Planning for Successful Engagement in Research

Chinenye Anyanwu, PharmD, MPH
Engagement Officer
Patient & Public Engagement
Discussion for Today

- Better research through engagement
- Engagement tools and resources
- Elements of Engagement
- Q&A
Better Research Through Engagement
We Fund Research That…

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
"You make a good point; we both hate the cat. I'm just not sure what it is you'd bring to a partnership."
What We Mean by Engagement…

- Meaningful involvement of patients, caregivers, clinicians, and other healthcare stakeholders throughout the research process

- Detailed, well-thought-out, and creative engagement plan

- Diverse groups of stakeholders

- Engagement takes many shapes and sizes, not one size fits all!
Core Engagement Principles

- Reciprocal relationships
- Co-learning
- Partnership
- Trust, transparency, honesty

Partnerships are built on trust.
PCORI projects engage many stakeholders

PCORI Projects ensure results are **USEFUL** by actively involving the **PEOPLE WHO KNOW**

**Top 5 Engaged Stakeholder Communities:**
(by percent of projects)

- **87%** PATIENTS
- **59%** ADVOCACY ORGS
- **50%** CAREGIVERS
- **88%** CLINICIANS
- **56%** HEALTH SYSTEMS

Note: Data from annual awardee report; 93 responses about project year 1; 145 responses about project year 2
PCORI projects engage stakeholders throughout the entire research process.

3 out of 5 PCORI projects engage stakeholders in every early phase of research so that the studies matter to patients.

Research Phases Engaging Stakeholders:
(by percent of projects)

- Deciding what the study is about: 61%
- Choosing outcomes: 75%
- Recruiting or retaining study participants: 63%
- Choosing interventions or comparators: 68%
- Choosing other aspects of study design: 66%
- Collecting data: 39%

Note: Data from annual awardee report; 93 responses about project year 1; 145 responses about project year 2
PCORI research partners change the research

Provide personal perspectives (*e.g.*, *priorities, experiences*)

Give guidance to improve research project processes and materials (*e.g.*, *outcomes studied, recruitment strategies*)

Active participation in conduct and dissemination (*e.g.*, *recruiting participants, collecting data, presenting results*)

Note: Data from annual awardee report and Patient and Stakeholder WE-ENACT. 258 responses from awardees, 254 responses from partners
Engagement makes a Difference in PCORI Projects

Better understanding of stakeholders’ personal perspectives (e.g., priorities, experiences)

Refined study that is more patient-centered
- Research questions
- Interventions and/or comparators
- Outcomes and measures
- Data collection
- Recruitment/retention strategies

Enhanced study participant enrollment rates

Note: Key themes from project years 1 and 2 (N = 258 awardees, 254 partners) Themes mentioned in >10% of responses of both partners and awardees.
A 20-member multidisciplinary stakeholder group was engaged in all phases of the randomized controlled trial (RCT) investigating the effects of a patient activation tool in uncomplicated pediatric appendicitis.

Stakeholders involved:
- Children ages 7 to 17 and their families
- Community-based pediatricians
- Emergency medicine physicians, surgeons, nurses
- Patient educators
- Payers

Minneci et al. 2016 JAMA

“Participant enrollment and 30-day retention rates in the RCT of pediatric appendicitis improved significantly after the adoption of stakeholder recommendations.”

**Stakeholder Recommendation:**

- Change the enrollment script
- Offer an online option to complete follow-up questionnaires

**Impact:**

- Enrollment in RCT increased from 65% to 95%
- Rate of completion for 30-day follow-up increased from 58% to 85%
Most Common Effects of Engagement on Partners

- Established new relationships
- Improved personal health management
- Made a difference in the lives of others
- Personal growth or self-improvement
- Gained new knowledge and insights about research
- New professional opportunities
- Belief in patient/stakeholder representation in research
Effects of Engagement on Partners

Understanding the various health disparities leading to diabetes, kidney disease has made me assess my personal life, my level of physical activity and my food intake. I have made changes in my lifestyle which include exercising 3 x per week and encouraging my family to take part in physical activities such as hiking, basketball and so forth... This was an eye opener.

– Other type of Stakeholder

Patients I've been working with have taught me to be a better patient, to self advocate. – Caregiver/Family Member

As an ‘older’ citizen, with mobility limitations, this involvement has allowed me to ... contribute "to the better good". Although I have personal medical issues and challenges, ... doing what I can in my very limited capacity to improving opportunities for broader patient involvement in healthcare decision making and the shaping of healthcare to reflect patient needs.

