PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Spring 2014 Funding Cycle

PCORI Funding Announcement: The Effectiveness of Transitional Care

This PCORI Funding Announcement applies to the funding cycle that closes May 6, 2014, at 5:00 p.m. (ET). Application guidelines, templates, and other resources are available at http://www.pcori.org/PFA/transitional-care

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. PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a nonprofit, 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."

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Overview

Published	February 5, 2014; revised April 15, 2014
Letter of Intent Due	March 7, 2014, by 5:00 p.m. (ET) Letters of Intent will be screened for responsiveness and fit to program goals. Only those selected will be permitted to submit full applications. Notification of request to submit full application will occur no later than March 21, 2014.
Summary	PCORI is soliciting applications for research to determine which transitional care service clusters are most effective in improving patient-centered outcomes—while optimizing re-admission rates—in different at-risk subpopulations and in different healthcare contexts (e.g., fee-for-service, capitation, new payment models, medical homes, and integrated delivery systems). The proposed research should consider obtaining the needed information by evaluating the results of the widespread experimentation now under way in hundreds of US communities. PCORI is particularly interested in proposals that also evaluate the acceptability of various transitional service clusters to patients, caregivers and providers, as well as other determinants of scalability. PCORI intends to fund one 3-year comprehensive study by an organization or a consortium of organizations that has the expertise, resources, and experience needed to answer rigorously all the questions of interest.
Applicant Resources	See pcori.org/pfa/transitional-care
Key Dates	Online System Opens: February 5, 2014 Applicant Town Hall Session: February 12, 2014, at 1:00 p.m. (E) Letter of Intent (LOI) Deadline: March 7, 2014, by 5:00 p.m. (ET) LOI Screening Notification: March 21, 2014 Application Deadline May 6, 2014, by 5:00 p.m. (ET) Merit Review: August 2014 Awards Announced: September 2014 Earliest Project Start Date: December 2014
Maximum Annual Budget (Total Costs)	There are no annual limits
Maximum Project Period	Three years
Funds Available **Up To** (Total Costs)	$15 million
Eligibility	Applications may be submitted by any private sector research organization, including any nonprofit or for-profit organization, and any public sector research organization, including any university or college hospital or healthcare system, laboratory or manufacturer, or unit of local, state, or federal government. All US applicant organizations must be recognized by the Internal Revenue Service. Non-domestic components of organizations based in the United States and foreign organizations 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 are not permitted to apply.

Review Criteria	• Impact of the condition on the health of individuals and populations • Potential for the study to Improve healthcare and outcomes • Technical merit • Patient-centeredness • Patient and stakeholder engagement
Contact Us	For programmatic questions, please email (pfa@pcori.org), phone (202-627-1884), or contact us online (http://www.pcori.org/PFA/inquiry). PCORI will provide a response within three business days. However, PCORI cannot guarantee that all questions will be addressed three business days prior to a Letter of Intent or application deadline. Please email (pfa@pcori.org) for any administrative, financial, or technical questions. PCORI will provide a response within two business days. Please note that during the week of the application deadline, response times may exceed two business days. Applicants may call the PCORI Helpdesk (202-627-1885) within a week prior to the deadline for technical or administrative support. Applicants are asked to plan accordingly. It is the applicant's responsibility to submit the application or before the application deadline.

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I. Introduction

Summary of Program

The Improving Healthcare Systems (IHS) program at the Patient-Centered Outcomes Research Institute (PCORI) seeks to fund innovative comparative clinical effectiveness research to provide new information that will help individual patients, caregivers, hospitals, other providers of care, payers, and healthcare systems to make wise choices about selecting effective, scalable healthcare services in the near future. Transitional care encompasses a broad range of services and environments designed to promote the safe and timely passage of patients between levels of health care and across care settings. A hospital-to-post-acute "transitional care strategy" is defined as one or a group of interventions initiated before hospital discharge with the aim of ensuring the safe and effective transition of patients from the acute inpatient setting, during the transition, and at home or other post-acute sites of care.[1]

