“The PCORI Research Agenda and the Role of Engagement”
Monday, October 21st, 4:00-5:00 PM
Shapiro Breakout Room

Anne Beal, MD, MPH
Deputy Executive Director and Chief Officer for Engagement, Patient-Centered Outcomes Research Institute
Save the Date!

Next Patient-Centered Outcomes Seminar

Monday, December 16, 4 pm – 5 pm

Sebastian Schneeweiss, MD, ScD, SM, Professor of Medicine, Harvard Medical School
Sharon-Lise Normand, PhD, MSc, Professor of Biostatistics, Harvard Medical School

PCERC Contact Information:
• Daniel Solomon, PCERC Co-Director (dsolomon@partners.org)
• Joel Weissman, PCERC Co-Director (jweissman@partners.org)
• Joshua Di Frances, Biomedical Research Institute Project Manager (jdifrances@partners.org)

Please email Josh to register for this Seminar
2013 BRiight Futures Prize
Join us and be part of this unique opportunity to help shape the future of research and patient care by watching each of the three 2013 finalists’ videos below, reading the Q & A with each finalist and voting for your favorite project! The project with the most number of votes will be awarded $100,000 at BWH Research Day on Thursday, November 21, 2013. Anyone can vote, but you may only vote once, so remember to share the BRiight Futures Prize link with your friends, family and colleagues and encourage them to vote as well!

Vote at: http://bwhresearchday.partners.org/bff/
Partnering with Patients and Families in Research: A New Paradigm

October 21st, 2013
Anne Beal, MD, MPH
Deputy Executive Director and Chief Officer for Engagement, PCORI
An independent non-profit funder of **clinical comparative effectiveness research**.

Authorized by Congress as part of the 2010 Patient Protection and Affordable Care Act (ACA).
Why PCORI?

- Research has not answered many questions patients face
- People want to know which treatment is right for them
- Patients need information they can understand and use
Our Mission

PCORI helps people make informed health care decisions, and improves health care delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader health care community.
Our National Priorities for Research

- Assessment of Prevention, Diagnosis, and Treatment Options
- Improving Healthcare Systems
- Communication & Dissemination Research
- Addressing Disparities
- Accelerating PCOR and Methodological Research
Gradations of Targeted Funding Approaches

- **Original PFAs**
  - Included a wide range of research questions

- **Asthma**
  - Focused set of comparative questions

- **Falls Prevention**
  - Single CER study and research question
Our Growing Research Portfolio

Total number of research projects awarded to date: **197**
Total funds committed to date: **$273.5 million**
Number of states where we are funding research: **36 states** (including the District of Columbia)
Minimum research commitment in 2013: **$400 million**
“Research Done Differently”
Patient engagement as a path to rigorous research

- Tell us what PCORI should study
- Help determine what we fund
- Tell us how we are doing
- Help us share research findings

Engagement
Tell us what PCORI Should Study

Submit your questions:
- online: www.pcori.org/questions
- Workshops
- Roundtables
- Ambassador program

I want to know which blood glucose testing approach is best for me to manage my diabetes.

Which Anti Epileptic Drug (AED) will have less long term impact on my child’s cognition?

Which support group intervention is best for Latina breast cancer survivors and their caregivers?

I want to know which asthma management tool will help my child’s asthma.
Help determine what we fund

Advisory Panels & Working Groups

PCORI Reviewers
PCORI’s Research Prioritization Process

Topics come from multiple sources

- Board topics
- Workshops, roundtables
- 1:1 interactions with stakeholders
- Guidelines development, evidence syntheses
- Website, staff, Advisory Panel suggestions

Gap confirmation

(1) PCORI staff in collaboration with AHRQ and others

- Eliminating non-comparative questions
- Aggregating similar questions
- Assessing research gaps
- Preparing topic briefs

Research prioritization

(Multi-stakeholder Advisory Panels)

Prioritized research topics
Post-Prioritization Process

Prioritized research topics

Additional topic assessment and refinement (staff with Board)

Final Disposition

Proceed to PFA
Neither
Place topic in a broad PFA

From Advisory Panel process

Landscape review

Topic-specific workgroup
Topics Under Consideration

Addressing Disparities
- Hypertension in minorities
- Heart attacks among racial and ethnic minorities
- Interventions for improving perinatal outcomes
- Reduce lower extremity amputations in minorities

Clinical Effectiveness Research
- Management strategies for ductal carcinoma in situ
- Medication treatment options for bipolar disorder
- Treatment strategies for symptoms of osteoarthritis
- Treatment strategies for adults with migraines

Improving Healthcare Systems
- Hospital to home transitional care
- Patient empowering care management for patients with chronic conditions
- Interventions for improving perinatal outcomes
PCORI Merit Review Criteria

1. Impact of the condition on the health of individuals and populations
2. Potential for the study to improve health care and outcomes
3. Technical merit
4. Patient-centeredness
5. Patient and stakeholder engagement
Patient-centered requirements for funding
(Review criteria)
Methodology Standards Associated with Patient-Centeredness

PC-1 Engage people representing the population of interest and other relevant stakeholders in ways that are appropriate and necessary in a given research context. Stakeholders can be engaged in the processes of:

- Formulating research questions;
- Defining essential characteristics of study participants, comparators, and outcomes;
- Identifying and selecting outcomes that the population of interest notices and cares about (e.g., survival, function, symptoms, health-related quality of life) and that inform decision making relevant to the research topic;
- Monitoring study conduct and progress; and
- Designing/suggesting plans for dissemination and implementation activities.
Promising Practices from First 150 Awards