– Patient/Consumer
Engagement Tools and Resources
“Engagement is hard…”

- Relationship building, maintaining throughout and between projects
- Budgeting for engagement expenses
- Feasibility of incorporating feedback
- Training and skill development needs (for partners and researchers)
- Compensation
- Determining level and depth of engagement of stakeholders
- Engaging hard to reach and vulnerable populations
Engagement Rubric

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
Additional Tools to Support Engaged Research

**PCORI Engagement Rubric**

<table>
<thead>
<tr>
<th>Planning of the study</th>
<th>Conduct of the study</th>
<th>Dissemination of study results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify the research question</td>
<td>Assist with recruitment and retention</td>
<td>Co-present and co-author</td>
</tr>
<tr>
<td>Identify outcomes</td>
<td>Collect and synthesize data</td>
<td>Develop non-traditional formats and methods</td>
</tr>
<tr>
<td>Develop study materials</td>
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</tbody>
</table>

**PCORI Principles:** Partnership, Reciprocal Relationships, Co-learning, Trust, Transparency, Honesty

*Created and first implemented in PCORI’s February 2014 funding cycle*

**Engagement Toolkit (under development),** a comprehensive package of materials on patient-engaged research.

**Engagement Budgeting Document,** a resource that provides guidance on how to appropriately budget for engagement activities.

**Engagement Webinar Series,** highlighting emerging promising practices of patient and stakeholder engagement from PCORI-funded projects.

- **2013**
  - Initial review of Engagement Plans in portfolio, posted exemplar plans to PCORI website

- **2014**
  - Creation of Engagement Officer, staff tasked with ensuring and supporting engagement in funded awards

- **2015**
  - Partner Biosketches, template created to capture expertise of patient/caregiver partners

- **2016**
  - PCORI Compensation Framework, a tool for evaluating the effort and appropriate financial compensation for patient/caregiver partners
Elements of Engagement
Elements of Engagement to Consider

- Structure
- Budget
- Level of involvement
- “Representativeness”
- Training
- Maintaining engagement through study conduct
- Evaluation
- Dissemination
Structure of Engagement

- Advisory Body Categories
  - single advisory group with patients and stakeholders
  - stakeholders/patients blended with core study team
  - stakeholder-only advisory group
  - patient-only advisory group
  - Other...
- Frequency of convenings
- Location of convenings (neutral? virtual?)
- Leadership
  - Designated engagement lead/point of contact
    - Representation of lead on key decision-making committee?
  - Engagement outsourced or subcontracted to a separate institute/institution/organization
Structure of Engagement

• Ongoing Communication
  – Mechanism in place to ensure transparency and equal access to information for all members of the research team including patient/stakeholder partners

• Roles and Responsibilities
  – Shared understanding and documentation of patient/stakeholder partners’ roles and responsibilities
**Study Advisory Committee (SAC)**

Co-leads: Matt Michaels & Eliza Singleton
Specific members TBD
Facilitated by: Samantha Moore
*Meets twice per year*

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**Core Research Team**

**ALPHA Org**
Matt Michaels  
Lee Rogers  
Beth McAdams  
Jim Sanders  
John Levingston

**XYZ Health System**
Eliza Singleton (PI)  
Andrew Fisher  
Steve Miller  
Alberto Sing

**Acme Research University**
Bob Jacobs  
Meredith Miller

Facilitated by: Samantha Moore  
*Meets every two weeks; participants vary based on agenda items*

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**Study Patient Panel**
Lead: Beth McAdams  
Facilitated by: Norman Bates  
*Meets quarterly*

**Study Caregiver Panel**
Lead: Jim Sanders  
Facilitated by: Norman Bates  
*Meets quarterly*

**Study Clinical Stakeholder Panel**
Lead: John Levingston  
Facilitated by: Samantha Moore  
*Meets quarterly*

**Study State Stakeholder Panel**
Lead: Lee Rogers  
Facilitated by: Samantha Moore  
*Meets quarterly*

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**Established Panels & Workgroups**

**ALPHA Patient Engagement Panel (PEP)**
Norman Bates (Co-Chair)  
Jim Sanders (Member)  
Beth McAdams (Member)  
*Meets monthly*

The investigators will update PEP quarterly, solicit feedback and report back to Research Team

**ALPHA Practice-Based Research Network (PBRN)**
Matt Michaels (Co-Chair)  
John Levingston (Member)  
*Meets monthly*

The investigators will update the PBRN quarterly, solicit feedback and report back to Research Team

**Medicaid Evidence-based Decisions Project (MED)**
Jessica McDonald (Member)  
*Meets monthly*

The investigators will update the MED quarterly, solicit feedback and report back to Research Team
Budget

