Winter 2014 Funding Cycle*

PCORI Funding Announcement:
Communication and Dissemination Research

Published September 5, 2013
Latest Revision November 5, 2013

This PCORI Funding Announcement applies to the funding cycle that closes January 21, 2014. Application guidelines, templates, and other resources are available at pcori.org/PFA/communication.

*Previously released as the December 2013 Funding Cycle
PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI uses a variety of forums and public comment periods to obtain public input to enhance its work. 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.

PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a non-profit, nongovernmental organization. PCORI’s purpose, as defined by the law, is to help patients, clinicians, purchasers, and policy makers make better informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions.”
Overview

PCORI seeks applications to study the comparative effectiveness of strategies to increase patient and clinician awareness of the uncertainty associated with specific healthcare interventions, with the goal of increasing knowledge about—and the use of—comparative effectiveness research results. This announcement is designed to include the context of the type of healthcare decision the patient faces as an important variable affecting the information needed and how it is provided. PCORI seeks studies that will provide information of value to patients, their caregivers and clinicians, as well as to healthcare leaders regarding which features of systems lead to better patient-centered outcomes.

See [pcori.org/PFA/communication](http://pcori.org/PFA/communication)

**Applicant Resources**

- **Key Dates**
  - Online System Opens: September 16, 2013
  - Letter of Intent (LOI) Due: October 15, 2013 by 5:00 pm ET
  - Applicant Town Hall Session (Event webinar will be archived post event): To Be Announced
  - Applicant Training Programs: To Be Announced
  - Application Deadline: January 21, 2014
  - Merit Review Dates: May 2014
  - Awards Announced: June 2014
  - Earliest Start Date: August 2014

**Maximum Annual Budget (Direct Costs)**

- $1,500,000 total direct costs

**Maximum Project Period**

- 3 Years

**Funds Available Up To (Direct Costs)**

- $8 Million

Applications may be submitted by any private sector research organization, including any non-profit or for-profit organization and any public sector research organization, including any university or college; hospital or healthcare system; laboratory or manufacturer; unit of state or local government. All US applicant organizations must be recognized by the Internal Revenue Service. Foreign organizations and nondomestic components of organizations based in the United States may apply, as long as there is demonstrable benefit to the US healthcare system, and US efforts in the area of patient-centered research can be clearly shown. Organizations may submit multiple applications for funding. Individuals may not apply.

**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
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<th>Other</th>
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<td>Deadlines are at 5:00 PM ET. If deadlines fall on a weekend or a federal holiday, the deadline will be the following Monday or the next day after the federal holiday. To propose a project budget that is greater than the direct costs or maximum project period listed for a PFA, submit a request by the LOI deadline using the templates provided above.</td>
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<th>Contact Us</th>
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<td>Please email (<a href="mailto:pfa@pcori.org">pfa@pcori.org</a>), phone (202-627-1884), or contact us online (<a href="http://www.pcori.org/PFA/inquiry">http://www.pcori.org/PFA/inquiry</a>) if you have questions regarding this PCORI Funding Announcement or would like to schedule a call with program staff.</td>
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<td>PCORI will provide a response within 72 hours. However, PCORI cannot guarantee that all questions will be addressed 72 hours prior to a Letter of Intent or application deadline.</td>
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1. Request for Proposals

Summary
Under this funding announcement, the Patient-Centered Outcomes Research Institute (PCORI) invites applications to study the comparative effectiveness of strategies to increase patient and clinician awareness of the uncertainty associated with specific healthcare interventions, with the goal of increasing knowledge about—and the use of—comparative clinical effectiveness research (CER) results. This announcement is designed to include the context of the type of healthcare decision the patient faces as an important variable affecting the information needed and how it is provided. PCORI seeks studies that will provide information of value to patients, their caregivers and clinicians, as well as to healthcare leaders regarding which features of systems lead to better patient-centered outcomes.

