Patient-Centered Outcomes Research Institute

Funding Announcement: Improving Healthcare Systems

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Opportunity Snapshot

A small health plan faces an important challenge to improve the quality and patient-centeredness of care for its enrollees. Resources are limited and the leaders want to make wise decisions that will lead to interventions that improve the effectiveness, safety, timeliness, equity, and efficiency of care—and certainly to more patient-centered care. They have heard and read many reports of successful interventions in other systems, but most of these have not been rigorously evaluated, and they have not been compared with each other. They are interested in the impact of programs on a variety of patient-centered outcomes, and they wonder whether particular interventions could work for organizations and patient populations similar to theirs.

In this PCORI Funding Announcement (PFA), we seek to fund projects that address critical decisions that face healthcare system leaders and policy makers, clinicians, and the patients and caregivers who rely on them. These decisions must be consequential and be occurring now without key evidence about the comparative effectiveness of two or more approaches. There must be substantial potential that patients/caregivers will benefit from the new knowledge in ways that are important. The premise of this research is that new knowledge will support critical choices by patients and other key stakeholders in health care, not that it will deliver a verdict that leads us to dictate a choice. This knowledge will provide insight about the comparative benefits and harms of the options and provide information about outcomes that are experienced by patients and important to patients.

Every day, healthcare organizations are faced with crucial decisions about improving their systems of care while lacking critical information needed to guide them. The research should be designed to help them provide better care to the patients in their organization effectively and efficiently.

We at the Patient-Centered Outcomes Research Institute (PCORI) are entrusted by the public to fund research that will matter to patients and their caregivers, and we now turn to you to help us. We have identified five national priorities and a research agenda that guides the projects we will fund. The agenda is focused on producing knowledge that is useful to patients, their caregivers and clinicians, and others who can affect their care. We believe that the important gaps in knowledge are widespread. Rather than dictate which conditions and questions are more important than others, we have chosen to seek wisdom from around the country in the form of applications for funding in the five priority areas. We also have identified some areas, such as rare conditions, that are often neglected and that we want to be sure to cover among our funded projects.

PCORI seeks to change how research is done by emphasizing the role of diverse research teams that
include varying perspectives. PCORI distinguishes itself by supporting research in which patients, caregivers, and practicing clinicians are actively engaged in generating the research questions, conducting the research, and using the results to understand and address patient needs.

Program Overview

Under this Improving Healthcare Systems PFA, PCORI seeks studies of approaches (eg, policies, interventions, service designs) employed by healthcare systems to improve the quality of care, the outcomes of care, or the efficiency of care for the patients they serve. Healthcare systems include: private health plans; physician groups; hospitals; academic medical centers; integrated delivery systems; community-based and safety net clinics; federal, state, and municipal providers and payers; and other entities organized to deliver, arrange, or coordinate healthcare services. PCORI seeks studies that will provide information of value to patients, their caregivers, and clinicians, as well as to healthcare leaders and decision makers on which types of systems and which system strategies lead to better patient outcomes. More recent and less-studied system strategies are of particular interest.

Research Areas of Interest

We are interested in the following broad topical areas:

- Research that compares alternative system-level approaches to supporting and improving patient access to care; receipt of appropriate evidence-based care; the quality, timeliness, and safety of the patient care experience; decision making based on patients’ personal values; and self-care.
- Research that compares alternative approaches to models of care delivery or coordination of care across healthcare services or settings, including care for patients with complex, chronic, and/or multiple conditions, are of interest. The emphasis is on comparing approaches for their effect on patients and, when relevant, their caregivers, in ways that they experience and think are important.
- Research that compares alternative system-level approaches that aim to improve the efficiency of healthcare delivery to patient populations. These may include efforts to reduce the use of ineffective or wasteful care, to reduce redundant and duplicative care, to shorten waiting times, or enhance the timeliness and quality of communications during referrals and transitions in care.

