PCORI Funding Announcement: Communication and Dissemination Research

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About PCORI: 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.

Our 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.

Our History: 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.”

Questions Regarding PCORI Funding Announcements: Please email (pfa@pcori.org), phone (202-627-1884), or contact us online (pcori.org/funding-opportunities/programmatic-inquiry/) if you have any questions regarding this PCORI Funding Announcement or would like to schedule a call with program staff. 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 Interest or application deadline.

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1. INTRODUCTION

1.1. Purpose
In this PCORI Funding Announcement (PFA), we seek to fund projects that address critical knowledge gaps in the communication and dissemination process—both the communication and dissemination of research results to patients, their caregivers, and clinicians, as well as the communication between patients, caregivers, and clinicians in the service of enabling patients and caregivers to make the best possible decisions in choosing among available options for care and treatment. This knowledge will provide insight about how to communicate and disseminate evidence on the comparative benefits and harms of available options.

Under this Communication and Dissemination PFA, PCORI seeks studies that evaluate and compare new and alternative approaches to the communication, dissemination, and uptake of patient-centered research to patients, their caregivers, and clinicians. Studies must address a critical gap in knowledge, and the potential of the research to benefit patients and their caregivers must be clear and important.

1.2. Funds Available
PCORI expects to fund projects totaling up to $16 million in total costs under this PFA. Because the nature and scope of the proposed research is expected to vary widely from application to application, it is anticipated that the size and duration of each award will also vary. PCORI reserves the right to change the funds available at any time.

1.3. Budgets and Project Periods
Budgets may not exceed $500,000 in direct costs per year. It is expected that, within these limitations, project budgets and duration will vary substantially, depending on the study design, needs for recruitment and/or primary data collection, required length of follow-up, and analytic complexity. Applicants wishing to propose prospective randomized trials or other complex studies that they believe will require more funding or longer duration may contact PCORI before the required deadline for the Letter of Intent (LOI) to request permission to increase the budget beyond $500,000 in direct costs in any project year or to extend the study duration beyond three years.

1.4. Organization Eligibility
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 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.

1.5. Questions Regarding PCORI Funding Announcements
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2. OVERVIEW

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.

The Patient-Centered Outcomes Research Institute (PCORI) is entrusted by the public to fund research that will matter to patients, their caregivers, and stakeholders (defined as clinicians and clinician societies, hospitals, and health systems; payers [insurance]; purchasers [business]; industry; researchers; policy makers; 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 stakeholder needs.

2.1. Background
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 comparative clinical effectiveness research (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 others in shaping the decision-making process.

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 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.

2.2. 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.

2.3. 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.

• 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?

2.4. Other Programmatic Considerations

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

• 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 in conditions that lead to high costs to the individual or to society. This is included in our 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. Also, 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.

2.5. Definition of Patient-Centered Outcomes Research

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.

PCORI funds PCOR, a type of comparative effectiveness research. The research PCORI funds requires inclusion of 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.

3. ELEMENTS OF PCORI-FUNDED RESEARCH

3.1. Technical Requirements and Review Criteria

Now that you understand the research focus and priorities, you will need to determine if your organization, proposed study, and approach meet PCORI’s technical requirements and review criteria for a successful project, which are described below:

1. The application demonstrates that the condition imposes a significant burden on the health of individuals and/or populations.

2. The application explains how the results of the proposed study:
   • Would likely improve health care and patient outcomes
   • Would likely improve the efficiency of health care

3. The application demonstrates strong technical merit, including:
   • A clear research plan with rigorous design and analytic methods
   • Key project milestones clearly articulated
   • A strong research team
   • A supportive research environment
   • A diverse population with respect to age, gender, race, ethnicity, clinical status; OR
   • A defined population for which effectiveness information is particularly needed

4. The application demonstrates patient-centeredness through:
   • Including outcomes that are meaningful to patients and other stakeholders
   • Research that addresses one or more questions of clear importance to patients

5. The application demonstrates a commitment to patient and stakeholder engagement through the integration of patients and stakeholders in key elements of the proposed project including:
   • Participation in formulation of research questions
   • Defining essential characteristics of the study, participants, comparators, and outcomes
   • Monitoring study conduct and progress
Dissemination of research results

The specific research questions, specific populations to which the research is intended to apply, and the specific research settings will all inform the nature of appropriate patient and stakeholder engagement.