Background
Every day, patients and their caregivers are faced with crucial healthcare decisions while lacking key information that they need. This information would not necessarily deliver verdicts or tell people what to do, but it would inform them of the trade-offs associated with the options they have—and enable them to make better decisions for themselves in collaboration with their clinicians—based on the facts, perhaps even personalized for them, and their own values, preferences, and goals.

PCORI is entrusted by the public to fund research that will matter to patients, their caregivers, and other stakeholders [defined as clinicians and clinician societies, hospitals, and health systems, payers (insurance), purchasers (business), industry, researchers, policymakers, and training institutions]. PCORI seeks to change how research is conducted by emphasizing the role of diverse research teams that include varying perspectives. PCORI distinguishes itself by supporting research in which patients, caregivers, practicing clinicians, and the broader stakeholder community are actively engaged in generating the research questions, reviewing the proposals, conducting the research, disseminating the findings, promoting the implementation of the findings, and using the results to understand and address patient and other stakeholder needs.

Because many patients and caregivers are not aware that they may have more than one viable option for prevention, diagnosis, or treatment decisions, the value of CER may not be immediately recognized. However, strategies can be developed to increase patient and clinician awareness of the uncertainty associated with specific healthcare interventions, with the goal of increasing knowledge about—and the use of—CER results. It should be noted that the type of healthcare decision the patient faces is an important variable affecting the information needed and how it is provided. (For example, the information needs of a patient weighing options for treating high blood pressure will be different from those of a patient facing a terminal cancer diagnosis with complicated treatment options.) Additionally, although a majority of patients prefers an active role in clinical decision making, the reasons some choose not to participate are unclear. Knowledge gaps in this area include the role of cultural norms and values in shaping preferences for participation in clinical decision making. Communication skills of both patients and healthcare providers are an important issue for the effective use of CER results. Research on doctor-patient communication has focused primarily on the doctor-patient dyad, but still little is known about the potential role of the patient’s family members or significant
Clinician Engagement with CER
Changes in practice on the part of providers in response to CER has been limited. It is unclear which methods for translating CER results into clinical care will prove to be most effective in terms of reaching the greatest proportion of patients and improving patient outcomes. Further research is needed to understand clinicians’ attitudes toward CER and shared medical decision making. Strategies can then be developed to increase clinicians’ utilization of CER and to increase clinicians’ willingness to engage their patients in the decision-making process. Little is known about how clinical decision making could be structured to reduce the potential time burden in individual clinical encounters. Additional information is also needed on how community-based healthcare resources are engaging, if at all, with CER findings.

Translating Research, Decision Support Interventions, and Risk Communication
Another important area of research in both clinical and community-based settings is translating existing scientific research into accessible and usable formats that clearly outline the risks and benefits of preventive, diagnostic, and treatment options for patients, caregivers, and healthcare providers. In clinical care, decision support intervention is one of the primary ways in which medical evidence is translated into a format that is usable by patients, families, and caregivers. The integration of patient decision support, electronic medical records, and associated patient systems holds considerable promise, but little, if any, evidence is available to guide best practices. More research is needed about how decision support interventions perform using different media, what level of information and detail they require, and how they perform in patient populations with lower levels of literacy and numeracy. A further significant gap is the limited research on risk communication, in general, and with underserved individuals and those with limited health literacy and numeracy, in particular. To date, research on effective methods for communicating risk information to healthcare providers and enabling them to use the information effectively is lacking.