Strategies of interest include but are not limited to: novel applications of health information systems, including electronic health records, patient systems, and personal health records; the use of incentives directed at clinicians or patients; of payment reforms such as value-based purchasing and bundled payments; reconfigurations (redesign) of care, such as the patient-centered medical home and accountable care organizations; models of care coordination and integration; organizational decision-making protocols to guide care referral and specialized assessment of patients with specific complex conditions; and new and extended roles for allied health professionals (eg, pharmacists, nurses, physician assistants, dentists, chiropractors, complementary and alternative medicine providers, patient navigators, health coaches, social and service coordinators, volunteers, and so forth).

Strategies may focus on patient or system enrollee populations with a single condition or with a range of
conditions. Systems strategies to support or improve 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. The term low prevalence is defined as meaning conditions that affect fewer than 200,000 individuals in the United States or have a prevalence of fewer than 1 in 1,500 persons.

Background

A healthcare system is characterized by the organization of people and resources to deliver and/or pay for services to meet the health needs of populations. Systems may be publicly or privately organized, and are often evaluated in terms of their ability to deliver accessible, high-quality, efficient, and equitable care. Governmental policies and market forces motivate health systems to improve these parameters, and these pressures in turn help to shape the clinical, organizational, workforce, and financing decisions made by systems. Importantly, the demographic and clinical characteristics of the populations served and the scope and mission of the organization also have strong influences on each of these system-level metrics by altering the access, patterns of use, and effectiveness of various health services. Over the past two decades, the Institute of Medicine (IOM) and others have sharpened the focus on ensuring that systems are also designed and oriented toward achieving the health outcomes most desired by individual patients—that is, to become more patient-centered.

Innovation and change in healthcare systems and in the behavior of health system participants (patients, caregivers, clinicians, payers, purchasers, industries, researchers, and policy makers) is often driven by economic, political, and social needs to improve access to care or quality of care, to attract patients or enrollees, and to contain costs. In recent times, rising healthcare costs, demographic trends, and the implementation of the Affordable Care Act have been important catalysts to many new approaches to change how healthcare systems respond to the current and expected future health needs of the US population.

Healthcare system interventions, however, are often initiated and adopted without robust evaluation of their impact on the health and well-being of the population—especially of more vulnerable patients within populations, such as the elderly, disabled, low-income patients, and those with multiple chronic illnesses. In the IOM’s 2009 recommendations for initial priorities for comparative clinical effectiveness research (CER), nearly half of the 100 priorities identified related to healthcare delivery systems, underscoring uncertainty on what constitutes best practice and a collective appreciation of the critical role of systems in implementing clinical evidence and improving care.

The importance of innovative care models, such as patient-centered medical homes (PCMHs) and accountable care organizations (ACOs), for improving system performance and patient outcomes has been widely discussed, but understanding of the impact of these new models remains underdeveloped. As an example, while elements of the PCMH have been associated with improved outcomes and care processes, there is relatively little evidence to date on the impact of implementing comprehensive PCMH interventions on outcomes that matter to patients. New payment models, such as bundled payments, are also being adopted as strategies for delivery reform, but their impact on patient care and outcomes remains unclear. The consolidation of physician practices by hospitals and the integration of health insurers and providers—most notably hospitals—have begun to alter the organizational landscape, again
with little information on the resulting impact on patients or clinicians.

Other system-level interventions have focused on helping patients and clinicians make more appropriate decisions. Performance measurement is widely used to enhance implementation and adherence to evidence-based guidelines. New tools that address both of these goals are emerging, such as clinical and patient decision support systems. The overall effectiveness of these tools as implemented within healthcare systems is less well understood, particularly for patient populations such as those with limited English language proficiency or education. Use of patient navigators has been shown to have promising effects in relatively limited applications, such as cancer screening, but could have promise in multiple therapeutic areas. A variety of system-level interventions have focused on the important goal of improving patient adherence to chronic medications, but most have had limited effects on clinical outcomes and have not measured more patient-centered outcomes.

