INCORPORATING STAKEHOLDER ENGAGEMENT INTO VA RESEARCH: WHAT WE CAN LEARN FROM THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE (PCORI)?

Susan Zickmund, PhD, Director, Qualitative, Evaluation And Stakeholder Engagement Core, VA Pittsburgh, CHERP
Goal for the Workshop

- Discuss the unique role of stakeholder engagement in PCORI applications as well as lessons that can be used for VA HSR&D research.
Audience

- Those interested in:
  - the paradigm shift in patient-centered research at the core of the PCORI mission.
  - how PCORI’s radical redefinition of the patient’s role in research may alter our views on stakeholder engagement within HSR&D research.

“Sir, the following paradigm shifts occurred while you were out.”
Paradigm Shift

...suggestions from experiences working with a dozen PCORI applications.
Overview

1. Describe how stakeholder engagement in PCORI constitutes a new approach.
2. Discuss a model for stakeholder engagement that may be tailored to HSR&D research.

“First, I want to give you an overview of what I will tell you over and over again during the entire presentation.”
Audience Poll

How familiar are you with the PCORI funding mechanism?

- Very familiar (PI or Co-I on a submitted proposal).
- Somewhat familiar.
- Not familiar.
PART 1. STAKEHOLDER ENGAGEMENT AND PATIENT-CENTERED RESEARCH
Definition of Stakeholder Engagement

- “Stakeholder engagement is the process by which an organization involves people who may be affected by the decisions it makes or can influence the implementation of its decisions.”

- “Our Mission: PCORI helps people make informed healthcare decisions…that comes from research guided by patients, caregivers, and the broader healthcare community.”


Definition of Patient-Centered Care...

“...focuses on the patient and the individual’s particular health care needs. The goal of patient-centered health care is to empower patients to become active participants in their care.”

Patient-Centered Research...

- “...focuses on the patient-centered approach, taking into account issues such as patient preferences and experiences...”

Relevance to VA HSR&D

- The VA:
  - is the largest integrated healthcare system in the US.
  - focuses on improving the health and well-being of a specific population.
  - embeds a core of Health Services Research and Development (HSR&D) researchers within it.
  - has a mission of improving the healthcare system and enhancing patient care.
The VA

- is at the forefront of qualitative, mixed methods research.
  - emphasizes the voice of the patient.
- has Centers of Innovation (COINs) which focus on partnering with VA Operations.
  - has the goal of aligning research priorities with the healthcare system’s needs.

Relevance to VA HSR&D
Timely
Patient-Centered, Stakeholder-Oriented

David Atkins, Director, HSR&D, “Director’s Letter.”
Jeff Murawsky, “Practicing, Teaching, and Researching in an Era of Transformational Change.”

Forum, October 2013.
Challenges

- “However, the simultaneous engagement of patients, clinicians, and other stakeholders in research is potentially complex and costly.”

Sara J. Knight, Deputy Director, HSR&D, “Accelerating Innovation and Translation through Strategic Partnership: Collaborative Research to Enhance and Transformation and Excellence (CREATE) and Centers of Innovation (COIN), Forum. August 2013.

Potential Solution

- Strengthen patient-centered research using a PCORI model of stakeholder engagement.
PART 2. EXPLORING THE NEW MODEL OF PATIENT ENGAGEMENT WITHIN PCORI
Not Research as Usual

- PCORI redefines research to best interface with the needs and values of patients and other stakeholders.
Grounded in PCORI’s Master Questions

## Defining Patient-Centered Outcomes Research (PCOR)

Helps people and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options. This research answers patient-centered questions such as:

<table>
<thead>
<tr>
<th>Expectations</th>
<th>Options</th>
<th>Outcomes</th>
<th>Decisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”</td>
<td>“What are my options and what are the potential benefits and harms of those options?”</td>
<td>“What can I do to improve the outcomes that are most important to me?”</td>
<td>“How can clinicians and the care delivery systems help me make the best decisions about my health and healthcare?”</td>
</tr>
</tbody>
</table>
“A defining principle of PCOR is ensuring that the patient’s voice and perspective drive every step of the research process, including prioritizing the research questions, designing and conducting the research, and implementing the results in practice.”

“Request for Proposal—Literature Review,” PCORI,
Patients are the Most Critical Stakeholders

- While there is a focus on multiple stakeholders, PCORI emphasizes patients the most.
Viewing Patients on a Continuum
Levels of Engagement

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

Criteria for PCORI Proposals

- “Does the proposal describe how patients and stakeholders were or will be identified and engaged in the research?
- What are the roles of patients and key stakeholders in formulating the study’s hypotheses and design and in the study’s conduct and dissemination of results?
- What roles do patients and stakeholders have in any planned dissemination or implementation plans?”
Patient Engagement Across the Research Process
What does Engagement across the Research Process Entail?

