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How The Patient-Centered Outcomes Research Institute Is Engaging Patients And Others In Shaping Its Research Agenda

ABSTRACT Clinical research has been driven traditionally by investigators, from generating research questions and outcomes through analysis and release of study results. Building on the work of others, the Patient-Centered Outcomes Research Institute (PCORI) is tapping into its broad-based stakeholder community—especially patients, caregivers, and their clinicians—to generate topics for research, help the institute prioritize those topics, select topics for funding, and ensure patients’ involvement in the design of research projects. This article describes PCORI’s approach, which is emblematic of the organization’s mandate under the Affordable Care Act to seek meaningful ways to integrate the patient’s voice into the research process, and describes how it is being used in selection of research that PCORI will fund. We also describe challenges facing our approach, including a lack of common language and training on the part of patients and resistance on the part of researchers to questions that are not researcher generated. Faced with the reality that PCORI will not be able to fund all research questions posed to it, there will also be difficult decisions to make when selecting those that have the highest priority for funding.

The Patient-Centered Outcomes Research Institute (PCORI) was authorized as part of the Affordable Care Act, section 6301, to fund research that will assist patients, caregivers, clinicians, payers, and policy makers in making informed health decisions. Its creation acknowledges that these interests are not always at the forefront in clinical research.

To meet its mission, and to have the greatest societal and health care impact, PCORI intends to prioritize and fund research that meets several key criteria, including whether the results will be likely to change practice and whether the research addresses an important question from the perspective of patients, their caregivers, and their clinicians.

Examples of research that lacks such relevance would include studying treatment options that patients would not choose, conducting studies that fail to include outcomes that are relevant to patients, or conducting studies in patient groups that are not broadly generalizable to real-world scenarios or patient populations.

Research studies have often failed to include and report clinical outcomes that matter most to patients, caregivers, and clinicians, focusing instead on study “endpoints” that are less relevant to these concerns—for example, in patients with Alzheimer’s disease, studies often report objective changes in cognition, when what is really relevant to patients and family members are changes in function, such as an increased ability to perform activities of daily living. Indeed,

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symptoms and their effects on daily life can be of greater concern to patients than the clinical measures often reported in trials. Under pressure to report results quickly, many studies settle for measuring intermediate outcomes that are not closely linked either to the experience of living with a disease or to long-term risks of complications or mortality.

Studies may also fail to provide relevant information to most patients because of highly selective eligibility criteria, which can lead to study populations that are not representative of typical patients. For example, there is a lack of studies that include women, children, and the elderly.¹ Few studies include patients with multiple chronic conditions, such as dementia, mental illness, end-stage renal disease, and heart failure. Yet these patients drive health care services and use, and they continue to be understudied in clinical trials.²

Patients Matter

Eliciting research questions directly from patients, their caregivers, and their clinicians and asking them what matters to them in their daily lives have the potential to focus clinical research activity on more practical, patient-centered questions. Segments of the patient community are increasingly ready to participate in a significant way to contributing meaningful research questions to the clinical research enterprise.

There is also growing empirical evidence that research is improved through the meaningful involvement of patients and other stakeholders at key decision points. Patients and stakeholders can improve the quality, relevance, and impact of research, because they often challenge assumptions held by researchers and emphatically bring forward the issues that are important and relevant to them.^{3,4}

Federal Agencies Join Effort

PCORI joins several federal agencies, including the Agency for Healthcare Research and Quality, the National Institutes of Health, and the Food and Drug Administration, that have begun to involve patients and stakeholders in a meaningful way in generating and reviewing research questions.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY The Agency for Healthcare Research and Quality has involved patients and stakeholder panels in the nomination and prioritization of topics for systematic reviews as well as in the selection of research questions and endpoints.⁵ For example, in a systematic review

comparing coronary artery bypass surgery to percutaneous coronary interventions—two procedures used to treat heart disease and some of its effects—mortality and morbidity outcomes were both included after focus groups of patients and clinicians reported different opinions on what constituted meaningful endpoints, with patients more concerned with relief from disabling angina, or chest pain, than with mortality as a study endpoint.