To improve access to health care and the match of skills with patient needs, new and expanded roles for allied health professionals are increasingly being developed and refined within systems. The roles of nurse practitioners (NPs) or physician assistants in providing primary and limited specialty care—and the roles of pharmacists and other health professionals in care management and adherence counseling—deserve greater scrutiny with a particular emphasis on outcomes that matter to patients, including: symptom management; self-efficacy; satisfaction; physical, emotional, and social functioning; as well as biometric measures of risk factor control, adherence, and clinical endpoints, including survival.

Other important trends in recent years include more sophisticated use of systems and technology, such as electronic health records, personal health records, Web-based applications, and other forms of digital communication for enhancing both efficiency and effectiveness in delivering information to patients and clinicians about evidence-based care for their conditions, including chronic and multiple conditions. Each of these deserves further study, especially when interventions have been taken to scale within healthcare systems.

Many system-level concerns require better understanding of the relationship between the organization and delivery of care within the system and the circumstances, characteristics, and values of the patient. For example, reducing unplanned and inappropriate hospital readmissions has importance to patients and families, as well as potential economic impact, and studying the effects of structured, individualized discharge planning on outcomes that patients care about is needed, along with a broader understanding of other contributors to readmission. Similarly, identifying and reducing the factors within health systems that contribute to patients’ development of disability or chronic conditions may significantly improve the lives of patients and their families. There is a lack of system interventions to deliver evidence-based practices, such as substance abuse or depression screening, or other early or supportive interventions (screening, coaching, navigation, coordination, management, knowledge sharing, and activation) to prevent or slow progression of conditions and to understand their impact on outcomes important to patients.

The emergence and continued expansion of retail clinics and other “retail” and “self-service” modes of healthcare delivery, such as home diagnostics, has received very little attention, despite concerns that these interventions may have mixed consequences, perhaps especially for populations lacking
adequate alternatives, such as access to traditional primary care.

With respect to all of the interventions outlined above, concerns remain that effectiveness may vary among population subgroups. Among the groups of particular concern are: patients with multiple chronic conditions; the disabled; frail elderly; patients with low literacy, numeracy, or health literacy; those of low income, including the dually eligible (Medicare/Medicaid); and rural populations. Research in this area has typically been less focused on outcomes that may be of great interest to patients, such as enhancing their confidence and ability to navigate the healthcare system, ability to maintain functioning in the home, and productivity.

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 and 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; and
- Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, availability of services, technology, and personnel, and other stakeholder perspectives.

Example Questions

The following research questions are meant as examples of the types of questions that patients, clinicians, or healthcare managers might ask, and which your research might help answer. They are expressed from the perspective of the patient and healthcare system.

- An 84-year-old woman with several chronic diseases is having increasing difficulties managing at home alone, but does not want to leave her home or neighborhood for a nursing home. What are the benefits and drawbacks of different programs or services that might help her stay at home and remain independent safely? Which should she choose?

- A 27-year-old man with diabetes, chronic back pain, and depression has been invited by his public hospital-based clinic to participate in a group visit program for patients with chronic conditions led by a behavioral care specialist and a health educator. How likely is it that he will benefit from this program compared to the current care offered, and what is the nature of the benefit? What should his primary care physician recommend?

- An elderly man has been hospitalized four times in the past year for congestive heart failure. One
challenge seems to be related to delays and poor communication during the transition from the hospital back to the primary care doctor. What could the hospital do to help this man reduce his chances of being hospitalized again?

Funding and Project Period Limits

PCORI expects to fund projects totaling up to $24 million in total costs under this PFA, per cycle. 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.

Projects may not exceed three years in duration. 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. To that end, PCORI will reserve a portion of funding for smaller (less than $500,000 in total costs) and intermediate-sized projects (less than $1 million in total costs). PCORI encourages studies that can deliver findings promptly, including studies that take advantage of research infrastructure already in place and of longitudinal studies already underway. Currently funded CER studies of healthcare systems may be considered for PCORI funding to support distinctive work related to extending follow-up, adding additional outcomes, or examining outcomes in key patient subgroups. Efficient use of research resources is a criterion that will be considered by merit reviewers and will also be reviewed by PCORI staff. The total amount awarded and the number of awards will depend on the quality, duration, and costs of the applications received.

