

Opportunities for Patient-centered Outcomes Research in Radiology

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Abbreviations and Acronyms

ARRA

American Recovery and Reinvestment Act of 2009

CER

Comparative effectiveness research

PCOR

Patient-centered outcomes research

PCORI

Patient-Centered Outcomes Research Institute

PPACA

Patient Protection and Affordable Care Act.

Recently created in 2010, the Patient-Centered Outcomes Research Institute (PCORI) supports patient-centered comparative effectiveness research with a focus on prioritizing high-impact studies and improving trial design methodology. The Association of University Radiologists Radiology Research Alliance Task Force on patient-centered outcomes research in Radiology aims to review recently funded imaging-centric projects that adhere to the methodologies established by PCORI. We provide an overview of the successful application of PCORI standards to radiology topics, highlight how these methodologies differ from other forms of radiology research, and identify opportunities for new projects as well as potential barriers for involvement. Our hope is that review of specific case examples in radiology will clarify the use and value of PCORI methods mandated and supported nationally by the Affordable Care Act.

Key Words: Patient-centered outcomes research; Comparative effectiveness research; Pragmatic trial design.

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INTRODUCTION

Established in 2010, the Patient-Centered Outcomes Research Institute (PCORI) redirects the focus and methodology applied to medical research in the United States toward promoting high-integrity, evidence-based research guided by patients, caregivers, and the broader healthcare community (1). As the name suggests, patient-centered outcomes research (PCOR) focuses on *patients*. What are the benefits of this approach? Simply put, patients and their doctors view health and disease from different vantage points. Radiologists and imaging researchers have traditionally studied diagnostic

accuracy of various imaging tests or technical success rates of interventional procedures; these end points are radiology-centric. Patients, on the other hand, are primarily concerned with their health status, including the ability to return to work and the quality of life. The PCORI agenda emphasizes patient-centered outcomes, assigning greater value to treatments and diagnostic options in the context of outcomes important to patients. Directly engaging multiple stakeholders, particularly patients, as partners in radiology research promises to bring these two vantage points into a single focus.

The broad research mandate advocated by the PCORI may seem intimidating to radiologists, but clarifying the focus and mission of the institute helps reveal opportunities for radiologists interested in pursuing PCOR. Not only is the institute focused on patient-centered outcomes, but also it holds an intrinsic responsibility to promote research quality with a multipart strategy. Through its Methodologies Committee, the institute has created a prioritization process and methodology standards to identify relevant research questions and ensure that funded research provides high-quality, valid data that aid healthcare decision-making processes.

Radiologists should note that research focusing on patient-centered end points is becoming a critical component of defining value in health care (2). The metrics devised through such research will help drive national guidelines, inform

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standards of care, and determine reimbursement. The radiology community must collaborate in this process to help establish our value in this new healthcare paradigm. This paper will present an overview of imaging in PCOR by discussing the national agenda for PCOR, issues specific to imaging, study design and methodology, funding opportunities, current research, and opportunities for PCOR involving medical imaging and radiologists.

NATIONAL AGENDA FOR PCOR

Vast innovation in medical imaging over the past 40 years has also fostered a concomitant rise in imaging utilization and cost. Annual Medicare expenditures, including part B spending for advanced imaging services are expected to continue growing at a rate that exceeds the overall growth rate of the U.S. economy (3). In 2007, the Congressional Budget Office identified comparative effectiveness research (CER) as a potential means to stem healthcare cost for both public and private insurers without “adversely affecting health overall” (4). The national interest for this type of research was bolstered in The American Recovery and Reinvestment Act of 2009, which allocated \$1.1 billion for CER and established the Federal Coordinating Council for Comparative Effectiveness Research. The council was created to direct the efforts of all federal agencies conducting CER.

The most recent large-scale effort in the United State to promote CER, arose as part of the Patient Protection and Affordable Care Act (PPACA) of 2010. The PPACA created the mandate and funding to establish PCORI as a non-profit, nongovernmental organization. The institute was authorized by Congress:

[To] help 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 hopes to achieve these goals by funding CER and improving methodology related to such studies. In contrast to other funding mechanisms, PCORI heavily involves patients in the entire research process, including identification of the study objectives, development and execution of research plans, and research dissemination. These patients, typically recruited from patient-driven advocacy groups or departmentally organized advisory groups, are often included as key investigators and authors.

PCORI considered the 100 CER priorities put forward by the Institute of Medicine (IOM) in 2009 among other public sources to inform five “National Priorities for Research and Research Agenda.” While the IOM priorities include many population- or disease-specific categories, there are only a few radiology-related topics. Opportunity for radiology-related outcomes research is increased because of the fact that PCORI priorities are deliberately broad. The five PCORI National Priorities are (5):

1. Assessment of Prevention, Diagnosis, and Treatment Options: Comparative research to see which works best for different people with a particular health condition.
2. Improving Healthcare Systems: Comparing health system-level approaches to improve access and care, including innovative use of health information technology and coordination of care for complex conditions.
3. Communication and Dissemination Research: Comparing approaches to providing CER information to patients and their providers.
4. Addressing Disparities: Identifying and addressing disparities in prevention, diagnosis, and treatment effectiveness across patient populations
5. Accelerating Patient-centered Outcomes Research and Methodological Research: Building data infrastructure and improving analytical methods for conducting PCOR.

DEFINING PCOR AND METHODOLOGY STANDARDS

Investigators engaged in PCOR should focus on helping patients make informed healthcare decisions and assess the value of various healthcare options, emphasizing comparisons and outcomes that matter most to patients and their caregivers. According to the PCORI, this type of research answers patient-centered questions such as (6):

“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?”

The PCORI Methodology Committee developed a “prioritization process and methodology standards.” When applied to PCOR in imaging, both help guide research yielding high-quality evidence-based information that is important to patients, caregivers, and the broader healthcare community.

Prioritization Process

Research prioritization begins by identifying the information needs of patients and clinicians. PCORI funds proposals based on the national priorities listed earlier in this article. A similar framework has been proposed for assessing the value of diagnostic imaging: the size of the at-risk population, the anticipated clinical benefits, and the potential economic impact of the technology (7). These three components can be used to estimate the level of outcomes data needed to determine efficacy, ranging from the evaluation of the basic properties of an imaging technology or treatment (i.e., proof of concept or low level of outcomes data) to the evaluation of the

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