The Agency for Healthcare Research and Quality has also sponsored the Consumers United for Evidence-based Healthcare partnership between consumer advocates and scientists. This program provides training and materials for consumer advocates to equip them to evaluate the health care literature and bring their own advocacy experience to bear on shaping research. In addition, the agency is funding several activities to help researchers engage the public in the use of scientific evidence and decision making, including web modules to support methods to engage stakeholders, guides to facilitating meetings with stakeholders, and a series of meetings on ways to engage patients and consumers in patient-centered outcomes research.⁶

NATIONAL INSTITUTES OF HEALTH The National Institutes of Health has a long history of involvement with public interest organizations. For example, the National Heart, Lung, and Blood Institute has worked on a number of partnerships with patient organizations to set priorities for research.⁷ Researchers partnered with the patient-driven LAM Foundation, which supports efforts aimed at improving treatment of and finding a cure for lymphangioleiomyomatosis (LAM), a rare and disabling lung disease. This partnership resulted in a trial that showed that sirolimus, a drug originally developed to prevent rejection of transplanted organs, improved health outcomes in this disease, which had not had any treatments available until then.⁸

FOOD AND DRUG ADMINISTRATION Recently, the Food and Drug Administration launched a patient-focused drug development initiative as part of the fifth authorization of the Prescription Drug User Fee Act of 1992. This program will involve obtaining the patient perspective on the disease severity and the currently available treatments for a set of disease areas. The Food and Drug Administration is publishing a preliminary list of nominated disease areas for this patient initiative and the criteria used for nomination. The public is invited to comment on the list, and public meetings have been scheduled.⁹

PCORI's National Priorities

PCORI is required by law to develop national priorities for patient-centered research as well as a research agenda. In May 2012 the PCORI Board of Governors approved the institute's first National Priorities for Research and Research Agenda,¹⁰ and five broad priorities for research were identified: assessing options for prevention, diagnosis, and treatment; improving health care systems; addressing disparities; communicating and disseminating research; and improving patient-centered outcomes research methods and infrastructure. Together, these priorities promise to increase both the quantity and the use of relevant patient-centered clinical information.

PCORI will now develop its research portfolio using two different but highly complementary approaches under the National Priorities for Research.

FUNDING OPPORTUNITIES The first approach invites research investigators from around the country to join with patients and other stakeholders in responding to broad funding announcements issued by PCORI.¹¹ To be successful, applicant research teams must involve patients and stakeholders in each step of the research, including the proposal, design, conduct, and dissemination of this research. To be funded, research teams must also explain why the proposed research question is patient centered and why its answer will be likely to change practice and improve decision making and patient outcomes.

On December 18, 2012, PCORI announced its first twenty-five awards, for a total of \$40.7 million over three years. The projects approved for funding include those that will study ways to improve care for people with such health problems as bacterial and viral infections, cardiovascular disease and stroke, certain cancers, chronic kidney disease, chronic pain, depression and other serious mental illnesses, and pediatric diabetes, as well cross-cutting proposals investigating how to improve care for people with multiple conditions. Other projects seek ways to improve patient-clinician communication, reduce selected health disparities, and improve the way health care systems operate.

The research applications had to meet PCORI's review criteria, be patient centered, engage with the populations that are being studied, be methodologically rigorous, and have a high probability of impacting clinical practice.¹²

PCORI's first set of funded projects all propose to generate information to address questions that are critically important to patients and clinicians making important health care decisions or to improve how health care is delivered. For

example, one funded project will evaluate a new tool kit to help doctors provide the best treatment options to patients suffering from non-specific back pain. The tool kit helps identify the type of treatment most likely to be successful based on the different pain experiences reported by the patient.

Another project identifies factors that are important for making critical decisions between different dialysis options for patients with kidney failure. Little evidence is available to help support this key decision making for patients and their caregivers.

Another project aims to provide culturally tailored information for Latina adolescents and their parents to help in making decisions on whether or not to receive the human papillomavirus vaccination. Rates of vaccination in this population are well below those of other populations, although the adverse health outcomes of not getting vaccinated are tremendous, leading to higher incidences of genital warts, abnormal pap smears, and cervical cancer.

Throughout these PCORI-funded projects, patients and other key stakeholders are engaged in the research process to ensure that the research questions are relevant to patients, caregivers, and their clinicians and to maximize the probability that future results will be implemented in practice.

For example, in the study of low back pain, people with back pain will be part of the research team. They will give their opinions about all details of the study, including the use of the method, the questions that patients and doctors are asked, and how the results of the study are reported. In the human papillomavirus vaccination study, a community advisory board of adolescent Latinas and their parents will be engaged to help refine the study's research questions and improve its design, implementation, and dissemination of results. PCORI-funded research thus engages patients, caregivers, and clinicians—the end users of this research—at all stages to maximize its potential impact once research findings become available.

