Obesity Treatment Options Set in Primary Care for Underserved Populations

Applicant Town Hall

February 18, 2014 2:00 pm ET
Agenda

Introductions

About PCORI

Obesity PFA Overview

Merit Review Criteria

Administrative Requirements

Resources

Submitting Questions:

Submit questions via the chat function in Meeting Bridge.

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

Romana Hasnain-Wynia, MS, PhD, Program Director, Addressing Disparities

Cathy Gurgol, MS Program Officer, Addressing Disparities

James Hulbert Pre-Award Manager, Contracts

Suzanne Schrandt, JD Deputy Director, Patient Engagement

Parag Aggarwal, PhD Merit Review Officer

Mari Kimura, PhD Merit Review Officer

Soknorntha Prum, MPH Contracts Associate, Contracts
About PCORI
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.
PCORI’s unique contribution to this field of research is its dedicated focus on outcomes that matter most to patients.

Inclusion of patient-centered outcomes is therefore a necessary component of PCORI-funded research.

PCORI involves patients and the entire healthcare community in every step of the research process — from selecting research questions to study, to the actual conduct of research, to sharing the research findings through platforms and channels that are accessible to everyone.
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
Obesity Treatment Options Set in Primary Care for Underserved Populations PFA Overview
Our Focus

Comparative Clinical Effectiveness Research

- Patient-centered
- Answering questions that matter to patients and other clinical decision makers
- Comparisons of outcomes that matter to patients
- Attention to possible heterogeneity of treatment effects
Definitions

What is a pragmatic clinical trial?

- A trial that takes place in a real world clinical population and setting, and aims to collect information to help make treatment decisions.

What is an explanatory trial? We are not interested in explanatory trials.

- A trial that is designed to increase the probability of obtaining maximal effect from an intervention of interest in an experimental population and setting. The results will show whether the intervention can work (efficacy) but not whether it will work in everyday clinical practice (effectiveness).
Reasons for the Obesity PFA

- Obesity disproportionately affects underserved populations, such as racial/ethnic minority groups, people with low socio-economic status and residents of rural areas
  - In 2010 almost 50 percent of African Americans and almost 40 percent of US Hispanics/Latinos were obese.
  - 2008 data show that rural residents were more likely to be obese compared with urban residents
- Obesity is associated with many health conditions including diabetes and heart disease
- Obesity treatments that have been tested in the general population have not been widely tested in the populations of focus for this PFA
Obesity PFA

Available funds: up to $20 million total for the PFA
- Maximum budget for each project is up to $10 million

Through this PFA, PCORI’s Addressing Disparities Program seeks to fund projects that:
- Focus on adults ages 20 and over
- Focus on racial/ethnic minorities, individuals with low socio-economic status, and/or rural populations with BMI ≥30 kg/m²
- Test strategies for obesity treatment that have at least one component within primary care
- Have two or more treatment arms
- Implement a two-year pragmatic clinical trial with a cluster-randomized design
Through this PFA, PCORI’s Addressing Disparities Program seeks to fund projects that:

- Test a multidimensional strategy designed for helping patients achieve weight loss, and which is feasible for future implementation in practice

- Strong technical merit and incorporate patients’ and other relevant stakeholders’ priorities and perspectives in all aspects of the study (e.g., identifying outcomes, formulating the study protocol and dissemination of study results)

- Compare the relative effectiveness of two or more alternatives for improving patient-centered outcomes
1. Comparator Arm

- Primary care obesity treatment currently reimbursed through Medicare:
  - Behavioral therapy for obesity (BMI >30) by a qualified primary care physician, nurse practitioner or physician’s assistant in a primary care setting. Items covered under this provision are BMI screening, dietary assessment, and intensive behavioral therapy to promote sustained weight loss.
  - One visit every week for the first month
  - One visit every other week for months 2-6
  - One visit every month for months 7-24 over the course of the intervention
  - CMS.gov behavioral therapy obesity treatment coverage details.

Reminder: the focus of this PFA is on adults ages 20 and over
2. Active Intervention Arm(s)

- At least one component within primary care
- Tests evidence-based comprehensive lifestyle intervention
  - Reduced calorie diet, increased physical activity, and behavior therapy
  - Contact sessions:
    - 14 in-person contact session in months 1-6
    - At least monthly contact sessions in months 7-24
- Interventionists must be trained in delivering evidence-based weight loss intervention, such as the Diabetes Prevention Program training
- Incorporate strong linkages with active follow-up to community-based organizations and/or practitioners
  - Linkages without active follow up between primary care providers (PCP) and between community-based partners is not adequate
- Could include:
  - Technology (e.g., health information technology, mobile health)
  - Referrals with active follow up to community-based practitioners
Obesity PFA: Additional Requirements

- Project Duration: up to 5 years
  - Stage 1 (Years 1-2): intervention refinement and recruitment
  - Stage 2: (Years 3-4): pragmatic clinical trial implementation
  - Year 5: data analysis, intervention evaluation

- Study design
  - Pragmatic, multi-site clinical trial
  - Cluster randomization of primary care practices

- Outcomes: must measure patient-centered outcomes
  - Primary outcome: e.g., weight loss, weight loss maintenance
  - Secondary outcomes: e.g., QOL, self-management, practice-level changes, etc.