- Preparatory Stage
  - Agenda setting and obtaining funding

- Execution Stage
  - Study design and procedures
  - Study recruitment
  - Data collection

- Translational Stage
  - Dissemination
  - Implementation
  - Evaluation
  - Data analysis


A. Soliciting Patient Input into the National Agenda

- PCORI reaches out to patient populations to solicit topics for funding.
  - Holds public comment periods on the draft research agenda.
- Sent themes to PCORI Board of Governors.

![Figure 1: PCORI's Path from Priorities to Research Patients Can Use](image)
B. Redefining the Investigative Team

- To be responsive to PCORI’s mission, a study should have a patient investigator.
- Involving patients in the research team is meant to profoundly change how a study is developed.

“May I offer a very different scenario?”
Patient Roles

- Patient Principal Investigator (PI) along with traditional PI investigators.
- Co-Investigators.
- Advisory board with multiple patients included (or all patients).
- Participatory action research approach with long history of patient involvement.
PCORI Example: Investigator

“Stakeholders and patients will be compensated co-Investigators. With their commitment and obvious dedication, the stakeholders are written into the grant as co-Investigators and will be compensated. They have written letters of support and submitted biosketches.”

PCORI Example:
Patient Advisory Panel

“Intervention Design. For designing…the clinic-community liaison role, patient and community partners will be engaged through participation in the patient-centered design team and community advisory boards.”

Personal Experience

- A patient on a team can ground the discussion in real world concerns.
- A patient helps break the research bubble.
Patients Team Members

- NIH Commons ID (if Co-PI) and a Federalwide Assurance (FWA).
- NIH-style biosketch.
- Letter of support.
- Salary, with budget / budget justification.
C. Redefining the Development of Topics/Specific Aims

- Need to show that the research is responsive to patient and other stakeholder needs and not superimposed upon them.
  - Questions: What role have patients played in the selection of the research topic?
  - Questions: What role have patients played in the creation of the specific aims?
  - Questions: What role have patients played in the selection of study outcomes?
Topics/Specific Aims

- Preliminary qualitative work to show that the topic is important to patients.
- Show that the specific aims were given to stakeholders and that they helped revise them.
- Shows that patients chose the outcomes.
- Track all of this throughout the grant.
PCORI Example:
Selection of Research Topics

“Stakeholders and patients have been involved from the conceptualization. When the Funding announcement was released…Dr. Lindquist, the PI, was extremely interested as this is a common issue that arises among the seniors she sees in her geriatrics clinics. She contacted Ms. M., a senior citizen patient who receives care at an area hospital and clinics…”

"Stakeholders and patients have been involved in writing of this grant proposal. Each of the stakeholders above has written a part of the research plan...Numerous phone calls and emails have connected this panel of stakeholders and patients into producing a thoroughly discussed grant proposal. Dr. Lindquist then performed editorial work to make this grant proposal cohesive and provide guidance on the testing phases."

<table>
<thead>
<tr>
<th>Date</th>
<th>Activities</th>
<th>Impact on Key Study Decisions</th>
</tr>
</thead>
</table>
| 2010-present | Preliminary studies/pilots                                                 | • Patients, providers, and other community stakeholders identify improving the health and wellness of individuals with SMI as a health system priority.  
• Wellness interventions designed based on patient feedback and pilot tested at two CMHCs in north central PA. |
| 5/22         | PFA released                                                                | N/A                                                                                            |
| Week 5/28    | • Study investigators confirmed                                             | • Patient-centered research questions drafted with peer PI and stakeholder input.               |
|              | • Key stakeholders engaged                                                  | • Preliminary outcome measures identified based on pilot study results and participating patient feedback. |
|              | • Weekly project team & stakeholder meetings begin                         |                                                                                                |
| Weeks 6/4-6/11 | Project team & stakeholder meetings continue                               | • Project team drafts logic model to show how research will produce outcomes of importance to patients with SMI.  
• LOI drafted and vetted with peer PI and other key stakeholders. |
| 6/14         | • LOI submitted                                                             | N/A                                                                                            |
| Week 6/18    | • Project team expanded to include subject matter experts on CER, statistics, mixed methods | • Peer PI emphasizes importance of creating a wellness culture at CMHCs; study design modified to include wellness training and support for CMHC staff as a pre-intervention component.  
• Peer PI identifies patient concerns about stigma experienced when accessing medical care; outcomes refined to include knowledge, skills, attitudes of providers related to medical needs of patients.  
• Qualitative data collection added to analysis plan in order to insure more complete understanding of study results from the patient perspective. |
| Week 6/25    | • Focus groups/interviews conducted with patients                           | • Research questions and outcomes refined to reflect patient feedback. (Table 2.2.2.2)              |
| Weeks 7/2-7/9 | • Project team & stakeholder meetings continue                             | • Peer PI recommends incorporating elements of individual patient choice, self-activation, and self-management into research questions 2 & 3; research questions finalized to reflect this recommendation. (Table 2.2.2.2)  
• Stakeholders recommend including measures relevant to caregiver experience; outcomes finalized to reflect this recommendation. (Table 2.2.3.3.1)  
• Specific aims finalized with stakeholder feedback to ensure alignment with patient-centered research questions.  
• Stakeholder input offered as “reality check” for logic model. |
| 7/16         | • Draft proposal reviewed by key stakeholders                              | • Study measures further refined based on feedback from stakeholders regarding primary and secondary outcomes; Primary Aim 1 hypotheses added with stakeholder agreement. |
| Weeks 7/23-7/30 | • Stakeholder recommendations incorporated & final proposal submitted          | N/A                                                                                            |
Personal Experience