SOLICITING QUESTIONS FOR FURTHER RESEARCH The second and complementary approach begins with PCORI's reaching out to its other key stakeholders—especially patients but also their caregivers, clinicians, and health care policy makers—to solicit the questions that matter most from these users' perspectives. It further asks for these stakeholders to come together with PCORI in a formal process to determine which questions should be of the highest priority for PCORI funding.

PCORI uses a number of vehicles to solicit research questions, including a web portal,

workshops, and outreach using social media. Over time, PCORI expects that questions will also be generated through direct interactions with patient and stakeholder organizations and with other research funding entities.

Questions that have come through the web portal since its launch on September 19, 2012, include the following: What are the best strategies for delaying the progression of chronic kidney disease, maintaining the patient's quality of life, and decreasing morbidity? What are the best strategies for coordinating follow-up care between hospitals and outpatient care providers for patients experiencing heart failure to improve disease management and reduce recurrence and hospital readmission? Is magnetic resonance imaging better than mammography for detecting breast cancer?

PCORI staff will examine and review the questions received to ensure that they broadly fall within its mission. For example, to be eligible for PCORI funding, a research question must be related to decision making in health or health care; it must be comparative—that is, it must include a comparison of two or more interventions for the condition of interest; and it must be aligned with at least one of PCORI's five National Priorities for Research, which we outlined above. PCORI will not fund studies proposed as cost-effectiveness or cost-comparison analyses, except those that consider only costs as experienced directly by patients, such as out-of-pocket costs, which can directly influence patients' treatment choices.

Research questions that meet these broad criteria will then be examined to confirm whether they reflect true gaps in clinical knowledge or whether any research addressing the question is currently under way or completed. These examinations will involve reviews of published literature and currently funded studies as identified on <http://ClinicalTrials.gov> and other relevant databases, consideration of recent systematic reviews, and consultation with clinical and research experts in appropriate areas. This process will be conducted by the Agency for Healthcare Research and Quality through a contract with PCORI.

PCORI will use this information to categorize questions as having sufficient evidence to guide decision making; as having data available that would benefit from evidence synthesis; or as unanswered and requiring new, empirical research to adequately address the question (see online Appendix Exhibit 1 for a schematic representation of the process).¹³

Questions that fall into either of the latter two categories—those that require either evidence synthesis or new research—will be forwarded

to multistakeholder advisory panels appointed and convened by PCORI. These panels will involve patients; caregivers; and other stakeholders, such as clinicians, researchers, and policy makers. Details of panel composition and the nomination and appointment processes are to be determined and made public by early 2013.

Advisory panels will employ a prioritization process that systematically applies PCORI's review criteria to the evaluation of each question. PCORI's authorizing legislation provides some insights into the prioritization criteria.

Section 6301 of the statute decrees that the institute “shall identify national priorities for research, taking into account factors of disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), gaps in evidence in terms of clinical outcomes, practice variations and health disparities in terms of delivery and outcomes of care, the potential for new evidence to improve patient health, well-being, and the quality of care, the effect on national expenditures associated with a health care treatment, strategy, or health conditions, as well as patient needs, outcomes, and preferences.”

PCORI has developed criteria that are intended to prioritize questions that are most likely to have an impact on clinical practice and improve outcomes. These criteria cover the following topics, which are described more fully in Appendix Exhibit 2:¹³ patient-centeredness, impact, differences in benefits and harms and reduction in uncertainty, implementation in practice, and durability of the information. Questions that are selected must address important problems for which there is current uncertainty and for which better evidence could have a durable impact on decision making for patient-centered outcomes research.

DELIBERATIVE PROCESS ENCOURAGES PARTICIPATION Details of the deliberative process are being developed, and PCORI is taking care to ensure that all members are able to contribute to discussions and decision making using specific processes developed for such purposes. One such process is the Nominal Group Technique, which is a moderated group discussion using a format that encourages participation of all group members and, thus, prevents one person or one group from dominating the discussion.¹⁴

PCORI is committed to allowing all participants to share their input, ensuring that one or several organizations do not dominate the process, regardless of size or resources. It also requires asking people to bring their experience to bear without advocating for one single disease or population and to work in collaboration.