Hypothesizing that the effectiveness of transitional care depends on providing transitional care services that are well aligned with the specific needs of different patient populations within different healthcare contexts, PCORI seeks to determine which clusters of transitional care services work best for whom under which circumstances. Specifically, with this targeted PCORI Funding Announcement (PFA), PCORI is soliciting applications for research to determine which transitional care service clusters are most effective in improving patient-centered outcomes—while optimizing re-admission rates—in different at-risk subpopulations and in different healthcare contexts (e.g., fee-for-service, capitation, new payment models, medical homes, and integrated delivery systems). Applicants should consider obtaining the needed information by evaluating the results of the widespread experimentation now under way in hundreds of US communities. PCORI is particularly interested in proposals that also evaluate the acceptability of various transitional service clusters to patients, caregivers and providers, as well as other determinants of scalability.

Background

The effectiveness of hospital-to-post-acute transitional care in the United States is suboptimal. Nearly 20 percent of Medicare beneficiaries are readmitted to a hospital within 30 days of discharge, and 90 percent of such readmissions are the result of clinical deterioration.[2] Patients who do not see their primary care providers after discharge are 10 times as likely as other discharged patients to be readmitted to the hospital within four weeks of discharge.[3] According to the Medicare Payment Advisory Commission (MedPAC), the failure to adequately attend to care transitions increases Medicare's annual spending by $12 billion because 75 percent of 30-day readmissions are preventable.[4] Furthermore, an estimated 19 percent of Medicare discharges are followed by an adverse event within 30 days; two-thirds of these are costly drug-related events, which are often preventable.[5]

Although the most visible adverse consequences of suboptimal transitional care are avoidable

readmissions and adverse drug events, other consequences include unnecessary repetition of tests, use of higher-intensity settings of care, decreased functional status, and reduced quality of life. Furthermore, recently discharged patients and their caregivers are often confused, frightened, and overwhelmed, leading to a condition newly recognized as the "post-hospital syndrome."[6]

Numerous factors are associated with ineffective hospital-to-post-acute transitions of care: poor communication between providers;[7] changes in medication during hospitalizations;[8] inadequate patient understanding of diagnoses, medications and follow-up needs;[9] incomplete diagnostic workups completed prior to discharge;[10] and several other patient- and healthcare system–related factors.

Underlying these system-wide inadequacies in the quality and outcomes of transitional care are long-standing deficiencies in provider accountability, process measurement and reporting, quality improvement programs, and performance incentives. In response, several policy initiatives have recently been implemented to encourage improvements in transitional care.

Over the past twenty years, several transitional care models have been developed and tested. Most notable are the Care Transition Intervention,[11] the Transitional Care Model,[12] and Project RED (Re-Engineered Discharge).[13] Little evidence, however, has been reported on the effects of such interventions on post-discharge adverse events, readmissions, or other indicators of patient well-being. A recent systematic review identified 47 controlled studies of at least fair methodological quality and concluded that the overall strength of evidence is low that bridging interventions (those that span the pre-discharge and post-discharge periods) reduce readmissions and emergency department visits. Most studies did not report the interventions' contexts or costs. A meta-analysis was not possible because of the heterogeneity of the interventions, the study settings, and the patient populations.[2]

Several national policy initiatives have been launched in recent years to address the widespread deficiencies in transitional care:

- Since August 2008, the 9th Statement of Work undertaken by CMS's Quality Improvement Organizations (QIOs) has focused on helping 226 US communities to provide Medicare beneficiaries with seamless transitions and to reduce preventable readmissions. The QIOs have incorporated evidence-based care transition models in their work and have helped bring communities together to improve care transitions.
- The Centers for Medicare & Medicaid Services (CMS) now posts public reports of hospitals' risk-adjusted 30-day readmission rates for patients hospitalized with pneumonia (PN), acute myocardial infarction (AMI), and congestive heart failure (HF).[14]
- Section 3025 of the Affordable Care Act (ACA) of 2010 added section 1886(q) to the Social Security Act establishing the Hospital Readmissions Reduction Program, which requires CMS to reduce payments to Inpatient Prospective Payment System (IPPS) hospitals with excess readmissions for PN, AMI, and HF. Three additional conditions will be added in 2015: chronic obstructive pulmonary disease (COPD), elective total hip arthroplasty (THA), and total knee

arthroplasty (TKA). Hospitals that have above-average readmission rates (within 30 days of discharge) for these conditions are at risk for incurring financial penalties of up to 2 percent of their Medicare reimbursements.[15]

