Diversifying Your Portfolio: Non-NIH Sources

Introduction to PCORI

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Director UCLA CTSI Rapid Response Team

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PCORI Mission Statement

The Patient-Centered Outcomes Research Institute (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.
PCORI Research answers patient-centered questions:

“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 they work in help me make the best decisions about my health and healthcare?”
• PCORI has allocated up to $96 million in funding for the first four areas of focus.
• Plus $24 million Funding Announcement on Accelerating Patient-Centered and Methodological Research to be released this summer.
The 4 Initial RFAs:

1. Assessment of Options for Prevention, Diagnosis, and Treatment
2. Improving Health Care Systems
3. Communication & Dissemination Research
4. Addressing Disparities
New PCORI Approved Review Criteria

1. Impact of the Condition on the Health of Individuals and Populations
2. Innovation and Potential for Improvement
3. Impact on Health Care Performance
4. Patient-Centeredness
5. Rigorous Research Methods
6. Inclusiveness of Different Populations
7. Research Team and Environment
8. Efficient Use of Research Resources
Observations from PCORI Grant Review from Roger Lewis

- Only a very small fraction of applications truly incorporated broad stakeholder involvement at all stages (these scored better)
  - Selection of study question and definition of aims
  - Design of study
  - Crafting of grant application
  - Conduct and interpretation of proposed work
  - Drafting and submission of publications
  - Non-publication dissemination to all community stakeholders
PCORI & Patient Engagement

JAMA papers released April 18, 2012
Continuous Patient Engagement in Comparative Effectiveness Research

C. Daniel Mullins, PhD
Abdulla M. Abdulhalim, BSPharm
Danielle C. Lavallee, PharmD, PhD

The goal of comparative effectiveness research (CER) is to provide patients, their advocates and caregivers, health care professionals, federal officials, policy makers, and payers with evidence-based information to make informed health care decisions. Previously, CER studies were designed by researchers and had relatively little input from patients. Patient engagement has rapidly gained acceptance as crucial to the successful translation of CER for all interested parties. Experiences with patient engagement in research, including community-based participatory research, suggest that success hinges on patients being interested and emotionally involved in the research question and understanding their role in the CER process.

Evaluation of information from the Agency for Healthcare Research and Quality and the Patient-Centered Outcomes Research Institute suggests that CER may be enhanced through continuous patient engagement. The framework for doing so, as proposed in this Viewpoint, reflects pragmatic experiences and observations in which patient engagement collection tool, and participate in pilot testing survey items. Traditionally, patient feedback is infrequently used during the development of the analysis plan. However, this framework proposes that patients could assist in helping to define or categorize variables even if they do not have training in research methods. When reviewing and interpreting results, patients could reflect on whether results are plausible and believable, what other factors should be considered, and how results may vary across subgroups of patients.

In the translation phase, patients could identify which results are easy or difficult to understand. If the results do not affect patients or are counterintuitive, CER findings will not be translated into medical practice. Patients could also offer suggestions for how best to explain study findings to other patients. Patients could help determine the best dissemination strategies, provide dissemination channels, and craft specific messages targeted to patients who will benefit most.

Thoughtful consideration should be given to determining which approach would best elicit the patient’s perspective at each particular step. For example, during the early stages of research, it may be most beneficial to engage patients through patient forums or telephone conversations to solicit potential topics of importance. As research progresses to protocol development, involving patients in stake-
10 Components of Stakeholder Engagement

<table>
<thead>
<tr>
<th>Step in CER Process</th>
<th>Purpose of Patient Engagement</th>
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</table>
| Topic solicitation  | - Identify topics that are important to patients, caregivers, and the community  
|                     | - Propose topics to be investigated |
| Prioritization      | - Solicit feedback on relevance and priority of topics  
|                     | - Discuss the urgency of addressing topics |
| Framing the question| - Ascertain questions’ relevance and usefulness  
|                     | - Assess “real-world” applicability |
| Selection of comparators and outcomes | - Identify comparator treatments of interest  
|                     | - Identify outcomes of interest  
|                     | - Incorporate other aspects of treatment |
10 Components of Stakeholder Engagement

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<tr>
<th>Step in CER Process</th>
<th>Purpose of Patient Engagement</th>
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<tbody>
<tr>
<td>Creation of conceptual</td>
<td>■ Provide a “reality check”</td>
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<tr>
<td>framework</td>
<td>■ Verify logic of conceptual framework</td>
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<tr>
<td></td>
<td>■ Supplement with additional factors not documented in the literature</td>
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<tr>
<td>Analysis plan</td>
<td>■ Verify importance of factors and variables</td>
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<td></td>
<td>■ Ascertain whether there is a good proxy for a specific concept</td>
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<td></td>
<td>■ Inquire about potential confounding factors</td>
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<tr>
<td>Data collection</td>
<td>■ Determine best approaches for data collection (eg, trial, registry, medical charts)</td>
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<td></td>
<td>■ Assist with selection of data sources</td>
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## 10 Components of Stakeholder Engagement