Distribution of CER
The distribution of CER information to patients, caregivers, and providers (in both clinical and community-based settings) is an area that has not received sufficient research attention. Little is known about which methods and approaches are most effective or the various impacts of different approaches. More research is needed to identify effective approaches to distribute CER results to healthcare providers, with the goals of sustained changes in clinical practice and effective distribution of results to patients in order to enable changes in behavior (for example, adherence and self-care). Research is also needed to identify trusted intermediaries and trusted channels of communication most often turned to by patients, caregivers, and clinicians. Additionally, further investigation is needed to explore how strategies used in public health communication and social marketing can be adapted to distributing the results of CER, and to identify creative ways of combining multiple channels of communication and dissemination to increase exposure to CER. Further exploration is also needed to understand the disparities that may remain regarding access to social media resources to ensure that the “e-health revolution” does not widen existing health-related knowledge gaps among low-income and racial and ethnic minority populations. Finally, further research is needed to examine the reliability of any CER data currently available through social media sites and to understand how individuals evaluate and use this information in their prevention, screening, diagnosis, and treatment decisions.
treatment decision-making processes. More specifically, there is a lack of information on how these media may influence patient self-care and adherence to treatment recommendations.

Research Areas of Interest
The Communication and Dissemination Research program is interested in the following broad topical areas:

- Research that compares alternative communication, dissemination, health literacy and/or implementation strategies that aim to improve patients’ health outcomes, by increasing patient, caregiver, and/or provider awareness of healthcare options in clinical or community-based settings.

- Research that compares the effectiveness of alternative approaches across a range of patient-centered outcomes to increase or encourage effective patient, caregiver, or clinician participation in care decisions and in shared decision making.

- Studies to develop and compare alternative methods and tools to elicit and include patient-desired outcomes in the healthcare decision-making process.

- Studies comparing alternative approaches, including use of public health strategies or social media, for providing new information to patients, caregivers, or clinicians, with attention to differences in effectiveness in different populations.

- Research that compares innovative approaches in the use of existing electronic clinical data and other electronic modalities from the healthcare system or from a network of systems to enhance clinical decision making by patients and providers.

Research studies may focus on patient populations with a single condition or involve patients with a range of conditions. Studies addressing care for patients with rare conditions are of interest. Rare diseases are defined as life-threatening or chronically debilitating diseases that are of such low prevalence in populations that special efforts, such as combining data across large populations, may be needed to address them. By “low prevalence” we mean conditions that affect fewer than 200,000 individuals in the United States or have a prevalence of less than 1 in 1,500 persons.

Sample Questions
The following research questions are meant as examples of the types of questions that your research may help answer. This list is by no means exhaustive. **All questions must have a comparative component.**
• How do designs for decision support interventions compare in their ability to assist patients and/or caregivers with lower levels of literacy/numeracy, and how do strategies for communicating risk information to vulnerable populations compare?
• How do methods for distributing CER findings to patients, caregivers, or healthcare providers compare in their ability to improve patients’ health outcomes?
• To whom are clinicians most likely to turn for trustworthy information about the effectiveness, relative effectiveness, benefits, and harms of different treatment options for a given condition, and how do they access that information?
• How do strategies learned from public health communication and social marketing compare in their ability to promote the distribution of CER to patients and/or their caregivers and to their clinicians?
• How do strategies in community-based settings compare with strategies in clinical-based settings in their ability to promote the distribution of CER to patients and/or their caregivers?
• How—and how effectively—can strategies using social media be deployed to distribute CER to patients and/or their caregivers and to their clinicians?
• How do patient outcomes compare when patient preferences around screening, diagnosis, treatment, and management strategies have been elicited and accounted for in the decision-making process?
• How do strategies compare in their ability to effectively engage patients with lower levels of literacy and/or numeracy in clinical decision making?
• How do strategies for training healthcare providers in imparting information about risk to patients and their caregivers compare in their ability to improve patient outcomes?
• How do interventions to promote shared decision making compare in their ability to influence patients’ health behaviors and self-care (e.g., adherence to medication) or patients’ behavior in the clinical encounter?