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 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. PCORI does not guarantee that permission will be granted, and applicants should expect that the deliberative process may result in delaying the submission for one or more cycles.

Elements of PCORI Funded Research

Now that you understand the research focus and priorities, you will need to determine if your organization and approach meet PCORI’s other eligibility requirements. To do that, please consider the following important issues.

Key Elements

Successful applicants for PCORI funds must:

1. Have a research team that includes patients and/or caregivers, as well as clinicians, health system managers, or other potential end-users of the study findings, along with researchers. Each member of the research team should participate actively in the design and implementation of the study and the dissemination of its results. A key concept here is ensuring that the research remains true to the interests of those who would use it.
2. **Be familiar with the four questions of our patient-centered outcomes research definition;** applicants must clearly explain how their proposed research aligns with one or more of these questions.
   
   - “Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?”
   - “What are my options, and what are the potential benefits and harms of those options?”
   - “What can I do to improve the outcomes that are most important to me?”
   - “How can clinicians and the care delivery systems they work in help me make the best decisions about my health and health care?”

   These questions articulate the needs of people as they make healthcare decisions.

3. **Demonstrate that the proposed research has the potential to provide important information that patients need to make decisions—but that is not currently available.** Consider what information patients, clinicians or health systems may need to make or support better healthcare decisions.

4. **Propose to use PCORI resources efficiently in producing new knowledge.** We aim to stretch our resources as far as possible because we recognize the vast information needs of patients. Research budgets will be used as one component to evaluate the use of resources, as detailed in Review Criterion #8 (see PCORI Review Criteria). We are looking for approaches that are highly efficient without sacrificing methodological rigor. We are also interested in the potential for findings to be applied in multiple areas, independent of the disease studied.

5. **Make clear how you are accounting for individual differences among patient groups.** Average results are useful, but we are also very interested in providing evidence that can be tailored to patient subgroups based on their clinical and demographic characteristics. We want products of the research that are scalable and generalizable—and can be customized for specific sites.

PCORI is interested in research that can be rapidly disseminated and implemented into clinical and community settings, yielding prompt improvements in patients’, clinicians’, and systems’ decisions and the resulting outcomes. To that end, projects of shorter duration and projects that take advantage of existing research infrastructure and data are of great interest. Applications must include a dissemination and implementation assessment that discusses prospects for dissemination and considers possible barriers as well. For projects that produce important findings deserving dissemination, PCORI will consider subsequent applications to fund dissemination and implementation efforts.

A variety of study designs and analytic methods may contribute valid new knowledge. These include evidence syntheses, randomized comparisons at either the individual or cluster level, or various observational approaches (eg, quasi-experimental studies). Qualitative methods may also be employed, either in mixed methods approaches or, potentially, as qualitative comparative studies. Evidence
syntheses should follow rigorous standards accepted in the field, such as those published by the Agency for Healthcare Research and Quality (AHRQ) and the Institute of Medicine (IOM). Issues of possible heterogeneity of treatment effects must be considered and discussed. Analyses of effects on subpopulations should be discussed. Inclusion of previously understudied population groups, including the elderly, children (if appropriate), and vulnerable populations, is particularly important. Randomized evaluations must be generalizable either by virtue of considering entire populations or by efficiently recruiting highly representative study populations rather than selected volunteers. 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. Applicants are encouraged to adhere to the contents of the PCORI revised Methodology Standards in developing their research plan. PFA applications will be required to comply with standards adopted by PCORI’s Board of Governors that have been approved by the Board at least six months prior to the PFA application due date. This time period, combined with a public comment period (45–60 days prior to adoption, as stated in PCORI’s enabling legislation), will erase any knowledge advantage and maintain Methodology Committee application eligibility.