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| Reviewing and interpreting results | - Assess believability of results  
                                - Suggest alternative explanations or approaches  
                                - Provide input for sensitivity analysis |
| Translation                  | - Interpret results to be meaningful  
                                - Document which results are easy or difficult to understand  
                                - Indicate which results are counterintuitive |
| Dissemination                | - Facilitate engagement of other patients  
                                - Help other patients to understand findings |
# Upcoming PCORI Submission Deadlines

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<th>Cycle II</th>
<th>Cycle III</th>
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<tr>
<td>LOI Due</td>
<td>Oct 15&lt;sup&gt;th&lt;/sup&gt;, 2012</td>
<td>Feb 15&lt;sup&gt;th&lt;/sup&gt;, 2013</td>
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<tr>
<td>Application Due</td>
<td>Dec 17&lt;sup&gt;th&lt;/sup&gt;, 2012</td>
<td>March 15&lt;sup&gt;th&lt;/sup&gt;, 2013</td>
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<td>Award Announced</td>
<td>April/May, 2013</td>
<td>Aug/Sept, 2013</td>
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[www.pcori.org](http://www.pcori.org)
What is the best qualitative methodology to get the greatest impact on your grant application? Get advice from the experts and join in a discussion about the future of focus groups.

Hosted by Dr. Michael Weisman Professor in Residence, Cedars-Sinai Med Center
Co-Host, Dr. Lenore Arab, Professor, GIM & HSR, UCLA

Featured Speakers:
Dominick Frosch, Associate Staff Scientist, Health Services Research, Palo Alto Medical Foundation
Deborah Glik, Professor, Public Health – Community Health Science, UCLA
Marjorie Kagawa-Singer, Professor, Public Health, Community Health Science, UCLA
Marian Katz, Assistant Researcher, GIM and HSR, UCLA
Gery Ryan, Senior Behavioral Scientist, RAND

Date: Wednesday, October 24th, 2012
Time: 2:00 – 4:00 pm
Location: Cedars-Sinai Medical Center, Thalians Building, Room E119
Webinar: http://ucla.adobeconnect.com/beyondfocusgroups/
Call-In Number: 310-825-9221
Parking and snacks will be provided

RSVP to Robin Faria at rfaria@mednet.ucla.edu and indicate whether you will be attending in person or remotely.
# CMORE Lunch Time Seminar Series

UCLA Center for Maximizing Outcomes and Research Effectiveness

**Next Event:** November 20, 2012  
12:00-1:00; 2nd Flr Conf. Rm, Broxton

## Past Events

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<th>Past Events</th>
<th>Future Topics</th>
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<td>Dr. Paul G. Shekelle and Dr. Tim Carey&lt;br&gt;<em>PCORI Discussion Panel on Patient-Engagement.</em></td>
<td><strong>1/15/2013,</strong> Wendy Slusser, MD&lt;br&gt;Associate Clinical Professor, UCLA Schools of Medicine and Public Health&lt;br&gt;Medical Director, Mattel Children's Hospital UCLA&lt;br&gt;Fit for Health Program.&lt;br&gt;<em>How to Build Stakeholder Engagement into Studies</em></td>
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<td>Brian Mittman, PhD – <em>&quot;Methods Matter&quot;: Goals and Content for the First PCORI Methodology Report and Standards.</em></td>
<td><strong>02/19/2013,</strong> Joel Kallich, PhD&lt;br&gt;Amgen&lt;br&gt;<em>New Data Bases for Comparative Effectiveness Research: Series 1: How to work with electronic records in medical oncology.</em></td>
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<td>David Reuben, MD&lt;br&gt;<em>UCLA Alzheimer’s and Dementia Care: Comprehensive, coordinated, patient-centered.</em></td>
<td><strong>03/19/2013,</strong> Mellissa Withers, PhD, MHS&lt;br&gt;Qualitative Health Research Consultant, UCLA&lt;br&gt;School of Dentistry, and Department of Anthropology at UCLA.&lt;br&gt;<em>Qualitative Research</em></td>
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Audio and slides available for past events online at [cmore.med.ucla.edu](http://cmore.med.ucla.edu).
Thank you!

http://healthsciences.ucla.edu

Contacts us at: rrt@mednet.ucla.edu