2. What Research Does PCORI Fund?

Research Priorities
PCORI funds patient-centered outcomes research, a type of comparative effectiveness research. The studies PCORI supports must include the patient perspective in the research. To be considered responsive to PCORI, applications to this PFA must describe research that:

• Studies the benefits and harms of different interventions and strategies that can be delivered in actual settings. By “actual settings,” we mean that the research evaluates treatments as they are delivered and received in typical clinical settings, not just in restricted trials of experimental care or at selected academic centers. PCORI is interested in innovative studies that can help patients and other stakeholders make informed decisions about their health care and health outcomes.
• Compares at least two alternative approaches. The types of interventions examined can include specific drugs, devices, and procedures, as well as other types of alternatives, such
as medical and assistive devices and technologies, diagnostic testing, behavioral change, and delivery system strategies. “Usual care” or no specific intervention may be an appropriate comparator, if this is a realistic choice faced by patients and other stakeholders (e.g., choosing not to have a PSA test).

- Compares health outcomes that are meaningful to the patient population under study. Certain physiological measurements, such as blood pressure and serum cholesterol, are strongly linked to complications or other outcomes that patients care about. For example, an application to PCORI which proposes to conduct a study comparing two approaches to helping people control their blood pressure would be well aligned with PCORI’s focus on patient-centeredness, assuming that the study would also compare the two approaches’ effects on any other relevant outcomes that are important to patients, such as treatment-related symptoms (side effects).

Applications to this PFA will be considered nonresponsive if the proposed research:

- Conducts a formal cost-effectiveness analysis in the form of dollar-cost per quality-adjusted life-year (including non-adjusted life-years) to compare two or more alternatives.
- Directly compares the costs of care between two or more alternative approaches as the criteria for choosing the preferred alternative.

However, PCORI does have an interest in studies that address questions about conditions that lead to high costs to the individual or to society. This is included in our review criterion on impact of the condition on the health of individuals and populations.

PCORI is also interested in studies that examine differentials in healthcare resources or costs as a determinant of, or barrier to, good outcomes. Examples include ways in which out-of-pocket costs may constitute a barrier to the receipt of care.

PCORI also considers it important for applicants to discuss cost-related issues such as resources needed to replicate or disseminate a successful intervention. PCORI is interested in evaluation of interventions to reduce health system waste or increase health system efficiency. Proposals that include studies of these issues without utilizing a formal cost-effectiveness analysis or directly measuring and comparing costs of care of alternatives will be considered responsive.

**Definition of PCOR**

Patient-centered outcomes research (PCOR) helps people and their caregivers communicate and make informed healthcare decisions, allowing their voices to be heard in assessing the value of healthcare options. This research:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health delivery system features to inform decision-making, highlighting comparisons of outcomes that matter to people.
• Is inclusive of an individual’s preferences, autonomy, and needs, focusing on outcomes that people notice and care about, such as survival, function, symptoms, and health-related quality of life.
• Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination.
• Investigates (or may investigate) optimizing outcomes while addressing burdens to individuals, availability of services, technology, personnel, and other stakeholder perspectives.

Review Criteria

Criterion 1. Impact of the condition on the health of individuals and populations
The proposal addresses the following questions:

• Is the condition or disease associated with a significant burden in the US population, in terms of prevalence, mortality, morbidity, individual suffering, or loss of productivity?
• Alternatively, does the condition or disease impose a significant burden on a smaller number of people who have a rare disease?
• Does the proposal include a particular emphasis on patients with one or more chronic condition?

Criterion 2. Potential for the study to improve health care and outcomes
The proposal has the potential to lead to meaningful improvement in the quality and efficiency of care and to improvements in outcomes that are important to patients. It addresses the following questions:

• Does the research question address a critical gap in current knowledge as noted in systematic reviews, guideline development efforts, or previous research prioritizations?
• Has it been identified as important by patient, caregiver, or clinician groups?
• Do wide variations in practice patterns suggest current clinical uncertainty?
• Is the research novel or innovative in its methods or approach, in the population being studied, or in the intervention being evaluated, in ways that make it likely to improve care?
• Do preliminary studies indicate potential for a sizeable benefit of the intervention relative to current practice? How likely is it that positive findings could be disseminated quickly and affect changes in current practice?

