



Patient-Centered Outcomes Research Institute

Major Themes from Public Comments on the Draft National Priorities for Research and Research Agenda and PCORI Response

This document outlines major themes identified from public comments submitted on PCORI's [draft National Priorities for Research and Research Agenda](#) with PCORI's responses and proposed revisions in the draft language. For ease of use, we have annotated this document with starred and bolded notes to indicate in which areas of the draft National Priorities and Research Agenda the proposed revisions to be considered by the Board of Governors would be placed. The original draft language is in black type, the proposed revisions in red. For more information about PCORI's draft National Priorities for Research and Research Agenda, please visit PCORI's [website](#).

What We Heard	PCORI Response	Specific Language Changes to Draft National Priorities for Research and Research Agenda
1. Recommends that PCORI choose a specific condition, disease area, or other issues in the Research Agenda and National Priorities	PCORI has proposed a condition-neutral Research Agenda and has introduced specificity through its comparative nature and emphasis on patient centeredness. While future funding announcements may specify conditions, the overall mission of PCORI is not served by excluding any conditions if there is compelling reason for a patient-centered, comparative clinical effectiveness study.	<p>*Note: refers to “Research Agenda Overview” section of draft Research Agenda</p> <p>Although no changes were made to reflect this feedback, we did add the following language on page X to elaborate on our position:</p> <p>PCORI's initial approach specifies a set of questions and topics that the multi-stakeholder Board of Governors, after the rigorous process set forth above, believes are most in need of attention – across a range of conditions and treatments. Within any National Priority and associated research agenda area, studies may focus on specific diseases, conditions and interventions, or they may be cross-cutting, including broader study populations or examining interventions or other questions that apply across multiple diseases and chronic conditions. This approach recognizes a compelling, novel opportunity, that as PCORI begins its funding program, researchers partnered with stakeholders are best positioned to present a range of compelling questions that form a truly patient-centered research agenda.</p>



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<p>2. Recommends that PCORI partner with organizations and stakeholders to carry out its mission</p>	<p>PCORI is committed to efficient use of its research investments. Where appropriate, PCORI will partner with other organizations after a transparent decision-making process and consideration of conflicts of interest. This theme impacts PCORI processes, rather than funding subjects, so no specific language changes were made to the document.</p>	<p>Not Applicable</p>
<p>3. Recommends greater focus on the patient, with particular attention to methods of engagement</p>	<p>PCORI has fully endorsed and appreciates the centrality of patient engagement to its mission. The National Priorities and Research Agenda reflect the patient centered focus of PCORI and include many of the themes from the public comments. Language has been added to the Agenda to specifically reflect the need for study of self care and to more clearly define personalized medicine.</p>	<p>*Note: refers to “Establishing the Scope of the Research Agenda” section of draft Research Agenda On page X, we now state: There is the strongest possible commitment to a patient-centered focus, which means that the interests of patients and caregivers will guide us. In each opportunity to improve, PCORI will seek to be ever more attentive to the needs of patients and caregivers.</p> <p>*Note: refers to “Research Agenda Overview” section of draft Research Agenda On page X, we now state: PCORI funded studies will have patients involved in the development of the research, its governance and oversight, and its dissemination strategy.</p> <p>*Note: refers to “Comparative Assessment of Options for Prevention, Diagnosis, and Treatment” section of draft Research Agenda On page X, we now state: Clinical effectiveness compares the effectiveness and safety of preventive, diagnostic, and treatment options to create a foundation of information for personalized decision-making. Personalized decisions acknowledge the centrality of patient preference and the need to provide information that is appropriate for each individual. For example, personalized information about what a patient might expect might take advantage of information about the patient’s profile as defined by a wide range of characteristics that might affect their outcomes, including but not limited to biology, demography,</p>



