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PCORI Funding Announcement: Addressing Disparities

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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.

Patient-Centered Outcomes Research Institute
1828 L St., NW, Suite 900
Washington, DC 20036
Phone: (202) 827-7700
Fax: (202) 202-355-9558
Email: info@pcori.org

Follow us on Twitter: @PCORI
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1. INTRODUCTION

1.1. Purpose
In this PCORI Funding Announcement (PFA), we seek studies that will inform the choice of strategies to reduce and eliminate health disparities. We seek studies that will identify the best options for reducing and eliminating disparities in health and healthcare services. We are not interested in studies that only describe disparities or causes of disparities. This PFA is particularly interested in comparative effectiveness studies that evaluate and compare new and alternative interventions with each other or with usual care to reduce or eliminate disparities in health and health care. Studies in the Addressing Disparities program should focus on overcoming barriers that may disproportionately affect the outcomes of specific groups of patients or identify best practices for sharing results and information about patient-centered research across patient groups. The research must address critical gaps in knowledge about clinical effectiveness. Proposed studies must focus on areas of importance to patients and other stakeholders where there are critical disparities that disadvantage members of a particular group and limit their ability to achieve optimal, patient-centered outcomes.

1.2. Funds Available
PCORI expects to fund projects totaling up to $8 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

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.

2. OVERVIEW

Every day, healthcare organizations and others are faced with the challenge of how to eliminate disparities in health and health care. After decades of attention to this issue, disparities remain pervasive, leading to preventable suffering and interfering with the ability of individuals and families to live full, healthy lives. The Patient-Centered Outcomes Research Institute (PCORI) seeks to fund studies that provide evidence to help guide decisions about how to eliminate these disparities and ensure that people receive care according to their needs and have the opportunity to achieve the best possible health outcomes.

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; 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 other stakeholder needs.

2.1. Background

Disparities in health and health care persist, based on race/ethnicity, gender, geographic location, socioeconomic status, disability, and other factors. These disparities contribute to poor quality care and poor overall health outcomes for specific populations. Solutions that can reduce persistent disparities have been understudied and are multifactorial, complex, and context specific. The health disparities literature has largely been devoted to describing disparities and identifying the potential sources and drivers of those disparities. Despite the heterogeneity of populations being studied, research has identified consistent disparities in access, healthcare quality, and health outcomes for a variety of
conditions across multiple settings.

Strategies to reduce disparities and promote health equity generally target a range of patient-level, provider-level, and system-level factors. There is widespread recognition that community and other contextual factors impact health outcomes for underserved and vulnerable patient populations. However, there have not been many studies comparing interventions at these different levels for improving health outcomes.

Generally, patient- and provider-level interventions are largely based on strategies to improve knowledge and facilitate behavior change, while system-level interventions seek to address the way in which health care is delivered, organized, or financed. PCORI is interested in studies that compare interventions targeting one or more of these levels. PCORI is particularly interested in studies focusing on multilevel interventions.

Interventions that incorporate the strengths, values, and beliefs of different communities have demonstrated positive trends toward improving measures of patient knowledge, self-efficacy, and experience of care, as well as some health outcomes. Replicable, targeted strategies directed to patient populations that experience or are at risk for experiencing disparities are needed across a wide range of clinical contexts and conditions. In recent years, several curricula on improving cross-cultural communication have been developed, targeting patients and clinicians. Yet, there is little knowledge regarding the best approaches to clinician training, the effectiveness of the training programs, and their impact on improving patient-centered outcomes. Patient-level educational modalities are also often used as a method for improving patient-centered outcomes, yet there is little evidence about what works best. PCORI seeks to support comparative effectiveness studies that address how to promote patient engagement and self-efficacy; how to adjust or tailor training for differences in language, literacy, and numeracy; and how to more clearly delineate reasonable patient-centered outcomes that have the potential to be positively affected by interventions focused on patient education and engagement.