- CMS's Community-based Care Transitions Program (CCTP), created by Section 3026 of the ACA, is testing models of transitional care in 102 communities. CCTP goals are to reduce readmissions for high-risk Medicare beneficiaries and to document savings to the Medicare program. Few other patient-centered outcomes are being measured across the sites of this national demonstration.[16]

The implementation of transitional care services has also been facilitated by the Society of Hospital Medicine's Better Outcomes by Optimizing Safe Transitions (BOOST) program[17] and the National Transitions of Care Coalition (NTOCC).[18]

As a result of these policies and professional initiatives, transitional care programs have been launched in more than 500 communities across the United States, but they vary considerably in the patient populations they serve and in the healthcare contexts (i.e., organizational and financial influences) in which they operate, as well as in their structure, patient selection, service provision and intensity, and staffing. Evaluations of these programs tend to focus more on re-admission rates than on other health-related outcomes that are important to patients and their caregivers.

Research of Interest and Research Approach

PCORI seeks to fund investigator-initiated research on the effects of system changes on the following broad outcomes:

- Overall health, functional ability, health-related quality of life, stress, severity of symptoms, survival, and other outcomes important to patients and their caregivers
- Patients' access to care, quality of care, and support for self-care
- Professionals' decision making based on patients' personal values and coordination of care across healthcare settings
- The efficiency of healthcare delivery, as measured by the amount of ineffective, duplicative, or wasteful care provided to patients

The goals of this initiative are to:

- Identify the forms of transitional care (clusters of specific services) that produce the best patient-centered results for different groups of at-risk patients in different healthcare contexts.
- Provide evidence-based knowledge that the nation's healthcare organizations can use to provide the specific clusters of transitional care services that will best meet their unique patient populations' needs as patients make transitions from acute care hospitals to post-acute sites of care.
- Provide patients and their caregivers with information that will help them obtain the transitional care services that will best meet their needs.
- Identify the factors that could promote or impede the scalability of different forms of transitional care.

To obtain this information, the research will need to address the considerable heterogeneity in

- The composition of transitional care programs, as defined by the clusters of services they provide, such as
    - Pre-discharge assessment of patients' (and caregivers') risks and capacity for self-care
    - Pre-discharge transitional care planning
    - Medication reconciliation
    - Teaching and empowering patients and caregivers to participate in self-care
    - Physiologic monitoring after discharge
    - Timely provision of accurate information to the "receiving" professionals
    - Professional monitoring and coordination of post-discharge follow-up
    - Access to medical help at all times
    - Promotion of adequate sleep, nutrition, physical activity, safety, and emotional well-being
- Patient populations, such as
    - Differences in residential environment (rural/urban/inner city)
    - Baseline functional ability
    - Ability to speak English
    - Support by family caregivers
    - Health insurance coverage
    - Risk of substance abuse
- The contexts in which transitional care occurs, such as
    - Integrated/non-integrated delivery systems,
    - Fee-for-service/capitated payment environments
    - Traditional primary care/patient-centered medical homes

The proposed research should compare the effectiveness of specified clusters of transitional care services to the effectiveness of usual care, as provided

- In similar healthcare contexts to similar hospitalized patients at risk for poor transitions,
- In matched comparator communities/contexts, in the same communities before the implementation of transitional care services, or
- In both.

In all cases, usual care should be adequately characterized in terms of what transitional care services it does and does not include.

