Fostering and Assessing Patient and Stakeholder Engagement in PCORI Pilot Projects

**Chair: Jason Gerson**, Patient-Centered Outcomes Research Institute

**Alison Rein**, AcademyHealth  
*Advancing Research Engagement through Shared Learning and Collaboration: The PCORI Pilot Projects Learning Network*

**Lauren Ellis**, Johns Hopkins University  
*Assessment of Patient and Stakeholder Engagement in the PCORI Pilot Projects*

**Clifton Bingham**, Johns Hopkins University  
*Engaging Stakeholder Input in a Study of Patient-Reported Outcomes in Arthritis Clinical Care*

**Zachary Rowe**, Friends of Parkside  
*Challenges and Facilitators to Patient and Stakeholder Engagement in a Research Prioritization Exercise and Beyond*
Advancing Research Engagement through Shared Learning & Collaboration: The PCORI Pilot Projects Learning Network

June 9, 2014

Alison Rein, M.S.
Senior Director, AcademyHealth
In February 2013, PCORI and AcademyHealth launched the PCORI Pilot Projects Learning Network (PPPLN)

The PPPLN:
- Connects the first cohort of researchers funded by PCORI
- Optimizes and extends learnings to advance patient-centered outcomes research (PCOR)
Four Primary Aims

Listen for, harvest, and synthesize information
Facilitate cross-project learning and collaboration
Capture key insights with potential to inform PCOR
Support Dissemination
Engagement: A Central Theme for Learning & Sharing

- Incoming diversity with respect to engagement expertise and infrastructure

- Clear interest in:
  - Learning about peer approaches to patient and other stakeholder engaged research
  - Sharing promising practices and lessons learned
Learnings on Engagement in the Pilot Projects

- Cross-project learning
- Scanning and synthesizing info from the field
- Data collection and analysis
- Progress monitoring
- Collaboration
Scanning & Synthesis

- Literature scan on stakeholder engagement in research
- Evaluative framework for stakeholder engagement in research
- Compendium of web-based stakeholder engagement resources
Cross-Project Learning

→ “Share and Tell” Webinars for pilot projects
→ Other virtual and in-person convenings
  – March 2014 in Washington, DC
→ Basecamp, an online platform for resource sharing and discussion
Data Collection & Progress Monitoring

→ Launched data collection instrument to better understand engagement activities and experiences
→ Reviewed interim progress reports
  – Wave 1: Fall 2013
  – Wave 2: Spring 2014
  – Wave 3: Fall/Winter 2014 (final)
Activities enabled identification of a number of shared challenges, including:

- Determining appropriate methods for soliciting and integrating patient and other stakeholder feedback
- Sustaining consistent communication and engagement with patients and other stakeholders
- Ensuring clarity of roles and responsibilities
Fostering Collaboration

→ Great interest and enthusiasm to contribute to PCOR knowledge
  – Four collaborative projects directly relate to patient and stakeholder engagement

→ Anticipated and potential work products:
  – Peer-review publications
  – Guidance documents, tool kits / other resources
  – Virtual / in-person presentations
  – Collaborative proposals
<table>
<thead>
<tr>
<th>Title</th>
<th>Purpose</th>
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<tbody>
<tr>
<td>Language of Engagement</td>
<td>To document how collaborative development of a common lexicon can begin to reconcile different frameworks for health and well-being</td>
</tr>
<tr>
<td>Engagement Infrastructure</td>
<td>To investigate and describe infrastructure necessary to support stakeholder engagement for PCOR</td>
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<tr>
<td>Telling Stories about Engagement</td>
<td>To share lessons learned, including facilitators and challenges, related to patient and other stakeholder engagement</td>
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<tr>
<td>Stakeholder Perspectives</td>
<td>Patient and consumer representative-led initiative to convey key insights that will better equip others to engage in PCOR</td>
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What Have We Learned?

- Limited practical and empirical evidence on the benefits of engaging patients and other stakeholders in research
- Through multiple mechanisms, the PPPLN has helped to:
  - Glean experiential knowledge from those “in the trenches”
  - Identify practice and research gaps
  - Accelerate translation and dissemination of findings to advance the field
Thanks & Acknowledgements

➔ Thanks to PCORI for the opportunity to collaborate
➔ Thanks to the 50 PCORI pilot projects for their interest, participation, and support
➔ Thanks to the AcademyHealth PPPLN Team: Amanda Brodt, Laura Esmail, Lauren Edmundson, Emily Moore, and Raj Sabharwal
Questions & Contact Information

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Assessment of Patient and Stakeholder Engagement in the PCORI Pilot Projects

