Impact and Influence of Engagement in Research: Lessons and Findings from PCORI

Michelle Johnston-Fleece, MPH
Senior Program Officer
Patient-Centered Outcomes Research Institute

Health Research Alliance Members Meeting
March 31, 2020
Objectives

- PCORI’s Approach to Engagement
- What We Have Learned
- Benefits to Organizations...and Stakeholders
- Appendix
  - Resources
PCORI’s Approach to Engagement
PCORI: Established (and Reauthorized!) to Meet Stakeholders’ Needs

“Research shall be designed, as appropriate, to take into account and capture the full range of clinical and patient-centered outcomes relevant to, and that meet the needs of, patients, clinicians, purchasers, and policy-makers in making informed health decisions....”

—from PCORI’s re-authorizing legislation
The Path to Impact: PCORI’s Conceptual Model

The PCORI Approach

- Pragmatic research in real-world settings
- Engagement in every step
- Intensive portfolio management (e.g., contracts)
- Investments in dissemination & implementation

Patient-Centered CER

Studies that matter to patients
- Quality, Relevance, etc.

Strategic Goals

- Produce useful information
- Speed uptake of information
- Influence others to be more patient-centered

Impact

- Health decisions
- Health care
- Health outcomes
What we mean by...

Patient-centeredness

- Research reflects what is important to patients and caregivers
- Questions and outcomes that matter to patients
- Study design is low burden to participants

Patient and stakeholder engagement

- Research partners vs. research subjects
- Active and meaningful partnership between scientists, patients, and other stakeholders with the purpose of improving feasibility, acceptability and relevance
- Forms: Input, consultation, collaboration, shared leadership
Engagement: A Foundation for Everything PCORI Does
PCORI created opportunities for Engagement at every step of the research process

**Research Partnerships and Capacity**
- 410 Eugene Washington Engagement Awards to build patient and stakeholder capacity to partner in research
- 253 PCORI Ambassadors

**Research Priorities**
- 190+ stakeholders have served on PCORI Advisory Panels
- 850+ unique organizations have participated in PCORI's workshops, work groups, and roundtables

**Funding and Conduct of Research**
- 600+ patients and other stakeholders have served as merit reviewers
- 639 research projects with unique requirements for engagement

**Dissemination and Implementation**
- 30 awards to actively disseminate and implement PCORI research results using approaches guided by stakeholders

**Policy and Practice**
- 10 stakeholder convenings to understand context for our portfolio, share findings, and get input on gaps
- 13 Hill Briefings and Salons to talk with public policymakers
PCORI Projects Engage With Partners From Many Communities

Communities engaged in PCORI research projects:
(by percent of projects, N=483)

- **Patients**: 89%
- **Advocacy Orgs**: 65%
- **Caregivers**: 61%
- **Clinicians**: 89%
- **Health Systems**: 65%

92% of projects engage with at least 1 of these communities

PCORI projects also engage with subject matter experts (57%), community-based organizations (24%), training institutions (26%), policymakers (24%), payers (25%), industry (8%), and purchasers (5%)

Note: Data from awardee reports collected through 3/31/19; N=483 awardees
Projects Engage Partners in Multiple Ways

% of all projects that use engagement approach:

- 86% Research Team Members
- 87% Advisory Groups
- 55% Co-Investigators

Note: Data from awardee reports collected through 3/31/19; N=483 awardees
PCORI Projects Engage Partners Throughout the Research Process

Percent of projects that reported engaging partners at each study phase

<table>
<thead>
<tr>
<th>STUDY PHASES</th>
<th>Percent</th>
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<tbody>
<tr>
<td>Research topics and/or research</td>
<td>62%</td>
</tr>
<tr>
<td>questions</td>
<td></td>
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<tr>
<td>Interventions and/or comparators</td>
<td>73%</td>
</tr>
<tr>
<td>Outcomes and/or measurement</td>
<td>73%</td>
</tr>
<tr>
<td>Other aspects of study design</td>
<td>66%</td>
</tr>
<tr>
<td>Recruitment and/or retention</td>
<td>72%</td>
</tr>
<tr>
<td>Data collection</td>
<td>56%</td>
</tr>
<tr>
<td>Data analysis and/or results review</td>
<td>63%</td>
</tr>
<tr>
<td>Sharing study information and/or</td>
<td>65%</td>
</tr>
<tr>
<td>results</td>
<td></td>
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Note: Data from annual awardee reports collected through 3/31/19; N=483 awardees
PCORI’s Findings on Engagement