Subpopulations of particular interest to PCORI include hospitalized patients at risk for poor transitions who are:

- Residents of sparsely populated rural or frontier geographic areas
- Residents of hazardous urban areas
- People who abuse intoxicants
- People with disabilities
- People with complex medical and/or psychiatric conditions
- People with limited proficiency in English
- People who are homeless
- People who have no family or other unpaid ("informal") caregivers

- People who have no private or public health insurance
- Native English-speaking, functionally independent people who live in relatively safe, urban and suburban areas and have family or other informal caregivers and health insurance

The proposed research should focus on transitional care services and outcomes that matter to patients, including:

- Patients' and caregivers' experience of transitional care, such as
    - involvement in planning of care;
    - receipt of information, training, empowerment, equipment, supplies, medications, monitoring, follow-up care, and care coordination
    - access to help for problems, questions, and self-care
    - adverse events that occur after discharge
    - satisfaction with transitional care services
- Clinical status, such as symptom severity, health and functional ability, and quality of life
- Need for (or avoidance of) acute services, such as visits to emergency departments and readmissions to hospitals

Because PCORI hypothesizes that different clusters of transitional care services will be more (or less) effective for different patient groups in different health care settings, the proposed research should aim to discern unique clusters of transitional care services that produce the best outcomes for as many targeted subpopulations in as many healthcare contexts as possible. Additionally, the proposed research should characterize the potential scalability of each cluster of services in each context, considering such factors as workforce availability, training requirements, resource intensity, and the satisfaction of the participants.

To illustrate some of the possible research settings of interest, the following grid defines 48 hypothetical subpopulation-context situations (eight subpopulations, six contexts) in which hospitalized patients who are at risk for poor transitions make transitions to post-acute care settings. The proposed research should attempt to determine which clusters of transitional care services are most effective in improving outcomes that matter to patients in as many subpopulation-context situations as possible.

	Healthcare Contexts					
Subpopulations	Fee-for-Service	Capitation	Integrated Delivery System	Non–Integrated Delivery System	Primary Care	Patient-Centered Medical Home
Rural and Frontier Areas						
Hazardous Urban Areas						
Substance Abuse						
Disabilities						
Limited English						

Lack Caregivers						
Lack Health Insurance						
Advantaged*						

*Native English-speaking, functionally independent people living in relatively safe, urban or suburban areas and who have caregivers and health insurance.

The following grid defines six hypothetical clusters of transitional care services. The actual number and composition of service clusters in widespread use will differ from those shown.

	Clusters					
Transitional Care Services	1	2	3	4	5	6
Pre-discharge:						
Assessment	X	X	X		X	X
Transitional care planning	X	X	X		X	X
Medication reconciliation	X		X		X	
Teaching and empowering for self-care	X		X		X	
Post-discharge:						
Physiologic monitoring		X		X	X	
Provision of information to "receiving" professionals		X		X	X	X
Professional monitoring and care coordination	X			X	X	X
Access to help at all times	X			X	X	X
Promotion of sleep, nutrition, physical activity, safety, and emotional well-being		X		X		

By surveying patients, caregivers, providers, and administrators in a sample of the more than 500 US communities that are participating in CCTP, BOOST, QIOs, and other programs by providing different clusters of transitional care services, research teams could address many questions of interest, such as:

- Among patients who receive health care in a rural, fee-for-service environment, does Cluster 2 improve patients' experience of transitional care, clinical status, and/or need for acute care, compared with usual care? Does Cluster 2 produce better outcomes than Cluster 4?
- Among patients with disabilities who receive health care in an integrated delivery system, does Cluster 1 improve patients' experience of transitional care, clinical status, and/or need for acute care, compared with usual care? Does Cluster 1 produce outcomes equal to Cluster 5?
- Among "advantaged" patients who receive healthcare in patient-centered medical homes, does Cluster 3 improve patients' experience of transitional care, clinical status, and/or need for acute care, compared with usual care? Does Cluster 3 produce outcomes equal to those produced by Clusters 1 and 5?
- Taking into account such factors as workforce availability, training requirements, resource intensity, and participant satisfaction, how scalable is each of the clusters? What obstacles

would have to be overcome to bring each successful service cluster into widespread use? What incentives would promote uptake?

