

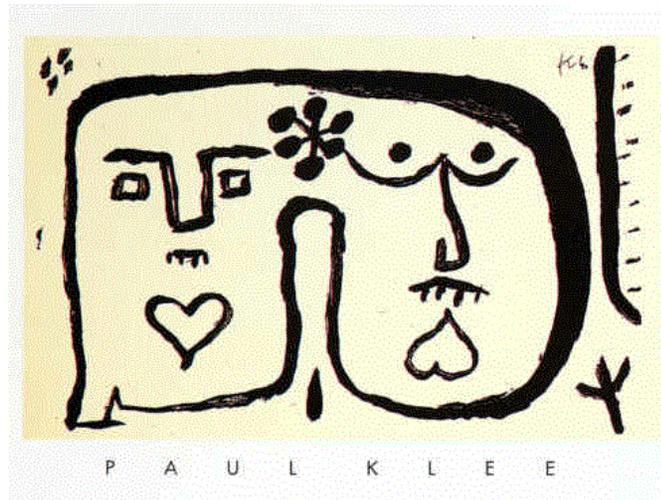
INCORPORATING  
STAKEHOLDER ENGAGEMENT  
INTO VA RESEARCH:  
WHAT WE CAN LEARN FROM  
THE PATIENT-CENTERED  
OUTCOMES RESEARCH  
INSTITUTE (PCORI)?

Susan Zickmund, PhD, Director, Qualitative, Evaluation And Stakeholder  
Engagement Core, VA Pittsburgh, CHERP

# Goal for the Workshop

2

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





# Paradigm Shift



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

# Overview

5

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."*

ART.  
COM

# 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.



*"O.K., on my signal we're going to shift from pre-millennial to post-millennial thinking."*

ART.  
COM

# PART 1. STAKEHOLDER ENGAGEMENT AND PATIENT-CENTERED RESEARCH

A New Model for Health 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.**”\*\*

\*Stakeholder Engagement,” Wikipedia, [http://en.wikipedia.org/wiki/Stakeholder\\_engagement](http://en.wikipedia.org/wiki/Stakeholder_engagement)

\*\*PCORI Funding Announcement: Improving Healthcare Systems, 2013 <http://www.pcori.org/assets/PCORI-PFA-August-2013-Improving-Healthcare-Systems-052013.pdf>

# 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.”*



April Reynolds, “Patient-Centered Care,” American Society of Radiologic Technologies, (2009), 81, 133-147.

# Patient-Centered Research...

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



Amos Peter Lee, “Patient-Centered Research,” *Physiotherapy* (2012), 98, 180.

# 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.

# Relevance to VA HSR&D



- 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.

# Timely

The screenshot shows a web browser window displaying the HSR&D Forum page for October 2013. The browser's address bar shows the URL: <http://www.hsrd.research.va.gov/publications/forum/oct13/oct13-dlr>. The page header includes the United States Department of Veterans Affairs logo and a search bar. Below the header is a navigation menu with links for VA Home, Veteran Services, Business, About VA, Media Room, Locations, and Contact Us. The main content area features the HSR&D logo and the title "FORUM" with the tagline "Translating research into quality health care for veterans". The page is dated "October 2013" and includes a link to "HSR&D Home".

**Contents**

- Director's Letter
- Commentary
  - [Practicing, Teaching, and Researching in an Era of Transformation: A Choice](#)
- Response to Commentary
  - [The Individual, Research, and Organizational Change](#)
- Research Highlights
  - [The Critical Role of Leadership in Creating a Culture of Improvement](#)
  - [Patient Engagement and Diabetes Self-Management](#)
  - [Process Toward Recovery Transformation in Mental Health](#)
- Dialogue
  - [A Conversation with VHA National Center for Organization Development's Linda Nelson](#)

[Download PDF version \(371 KB\)](#)

### Director's Letter



The late Senator (and former sociologist) Daniel Patrick Moynihan famously said, "The central conservative truth is that it is culture, not politics, that determines the success of a society. The central liberal truth is that politics can change a culture..." Health care systems and researchers are increasingly paying attention to organizational culture in health care settings and how to improve it. Patient safety events often reveal local breakdowns in communication, teamwork, and leadership that enable problematic practices to develop; positive culture as assessed by VA's AR Employee Survey and other markers is correlated with better health care outcomes.