Impact, influence, benefits and challenges
PCORI Has Created a Body of Evidence about Engagement

Findings synthesized across efforts to build evidence and inform practice

Data Collection and Analysis
- Administrative and project monitoring
- Surveys and interviews with researchers and partners
- Analysis of publications

Products and Support
- Tools, guidance, and peer learning
- Publications about engagement
- Support from engagement and program officers

Learnings
- How engagement influences and impacts the work, individuals, and organizations
- Opportunities, challenges, and tensions
- Engagement methods that are working

PRACTICE-BASED EXPERIENCE
There Is A Continuum Of Engagement Practices

Levels of partners’ decision making authority for study design and implementation

**Input**
- Focus Groups, Town Halls, Crowdsourcing

**Consultation**
- Advisory Committee

**Collaboration**
- Patient Co-I or Multi-Disciplinary Executive Team

**Shared Leadership**
- Patient Co-PI, Patient-led tasks

Adapted from:
Hanley et al. (2004). Involving the public in NHS, public health and social care research.
# Ways that Engagement Shapes PCORI-Funded Research Projects

<table>
<thead>
<tr>
<th><strong>User-Orientation &amp; Acceptability:</strong></th>
<th>studies in which patients and clinicians will be willing to participate based on burden, usability, and alignment with preferences, values, and needs</th>
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<tbody>
<tr>
<td><strong>Feasibility:</strong></td>
<td>interventions, enrollment, and data collection that are more doable in real-world settings</td>
</tr>
<tr>
<td><strong>Study Quality:</strong></td>
<td>study rigor, comprehensiveness, and quality of materials and products</td>
</tr>
<tr>
<td><strong>Relevance:</strong></td>
<td>results applicable and important for decision-making</td>
</tr>
<tr>
<td><strong>Engagement Scope &amp; Quality:</strong></td>
<td>engagement processes are effective, and stakeholders are well equipped</td>
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</table>
Engagement Makes Meaningful Differences in Research Projects

Core themes emerged across multiple studies of engagement

Engagement influenced...

- Study conceptualization, execution, materials and dissemination products
- Carrying out study tasks
- Engagement design and practice
- Researchers’ understanding of patients, clinicians, and health care organizations

For example, in one recent study about engagement in PCORI-funded research projects, nearly 400 distinct examples of engagement influence were analyzed from in-depth interviews with 60 projects.
Engagement Benefits Those Involved

Patients & Stakeholders
- More knowledge and enthusiasm for research
- Developed skills and professional opportunities
- Improved personal health and healthcare
- New or better relationships
- Feeling of making a difference

Communities
- Built trust
- Increased research capacity
- Strengthened relationships among stakeholders
- Increased awareness of different stakeholder perspectives

Researchers
- Deeper understanding of real-world experiences and concerns of their study populations
- More knowledge about engagement
- Commitment to engagement in the future

Hemphill, RC, Forsythe, LP, Heckert, A, et al. (2019) Understanding what motivates patients and caregivers to engage in research and how engagement affects their lives: Qualitative findings from a survey of PCORI research partners
PCORI’s Approach Is Helping to Influence the Culture of Research

Change at other organizations and institutions

- Seed funding for partnerships
- Training of students, fellows, and partners
- Patient reviewers
- Requirement to involve patients & stakeholders in strategic research planning
- Policies to support engagement in research
- Journal policies for person-centered language
- Adoption of patient-centered approaches by federal agencies, academic institutions, and funders

Specific examples are described in more detail at https://www.pcori.org/engagement/influencing-culture-research
Engagement Can Be Challenging

Infrastructure and Resources
- Knowledge
- Skills & Experience
- Money
- Time

People and Teams
- Access
- Ensuring Diversity & Inclusivity
- Relationships & Communication