II. Guidance for Proposing Research

Research Priorities

PCORI funds patient-centered outcomes research (PCOR), a type of comparative clinical effectiveness research. The studies PCORI supports must include the perspectives of patients and other healthcare stakeholders. To be considered responsive to PCORI, applications must describe research that:

- Studies the benefits and harms of interventions and strategies delivered in actual settings. By "delivered in actual settings," we mean delivered and received in typical "real-life" clinical settings, not just in restrictive trials of experimental care or at selected academic centers. PCORI is interested in innovative studies that provide practical information 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 tested 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 a wide variety of strategies for improving delivery systems, but the studies must be comparative. "Usual care" (or no specific intervention) may be an appropriate comparator if this is a realistic choice faced by patients and other stakeholders.
- Is based on health outcomes that are meaningful to the patient population under study.

Non-responsiveness

Applications will be considered non-responsive if the proposed research:

- Conducts a formal cost-effectiveness analysis in the form of dollar-cost per quality-adjusted life-year to compare two or more alternatives.
- Measures the relative costs of care of two or more alternative approaches as the primary criteria for choosing the preferred alternative.

PCORI does have an interest, however, in studies that address questions about conditions that lead to high costs to the individual or to society. This is included in our review criterion on impact of the condition on the health of individuals and populations. PCORI is also interested in studies that examine differentials in healthcare resources or costs as a determinant of, or barrier to, good outcomes. Examples include ways in which out-of-pocket costs may constitute a barrier to the receipt of care.

Further, PCORI considers it important for applicants to discuss cost-related issues such as the resources needed to implement, replicate, or disseminate a successful intervention. PCORI is also

interested in evaluation of interventions intended 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 comparing the costs of alternatives are considered responsive.

PCORI discourages proposals that include studies of the natural history of disease, instrument development, pharmacodynamics, and fundamental science or study of biological mechanisms. It also discourages studies that have the primary purpose of developing and evaluating new decision aids or clinical prognostication tools.

Features of 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 the choices 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, functioning, 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.
- Directly compares clinical interventions that are generally available in the clinical settings that people use to access health care.
- Obtains the perspectives of stakeholders to address the burdens to individuals, availability of services, and requirements for technology and personnel.

Comparative Clinical Effectiveness Research

Applications submitted in response to this funding announcement should compare the effectiveness of two or more clinical interventions. The application must provide information from systematic reviews or credible literature reviews on the nature of the research gap being addressed and the data about efficacy of the clinical interventions that will be compared. If "usual care" is one of the interventions, the clinical characteristics of this intervention must be well specified.

Leveraging Existing Resources

Investigators are encouraged to propose studies that leverage existing resources, such as adding PCOR to an existing large clinical trial or analyzing existing large databases that contain valuable, relevant information that may be used to answer important comparative clinical effectiveness research questions.

Preliminary Data and Use of Accepted Measures

PCORI encourages investigators to design their research using valid patient-centered outcomes measures. Include preliminary data that supports the proposed measures. Investigators are encouraged to consider those measures described in the Patient Reported Outcomes Measurement Information System* (PROMIS).

Documentation of Assumptions

PCORI specifically seeks studies that are sufficiently powered to detect clinically meaningful effects. To that end, please justify the proposed sample sizes by explaining the assumptions used in all study power calculations. The application should clearly state all the necessary assumptions (i.e., the primary outcome measure, the estimated difference in the mean value of this measure between study arms, standard deviation of the measure, type I error rate, and any other assumptions). All such estimates must be justified by referring to prior published research or preliminary data.

Review Criteria

PCORI's review panels rate all submitted applications on the following five criteria:

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

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

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

- Does the research question address a critical gap in current knowledge as noted in systematic reviews, guideline development efforts, or previous research prioritizations?
- Has it been identified as important by patient, caregiver, or clinician groups?
- Do wide variations in practice patterns suggest current clinical uncertainty?
- Is the research novel or innovative in its methods or approach, in the population being studied, or in the intervention being evaluated in ways that make it likely to improve

* Available at nihpromis.org

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 and implemented quickly, resulting in improvements in practice and patient outcomes?