3.2. Additional Guidance and Characteristics

Dissemination and Implementation Potential
In addition to the elements described above that represent the criteria by which we review proposed projects, PCORI is interested in research that can be rapidly disseminated and implemented into clinical and community settings, facilitating improvements in patients’ and other stakeholders’ decision making about health care. Therefore, applications should include a section that describes the potential for disseminating and implementing the results of your work in other settings. We also request that you describe possible barriers to dissemination and implementation of your work 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 Methodology Standards (dated December 2012). A variety of study designs and analytic methods may contribute valid new knowledge. These include randomized comparisons at either the individual or 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 to relevant alternatives or to “usual care”—such as other interventions or clinical policies designed to address the same need in the same or in a different healthcare system, or to a previous approach used within the same system.

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 population. However, the burden is on the applicant in such cases to justify the 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 limited English proficiency
- Lesbian, gay, bisexual, transgender (LGBT) persons

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, data definitions) so that other researchers may replicate the findings in other populations. For large studies—those with direct costs greater than $500,000 in any year—PCORI requires that applicants propose a plan for sharing of de-identified data, so that results may be reproduced by others in 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, as found on the National Institutes of Health (NIH) website: http://grants.nih.gov/grants/funding/phs398/phs398.html

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.
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<th>PCORI Criteria</th>
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| 1. Impact of the condition on the health of individuals and populations | - 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?  
- Does it impose a significant burden on a smaller number of people who have rare diseases?  
- A particular emphasis is on patients with chronic conditions, including those patients with multiple chronic conditions. |
| 2. Potential for the study to improve health care and outcomes | Refers to the potential for the proposed research to lead to meaningful improvement in the quality and efficiency of care and to improvements in outcomes that are important to patients.  
- 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? |
| 3. Technical merit | Refers to inclusion of the following:  
- Clear research plan with rigorous methods and key milestones clearly articulated  
- Research team has appropriate expertise, and project organizational structure is appropriate for the study  
- Research environment is sufficient to support conduct of the work; appropriate resources are available  
- Includes diverse population with respect to age, gender, race, ethnicity, and clinical status as appropriate for the study  
- Focuses on defined population for whom effectiveness information is particularly needed |
### 4. Patient-centeredness

- Is the proposed 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 the application’s 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?

### 5. Patient and stakeholder engagement

- Does the proposal describe how patients and stakeholders were or will be identified and engaged in the research?
- What are the roles of patients and key stakeholders in formulating the study’s hypotheses and design and in the study’s conduct and dissemination of results?
- What roles do patients and stakeholders have in any planned dissemination or implementation plans?

Applications need to demonstrate patient and stakeholder engagement through the integration of patients and stakeholders in the development of the research plan and in key elements of the proposed project including:

- Participation in formulation of research questions.
- Defining essential characteristics of the study, participants, comparators, and outcomes.
- Monitoring study conduct and progress.
- Dissemination of research results.

If the project has not included patient and stakeholder engagement (for example, in the area of analytic methods), has the application justified their non-inclusion?

If engagement is not applicable, explain why it is not.

### 4. APPLICATION AND SUBMISSION GUIDELINES

#### 4.1. Submission Procedures

To apply with PCORI, you must register with the PCORI Online System and submit both a timely and required LOI and a timely application for each cycle that you are applying. To learn more about completing your application, please see the PCORI Application Guidelines.

#### 4.2. Funding and Project Period Limits

This is a standing announcement. Applicants must submit an LOI and application to PCORI, in accordance with the published dates and times listed in the PCORI Funding Center.