- Collaboration
  - Awardees will work together on, for example, collection of common measures and data analyses, recruitment strategies

- DSMB
  - PCORI will establish an independent DSMB
Obesity PFA: Non-responsiveness

We are not interested in the following types of projects as a response to this PFA:

- We are not interested in studies that merely describe disparities in obesity treatment and outcomes
- We are not interested in studies of comparative efficacy
- We are not interested in projects where the active intervention arm incorporates referrals from PCP to community-based programs or practitioners without active follow-up
  - Referral alone is not adequate
- We are not interested in projects where recruitment from PCP is the only primary care component
  - Recruitment from PCP alone is not adequate
Sample Research Questions

The following research questions are meant as examples of the types of questions that your research may help answer:

1. Does the addition of a team-based, patient-centered, and culturally and socially tailored obesity intervention in primary care improve weight-loss outcomes, as compared with the primary care obesity treatment currently reimbursed through Medicare?

2. Do different models for team-based care within the primary care setting (e.g., using different combinations of nurse case managers, community health workers, physicians, dieticians, social workers, other allied health professionals, and health services contractors) and combining clinical care with community-based care improve weight-loss outcomes in underserved populations?

3. Do remotely delivered interventions within the context of primary care produce comparable weight-loss outcomes as in-person or hybrid (remote plus in-person) treatment in underserved populations?

4. Does involving health professionals outside the clinical system (e.g., community health workers, home visitors, patient navigators) improve adherence to lifestyle interventions compared to primary care providers alone?

Reminder: All research questions must have a comparative component.
Merit Review Criteria
Merit Review Criteria

Applicants must respond to the five PCORI Merit Review Criteria.

1. Impact of the condition on the health of individuals and populations
2. Potential for study to improve healthcare and outcomes
3. Technical Merit
4. Patient-centeredness
5. Patient and stakeholder engagement
Engagement describes how patients and stakeholders will partner with scientists in the development of the research plan and in key elements, including:

- Participating in formulation of research questions
- Defining essential characteristics of the study participants, comparators, and outcomes
- Monitoring study conduct and progress
- Drafting a plan for disseminating research results
Methodology Standards

Applicants must:

- Adhere to all PCORI Methodology Standards dated November 2013

The standards are:

- Minimum standards for performing comparative effectiveness research
- Intended to provide guidance to researchers and those who use research results
- Used to assess the scientific rigor of funding applications

Cross-cutting standards:

- Formulating research questions
- Patient-centeredness
- Data integrity and rigorous analysis
- Preventing and handling missing data
- Heterogeneity of treatment effects
Use the Research Plan to describe:

A. **Background**
B. **Significance**
C. **Study Design or Approach**
D. **Project Milestones**
E. **Patient Population**
F. **Research Team and Environment**
G. **Research Engagement Plan**
Project Milestones

Milestones are concrete, specific events or accomplishments that are documented by deliverables. Below are some examples of project milestones:

- IRB Approval
- Recruitment of patients or research subjects
- Patient/stakeholder engagement
- Study protocol finalization
- Inception of the intervention
- Analysis of study results

**Reminder:** PCORI awards contracts NOT grants
PCORI is mandated to publically disseminate PCORI-funded research findings. We are interested in research that can be rapidly disseminated and implemented into clinical and community settings.

Applicants must:

- Describe the potential for disseminating and implementing the study results in other settings.
- Describe potential barriers to dissemination and implementation in other settings.

Of note: PCORI is not expecting applicants to disseminate and implement findings at this time. We are asking applicants to describe the potential for dissemination and implementation.
Administrative Requirements
Eligibility Requirements

Applications may be submitted by:

- Any private sector research organization, including any:
  - non-profit organization
  - for-profit organization

- Any public sector research organization, including any:
  - university or college
  - hospital or healthcare system
  - Laboratory or manufacture
  - unit of state or local government

- Foreign Organizations

- Nondomestic Components of Organizations based in the United States

Please Note: Individuals are not eligible to submit applications to PCORI.
Understanding the Letter of Intent (LOI)

An LOI is required in order to submit an application.

LOIs will be screened for programmatic fit.

Following the LOI screen, applicants will receive an invitation to submit an application.

An individual can only be listed as a PI on one application.

Of note: PCORI encourages applicants to submit their LOI before the stated due date. LOIs are due 5:00 pm ET.
Submitting the Letter of Intent (LOI)

Include the following information in your LOI:

- Background
- Objectives
- Methods
  - Sample size and effect size justifications
  - Clear description of treatment arms
  - Patient-centered outcomes and comparators
  - Analysis plan
- Previous experience recruiting and retaining target population for similar trial designs
- Previous experience conducting research in target health settings
  - Letters of support from key research partners are encouraged
- Willingness to collaborate
- Engagement plan
- Anticipated impact
Total Budget and Period Limitations

Total Budget
- Up to $2.5 million in total costs in stage 1 (years 1-2)
- Up to $7.5 million in total costs in stage 2 (years 3-5)
- Indirect costs are capped at 40%
- *Total costs include direct and indirect costs
- **Request for exception can be made during the LOI submission

Period of Performance
- Maximum of five years
## Key Dates

<table>
<thead>
<tr>
<th>Action</th>
<th>Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>System Opening Date</td>
<td>Wednesday, February 5, 2014</td>
</tr>
<tr>
<td>Letter of Intent (LOI) Due Date</td>
<td>Friday, March 7, 2014</td>
</tr>
<tr>
<td>LOI selected for full application</td>
<td>Friday, March 21, 2014</td>
</tr>
<tr>
<td>Application Deadline</td>
<td>Tuesday, May 6, 2014</td>
</tr>
<tr>
<td>Merit Review Dates</td>
<td>August 2014</td>
</tr>
<tr>
<td>Awards Announced</td>
<td>September 2014</td>
</tr>
<tr>
<td>Earliest Start Date</td>
<td>November 2014</td>
</tr>
</tbody>
</table>
Questions

Please use this time to ask any question you may have about the PFA or the LOI submission process.

If we are unable to address your question during this time, e-mail the help desk at pfa@pcori.org.

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

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