Comparisons must be to relevant alternatives, which may include other system features designed to address the same need, or to “usual care.” The research will provide information about outcomes that are experienced by and important to patients. These outcomes may include quality of life, self-rated health, ability to participate in desired activities, degree of suffering from pain or other symptoms, ability to live independently, survival, and satisfaction with health care.

Comparisons should examine the impact of the system features in various subpopulations with attention to the possibilities that the effects of the features might differ across various subpopulations. Subpopulations of interest include those that are less frequently studied (eg, the elderly; children, if appropriate; patients with multiple chronic conditions; patients with rare conditions) and other vulnerable populations, including those of low socioeconomic status, low literacy, and/or numeracy; patients with disabilities; and patient groups known to experience disparities in health care and outcomes, such as racial/ethnic minorities and those living in rural or inner-city areas. Alternatively, the study may focus primarily on comparative effectiveness of system features for prevention, treatment, screening, diagnosis, or management in one or more of these populations of interest.

**Relevance to Patients**

Research proposals should clearly identify the relevant patient population, the health decision(s) examined in the proposed study, and the patient outcomes that will be affected by the research, as outlined in PCORI Review Criterion #4. As patient-centered research, the focus should be on the identification of the primary concerns and questions of patients and their caregivers.

**Patient and Stakeholder Involvement**

Persons representative of the population of interest—referred to here as patients, their caregivers, and clinicians—should be engaged in all phases of the research process, as outlined in PCORI Review Criterion #7. Patients may include individuals who have or had the condition or who are at risk of the
condition under study; it may also include patient surrogates or caregivers. In some instances, representatives of patient advocacy organizations may be appropriate research collaborators. Clinicians who face these decisions in collaboration with their patients are also relevant team members. Engagement should include participation in formulation of research questions; defining essential characteristics of study participants, comparators, and outcomes; monitoring of study conduct and progress; and dissemination of research results. In essence, patients and stakeholders must be important contributors throughout the research enterprise.

A key goal of patient engagement in research is to present information that best supports health decisions through generation of evidence relevant to patients, their caregivers, and clinicians. As a result, patients and other key stakeholders should be meaningfully involved in the research team. The specific members of the team will vary from study to study.

**Dissemination and Implementation Assessment**

PCORI is interested in funding studies that produce findings that can be readily disseminated and implemented—and are highly likely to be valued by patients and caregivers. To that end, it is important that potential facilitators and barriers to dissemination and incorporation into practice be assessed and anticipated.

**Reproducibility and Transparency of Research**

The ability to replicate potentially important findings from PCORI-funded studies in other datasets and populations is essential to building confidence in the accuracy of these findings. PCORI will support policies to promote sharing of study documentation (eg, 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 dataset.

**Inclusiveness of Different Populations**

PCORI seeks to fund research that includes diverse populations with respect to age, gender, race, ethnicity, geography, or clinical status. 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.
Protection of Human Subjects
PCORI adheres to, 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) Web site: www.grants.nih.gov/grants/funding/phs398/phs398.doc.

Application Development and Submission Overview
Application Development
There are five steps to developing a PCORI application:

- **Step 1: Inform PCORI with the Letter of Intent**: submit a required Letter of Intent (LOI) by the deadline.

- **Step 2: Design the research plan**: As part of your application, you must state the specific aims of the project, the research question(s) to be studied, and how you will answer that question. In addition, applicants must:
  - Explain how the research plan aligns with PCORI review criteria.
  - Describe plans for dissemination and implementation.
  - Describe plans for supporting replication and reproducibility of research and data sharing.

- **Step 3: Document the people and places**: Determine and document who will be on the research team, what their roles will be, and where the research will be conducted. Describe plans for engaging patients and other relevant stakeholders as part of the research team in the research project.

- **Step 4: Develop the budget**: Determine, list, and justify the costs associated with the project.

- **Step 5: Submit the application**: Compile and submit your application using PCORI Online.