The role of health care culture is central to at least three important clinical initiatives in VA. First, team training developed by the SimLearn Center is targeting the critical role of team communication in reducing surgical errors. Second, the Patient Aligned Care Team (PACT) rollout is illustrating the importance and challenge of building functioning, collaborative teams that include physicians, nurses, and support staff. Finally, the Office of Patient Centered Care and Cultural Transformation is piloting programs to transform VA culture into one where patients, rather than providers, are at the center of care.

A 2003 review in the International Journal for Quality in Health Care identified key factors that impede culture change, including inadequate leadership; constraints imposed by external stakeholders and professional allegiances; perceived lack of ownership; and competing cultures within health care systems.<sup>1</sup>

Health services research has contributed in various ways to our

# Patient-Centered, Stakeholder-Oriented

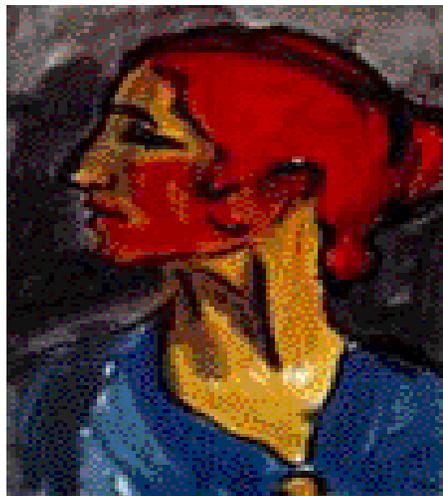
David Atkins, Director, HSR&D, “Director’s Letter.”

Jeff Murawsky, “Practicing, Teaching, and Researching in an Era of Transformational Change.”

Saul J. Weiner, “The Individual, Research, and Transformational Change.”

Forum, October 2013.

<http://www.hsrd.research.va.gov/publications/forum/oct13/oct13-2.cfm>



# Challenges

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

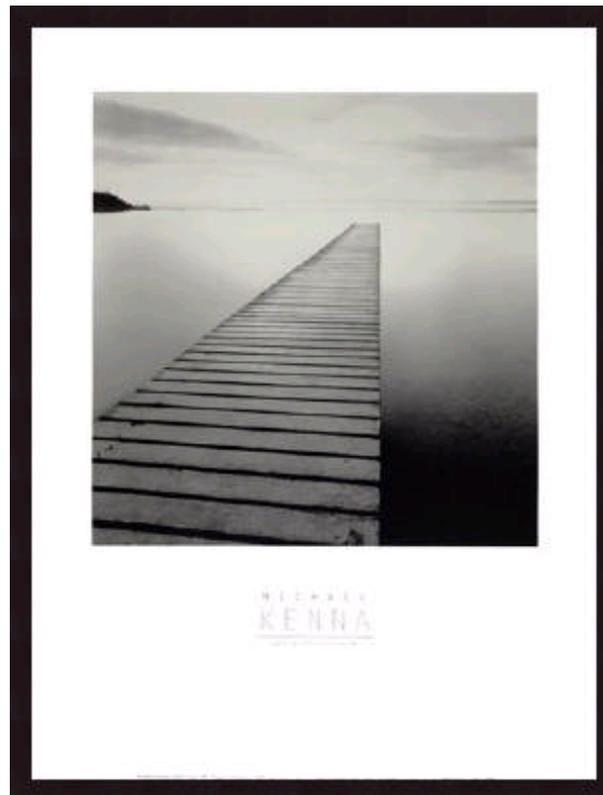


Sara J. Knight, Deputy Director, HSR&D, “Accelerating Innovation and Translation through Strategic Partnership: Collaborative Research to Enhance and Transformation and Excellence (CREATE) and Centers of Innovation (COIN), Forum. August 2013.

[http://www.hsr.d.research.va.gov/publications/internal/forum07\\_13.pdf](http://www.hsr.d.research.va.gov/publications/internal/forum07_13.pdf)

# 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:

Expectations	Options	Outcomes	Decisions
"Given my personal characteristics, conditions and preferences, what should I expect will happen to me?"	"What are my options and what are the potential benefits and harms of those options?"	"What can I do to improve the outcomes that are most important to me?"	"How can clinicians and the care delivery systems help me make the best decisions about my health and healthcare?"