In addition to patient- and provider-level interventions, system-level interventions have been developed to promote health equity. Earlier research in these areas shows promising results. For example, when community health workers or patient navigators are integrated into the healthcare delivery team, beneficial effects are seen in patient knowledge and behavior and in rates of health services utilization for patients with a variety of conditions that range from asthma to cancer. Among the most effective strategies in reducing disparities described in the literature are those that combine a variety of interventions to improve healthcare quality. Research has demonstrated that general system-level quality improvement approaches that are designed to improve outcomes for everyone may have a disproportionately positive effect on underserved populations or, conversely, they may further exacerbate disparities. It is important to delineate when generic quality improvement can improve outcomes versus when a more targeted approach, with a focus on reducing disparities, is needed. The evidence base regarding which of these approaches works best, when, and for whom, is currently lacking. Some studies have started to examine how redesigning the healthcare system may reduce disparities in care and advance health equity. For example, preliminary data show that the patient-centered medical home model of care delivery may eliminate disparities in prevention, diagnosis, and treatment for a variety of conditions, even in the most vulnerable patient populations, by providing comprehensive, coordinated, and accessible care. Accountable care organizations may also provide a
promising model for reducing disparities. Comparative effectiveness studies examining how different care delivery models can reduce disparities are needed (e.g., comparing different models of how patient-centered medical homes and accountable care organizations are structured and operate).

Other system-level research has examined performance incentive models such as pay-for-performance and pay-for-reporting programs, the role of public reporting, and the use of health information technology (HIT) in reducing disparities. Multiple studies show that vulnerable patient populations are more likely to receive care in poorer performing inpatient and outpatient settings, raising concerns about performance- or incentive-based payments. Likewise, experts have theorized that HIT could reduce disparities by improving care coordination, but simultaneously an emerging digital divide among providers and clinicians has raised questions as to whether these innovations could exacerbate disparities or whether they can be an effective approach for promoting health equity. PCORI is interested in comparative effectiveness studies examining which system-level interventions are most effective in reducing disparities in care.

For example, what are the best system-level interventions for improving overall performance and promoting healthcare equity? What are the promising models for healthcare delivery that promote health equity? While the preliminary data on the medical home is very promising for improving care and promoting health equity for minority populations, can the same findings be replicated for other vulnerable populations, such as those living in rural areas? What are the best pay-for-performance models available for achieving improved outcomes? Should standards be set around “pay for improvement” or “pay for an absolute level of performance”? How could payments be adjusted to account for achieving high levels of performance among more vulnerable, “hard-to-reach” populations?

2.2. Research Areas of Interest

The Addressing Disparities program is interested in the following areas of inquiry:

- Research that compares interventions to reduce or eliminate disparities in patient-centered outcomes, including health, health care, and patient-reported outcomes. For example, by accounting for possible differences at the patient, provider, or systems level, we are interested in research to determine what interventions can be most effective for eliminating disparities in outcomes.
- Research that identifies and compares promising practices that address contextual factors (e.g., socioeconomic, demographic, or community) and their impact on patient-centered health outcomes.
- Research that compares benefits and risks of treatment, diagnostic, prevention, or service...
options across different patient populations, with attention to eliminating disparities.

- Research that compares and identifies best practices within various patient populations for information sharing about treatment outcomes and patient-centered research.

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. All questions must have a comparative component.

- Compare which characteristics of the patient-centered medical care are most critical to implement to improve patient-centered outcomes, reduce disparities, and promote health equity.
- How does the availability of a patient navigator for patients and/or caregivers improve patients’ health outcomes compared to usual strategies? Under what circumstances, or for what conditions, are patient navigators most effective?
- Compare best options, materials, and venues for patient education materials that take into consideration patient and caregiver culture, beliefs, literacy, and numeracy to reduce disparities and improve outcomes.
- How do the practices of the top-performing facilities that primarily serve racial or ethnic minority groups, low-income populations, or other groups at risk for experiencing disparities compare with lower performing facilities? Which of the promising practices are replicable?
- Given that effective interventions to improve care in vulnerable populations often require a multipronged approach, compare what options work best under different circumstances.

Certain physiological measurements, such as blood pressure and serum cholesterol, are strongly linked to complications or other outcomes that patients care about. Therefore, 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).
To be competitive for a PCORI contract, an application must make the case that its proposed research question(s) and outcomes will matter to patients and/or other stakeholders.

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. PCORI also 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 patient-centered outcomes research, 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)](https://www.pcori.org/mетодология-стандартов-декабрь-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.

Table 1. PCORI Review Criteria and Description

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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 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 a LOI and application to PCORI, in accordance with the published dates and times listed in the PCORI Funding Center.