For further guidance and resources, visit the PCORI Application Center (www.pcori.org/funding-opportunities/funding-announcements/application-center/)

Review Criteria
The PCORI review process for each complete, submitted application includes the three components listed below. This process typically takes about six months.

- Completeness, Compliance, and Eligibility Check
- Merit Review
- Business Review

Carefully read and thoroughly understand the PCORI review criteria before applying.
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<th>PCORI Criteria</th>
<th>Brief Description</th>
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<td><strong>RESEARCH STRATEGY: Background and Significance</strong></td>
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<tr>
<td>1. Impact of the condition on the health of individuals and populations</td>
<td>Refers to the current 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? A particular emphasis is on patients with chronic conditions, including those patients with multiple chronic conditions.</td>
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<td>2. Potential for improving care and outcomes</td>
<td>Refers to the potential that the proposed research may lead to meaningful improvement in patient health, well-being, or quality of care. 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 effect changes in current practice?</td>
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<td>3. Effects on healthcare delivery</td>
<td>Refers to the potential that the proposed research could lead to improvements in the efficiency of care for individual patients or for a population of patients. Does the research promise potential improvements in convenience or elimination of wasted resources, while maintaining or improving patient outcomes?</td>
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<td><strong>RESEARCH STRATEGY: Relevance to Patients</strong></td>
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<td>4. Patient-centeredness</td>
<td>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? Is the absence of proposed measurement any important outcomes justified?</td>
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<td><strong>RESEARCH STRATEGY: Approach</strong></td>
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5. Rigorous research methods

Refers to the use of appropriate and rigorous research methods to generate patient-centered evidence, including appropriate choice of study design and of analytic methods. How likely is it that the proposed study population, study design, and available sample size will yield unbiased, generalizable information with sufficient precision to be useful and reliable for patients, their caregivers, clinicians, and health system leaders?

RESEARCH STRATEGY: Inclusiveness of Different Populations

6. Inclusiveness of different populations

Does the proposed study include a diverse population with respect to age, gender, race, ethnicity, geography, or clinical status? Alternatively, does it focus on a population for whom effectiveness information is particularly needed?

PEOPLE AND PLACES

7. Research Team and Environment

The research team must be appropriately trained and experienced to carry out the planned studies. Does the study team have complementary and integrated research expertise in implementing the study? Are relevant patients and other key users of the study information (eg, caregivers, clinicians, health system leaders, community, or policy makers) appropriately involved in the design and implementation of the study? Will the research environment contribute to the probability of success? Are features of the research environment, such as health system or community involvement or collaborative arrangements, described? Are institutional and community investment in the success of the research described?

BUDGET

8. Efficient use of research resources

Does the budget appear to be reasonable in relation to the potential contribution of the research? Does the justification address the efficiency with which PCORI resources would be used? Are there opportunities to make the study more efficient? Are there additional benefits to a PCORI investment in this study through the creation of common data or infrastructure that could support future research?

Organizational 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.

Submission Procedures
To apply with PCORI, you must register with PCORI’s online system and submit both a timely Letter of Intent and a timely application. To learn more about completing your application, please see the PCORI Application Guidelines (www.pcori.org/assets/PFAguidelines.pdf).

Submission Deadlines
This is a standing announcement, with three application deadlines per year. Applicants must submit a Letter of Intent and application to PCORI, in accordance with the published dates and times listed in the Application Center (www.pcori.org/funding-opportunities/funding-announcements/application-center/#anchor).
About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) is an independent organization created to help people make informed healthcare decisions and improve healthcare delivery. PCORI will commission research that is guided by patients, caregivers, and the broader healthcare community and will produce high-integrity, evidence-based information.

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI will use a variety of forums and public comment periods to obtain public input throughout 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.”

The statutory language defining PCORI is broad and authorizes research that will support a strong patient-centered orientation, inform better choices among alternative treatment and prevention strategies, and direct attention to individual and system differences that may influence strategies and outcomes. PCORI was designed to produce knowledge through the analysis and synthesis of existing research or the support of new research.