- Help determine what needs to be researched
- Help create the intervention to be studied
- Define outcomes important to patients
- Help write proposal
- Participate as Co-PI, consultant or advisory committee member
- Help determine methods and processes of research study
- Help recruit participants
- Evaluate the engagement throughout the life of the project
- Disseminate research results to advocacy organizations and community
Experience from the PCORI Pilot Projects Program

- 50 projects in 24 states and Washington, DC
- $31 million (over two years)
PCORI Pilot Projects: Stakeholder Engagement

Percent Reporting Engagement

- Patient(s)/Consumer(s): 90%
- Caregiver(s)/Family Member(s) of Patient: 40%
- Patient/Consumer/Caregiver Advocacy Organization(s): 40%
- Clinician(s): 90%
- Clinic/Hospital/Health System Representative(s): 40%
- Purchaser(s): 5%
- Payer(s): 5%
- Industry Representative(s): 5%
- Policy Maker(s): 20%
- Other: 5%
Patient Engagement: Stages of the Research Process

- Topic solicitation/agenda setting
- Question development/framing
- Proposal development
- Methods/study design
- Data collection
- Data analysis
- Results review/interpretation/translation
- Dissemination
# Facilitators for Engagement

<table>
<thead>
<tr>
<th>Facilitator</th>
<th>Not at all Important</th>
<th>Somewhat Important</th>
<th>Important</th>
<th>Critically Important</th>
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</thead>
<tbody>
<tr>
<td>Remuneration (e.g., honoraria, travel support)</td>
<td>16%</td>
<td>28%</td>
<td>40%</td>
<td>16%</td>
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<tr>
<td>Training/education of stakeholders</td>
<td>24%</td>
<td>16%</td>
<td>44%</td>
<td>16%</td>
</tr>
<tr>
<td>Training/education of researchers</td>
<td>13%</td>
<td>29%</td>
<td>42%</td>
<td>17%</td>
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<tr>
<td>Communications strategies</td>
<td>7%</td>
<td>7%</td>
<td>33%</td>
<td>52%</td>
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<tr>
<td>Shared leadership strategies</td>
<td>8%</td>
<td>21%</td>
<td>21%</td>
<td>50%</td>
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</tbody>
</table>
Most Significant Contributions To-Date (~6 months into funding)

- Changes to project methods, outcomes, or goals
- Modifications to interventions
- Helps open doors to clinical settings/ access to clinical professionals
- Refinement of instruments and interview questions
- Contribute to interpretation of qualitative findings
- Ways to improve the ease of data collection for patients and providers, should speed data collection
- Inform dissemination strategies
Pilot Projects: Lessons Learned

- Seek genuine partnership
- Strategic selection of stakeholders
- Continuous involvement of stakeholders
- Adapt to the practical needs of stakeholders
- Define expectations and roles
- Building relationships requires in-person contact
Patient engagement in research

- Improved research recruitment and retention rates
  (Edwards et al. 2011)
- Enhanced trust between researchers and participants
  (Decker et al. 2010; Edwards et al. 2011; Staniszewska et al. 2007)
- Improved content and construct validity of measures
  (Cashman et al. 2008; Cotterell 2008)
- Improved patient understanding of results
  (Chalmers 1995; McCauley et al. 2001; Doyle 2010)
- Increased relevance of research results to patients
  (summarized in Nass et al. 2012)
Other Resources on Meaningful Engagement in the Conduct of Research

Webinar: “Promising Practices on Meaningful Engagement in the Conduct of Research”

Engagement Awards/Pipeline to Proposals
http://www.pcori.org/blog/pcoris-engagement-awards-a-new-opportunity-to-build-new-research-partnerships/

Systematic Review
Facilitating patient partnership in research

Engagement Awards

Pipeline to Proposals
In honor of PCORI’s First Chairman -
Dr. Eugene Washington
PCORI Engagement Awards

“Today the Engagement imperative is evident in all of PCORI’s work because Dr. Washington’s vision and leadership were so keen in bringing patients and stakeholders of the entire healthcare community into the work that we do.”

Joe V. Selby, MD, MPH
Executive Director
Purpose of Engagement Awards

Projects designed to provide “wrap-around” support and enhance impact of our major research awards

NOT meant to be research, but meant to:
- Support knowledge of PCORI’s work, and inform about our program efforts
- Training and development of “non-usual suspects” and others
- Disseminate the results of our research to promote implementation into practice

Smaller awards, up to $250,000 total, and less than two years in length

Other objectives:
- Engage new groups who have not previously been involved with PCORI
- Develop new mechanisms for disseminating research findings
- Promote research done differently by supporting the engagement and partnering
Engagement Awards

Develop PCOR community

Knowledge Awards
- Background papers
- Efforts to share information on PCORI and PCOR
- Gaining knowledge of the current state of CER

Engage the Community in Research
- Develop a skilled “PCOR-ready” community
- Data challenge
- Researcher outreach
- Identification of best practices for engagement

Training and Development Awards

Promote dissemination for implementation
- Surveys and evaluation of current implementation practice
- Dissemination collaborations
- Any project to promote impact of PCORI’s findings

Enhancing the impact of PCORI’s research
Researchers who unsuccessfully submitted a PFA and need to improve proposal

Example of a Training and Development Award: Pipeline to Proposals

Tier 1
Up to $15,000
Up to 9 month term

Tier 2
Up to $25,000
Up to 12 month term

Tier 3
Up to $50,000
Up to 12 month term

PCORI Funding Announcement

Or submissions to other PCOR/CER Funders
Budget

Proposed $15M budget request for board approval in November

Most of the projects will focus on training and development in 2014.

Pilots are currently being developed in FY13 within each category:
- Knowledge
- Training and development
- Dissemination