Criterion 3. Technical merit

The proposal has sufficient technical merit to ensure that the study goals will be met. It includes:

- A clear research plan with rigorous methods that adhere to PCORI's Methodology Standards
- A realistic timeline that includes specific scientific and engagement milestones
- A research team with the necessary expertise and an appropriate organizational structure
- A research environment sufficient to support the conduct of the work with appropriate resources
- A diverse study population with respect to age, gender, race, ethnicity, and clinical status, as appropriate for the proposed research

Criterion 4. Patient-centeredness

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

- Is the research focused on questions that affect outcomes of 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?

Criterion 5. Patient and stakeholder engagement

The proposal demonstrates that people representing the population of interest and other relevant stakeholders are engaged in ways that are appropriate and necessary in a given research context.

- Are patients and other stakeholders engaged in:
    - Formulating research questions
    - Defining essential characteristics of study participants, comparators, and outcomes
    - Identifying and selecting outcomes that the population of interest notices and cares about (e.g., survival, function, symptoms, health-related quality of life) and that inform decision making relevant to the research topic
    - Monitoring study conduct and progress
    - Designing/suggesting plans for dissemination and implementation activities
- Are the roles and the decision making authority of all research partners clearly stated?
- Does the proposal demonstrate the PCOR principles of reciprocal relationships, co-learning, partnership, trust, transparency, and honesty?

Methodological Considerations

Regardless of study design, proposals must adhere to all relevant PCORI Methodology Standards. [†] PCORI Methodology Standards include 47 individual standards that fall into 11 categories. The first five categories are cross-cutting and are relevant to most PCOR studies. Researchers should refer to all of these standards when planning and conducting their research projects. These categories are:

- Standards for Formulating Research Questions
- Standards Associated with Patient-Centeredness
- Standards on Data Integrity and Rigorous Analyses
- Standards for Preventing and Handling Missing Data
- Standards for Heterogeneity of Treatment Effect (HTE)

Five other categories of standards will be applicable to particular study designs and methods. The standards in each of these categories should be used for guidance when they are relevant to a particular study:

- Standards for Data Registries
- Standards for Data Networks as Research-facilitating Infrastructures
- Standards for Causal Inference Methods
- Standards for Adaptive and Bayesian Trial Designs
- Standards for Studies of Diagnostic Tests

Most of these standards should be considered "minimal" standards. Additional best practices, including relevant guidelines for the conduct of clinical trials developed by other organizations, should be addressed in the application for PCORI funding.

All applicants should specifically discuss their capacity to measure factors such as differential adherence to chosen treatments (or participation in intervention programs) that could create or explain apparent differences in the effectiveness of the alternative interventions being compared in clinical populations. If an application proposes to make comparisons to "usual care," then the aspects of that care must be well-specified.

Patient and Stakeholder Engagement

PCORI encourages all applicants to clearly describe the patient and stakeholder engagement in their research proposals. PCORI understands that patient and stakeholder engagement in research can take many forms; it is not seeking one particular type or method of engagement. Rather, applicants should communicate how patients (those with lived experience), family members, caregivers, and the organizations that represent them, as well as any other relevant stakeholders, will be involved in study activities. Because this type of engagement in research is a relatively new concept, PCORI has developed a

[†] Available at pcori.org/research-we-support/research-methodology-standards/

Patient and Family Engagement Rubric (see the appendix to the Engagement Template) to guide both applicants and merit reviewers. Additionally, studies are expected to adhere to PCORI's Methodology Standards Associated with Patient-Centeredness and to the PCOR Engagement Principles found within the rubric. These and additional resources are available in PCORI's Funding Center.