All participants will receive background materials developed and organized by PCORI to help in applying the PCORI criteria. Once topics are prioritized, PCORI's Board of Governors will make the final selections of the list of topics to be developed into specific funding announcements that will solicit one or multiple research studies on the topic. A graphic representation of this process is presented in Appendix Exhibit 3.¹³

In contrast to the other prioritization processes described above, PCORI will be prioritizing across a much broader potential range of topics. Prioritizing topics from a broad list generated by patients and stakeholders will not be an easy task. Asking patients and stakeholders to think about research questions using explicit criteria puts a structure into the process and moves away from a number of previous priority-setting models based on experts' achieving consensus through discussions.¹⁵ These criteria require that patients and stakeholders consider what constitutes a good question for further research and how best to allocate limited research funds using an explicit process.

PCORI is piloting the use of an approach called "conceptual Value of Information" to help support the prioritization decision-making process.¹⁶ Information on conceptual elements that include patient-centeredness, impact, differences in benefits and harms and reduction in uncertainty, implementation in practice, and durability of the information are used to help determine whether the research question constitutes a high priority for funding.

It is not likely that prioritizing and engaging in additional research would be an effective use of research funds for research questions in which the values for the conceptual value of information are low.

For example, a research study that proposed to show that one intervention was more effective than another in an area where the uncertainty around treatment effectiveness is low and where members of the scientific and clinical community already largely agree on the best management strategy would probably rank low on the priorities list for further research.

However, if the evidence remains sufficiently uncertain in specific populations, this fact may warrant further research to establish the best treatment options for these populations. For example, we know that lifestyle interventions can reduce cardiovascular disease risk by as much as 44 percent. However, there is uncertainty as to how to provide such strategies to populations living in poverty with limited access to health care, so further research in this area would be helpful.

In October 2012 PCORI issued a call for

patients and stakeholders to review and test its proposed process for prioritizing specific research topics in a pilot exercise involving ten topics. The pilot recruited thirty-five patients, caregivers, and stakeholders to test this process using the PCORI-specific criteria. The final process for prioritizing specific research topics will be used in 2013 by advisory panels to begin setting priorities between research questions to submit to PCORI's Board of Governors.

Impact Of Involving Patients As Equal Partners

There are clear indications that patients are ready to participate with PCORI in setting its research agenda and to get involved despite the challenges of pursuing these new paths.¹⁷ These challenges include a lack of common language and training on the part of patients and resistance on the part of researchers to questions that are not researcher generated.

To participate effectively, patients and stakeholders will need to acquire a certain level of training to have productive conversations with research partners and to "translate" their health and health care questions into meaningful research. Successful participation can be facilitated by additional training and access to appropriate resources to do so.¹⁸ Similarly, researchers will need to adopt a vernacular that is familiar to patients and stakeholders and that facilitates best communication.

More research into approaches to ensure that all voices are heard will also have to be investigated and tested.¹⁹ Organizations such as the aforementioned Consumers United for Evidence-based Healthcare have been established to provide this training.²⁰ This national coalition of health and consumer advocacy organizations came together in an effort to improve consumers' ability to engage in and demand high-quality health care by training them in basics of evidence-based medicine.

Conversely, researchers will need to learn to collaborate in meaningful ways with groups bringing different perspectives to the table. The research community may also need additional training to think about research questions that are not researcher driven. Whether there will be resistance within the research community to patient-generated research is also a question.

We also expect that there will be some frustration on the part of patients, stakeholders, and researchers when faced with the reality that PCORI will not be able to fund all research questions. There will be difficult decisions to make when selecting the questions that have the highest priority to receive funds for research. There

will also be times where professional researchers and patients vehemently disagree on the value of a particular research question.

Resources such as online learning modules, webcasts, and other materials exist to facilitate the engagement of researchers and the public in the research process.⁶ Despite these potential challenges, PCORI is embarking on a large-scale

and exciting effort to reach out to the community of patients and stakeholders to tap into their wisdom, to hear what questions matter to them, and to fund studies whose answers will help improve their health care and their health outcomes. We hope that this effort at engagement will make a real difference to patients and that they will join us in this important endeavor. ■

The findings and conclusions presented in this article are those of the authors and do not necessarily represent the

views of the Agency for Healthcare Research and Quality (AHRQ). No statement in this article should be

construed as an official position of AHRQ or of the Department of Health and Human Services.

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In this month's *Health Affairs*, Rachael Fleurence and coauthors describe how the Patient-Centered Outcomes Research Institute (PCORI) is working with patients, caregivers, and their clinicians to generate topics for research, help the institute prioritize those topics, select topics for funding, and ensure patients' involvement in the design of research projects. The authors also identify challenges, including the fact that PCORI won't be able to fund all research questions posed to it and faces difficult decisions in selecting those that have the highest priority for funding.

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