# PCORI and Stakeholder Engagement

*“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.”*

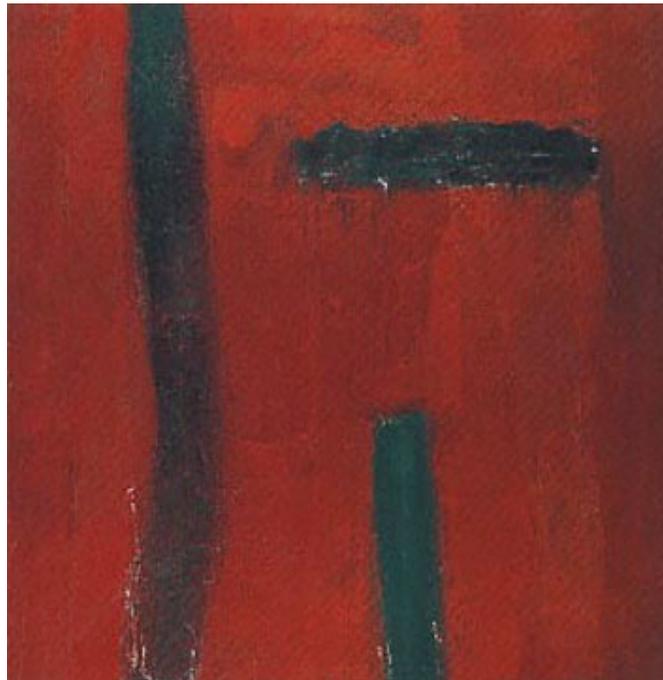


“Request for Proposal—Literature Review,” PCORI,

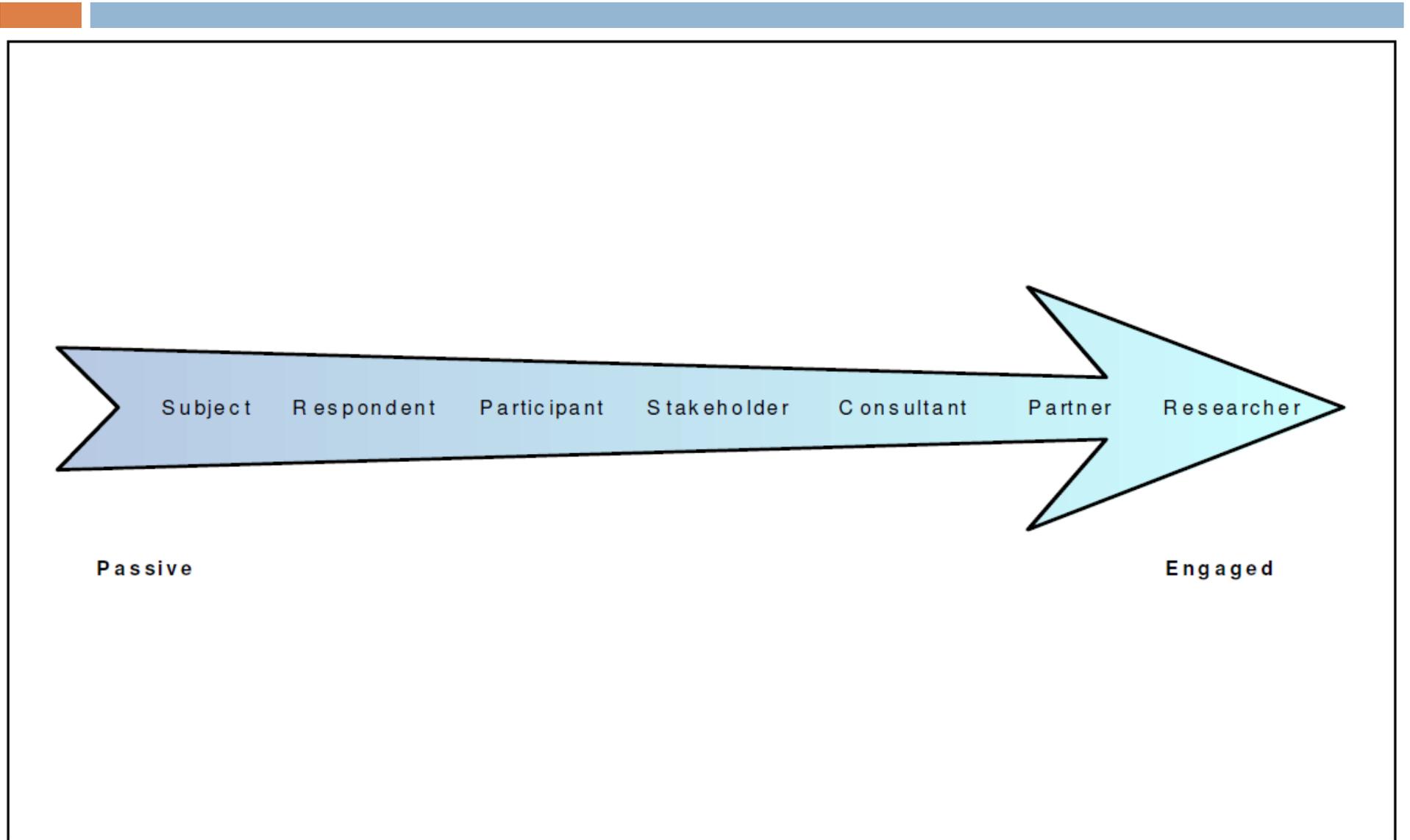
<http://www.pcori.org/assets/PCORI-Patient-Centeredness-Literature-Review-RFP1.pdf>