Presenter: Lauren Ellis, MA
Coauthors: Raj Sabharwal, MPH; Laura Forsythe, PhD, MPH; Lauren Edmundson; Alison Rein, MS; and Lori Frank, PhD

AcademyHealth Annual Research Meeting, June 9, 2014
Introduction to Data Collection
Introduction

Engagement refers to patients and stakeholders taking an active role in the research process in a way other than as subjects of research (Hanley et al. 2003, Telford 2002)

Positive suggested impact: producing research that is more relevant and more able to address their healthcare needs (Shippee 2013, Staley 2009, Entwistle 1998, Caron-Flinterman et al. 2005)

Despite growing interest, limited descriptive information (Workman 2013)
Research Objectives

- Characterize patient and other stakeholder engagement in PCORI Pilot Projects
- Identify early lessons learned
- Lay groundwork for future assessments of research engagement
- Answer questions of use to PCORI, its awardees and the PCOR community
AcademyHealth and PCORI developed the self-report instrument to characterize engagement:

- Domains of interest: types of stakeholders engaged, stages and levels of engagement, facilitators and barriers, contributions of engagement, and lessons learned.

Administered through the an online survey platform in Summer – Fall 2013 to all 50 principal investigators.

Quantitative and qualitative analyses.
### PCORI Pilot Project Respondents

<table>
<thead>
<tr>
<th>Survey Respondent (N = 47)</th>
<th>N (%)</th>
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<tbody>
<tr>
<td><strong>Respondent Type</strong></td>
<td></td>
</tr>
<tr>
<td>Principal Investigator</td>
<td>33 (72%)</td>
</tr>
<tr>
<td>Other Research Staff</td>
<td>13 (28%)</td>
</tr>
<tr>
<td><strong>Region</strong></td>
<td></td>
</tr>
<tr>
<td>East North Central</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>East South Central</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Mid-Atlantic</td>
<td>5 (11%)</td>
</tr>
<tr>
<td>Mountain</td>
<td>4 (9%)</td>
</tr>
<tr>
<td>New England</td>
<td>9 (19%)</td>
</tr>
<tr>
<td>Pacific</td>
<td>10 (21%)</td>
</tr>
<tr>
<td>South Atlantic</td>
<td>10 (21%)</td>
</tr>
<tr>
<td>West North Central</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>West South Central</td>
<td>1 (2%)</td>
</tr>
<tr>
<td><strong>Content area of project</strong></td>
<td></td>
</tr>
<tr>
<td>Health Care Decision Supports</td>
<td>20 (46%)</td>
</tr>
<tr>
<td>Outcomes Instruments</td>
<td>7 (15%)</td>
</tr>
<tr>
<td>Research Prioritization and Analytic Methods</td>
<td>14 (30%)</td>
</tr>
<tr>
<td>Technology &amp; Infrastructure</td>
<td>6 (13%)</td>
</tr>
</tbody>
</table>
Results Overview

- Responses from 47 of the 50 projects (94%)
- Majority of projects report engaging at least one stakeholder community (83%)
- Stakeholders were most commonly engaged as consultants or collaborators
- Additional insights from qualitative data
Characterizing Stakeholder Engagement (Quantitative Data)
Engagement of Stakeholder Communities

Stakeholder Engagement in the Pilot Projects (n = 39)

<table>
<thead>
<tr>
<th>Stakeholder Group</th>
<th>Percent Reporting Engagement</th>
</tr>
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<tbody>
<tr>
<td>Patient(s)/Consumer(s) (unaffiliated individuals)</td>
<td>90</td>
</tr>
<tr>
<td>Caregiver(s)/Family Member(s)/ of Patient (unaffiliated individual)</td>
<td>41</td>
</tr>
<tr>
<td>Patient/Consumer/Caregiver Advocacy Organization(s)</td>
<td>41</td>
</tr>
<tr>
<td>Clinician(s)</td>
<td>87</td>
</tr>
<tr>
<td>Clinic/Hospital/Health System Representative(s)</td>
<td>44</td>
</tr>
<tr>
<td>Purchaser(s)</td>
<td>3</td>
</tr>
<tr>
<td>Payer(s)</td>
<td>3</td>
</tr>
<tr>
<td>Industry Representative(s)</td>
<td>10</td>
</tr>
<tr>
<td>Policy Maker(s)</td>
<td>18</td>
</tr>
<tr>
<td>Other</td>
<td>10</td>
</tr>
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</table>
Patient and Clinician Engagement

