Patient-Centered Outcomes Research: A "New" Research Agenda

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There is a new player among funders of health care research—the Patient Centered Outcomes Research Institute (PCORI). PCORI was established by Congress as part of the Patient Protection and Affordable Care Act of 2010. Through the Patient-Centered Outcomes Research Trust Fund (PCORTF) established at that time, PCORI receives funding from two sources: the general fund of the Treasury and a fee assessed on Medicare, private health insurance, and self-insured plans. PCORI is expected to receive an estimated $3.5 billion from the PCORTF to fund patient-centered outcomes research through September 30, 2019, at which point its authorization expires. PCORI is governed by a Board of Governors appointed by the U.S. Government Accountability Office (http://www.pcori.org/about-us/governance-and-leadership/).

This article will describe patient-centered outcomes research (PCOR) as it has evolved over time, particularly since the establishment of PCORI. We will further briefly address the potential of PCOR to revolutionize research and review some of the barriers that may thwart its potential. We will conclude with a challenge to advanced practice nurses and specifically pediatric nurse practitioners to become involved in PCOR for the betterment of health care for patients and families.

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PATIENT-CENTERED OUTCOMES RESEARCH

Although "patient-centered care" has been touted as a basic tenet of nursing practice for decades, the idea that care should be patient centered gained impetus with the publication of *Crossing the Quality Chasm, a New Health System for the 21st Century* (National Research Council [NRC], 2001), where it was noted that in order to improve health care delivery, care should be provided in a way that is respectful of and responsive to individual patient preferences, needs, and values, as well as ensuring that patient values help guide clinician decisions. Although it was perhaps missed in the discussion following the report's publication, the NRC made clear that "patient centered" meant that the outcomes of care were outcomes that patients valued and desired and that these were the outcomes that should be studied, which begs the question: What outcomes are important to patients?

To answer this question, we need to consider various ways in which "patient centeredness" is defined. Although researchers and clinicians often believe they know the answer to this question, evidence shows that a shared definition between patients and researchers of what counts as patient centered is lacking (Lutz & Bowers, 2000). For example, in a recent integrative review, few common definitions of "patient centeredness" were found, although some common themes were identified, including patient participation and involvement, the relationship between the patient and the health care professional, and the context in which care is delivered (Kitson, Marshall, Bassett, & Zeitz, 2013). However, different professions emphasized different elements within the themes, with health policy observers and nurses focusing on the broader system and contextual issues such as the professional–patient relationship, whereas physicians were more focused on a clearly delineated therapeutic relationship. The nursing literature tended to highlight respect of patients' values and beliefs, whereas the medical literature centered on understanding the nature of the informed decision-making process between the physician and the patient. Patient perspectives on the meaning of patient centeredness have also been studied with surprising results; generally, there is "an overwhelming lack of familiarity" with the term "patient-centered care," although patients believe that patient-centered care should focus on quality, include their involvement, meet their needs, and be respectful of them and their needs (Marshall, Kitson, & Zeitz, 2012). By extension, we can assume that the idea of patient-centered outcomes research is also unfamiliar to most patients, who, with the growing emphasis on PCOR, are being asked, if not expected, to participate in research projects in ways very dissimilar to those of the past.

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The absence of a shared understanding of patient centeredness among health professionals, researchers, and patient stakeholders is particularly noticeable in the aims, methods, and outcomes of many research projects (Chafe, Born, Slutsky, & Laupacis, 2011). Research, and perhaps especially research funded by the National Institutes of Health, has at times failed to include the measurement of clinical outcomes that matter most to patients, caregivers, and clinicians. For example, in a recent systematic review of the literature aimed at defining current patient-focused management issues and outcomes in asthma control and identifying emerging treatments related to patient outcomes and perspectives, the authors concluded that little agreement existed between physicians and patients regarding patients' needs, beliefs, and expectations about asthma (Qamar, Pappalardo, Arora, & Press, 2011). Thus, whereas researchers and clinicians may be most interested in markers of asthma control, health care utilization, and costs, parents report concerns about the use, safety, and long-term complications of asthma medications, the impact of limitation of exercise on their child's quality of life, and their own quality of life (Mansour, Lanphear, & DeWitt, 2000).

The establishment of PCORI may help close the gap between researchers, clinicians, and patients. For example, PCORI has defined PCOR as research that helps patients and their caregivers communicate with health care providers, make informed health care decisions, and contribute to the dialogue about what the important health care options are (PCORI, 2012). From this perspective, PCOR is research that addresses clarity around what patients and their caregivers should expect from health care. PCOR also is research that explores benefits and harms of various treatment options, tests strategies for improving outcomes important to patients and their caregivers, and investigates ways to enhance patient decision making about their health and health care (http://www.pcori.org/research-we-support/pcor/).

> …the PCORI has mandated that patients and caregivers, as well as other stakeholders including clinicians, health care institutions, payers, policy makers, and others in the broader health care community, provide guidance regarding the research that the institute funds.

A NEW RESEARCH PARADIGM

It is our view that PCORI will help shift the current research paradigm from one that is researcher centered to one that is patient centered. The PCORI has specified that research priorities are those that address prevention, diagnosis, and treatment of patient-centered health concerns, improve health care systems, enhance the communication and dissemination of research findings, address health disparities, and/or develop PCOR methods. These priorities may seem similar to those of other funders, but the implementation of PCOR studies addressing these priorities is markedly different because of the inclusion of the patient not just as