Criterion 3. Technical merit
The proposal has the technical merit to ensure that the study goals are met. It includes:

• A clear research plan with rigorous methods and key milestones clearly articulated
• A research team with necessary expertise, and an appropriate project organizational structure
• A research environment sufficient to support the conduct of the work with appropriate resources
• A diverse study population with respect to age, gender, race, ethnicity, and clinical status as appropriate for research
• A focus on a defined population for whom effectiveness information is particularly needed

Criterion 4. Patient-centeredness
The proposal demonstrates patient-centeredness at every stage of the research. It addresses the following questions:

• Is the research focused on questions that affect outcomes of specific interest to patients and their caregivers?
• Does the research address one or more of the key questions mentioned in PCORI’s definition of patient-centered outcomes research?
• How credible are claims that engaged patients and stakeholders will exert meaningful influence on the design and conduct of the research, to ensure patient-centeredness of the questions and outcomes addressed?

Criterion 5. Patient and stakeholder engagement
The proposal integrates patients and stakeholders in the development of the research plan and in key elements of conducting the research. It addresses the following questions:

• Does the proposal describe how patients and stakeholders were or will be identified and engaged in the research?
• Are the roles of patients and key stakeholders significant in formulating the study’s research questions, hypotheses and design and in the study’s conduct and dissemination of results?
• Are the roles proposed for patients and stakeholders in any planned dissemination or implementation plans meaningful and likely to be effective?
• If engagement is not applicable to the proposed research, does the application justify why it is not?

Dissemination and Implementation Potential
PCORI is interested in research that can be rapidly disseminated and implemented in clinical and community practice, facilitating improvements in patients’ and other stakeholders’ decision-making about health care. Therefore, applications should include a section that describes the potential for disseminating your findings and facilitating their widespread use in practice. We also request that you describe possible barriers to dissemination and implementation the results in other settings. Please note, we are asking you to describe the potential for dissemination and implementation. PCORI does not expect you to undertake this dissemination and implementation work at this juncture. For projects that produce important findings, PCORI
will consider subsequent applications that support dissemination and implementation efforts through separate funding announcements.

Methodological Considerations
Regardless of study design, proposals must adhere to all relevant PCORI’s Methodology Standards. A variety of study designs and analytic methods may contribute valid new knowledge. These include randomized trials, at either the individual or group/cluster level, or various observational approaches (e.g., quasi-experimental studies). Qualitative methods may also be employed, either in mixed methods approaches or, potentially, as qualitative comparative studies. Issues of possible heterogeneity of treatment effects must be considered and discussed. Observational comparisons must employ study designs and analytic methods that convincingly protect against selection bias and other threats to validity.

Applicants should specifically discuss the need to measure factors such as differential adherence to chosen treatments that could create apparent differences in effectiveness in clinical populations. Regardless of the particular methods employed, proposals are expected to use rigorous methodology. Comparisons must be made to relevant alternatives. If an application proposes to make comparisons to “usual care”, then the aspects of that care need to be well specified. The Methodology Standards include four categories that apply to all planned research:

- Patient-Centeredness
- Formulating Research Questions
- Crosscutting Methods for PCOR
- Preventing and Handling Missing Data

The Methodology Standards also include seven other categories that apply to specific types of data sources or study designs. These standards should be followed in all cases when they are applicable. The additional categories include:

- Causal Inference
- Heterogeneity of Treatment Effects
- Data Registries
- Data Networks
- Adaptive and Bayesian Trial Designs
- Studies of Diagnostic Tests
- Systematic Reviews

Populations Studied
PCORI seeks to fund research that includes diverse populations with respect to age, gender, race, ethnicity, geography, or clinical status, so that possible differences in comparative effectiveness may be examined. PCORI recognizes that some proposed studies may represent important PCOR opportunities even in the absence of a broadly diverse study population. However, the burden is on the applicant in such cases to justify the