• Adequate budgeting for engagement activities (e.g., compensation of partners, meeting support, etc.)
• Equity in partner compensation
• Support all aspects of partners’ roles (e.g., meeting preparation support, stipend, childcare, travel, presentations, etc.)
Level of Involvement

Level of involvement: Patient

- Information: Researcher(s) describe decisions to patients after decisions are made.
- Consultation: Patients provide input to researchers that may inform decision-making but have no representation within study leadership (steering, executive, or investigator committee).
- Collaboration: Patients work directly with the researcher, may be invited to participate in leadership meetings (e.g., steering, executive, investigator committees) in active partnership, to ensure that their perspectives are incorporated in decision-making.
- Patient/stakeholder direction: Also known as “user control,” patients have control over the research process and the final decision-making. Co-I or Co-PI.
Level of involvement: Stakeholder

• Information: Researcher(s) describe decisions to stakeholders after decisions are made.

• Consultation: Stakeholders are consulted for their input but have no representation within study leadership

• Collaboration: Stakeholders work directly with the researcher, may be invited to participate in leadership meetings (e.g., steering, executive, investigator committees) in active partnership, to ensure that their perspectives are incorporated in decision-making.

• Patient/stakeholder direction: Stakeholder level of involvement exceeds serving in an advisory capacity and includes any of the following; covering intervention costs, supporting study sites, overseeing data coordinating centers, serving on study leadership committees, is a Co-Investigator/Co-Principal Investigator,
“Representativeness”

• The extent to which members serving on advisory committees or in any partnership capacity are representative of the study population or range of end users
• Challenging issue in engaged research

Also... think about adequate balance of interests
In this study, what are the anticipated central issues at stake for each of the stakeholders?

<table>
<thead>
<tr>
<th>Which Stakeholder?</th>
<th>(1) Patients</th>
<th>(2) ED Clinicians</th>
<th>(3) Primary care physicians</th>
<th>(4) Health policy decision makers/Payers</th>
<th>(5) Cardiologists</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is at stake?</td>
<td>Access to outpatient care</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Quality &amp; safety of care</td>
<td>X</td>
<td>X</td>
<td></td>
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<tr>
<td></td>
<td>ED operations (flow, utilization)</td>
<td></td>
<td>X</td>
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<tr>
<td></td>
<td>Cardiology procedural services (e.g., stress testing, catheterization)</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
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<tr>
<td></td>
<td>Healthcare utilization/costs</td>
<td>X</td>
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</tbody>
</table>

Given these anticipated issues and the potentially affected parties, which individuals will comprise the patient and stakeholder advisory group?
Training

- Patient/Stakeholder training on research, human subjects protection and/or ethics
- Study team member skill-based training on engagement (e.g. meeting facilitation, developing consensus etc.)
- Combined training of partners and researchers on team science, basics of engaged research
Maintaining Engagement

• Involvement in Recruitment
  – developing and reviewing recruitment materials
  – developing recruitment strategies
  – collecting data from study participants
  – training staff on recruitment process

• Data Analysis
  – Training/preparing
  – Interpretation
Evaluation

- Mechanism in place to assess patient/stakeholder partner involvement throughout the course of the study

Consider...
- periodic survey of patient/stakeholder partners to gather feedback/satisfaction
- assessment of patient/stakeholder engagement via validated survey instrument or semi-structured interviews to continuously improve engagement
Dissemination

- Patient and stakeholder partners have a defined role in disseminating study findings (e.g. beyond professional society memberships, social media postings, website postings)
Additional Engagement Resources

- **PCORI’s Methodology Standards PC-1 to PC-4**

- PCORI has developed other resources to help guide your engagement activities, housed on the “What We Mean by Engagement” page on the PCORI website

- Engagement Resources include:
  - Framework for Financial Compensation of Patient, Caregiver and Patient Organization Stakeholders
  - Engagemet Rubric
  - Sample Engagement Plans
  - PCORI Stakeholder Groups
  - Short Videos on Engagement in Research
Engagement is hard….but not Impossible!

- Communication is KEY!
- Always keep the end user in mind (clinicians, patients, caregivers, stakeholders, etc.)
- Mistrust takes seconds to form and years to deconstruct
- Training, training, training!
- Engagement is relational, not transactional
- Create equity—environment that supports partnerships, bi-directional learning, etc.
- Mentorship
- Culture shift—Researchers are afraid of patients, patients are afraid of researchers
Questions?

Chinenye Anyanwu
Engagement Officer
Patient & Public Engagement
canyanwu@pcori.org