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		<p>culture, socioeconomic status, comorbidity, and geography. This research places emphasis on the practical utility of the comparisons, the examination of all outcomes that may be important to patients and the possible differences in outcomes across patient subgroups.</p> <p>*Note: refers to section of draft Research Agenda related to priority “Comparative Assessment of Options for Prevention, Diagnosis, and Treatment”</p> <p>On page X, we now state: Topics are not limited to medical or surgical therapy and may include a range of strategies including self-care.</p>
<p>4. Recommends a greater focus on care coordination</p>	<p>PCORI appreciates the need to study care coordination and has expanded the language in the Research Agenda to reflect its importance.</p>	<p>*Note: refers to section of draft Research Agenda related to priority “Improving Health Systems”</p> <p>On page X, we now state: PCORI is interested in the following topics:</p> <ul style="list-style-type: none"> • Research that compares alternative system-level approaches to supporting and improving patient access to care, receipt of appropriate care, personalized decision-making and self-care. • Research that compares alternative approaches to models of care delivery or coordination of care across healthcare services or settings, including for patients with complex, chronic, and/or multiple conditions.



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5. Recommends funding towards improving patient and provider health literacy and education	Improving communication between patient and provider is one of the five PCORI National Priorities for Research. Language has been added to the Research Agenda to reflect the importance of health literacy to achieving this goal.	<p>Note: refers to section of draft Research Agenda related to priority “Communication and Dissemination Research”</p> <p>On page X, we now state: PCORI is interested in the following topics:</p> <ul style="list-style-type: none"> • Research that compares alternative communication, dissemination, health literacy, and implementation strategies that aim to improve shared decision-making by increasing clinician and/or patient awareness of healthcare options and use of comparative effectiveness research results at the point of decision-making. There is an interest in ensuring that research takes into account the health literacy of individual patients.
6. Recommends funding for and use of health IT infrastructure, networks, tools and patient data acquisition efforts in and outside the practice setting	The foundation for performing comparative clinical effectiveness requires substantial health IT and data infrastructure. The National Priorities and Research Agenda contain substantial language about this infrastructure. Therefore, no additional language was added to the document. PCORI will support reusable infrastructure for comparative clinical effectiveness research.	<p style="text-align: center;">Not Applicable</p>
7. Recommends that PCORI pay greater attention to the role of caregivers and other stakeholders in the patient decision making process	PCORI appreciates the role of caregivers in patient centered care and has mentioned them in the document and included studies of caregiving in the Research Agenda. Therefore, no additional language was added to the document.	<p style="text-align: center;">Not Applicable</p>



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<p>8. Recommends that PCORI pay greater attention to access to care, including the social and environmental determinants that determine access and use of care</p>	<p>Access to care is a key issue for patients. Language has been added in both the comparative assessment and the healthcare systems Research Agenda topics to include the comparative study of access as a determinant of health.</p>	<p>Note: refers to section of draft Research Agenda related to priority “Improving Health Systems” On page X, we now state: PCORI is interested in the following topics:</p> <ul style="list-style-type: none"> • Research that compares alternative system-level approaches to supporting and improving patient access to care, receipt of appropriate care, personalized decision-making and self-care. Research that compares alternative approaches to models of care delivery or coordination of care across healthcare services or settings, including for patients with complex, chronic, and/or multiple conditions.
<p>9. Recommends that PCORI provide greater rationale and transparency in the public comment, grants, and research evaluation processes, as well as the performance measurement process for PCORI as a whole</p>	<p>PCORI is committed to fully transparent processes as it works towards achieving its mission. The Research Agenda articulates the ongoing engagement that will occur continuously as PCORI evolves and funds research. Therefore, no additional changes were made to the document. PCORI intends to roll out a comprehensive communications and engagement plan that will clearly define when and how stakeholders can provide input into PCORI decision making.</p>	<p>Not Applicable</p>
<p>10. Recommends that PCORI's research and funding should impact the practice setting, with particular attention to patient and provider behavioral change needed to obtain true shared decision making</p>	<p>PCORI is fully committed to the idea that its research should improve decision making and help patients at the point of care. Language has been added to the section “Establishing the Scope of the Research Agenda” to emphasize the importance of using the evidence developed through PCORI research to change the way medicine is practiced.</p>	<p>*Note: refers to “Establishing the Scope of the Research Agenda” section of draft Research Agenda On page X, we now state: PCORI intends to be a learning organization; it will continue to evolve as it gains experience. There is the strongest possible commitment to a patient-centered focus, which means that the interests of patients and caregivers will guide us. In each opportunity to improve, PCORI will seek to be ever more attentive to the needs of patients and caregivers.</p>