# 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

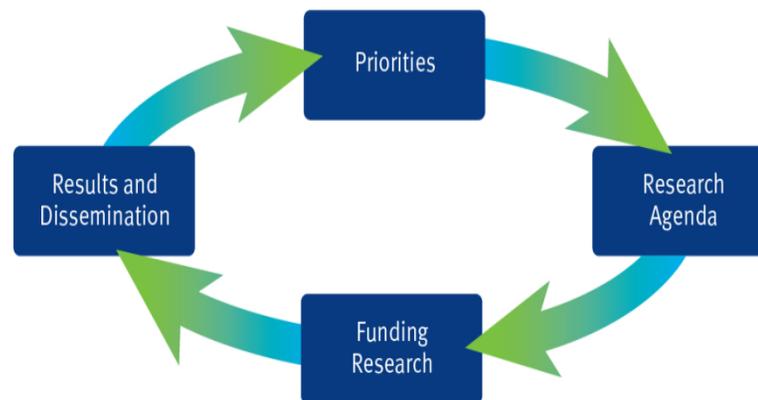
Eliciting Patient Perspectives in Patient-Centered Outcomes Research: A Meta Narrative Systematic Review (report prepared for the Patient Centered Outcomes Research Institute, 2012)

<http://www.pcori.org/assets/Eliciting-Patient-Perspective-in-Patient-Centered-Outcomes-Research-A-Meta-Narrative-Systematic-Review1.pdf>

