Agenda

Introductions

About PCORI

Programmatic Requirements

Merit Review Process

Administrative Requirements

Submitting Questions:
- Submit questions via the chat function in Meeting Bridge.
- Ask a question via phone (an operator will standby to take your questions).
Introductions

Steve Clauser, PhD, MPA
Program Director
Improving Healthcare Systems

Chad Boult, MD, MPH, MBA
Consultant
Former Program Director
Improving Healthcare Systems

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Senior Program Officer,
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Lauren Holuj, MHA
Program Associate,
Improving Healthcare Systems

Lynn Rogut, MCRP
Merit Review Officer

Suzanne Schrandt, JD
Deputy Director,
Patient Engagement

James Hulbert
Pre-Award Manager,
Contracts

Ashton Burton
Contracts Specialist,
Contracts
About PCORI
PCORI’s Mission and Vision

- The Patient-Centered Outcomes Research Institute (PCORI) is an independent, non-profit health research organization authorized by the Patient Protection and Affordable Care Act of 2010.

- PCORI funds patient-centered research to assist patients, caregivers, and other stakeholders in making informed health decisions.

**Mission**

PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

**Vision**

Patients and the public have the information they need to make decisions that reflect their desired health outcomes.
Focus on Comparative Clinical Effectiveness Research

Per legislation, PCORI funds research that supports clinical comparative effectiveness research (CER)—studies that compare health outcomes and the clinical effectiveness, risks, and benefits of two or more approaches to healthcare.

All applicants should:
- Explain how the research is comparative
- Name the comparators
- State why the comparisons are important to decision-makers
Funding Exclusions: Cost-Effectiveness Analysis (CEA)

- Based on PCORI’s authorizing legislation, PCORI is not permitted to fund studies of CEA.
- **NOTE:** PCORI does fund studies that explore the burden of costs on patients—for example, out-of-pocket costs.

**Examples of CEA**

- Research that conducts a formal CEA in the form of dollar-cost per quality-adjusted life-year (including non-adjusted life-years) to compare two or more alternatives
- Research that directly compares the overall costs of care between two or more alternative approaches as the criterion for choosing the preferred alternative
The Effectiveness of Transitional Care
PCORI intends to fund research that:

Will produce **knowledge** that is meaningful and useful to patients, caregivers, providers, hospitals, payers, etc. when making decisions about care provided to patients during transitions from the hospital to post-acute settings.

- Study widespread experimentation in transitional care now underway across 500+ U.S. communities
- Measure the effectiveness and scalability of specific clusters of transitional care services
- Focus on outcomes that are important to patients, including re-admission rates.
- Address the needs of specific sub-populations
- Account for varying healthcare contexts

**Available funds:** Up To $15 Million

**Number of Awards:** 1

**Study Period:** 3 years
Approach

Development Phase
- Develop and validate data collection instruments and protocols
- Reach agreements with the organizations which will participate

Research Phase
- Data collection – from patients, caregivers, providers and stakeholders
- Data analysis – compared to relevant, well-defined “usual care”
  - Which specific clusters of services improve outcomes for specific populations in specific healthcare contexts?
  - What are the obstacles, facilitators and prospects for widespread implementation of effective clusters of services?
- Dissemination of results
Determine which clusters of transitional care services are most effective in improving outcomes that matter to patients in as many population-context situations as possible.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Healthcare Contexts</th>
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<tbody>
<tr>
<td></td>
<td>FFS</td>
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<td>Rural/frontier areas</td>
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<td>Hazardous urban areas</td>
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<td>Substance abuse</td>
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<td>Disabilities</td>
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<td>Limited English</td>
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<td>Lack caregivers</td>
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<td>Lack health insurance</td>
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<td>Advantaged</td>
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**FFS** = fee-for-service, **IDS** = integrated delivery system, **PC** = traditional primary care, **PCMH** = patient-centered medical home, **advantaged** = native English-speaking, functionally independent people who live in relatively safe, urban/suburban areas and have caregivers and health insurance.
Hypothetical* Clusters of Transitional Care Services

<table>
<thead>
<tr>
<th>Clusters of Services</th>
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<th>3</th>
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<th>5</th>
<th>6</th>
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<tbody>
<tr>
<td>Transitional Care Services</td>
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<td>Pre-discharge:</td>
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<td>Assessment</td>
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<td>Medication reconciliation</td>
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<tr>
<td>Teaching/empowering for self-care</td>
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<tr>
<td>Post-discharge:</td>
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<td>Physiologic monitoring</td>
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<td>Provision of information to “receiving” professionals</td>
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<tr>
<td>Professional monitoring and care coordination</td>
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<td>Access to help 24/7/365</td>
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<tr>
<td>Promotion of sleep, nutrition, physical activity, safety and emotional well-being</td>
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* The actual number and composition of service clusters in widespread use will differ.
A LOI is required in order to submit an application.

Enter information into all required fields in PCORI Online.

Use the Technical Abstract Template provided and upload into the system. The Technical Abstract has a three-page limit.
The “Technical Abstract” template is available as a guide and must be completed as part of the LOI submission process.

1. Does LOI address the goals of the Transitional Care PFA?
   - Does the LOI have potential to:
     - Inform the design and delivery of transitional care services
     - Provide patients and their caregivers with information that will help them choose the transitional care services they need
     - Identify the factors that could promote or impede scalability

2. Does the research team have appropriate composition and credentials?
   - PI experienced in leading and managing large scale projects
Review Process
Overview of the Merit Review Process

Submit a LOI

Apply*

Preliminary Review

In-Person Panel Review

Final Decision

* Applicants will receive notifications by March 21, 2014 about whether or not they are invited to submit a full application.

The entire process takes up to four-five months
Merit Review Criteria

1. Impact of the condition on the health of individuals and populations

2. Potential for the study to improve healthcare and outcomes

3. Technical Merit

4. Patient-centeredness

5. Patient and stakeholder engagement
Applicants must:

- Adhere to all relevant **PCORI Methodology Standards** dated November 2013.*
- Consider and discuss issues of possible heterogeneity of treatment effects.
- Employ study designs and analytic methods that convincingly protect against selection bias and other threats to validity, especially with *observational designs*.
- Discuss the need to measure factors such as *differential adherence* to chosen treatments that could create apparent differences in outcomes.

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Administrative Requirements
Budget and Period Limitations

**Budget**
- Total costs up to $15M over the life of the project
- Indirect costs up to 40%
- Up to $10,000 for Scientific Travel over the life of the project

**Period of Performance**
- Maximum of 3 years
- Do not anticipate receiving a cost OR no-cost time extension
Key Dates

- Letters of Intent are due March 7<sup>th</sup> at 5:00 pm ET
- Screening notifications will be sent out by March 21<sup>st</sup>.
- Applications are due on May 6<sup>th</sup> at 5:00 pm ET
- Merit Review will occur in August 2014.
- Funding decisions announced in September 2014.
Where to get help...

Applicant Resources:
- Application Guidelines
- Sample Engagement Plans
- Engagement Rubric
- Topic Generation and Research Prioritization Process Description

Contact us...
- E-mail pfa@pcori.org or transitionalcare@pcori.org
- Call 202-627-1884
- Submit programmatic inquiry form
Questions

Please use this time to ask any programmatic and administrative questions you may have about the application submission process.

Additional questions after this meeting must be submitted by Friday, February 14th at 5pm EST via email to transitionalcare@pcori.org.

Submitting Questions:
Submit questions via the chat function in Meeting Bridge.

Ask a question via phone (press 7 on your phone).