Patient (n=34) & Clinician (n=29) Engagement by Research Stage

- Topic solicitation/agenda setting: 50% Patients, 53% Clinicians
- Question development/framing: 76% Patients, 76% Clinicians
- Proposal development: 41% Patients, 56% Clinicians
- Methods/study design: 59% Patients, 63% Clinicians
- Data collection: 56% Patients, 66% Clinicians
- Data analysis: 24% Patients, 38% Clinicians
- Results review/interpretation/translation: 41% Patients, 47% Clinicians
- Dissemination: 24% Patients, 28% Clinicians
- Other: 6% Patients, 6% Clinicians

Percent Response
Additional Insights (Qualitative Data)
Contributions of Patients and Other Stakeholders

Commonly reported early tangible contributions of engagement include:

- Changes to project outcomes or goals
- Changes to project methods
- Enhanced access to populations or study settings
- Refinement of instruments and interview questions
- Interpretation and dissemination of results

“Toward these ends, they have piloted our patient interview tool and provided very valuable feedback about the content and process we are using to interview patients.”

“I can say with confidence that our project (the methods and even the project goals) has evolved, in some cases dramatically, based on our collaborations with stakeholders.”
Early lessons learned identified by respondents include:

- Seek genuine partnership
- Select stakeholders strategically
- Involve stakeholders continuously
- Define expectations and roles
- Adapt to the practical needs of stakeholders
- Meet in person to build relationships

“Their participation was enhanced because they quickly realized that their role was not symbolic in nature but was integral to the project’s development in many ways.”

“Stakeholder engagement is project specific. Think wisely about what stakeholders are needed and which ones are missing.”
Limitations and Strengths

Limitations
- First time fielded
- Potential for response bias
- Administered early into projects
- PI perspective only

Strengths
- Systematic data collection tool
- Provides comprehensive descriptive information on a topic for which there is a limited evidence base
Conclusions and Implications

- PIs report engaging a variety of stakeholder groups across multiple stages of research.
- PIs recognize the influence of engaged stakeholders on the research.
- Systematic characterization of engagement at multiple stages research is needed to further build the evidence base around promising practices for, and effects of, engagement.
Thank you!

Acknowledgements
- Respondents from the PCORI Pilot Projects
- Collaborators: Raj Sabharwal, Laura Forsythe, Lauren Edmundson, Alison Rein, and Lori Frank

Citations


Engaging Stakeholder Input in a Study of Patient-reported Outcomes in Arthritis Clinical Care

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Associate Professor of Medicine
Director, Johns Hopkins Arthritis Center
Director, Center for Patient Centered Outcomes Research in Rheumatology
Co-Director, Rheumatic Diseases Research Core Center
Disclosures

• Research Funding:
  – Patient Centered Outcomes Research Institute (PCORI)

• Positions of Influence:
  – Executive Committee, Outcome Measures in Rheumatology (OMERACT)
Objectives

• Discuss the potential benefits of stakeholder engagement in research
• Identify potential stakeholders
• Demonstrate when and how stakeholders can contribute
• Identify barriers and facilitators for stakeholder engagement
Stakeholder Engagement: Why?

- Providing expertise and perspective
- Improving clarity of research question
- Ensuring relevance
- Defining appropriate context
- Verifying appropriate content
- Exchanging knowledge, mutual learning
- Applying and interpreting evidence
- Facilitating dissemination
- Ensuring end-user buy in
Stakeholder Engagement: Who?

- Patients (representative)
- Caregivers
- Providers
  - MD, nursing, OT, PT, etc
  - Academic/Community Settings
- Research Methodologists
- Consumers
- Policy Makers
- Regulatory
- Payers
- Research Funders
- Health Care Systems
- Pharmaceutical Industry
- Manufacturers
- Etc.
Stakeholder Involvement: When

- Prioritize research topics
- Refine research topics
- Conduct research
- Comment on draft research results
- Create audience-specific information
- Disseminate information
- Use research
- Suggest a research topics

Stakeholder Engagement: How?

Case Study: PCORI Pilot Project

“Integrating Patient-reported Outcomes in Arthritis Clinical Care”
Rheumatoid Arthritis

- RA is a chronic, incurable, systemic, and frequently disabling disease that affects up to 1% of the population
- Considerable disease- and treatment-related morbidities and premature mortality
- Physical, emotional, and social health are significantly impacted
- Heterogeneous presentation and response to treatment
- **Current outcome measures** used as the basis for making treatment decisions and for comparative effectiveness research **have limited inclusion of patient-valued outcomes**
What Needs to be Measured?

- What is important and relevant to patients with a particular condition?

