Engagement in Clinical Research: Opportunities for Implementation Science

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Aims for today’s presentation

• Introduction to PCORI
• Define patient and stakeholder engagement
• PCORI’s Engagement Rubric
• Engagement and Implementation Science
• Funding Opportunities
• Questions/Discussion
Introduction to PCORI
About Us - PCORI

- An independent research institute authorized by Congress in 2010 and governed by a 21-member Board of Governors representing the entire healthcare community
- 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 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 PCORI’s authorizing legislation
How is Our Work Different?

• We fund research on which care options work, for whom, under which circumstances.
• We focus on answering questions most important to patients and those who care for them.
• We aim to produce evidence that can be easily applied in real-world settings.
• We engage patients, caregivers, clinicians, insurers, employers and other stakeholders throughout the research process.
• This makes it more likely we’ll get the research questions right and that the study results will be useful and taken up in practice.
Our Research Focus
Comparative Clinical Effectiveness Research

- Generates and synthesizes evidence comparing benefits and harms of at least two different methods to prevent, diagnose, treat, and monitor a clinical condition or improve care delivery
- Measures benefits in real-world populations
- Describes results in subgroups of people
- Helps consumers, clinicians, purchasers, and policy makers make informed decisions that will improve care for individuals and populations
- Informs a specific clinical or policy decision
- *We do not fund cost-effectiveness research*

Adapted from Initial National Priorities for Comparative Effectiveness Research, Institute of Medicine of the National Academies
Patient-Centered Outcomes Research

PCOR is a relatively new form of CER that...

- Considers patients’ needs and preferences, and the outcomes most important to them
- Investigates what works, for whom, under what circumstances
- Helps patients and other healthcare stakeholders make better-informed decisions about health and healthcare options
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:

- Prevention, diagnosis, or treatment effectiveness
- Preferred clinical outcomes across patient populations
- Health care required to achieve best outcomes in each population
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
Better Research Through Engagement
Patient-centeredness versus Engagement

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
Why Engage?

To influence research to be patient-centered, relevant, and useful

To establish trust and a sense of legitimacy in research findings

To encourage successful uptake and use of research results
Our Engagement Rubric—A Valuable Resource

Provides practical guidance to applicants, merit reviewers, awardees, and engagement/program officers on effective engagement in research

- **Planning the Study**: How patient and stakeholder partners will participate in study planning and design
- **Conducting the Study**: How patient and stakeholder partners will participate in the conduct of the study
- **Disseminating the Study Results**: How patient and stakeholder partners will be involved in plans to disseminate study findings and ensure that findings are communicated in understandable, usable ways
- **PCOR Engagement Principles**: Reciprocal relationships, co-learning, partnership, trust, transparency, honesty
Who Are Our Stakeholders?

- Payers
- Caregivers/Family Members
- Clinicians
- Purchasers
- Policy Makers
- Patients/Consumers
- Industry
- Hospitals/Health Systems
- Training Institutions
- Patient/Caregiver Advocacy Organizations
Engagement and Implementation Science
Factors contributing to sparse uptake of evidence-based interventions to date

• Not a good pipeline from the intervention developers/researchers to the patients, communities, and organizations that would utilize the intervention(s)

• Many interventions are not developed in real-world settings and have little to no input from the end-users
  – Makes for difficulty in using the information
  – Makes for difficulty in readily adopting and applying the intervention
Dissemination and Implementation

• Dissemination – (knowledge)
  – getting information out, taking knowledge and translating that knowledge so that it’s acceptable so that people can understand it and then using information channels so they get out.
  – Current focus of PCORI
    • CDR program
    • Engagement program
    • Dissemination
• Implementation – more about practice
  – Taking an effective intervention and figuring out how best to get that in use, in practice in an effective and sustainable way
    • New focus for CDR program – effectiveness-implementation hybrid designs
Context and Engagement
Understanding context – use of qualitative methods
Engagement and Implementation Science

Take away points

• Engagement is being used to help plan programs and improve their chances of working in "real-world" settings.
• Engagement is necessary for understanding “real-world” settings.
• Effective engagement of patients and other stakeholders in research requires a well-thought-out plan.
• Engagement and implementation research are designed to enhance the quality, impact, and speed of efforts to translate research into practice.
Funding Opportunities
Funding Opportunities

Research Awards:
• Broad PCORI Funding Announcements
• Targeted PCORI Funding Announcements
• Pragmatic Clinical Studies

Engagement Awards:
• Knowledge, Training and Development, and Dissemination Awards
• Research Meeting and Conference Support
• Pipeline to Proposal Awards
PCORI Funding Opportunities

Our research funding is awarded through PCORI Funding Announcements. Open opportunities are posted at pcori.org/apply.
Q&A
Contact Us

www.pcori.org
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Thank you