Organizations
- Competing Priorities
- Contracting Policies
- IRBs

Balancing Views and Priorities
- Differing Perspectives
- Value Conflicts
- Internal vs. External Validity
## Future Actions to Build on PCORI’s Accomplishments

<table>
<thead>
<tr>
<th>Opportunities for Engagement</th>
<th>Guidance</th>
<th>Portfolio of Projects and Research</th>
<th>Science of Engagement</th>
<th>Culture Change</th>
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<tr>
<td>Expanded approaches and mechanisms to ensure participants are diverse and representative</td>
<td>Update Rubric; explore opportunities to expand standards and criteria for engagement</td>
<td>Make engagement easier and more efficient through portfolio management and support</td>
<td>Implement innovative methods, including exploring new funding opportunities</td>
<td>Spread learnings about engagement</td>
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<td>Develop and use validated measures of engagement</td>
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Contact Information

Michelle Johnston-Fleece, Senior Program Officer

202-370-9383

@ mfleece@pcori.org

www.pcori.org

@pcori

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/pcori
Appendix:
PCORI Engagement Resources
Coming Soon: Research Fundamentals Learning Package

For **stakeholder partners** who are new to research, this package uses plain language to help learners **understand the language and logic of the research process**.

The ultimate goal is to help all stakeholders, regardless of experience conducting research, to engage with confidence and contribute individual experiences to shape studies from start to finish.
Coming Soon: Working as a Team Learning Package

For **new and experienced researchers and stakeholder partners**, this package offers **practical guidance on how to work successfully as a unified team** where everyone is engaged and contributes confidently throughout the research process. From conducting meetings to resolving conflict, the package helps team members in any role to work collaboratively during a study.

Coming late 2020
PCORI Engagement Resources

- Ambassadors Program
- Budgeting for Engagement Activities
- Compensation Framework for Engaged Research Partners
- Engagement Rubric
- Eugene Washington PCORI Engagement Awards
- Methodology Report
- PCORI in Practice Webinar Series
- Sample Engagement Plans
- Updated Engagement Plan template

COMING SOON: Guidebook on Engaging with Research Partners about Data and Analysis
How to Engage? Engagement Rubric Overview

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| Developing research questions  
Selecting relevant outcomes  
Define study population characteristics | Drafting or revising study materials  
Participating in study recruitment  
Participating in data analysis | Identifying partners for dissemination  
Participating in dissemination efforts  
Presenting information about the study |

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| Patient organization surveys members on treatment preferences  
Clinicians suggest a third arm to study based on variability in practice | Patients develop informed consent to make it understandable to participants  
Patient representative serves on data safety monitoring board | Research team holds stakeholder summit to speed implementation of findings  
Research team introduces study at a patient advocacy conference to inform community of the research |

PCOR Principles
Reciprocal Relationships • Co-Learning • Partnerships • Transparency, Honesty, Trust

Reciprocal Relationships: Demonstrated when roles and decision-making authority of all research partners are defined collaboratively and clearly stated
Co-Learning: Researchers help patient partners better understand the research process, and researchers will learn about patient-centeredness and patient/stakeholder engagement
Partnerships: The time and contribution of patient and other stakeholder partnership is valued and demonstrated through compensation, cultural competency, and appropriate accommodations
Transparency, Honesty, Trust: Major decisions are made inclusively and information is shared readily among all research partners

Engagement in Health Research Literature Explorer

• This searchable, catalogued resource for peer-reviewed literature can help identify publications about engagement.

• It contains over 1,000 articles that include:
  • Examples of engagement in health research
  • Evaluations of engagement in health research
  • Syntheses of engagement methods and impacts
  • Frameworks, editorials, and commentaries on engagement in health research

• Articles can be filtered by communities that were engaged, phase of research engagement (e.g., study design, recruitment, etc.), and publication year

• Link: Engagement in Health Research Literature Explorer
Engagement Tool and Resource Repository

A searchable catalogue of work products from Research Awards and Engagement Awards to facilitate engagement in research.

Resources range from kick-off meeting agendas, to Research 101 trainings, to committee charters, and more!

Link: Engagement Tool & Resource Repository