- What is important in the particular setting and situation?

- What is important in the individual and personal context?
Identifying Domains to Measure Worsening RA Disease Activity

- Parallel and interactive workstreams for patients and “health care providers”
  - HCPs = clinicians, methodologists, researchers, pharma, regulator, funders
- Qualitative Focus Groups
  - Patients in 5 Countries
- Sequential Delphi Exercises for Prioritization
  - 23 Countries
  - 125 patients
  - 108 HCPs

OMERACT 8 (2006)

OMERACT 9 (2008)

FOCUS GROUPS

HCP DELPHI 1

Patient DELPHI

HCP DELPHI 2

Combined DELPHI (N=233)

OMERACT 10 (2010)

OMERACT 11 (2012)

RA Flare Core Domain Set

OMERACT Patient Involvement

- Recognition of the importance of patient perspective of disease and impact in developing and evaluating outcomes in rheumatology
- Patients involvement in consensus meetings initiated in 2002
- Identification of domains (Fatigue, Sleep, Participation) important to patients not contained within the RA Core Set of measures
- Defining MCID/PASS for outcome measures is important
- Developed and refined guidelines for patient participation in research
- Established framework for patient inclusion in PRO development and validation

RA Patients and Providers have Different Perspectives When Rating the Importance of Disease Signs and Symptoms

How to Measure?

• (How) can these features be best measured?

• Have measures undergone appropriate validation in the context of intended use?
  • Face, content, construct, discriminative, responsiveness, etc

• Are the measures feasible in the context of use?
Multiple Stakeholders Contributed to Defining *What to Measure*

**Input**

- RA Patients
- OMERACT
- CPATH/FDA
- NIH/PROMIS
- EULAR

**PCORI Pilot Project: Integrating PROMIS in Arthritis Clinical Care**

*How to Measure*
PCORI Pilot Project: Question

• **Objective:**
  - To evaluate the **feasibility** and **impact** of integrating expanded PRO assessment using PROMIS in a clinical practice setting
  - PROMIS includes domains identified by RA patients as important
  - PROMIS has not been examined in RA
  - Evaluation of PROMIS has been largely limited to research settings
  - Most evaluation of RA PROs in clinical trial settings
  - Is it possible to use PROMIS in practice?
  - So what?
Pilot Project: Outcomes

**Input**
- RA Patients
- OMERACT
- CPATH/FDA
- NIH/PROMIS
- EULAR

**Research Team**

**Outcomes**
- Feasibility and Acceptability
  - RA Patients
- Truth, Relevance, and Content Validity
  - RA Patients
- Effects on Communication and Decision Making
  - RA Patients
- Ability to Detect Change/Discrimination
  - RA Patients
- "Value" and Implications of Study Results
  - RA Patients

**Stakeholders**
- RA Patients
Research Methods (1)

- RA patients enrolled in registry with collection of routine clinical measures and legacy PROs
- In waiting room, patient given iPAD linked to online PROMIS Assessment Center module (www.assessmentcenter.net)
- PROMIS SFs, CATs, and other measures completed
- Routine clinic visit with provider takes place
Research Methods (2)

• Review/discussion of PROMIS results
• Patient and provider rate “value” of information and impact on clinical decision-making
  – New problem or symptom identification
  – Additional workup or referral
  – Change in RA management as a result of information
  – Patient: satisfaction, communication

• Interviews and focus groups with patients, providers, clinic and research staff
Example PROMIS Report

Your scores for the CATs you completed are shown below.

- Pain Interference: 87
- Fatigue: 85
- Sleep Disturbance: 84
- Sleep-Related Impairment: 47
- Depressive Symptoms/Sadness: 35
- Anxiety/Fear: 46
- Anger: 34

Physical Function: 25

Active RA
Assembling Stakeholders for the Study

- Clinicians
  - Rheumatologists
  - Psychologists
  - Nurses
  - Professional Orgs. (MD and RN)

- Patients
  - RA Patients
  - Pt. Advocates
  - Foundations

- Clinic Staff
  - Psychometric
  - Qualitative
  - Comparative
  - Effectiveness (CER)

- Research Staff
  - Industry
  - Government

- Funders
  - NIH
  - Foundations
  - Professional Orgs.
Stakeholder Roles

- Discussion of preliminary protocol
- Identifying additional outcomes of interest
- Monitor study progress and timelines
- Gap identification for additional study
- Identification of key messages
- Implications of findings
- Optimal methods of dissemination
Stakeholder Contributions