1 Available at pcori.org/assets/PCORI-Methodology-Standards.pdf
importance of the study given the absence of diversity. Alternatively, PCORI is interested in the inclusion of previously understudied populations for whom effectiveness information is particularly needed, such as “hard-to-reach” populations or patients with multiple conditions. Thus, comparisons should examine the impact of the strategies in various subpopulations with attention to the possibilities that the effects of the strategy might differ across various populations. Populations of interest include those that are less frequently studied. PCORI has developed the following list of priority populations to guide our efforts in research and engagement, which includes:

- Racial and ethnic minority groups
- Low-income groups
- Women
- Children (age 0–17)
- Older adults (age 65 and older)
- Residents of rural areas
- Individuals with special healthcare needs, including individuals with disabilities
- Individuals with multiple chronic diseases
- Individuals with rare diseases
- Individuals whose genetic make-up affects their medical outcomes
- Patients with low health literacy/numeracy and/or limited English proficiency
- Lesbian, gay, bisexual and transsexual (LGBT) persons.

3. How to Submit a Proposal

PCORI Online System
To submit a proposal, you must register with the PCORI Online System\(^2\) and submit both a Letter of Intent and an application for each cycle in which you are applying. See the PCORI Funding Center\(^3\) for applicant resources, including application guidelines and templates.

Additional Guidelines

Submission Dates
This is a standing announcement. Applications must be submitted in accordance with the published dates and times listed in the Overview of this document and in the PCORI Funding Center\(^4\).

Organizational Eligibility
Applications may be submitted by any private sector research organization, including any non-profit or for-profit organization, and any public sector research organization, including any: university or college; hospital or healthcare system; laboratory or manufacturer; or unit of state or local government. All US applicant organizations must be recognized by the Internal Revenue Service. Foreign organizations and

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\(^2\) Available at https://pcori.fluxx.io/user_sessions/new
\(^3\) Available at pcori.org/funding-opportunities/funding-center
\(^4\) Available at pcori.org/funding-opportunities/funding-center
nondomestic components of organizations based in the United States may apply, as long as there is
demonstrable benefit to the US healthcare system, and US efforts in the area of patient-centered research can
be clearly shown. Organizations may submit multiple applications for funding. Individuals may not apply.

Reproducibility and Transparency of Research
The ability to replicate potentially important findings from PCORI-funded studies in other data sets and
populations is essential to building confidence in the accuracy of these findings. PCORI will support policies to
promote sharing of study documentation (e.g., study protocol, programming code, and data definitions) so
that other researchers may replicate the findings in other populations. For large studies—those with total
direct costs greater than $1,500,000 and those with durations of more than three years—PCORI requires
that applicants propose a plan for sharing of de-identified data, so that others may analyze the same data set.

Protection of Human Subjects
PCORI adopts, by reference, the Human Subjects requirements of 45 CFR Part 46. If the proposed research will
involve human subjects, refer to the Supplemental Instructions for Preparing the Protection of Human Subjects
Section of the Research Plan in Part II of the Instructions for the PHS 398 Form provided by the National
Institutes of Health. Note: PCORI requires engagement in the research by patients and/or other
stakeholders, as research partners. Research subjects protection requirements do not apply to co-
investigators, members of the research team, or research partners.

Applicant Resources

PCORI Funding Center: pcori.org/PFA/communication
Communication and Dissemination Research

PCORI Online System https://pcori.fluxx.io/user_sessions/new

PCORI Funding Awards
General: http://www.pcori.org/pfaawards/
Past Awards by Priority Area: http://www.pcori.org/pfaawards/?viewby=priority

PCORI Methodology Standards http://www.pcori.org/assets/PCORI-Methodology-Standards.pdf

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Email: pfa@pcori.org
Phone: 202-627-1884
Online: http://www.pcori.org/PFA/inquiry

5 Available at http://grants.nih.gov/grants/funding/phs398/phs398.html