinical comparative effectiveness research
• Biostatistics
• Genomics
• Other research methods.
Methodology Standards

• 47 Methodology Standards guide the conduct of patient-centered outcomes research (PCOR).

• A full narrative report, providing context for these standards, was published in late 2013.
PCORI’s Leadership

Executive Director
Joe Selby, MD, MPH

Chief Science Officer
Bryan Luce, PhD

Science Programs (5)

Chief Officer for Engagement
Anne Beal, MD, MPH

Patient Engagement Program
Stakeholder Engagement Program

Chief Operating Officer
Regina Yan, MA

Finance, Contracts, IT, HR, and Communications Departments
PCORI’s Projects

PCORI funding requires:

- **Comparisons** of alternatives
- Outcomes that **matter to patients** and are likely to be **implemented in real-world practice**
- Engagement of patients and relevant stakeholders as **partners** in research
- Adherence to the **PCOR methodology standards**
- **No** cost-effectiveness analyses.
Engagement on Research Teams

Engaged patients and stakeholders are partners with researchers:

– Participate in the formulation of the research questions to be answered
– Help define the essential characteristics of study participants, the comparators, and the outcomes to be measured
– Help monitor the conduct and the progress of the study
– Help disseminate the study’s results.
Interest in Subpopulations

PCORI is interested in research on the differential effectiveness that treatments may have in different subpopulations, e.g., in:

• Racial/ethnic minorities
• Older persons, children, LGBT populations
• People with multiple chronic conditions, rare conditions, low socioeconomic status, rural or inner-city residence, low literacy or disabilities.
Traditional Path to Funding

Figure 1: Traditional Process

Investigator-Generated Research Just One Part of the Process

- PCORI issues broad funding announcements
- Researchers partner with stakeholders to generate questions
- Researchers, stakeholders apply review criteria in their applications
- Peer review prioritizes applications by level of alignment with criteria

Diverse Research Portfolio answering key questions for patients and clinicians
Alternate Path to Funding

Figure 2: Unique Process

Patient/Stakeholder-Led Approach

PCORI and stakeholders generate and prioritize questions based on review criteria

PCORI issues specific, funding announcements for highest priority topics

Researchers and stakeholders develop responsive proposals

Peer review prioritizes applications by level of alignment with criteria

Diverse Research Portfolio answering key questions for patients and clinicians
Newest Path to Funding

“Pragmatic Clinical Studies”

• Many possible topics
• Up to $10 million (direct costs) for projects lasting up to 5 years
• First cycle began on February 5, 2014
  – LOIs due March 7
  – Applications due August 8
  – Funding decisions in January 2015.
Review Criteria

• Burden of the condition on the health of individuals and populations
• Potential for the study to improve health care and outcomes
• Technical merit
• Patient-centeredness
• Patient and stakeholder engagement
PCORI’s Growing Research Portfolio
(as of January 2014)

Research projects awarded: 279

Total funds awarded: $464.2 million

Number of states where PCORI has funded research: 39
(plus District of Columbia and Quebec)
PCORI’s Research Portfolio

- PCORI awarded more than $350 million in 2013 and will award upwards of $500 million in 2014.
- Its next awards will be made in early Summer 2014.
- The current broad and targeted PFA cycle opened February 5; applications are due May 6 for funding decisions in September 2014.
Questions about PCORI
PCORI’s “Improving Healthcare Systems” Program
Mission

PCORI’s IHS program will:

- Produce new scientific knowledge that will
- Transform the quality and efficiency of critical components of the U.S. healthcare system, and thereby
- Improve the health-related outcomes that matter most to people.
Goal

To provide patients and stakeholders with useful knowledge of the effects of innovations in:

• Technology
• Incentives
• Deployment of personnel

...on patients’ quality of care, self-care, health, quality of life and functional ability.
What is a Healthcare System?

- Through the **patient’s** lens – all the **providers** of the care I receive, as well as my insurer
- Through the **provider’s** lens – all the **providers** with whom I interact, as well as the **insurers**
- Through the **insurer’s** lens – all the **providers** I pay to care for my insured lives
- Through the **economist’s** lens – all the **patients**, **providers** and **insurers** in a geographic area
Funding Mechanism

PCORI’s IHS program enters into contracts

• Selected organizations perform specified health systems-related research.
• Research partners report attainment of agreed milestones semi-annually.
• PCORI team helps overcome obstacles.
• PCORI makes agreed payments.
IHS Program’s Research Portfolio

• 42 awards totaling $115 million so far
  – More than $100 million in 2013.
• Its next awards will be made in early Summer 2014.
• The current funding cycle opened February 5; applications are due May 6 for funding decisions in September 2014.
“Targeted” PFA #1

- “Reducing Injurious Falls in Older People”
- Partnership with NIA
- $30 million for a five-year RCT of the effectiveness of a multifactorial intervention
- Awardee should be announced in March 2014.
“Targeted” PFA #2

• “Effectiveness of Transitional Care”
• PFA released February 5, 2014
• $15 million for a three-year study of the effectiveness of different clusters of transitional care services for different populations
• Applications are due on May 6 for a funding decision in September 2014.
Apply for Funding

• Broad PFAs — from CER, AD, IHS, M&I programs
• Targeted PFAs — from CER, AD, IHS, M&I programs
• Pragmatic Clinical Studies — from PCORI

Total >$500 million/year for each of the next few years
Become a PCORI Reviewer

- PCORI invites professional and lay people to become reviewers of research applications.
- Help identify research that will be both scientifically rigorous and patient-centered.
- Learn more and apply at pcori.org/get-involved/review funding applications.