- Increase diversity of patient population
  - Targeted recruitment strategy
- Generalizability of findings to the “nonactivated” patient
- Recognition that CATs not possible in many settings
  - Importance of ultimately examining short forms
- Need to demonstrate “added value” of PRO collection
  - “Use cases” need to be developed, ROI demonstrated
- How to interpret PROMIS data
  - What is meaningful and actionable
  - Patients and providers
- Responses to PROMIS RFI
  - General Concerns, Specific Regulatory Considerations
- Generation of research question for Spring PCORI PFA
Barriers

- Scheduling
- Communication
- Roles
- Changes in position
Facilitators

• Clarification of Roles and Expectations
• Principles for Collaboration:
  – Trust, Respect, Transparency, Partnership, Ensuring Understanding, Opportunities for Questions and Discussion, Recognition of Agreement and Dissention, and Confidentiality
• Prebriefing/Debriefing
  – Tailored to specific members
• One-on-one discussions
• Research terms and acronym glossary
• Time for advance review of materials
Stakeholder Communication

- Teleconferences
- Phone Calls
- Emails
- Face-to-face
- Website
Conclusions

• Identifying stakeholders should be done with consideration of the totality of the work
  – Stakeholder engagement begins with formulation of the research question
  – Stakeholder engagement continues throughout the project
  – Specific stakeholders and roles may vary throughout the project

• Anticipating barriers and introducing facilitators may increase stakeholder participation, improve experiences, and increase value of input
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• Outcome Measures in Rheumatology (OMERACT)
Thank You

www.hopkinsarthritis.org
Challenges and Facilitators to Patient and Stakeholder Engagement in a Research Prioritization Exercise and Beyond

Presented by: Zachary Rowe

CHAT
Choosing All Together
Research Objective

• Community-based participatory research project
• Informed deliberations about PCOR priorities
  – More just, more accountable and responsive to patients’ needs and values
• Increased public participation by
  – Developing tools and materials that help educate the public about the research priority setting process and opportunities for public input
  – Continuing to search for mechanisms that encourage public input into the research priority setting process and that are easily accessible and provide information-sharing opportunities
Partners

• Terrance Campbell – YOUR Center, Flint, MI
• Carla Cunningham – Reynolds County Health Dept., Centerville, St. Louis MO
• Ray De Vries – University of Michigan
• Susan Goold, Co-PI – University of Michigan
• Jennifer Griggs – University of Michigan
• Charo Ledon – Casa Latina, Ann Arbor, MI
• Sal Martinez – Community Renewal and Development Inc., St. Louis, MO
• Dan Myers – University of Minnesota
• Zachary Rowe, Co-PI – Friends Of Parkside, Detroit, MI
• Stephanie Solomon – University of St. Louis
CHAT – a serious game

• Game about health research spending

• Make choices sometimes for yourself; sometimes for other CHATrs

• Able to choose everything; however, there maybe tough choices

• Patients and stakeholders input used to inform decision makers
Data Collection (Partial)

- Convened 16 focus groups (n=185) in underserved areas in Missouri and Michigan
- Professionally facilitated deliberations lasting 2.5-3 hours
- Data collection - pre- and post-deliberation surveys and individual and group priorities
Findings (Partial)

- Exercise appears informative and presenting adequate choices
- Deliberations judged fair and reason-based by participants from underserved communities
- About 2/3 support and trust this method for informing funding decisions
Challenges

• Community members navigating IRB
• Cross-state and cross-university collaboration
• Navigating institutional barriers
• Creating content about PCOR that is accurate but accessible to laypersons
• Identifying and describing options for setting research priorities relevant to patients and policy makers
Facilitators (Partial)

• Face-to-face meetings
• Treated everyone like a VIP
• Listened to feedback
• $$$ for community partners to serve as chat facilitators, team members, or host meetings
• Food and gift cards for patients and stakeholders to participate in CHAT game
• Used Ipads to play CHAT
• Excellent support staff and research team
PCORI Pilot Projects
Learning Network (PPPLN)

Stakeholder Engagement Collaborative:
Susan Goold, Dee Burton & Zachary Rowe, Co-chairs

>Current Workgroups
  - Stakeholder Stories and Rubric Group
  - Infrastructure

>Broader experience
• Collaborative publications
  – Will inform the field of PCOR
  – Identify successful facilitators for engaging patients and stakeholders
Conclusion

Identification of challenges experienced by the PCORI Pilot Projects is a crucial first step to identifying promising practices for patient and stakeholder engagement.
On the Web

Visit usechat.org for more information about CHAT
Thank you!

Please contact us at:

Decidersproject@umich.edu

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