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 clinical effectiveness research may be examined. PCORI recognizes that some proposed studies may represent important PCOR opportunities even in the absence of a broadly diverse study population. However, the burden is on the applicant in such cases to justify the importance of the study in 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 years)
- Older adults (age 65 years and older)
- Residents of rural areas
- Individuals with special healthcare needs, including individuals with disabilities
- Individuals with multiple chronic diseases
- Individuals with rare diseases
- Individuals whose genetic make-up affects their medical outcomes
- Patients with low health literacy/numeracy and/or limited English proficiency
- Lesbian, gay, bisexual, and transsexual (LGBT) persons

Protection of Human Subjects

PCORI adopts, by reference, the Human Subjects requirements of 45 CFR Part 46. If the proposed research will involve human subjects, refer to the Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan in Part II of the Instructions for the PHS

398 Form provided by the National Institute of Health.[‡] Note: PCORI requires engagement in the research by patients and/or other stakeholders as research partners. Research subjects protection requirements do not apply to co-investigators, members of the research team, or research partners.

Collaboration

Innovation and changes in healthcare systems and in the behavior of healthcare-system participants are often driven by economic, political, and social imperatives to improve access to or quality of care, to attract patients/enrollees, and to contain costs. As such, PCORI is particularly interested in applications that involve community and commercial organizations that can help researchers design, implement, disseminate, and sustain effective interventions. We encourage proposals that include novel collaborations with accreditation organizations, credentialing bodies, educational enterprises, patient advocacy groups, industry, professional societies, and subspecialty societies.

Budget and Duration of Project

Budgets in excess of $15 million in total costs and programs lasting more than three years will not be accepted.

PCORI intends to fund one 3-year comprehensive study by an organization or a consortium of organizations that has the expertise, resources, and experience to answer rigorously all the questions of interest. Proposals will be reviewed and evaluated in their totality. Project funds will be disbursed in two stages, however, with disbursal of Stage 2 funds (covering Years 2 and 3) contingent on successful performance in Stage 1 (Year 1). Stage 1 activities should include developing and validating survey instruments and protocols, as well as reaching agreements with the many institutional and community organizations that will participate in the research. Stage 2 activities should focus on data collection, analysis, and dissemination.

Letters of Intent Review Process

LOIs will be evaluated on their responsiveness to this PFA. Applicants will be notified whether they have been selected to submit full applications; PCORI will accept full applications from only those organizations selected.

Useful Reports

Applicants are encouraged to read:

- The Transitional Care Workgroup Meeting Summary[§] --multidisciplinary perspectives on transitional care presented during a workgroup held July 2013
- *The Framework for Measuring Transitions of Care*[19] -- proposed by the NTOCC Measures Workgroup, based on the key elements of optimal transitions of care

[‡] Available at grants.nih.gov/grants/funding/phs398/phs398.html

[§] Available at pcori.org/assets/2013/08/PCORI-Transitional-Care-Workgroup-April-2013-Meeting-Summary-071213.pdf

- *Preferred Practices and Performance Measures for Measuring and Reporting Care Coordination*[20]
- *Transitional Care Performance Measurement*[21]
- *Innovations in Reducing Preventable Hospital Admissions, Readmissions, and Emergency Room Use*[22]

III. How to Submit a Proposal

PCORI Online System

To submit a proposal, you must register with the PCORI Online System[**] and submit a Letter of Intent (LOI).

Submission Dates

Letters of Intent and applications must be submitted in accordance with the published dates and times listed in the Overview of this document and in PPCORI's Funding Center.[††]

Applicant Resources

PCORI Funding Center	pcori.org/pfa/transitional-care
PCORI Online System	pcori.fluxx.io
PCORI Funding Awards	pcori.org/pfaawards
Contact Us	**Programmatic Inquires:** Please contact the PCORI Helpdesk via email (pfa@pcori.org), phone (202-627-1884), or online (http://www.pcori.org/PFA/inquiry). PCORI will provide a response within three business days. However, we cannot guarantee that all questions will be addressed three business days prior to a Letter of Intent or application deadline. **Administrative, Financial, or Technical Inquiries:** Please contact the PCORI Helpdesk at pfa@pcori.org. PCORI will provide a response within two business days. Please note that during the week of the application deadline, response times may exceed two business days. One week prior to an application deadline, applicants may also call the PCORI Helpdesk (202-627-1885). Applicants are asked to plan accordingly. It is the applicant's responsibility to submit the application or before the application deadline.

[**] Available at pcori.fluxx.io
[††] Available at pcori.org/apply

VI. References

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