# 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



## 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.”***

<http://www.pcori.org/assets/2013/11/PCORI-Sample-Engagement-Plans.pdf>



# 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.”***

<http://www.pcori.org/assets/2013/11/PCORI-Sample-Engagement-Plans.pdf>



# 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...”***

<http://www.pcori.org/assets/2013/11/PCORI-Sample-Engagement-Plans.pdf>



# PCORI Example: Development of Proposal

*“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.”*

<http://www.pcori.org/assets/2013/11/PCORI-Sample-Engagement-Plans.pdf>



**Table 2.2.2.1. Study Evolution Resulting from Patient Partnership and Stakeholder Engagement**

Date	Activities	Impact on Key Study Decisions
2010-present	Preliminary studies/pilots	<ul style="list-style-type: none"> <li>Patients, providers, and other community stakeholders identify improving the health and wellness of individuals with SMI as a health system priority.</li> <li>Wellness interventions designed based on patient feedback and pilot tested at two CMHCs in north central PA.</li> </ul>
5/22	PFA released	N/A
Week 5/28	<ul style="list-style-type: none"> <li>Study investigators confirmed</li> <li>Key stakeholders engaged</li> <li>Weekly project team &amp; stakeholder meetings begin</li> </ul>	<ul style="list-style-type: none"> <li>Patient-centered research questions drafted with peer PI and stakeholder input.</li> <li>Preliminary outcome measures identified based on pilot study results and participating patient feedback.</li> </ul>
Weeks 6/4-6/11	<ul style="list-style-type: none"> <li>Project team &amp; stakeholder meetings continue</li> </ul>	<ul style="list-style-type: none"> <li>Project team drafts logic model to show how research will produce outcomes of importance to patients with SMI.</li> <li>LOI drafted and vetted with peer PI and other key stakeholders.</li> </ul>
6/14	<ul style="list-style-type: none"> <li>LOI submitted</li> </ul>	N/A
Week 6/18	<ul style="list-style-type: none"> <li>Project team expanded to include subject matter experts on CER, statistics, mixed methods</li> </ul>	<ul style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>Qualitative data collection added to analysis plan in order to insure more complete understanding of study results from the patient perspective.</li> </ul>
Week 6/25	<ul style="list-style-type: none"> <li>Focus groups/interviews conducted with patients</li> </ul>	<ul style="list-style-type: none"> <li>Research questions and outcomes refined to reflect patient feedback. (Table 2.2.2.2)</li> </ul>
Weeks 7/2-7/9	<ul style="list-style-type: none"> <li>Project team &amp; stakeholder meetings continue</li> </ul>	<ul style="list-style-type: none"> <li>Peer PI recommends incorporating elements of individual patient choice, self-activation, and self-management into research questions 2 &amp; 3; research questions finalized to reflect this recommendation. (Table 2.2.2.2)</li> <li>Stakeholders recommend including measures relevant to caregiver experience; outcomes finalized to reflect this recommendation. (Table 2.2.3.3.1)</li> <li>Specific aims finalized with stakeholder feedback to ensure alignment with patient-centered research questions.</li> <li>Stakeholder input offered as “reality check” for logic model.</li> </ul>
Week 7/16	<ul style="list-style-type: none"> <li>Draft proposal reviewed by key stakeholders</li> </ul>	<ul style="list-style-type: none"> <li>Study measures further refined based on feedback from stakeholders regarding primary and secondary outcomes; Primary Aim 1 hypotheses added with stakeholder agreement.</li> </ul>
Weeks 7/23-7/30	<ul style="list-style-type: none"> <li>Stakeholder recommendations incorporated &amp; final proposal submitted</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>

# 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."*

ART.  
COM

## 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...”***

<http://www.pcori.org/assets/2013/11/PCORI-Sample-Engagement-Plans.pdf>

## 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.

# PCORI Example:

## Patients and Dissemination

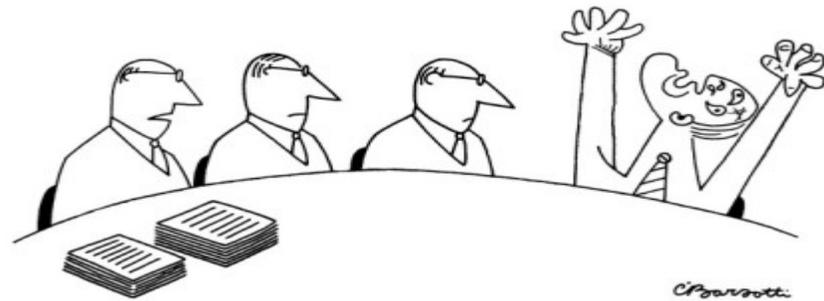
- ***“Stakeholders and patients will be active in the Dissemination of the APHS Tool or subsets. Upon completion of the RCT, the stakeholders will meet to discuss the findings and further dissemination. ...[w]e will disseminate the tool to seniors nationally through a national community network for seniors... We also plan to disseminate through national nursing associations of which Ms. McM. is a current board member.”***

<http://www.pcori.org/assets/2013/11/PCORI-Sample-Engagement-Plans.pdf>



## 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."*

ART.  
COM

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.