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11. Recommends that PCORI place stronger emphasis on patients with multiple conditions, especially chronic conditions	PCORI understands the difficulty of managing multiple chronic conditions when most evidence is generated in trials that exclude these patients. Language has been added to emphasize this in the Research Agenda.	<p>*Note: refers to “Research Agenda Overview” section of draft Research Agenda</p> <p>On page X, we now state: Especially needed are studies to improve care and outcomes for patients faced with multiple conditions. (See also language added in response to theme #4 and #8)</p>
12. Recommends that PCORI study new and expanded roles for allied health professionals	PCORI recognizes the diverse health professionals involved in patient centered care. In the Research Agenda, the description of allied health professionals has been expanded to be more inclusive of all of potential members of a health care team.	<p>*Note: refers to section of draft Research Agenda related to priority “Improving Health Systems”</p> <p>On page X, we now state: PCORI is interested in the following topics:</p> <ul style="list-style-type: none"> • Research that compares the effectiveness on patient outcomes of a wide range of system-level strategies to incorporate alternative, new, and or extended roles for health care providers or other allied health professionals (e.g., pharmacists, nurses, physician assistants, dentists, integrative healthcare providers, complementary and alternative medicine providers, patient navigators, volunteers, etc.) into the healthcare team. Research that compares the effectiveness on patient outcomes of alternative strategies to composition of health care teams through alternative workforce deployment models including care collaboration and team based care approaches.
13. Recommends paying attention to international models	PCORI recognizes the significant achievements of many countries in developing the methods and practices of patient engaged comparative clinical effectiveness research that may inform investigators as they seek PCORI funding. As this is not central to PCORI research, no change is proposed to the priorities or agenda.	Not Applicable



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14. Recommends exploring novel methods to obtain patient centered focus	PCORI supports the approach of exploring innovative methods for focusing on the patient. The fundamental basis of PCOR, however, is the science of evidence-based medicine. PCORI will support and promote approaches that seek rigorous, scientific results; therefore no changes were made to the document.	Not Applicable
15. Recommends that PCORI study rare diseases	PCORI recognizes the challenges faced in studying rare diseases. In the Research Agenda, language about rare disease has been expanded.	<p>*Note: refers to “Research Agenda Overview” section of draft Research Agenda On page X, we now state: The portfolio of research supported by PCORI’s research agenda will be balanced based upon the characteristics of study populations such as age, gender, race/ethnicity, socio-economic status, and disease or conditions. PCORI has a commitment to include studies of patients with rare conditions as well as those with more common illnesses.</p> <p>*Note: refers to section of draft Research Agenda related to priority “Comparative Assessment of Options for Prevention, Diagnosis, and Treatment” On page X, we now state: PCORI is interested in the following topics: Studies that compare situations in which the effectiveness of strategies for prevention, treatment, screening, diagnosis, or surveillance have not been adequately studied against alternative options and better evidence is needed to support decision-making by patients, caregivers, and healthcare professionals. Rare diseases are an area of interest.</p> <p>*Note: refers to section of draft Research Agenda related to priority “Accelerating PCOR and Methodological Research” On page X, we now state: There is also a need to develop methods that are appropriate for rare conditions as it may be particularly challenging to assemble cohorts and obtain large numbers of individuals. There is interest in producing novel methodologies that assist in areas where current approaches have limitations.</p>