- Area of most radical change from PCORI.
- Requires exploratory data before writing the specific aims.
- Requires (typically qualitative) data on patient’s desired outcomes.

"O.K., on my signal we’re going to shift from pre-millennial to post-millennial thinking."
D. Data Collection

- The data collection section is more similar to an NIH and VA HSR&D style of proposal.
- Important to show that interventions, decision aids (etc.) have been tailored to the unique needs of the study stakeholders.
- Qualitative approaches are frequently used in this process.
PCORI Example:

Involvement in Data Collection

- “Stakeholders and patients plan to be involved during all 3 years of the study. Each of the stakeholders and patients asked and expected to be involved during all three years of the study….They will be instrumental in recruiting seniors and caregivers from their organizations…”

E. Dissemination

- Patients need to be a part of the dissemination plan.
- Often combined with a discussion of an organization that a patient is affiliated with.
“Stakeholders and patients will be active in the Dissemination of the APHS Tool or subsets. Upon completion of the RCT, the stakeholders will meet to discuss the findings and further dissemination. …[w]e will disseminate the tool to seniors nationally through a national community network for seniors...We also plan to disseminate through national nursing associations of which Ms. McM. is a current board member.”
F. Reviews

- PCORI incorporates patients into the review process.
- Patients and other stakeholders are assigned to each of the proposals and provide their own specific review.
  - This does not focus on a review of the science.

“Just a few more pages, Hansen, and we’ll take a short break.”
PART 3. HOW APPLICABLE IS THE PCORI MODEL TO THE VA HSR&D?
Larger Questions

Should the VA HSR&D embrace part/all of the PCORI model?

- If so, what parts should be focused on first?

“The development of these and other principles of stakeholder engagement and of new conceptual frameworks for partnered research are essential as diverse stakeholders participate in research processes.”

Sara J. Knight, Deputy Director of HSR&D, “Accelerating Innovation and Translation through Strategic Partnership: Collaborative Research to Enhance and Transformation and Excellence (CREATE) and Centers of Innovation (COIN), Forum August 2013.
VA Engagement

- Engagement can begin by fully expanding stakeholder engagement to include Operations partners.
- Example: A new study includes interviews with key administrative, clinical, and operational stakeholders across the length of the study.
Beyond Investigators to Operations and Patients

- An immediate switch to a PCORI model?
- A gradual model of expanding the inclusion of stakeholders in HSR&D research?

Could involve a tiered approach:
  - Research funding priorities.
  - Data collection.
  - Dissemination Team members.
  - Topic/specific aims.
  - Review process (HSR&D Scientific Merit Review Board, etc.)
VA Based Approach to Stakeholder Engagement

Grant Review Process with Patient/Operation-Centered Stakeholders
Conclusion

- PCORI applications place patients and stakeholders at the center of the research process in a way that is new to many investigators.
- The VA may consider this an approach to best increase patient and Operations-centered research within HSR&D.
WHITE BOARD QUESTION: SHOULD HSR&D USE THE PCORI MODEL FOR ENGAGEMENT? IF YES, WHAT SHOULD THEY INCORPORATE FIRST?
Questions?

Susan Zickmund, PhD
Director, Qualitative, Evaluation And Stakeholder Engagement Core
Center for Health Equity Research and Promotion
VA Pittsburgh Healthcare System
University of Pittsburgh, Department of Medicine
Susan.Zickmund@VA.Gov