[http://www.hsr.d.research.va.gov/publications/internal/forum07\\_13.pdf](http://www.hsr.d.research.va.gov/publications/internal/forum07_13.pdf)

# VA Engagement

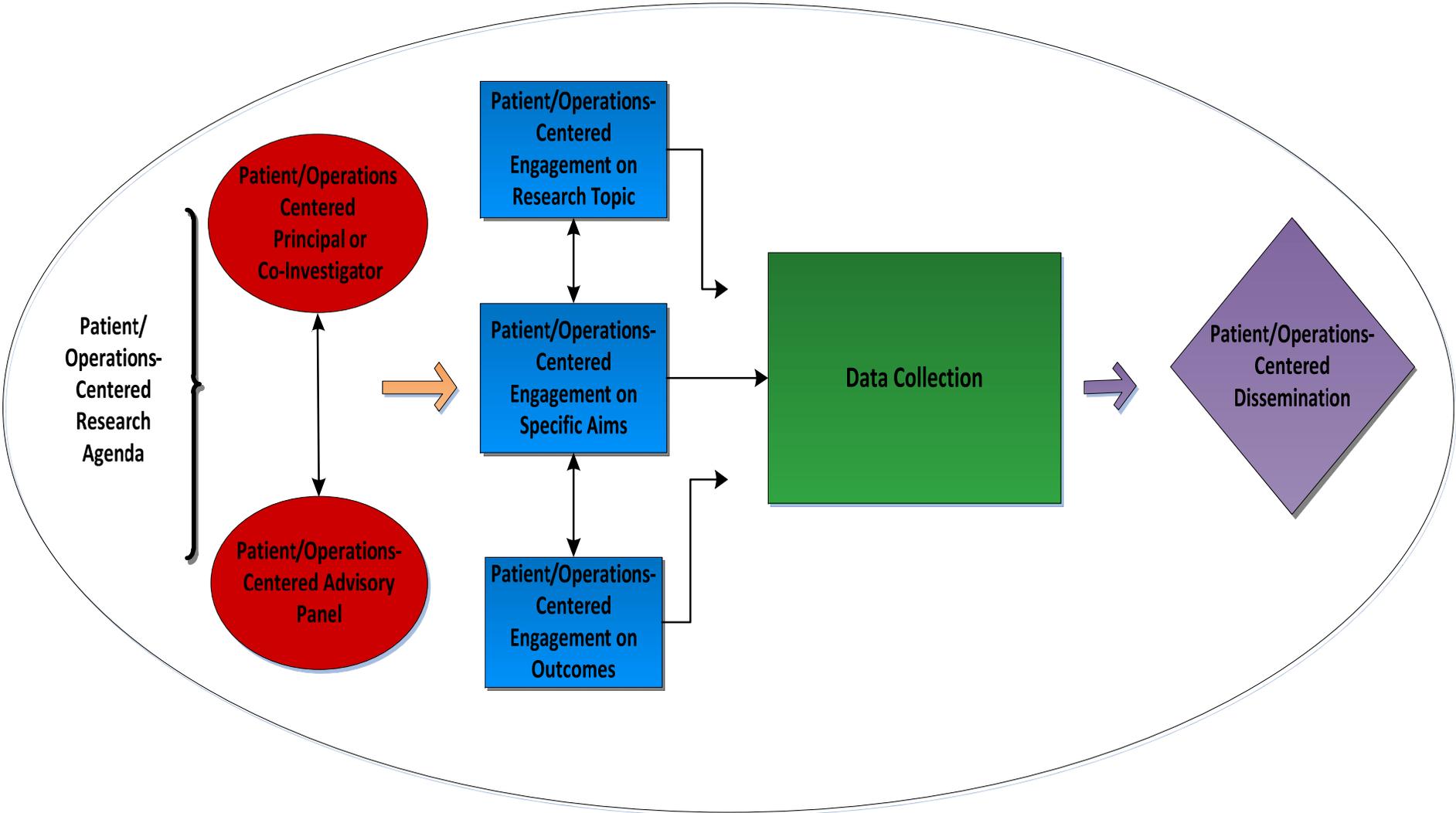


- Engagement can begin by fully expanding stakeholder engagement to include Operations partners.
- Example: A new study includes interviews with key administrative, clinical, and operational stakeholders across the length of the study.

# 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](mailto:Susan.Zickmund@VA.Gov)

