

FROM THE SOCIETY: PART II

PCORI Sessions at the 2015 Annual Meeting in Toronto

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The Patient-Centered Outcomes Research Institute (PCORI) aims to teach clinicians and clinician-educators about the process and opportunities within their research networks and foster a climate that allows key community stakeholders greater participation at all stages of research. SGIM members represent important stakeholders in this process, so sessions were held at last year's annual meeting to address patient-centered outcomes research (PCOR) topics for clinicians, clinician-educators, and researchers.

Pragmatic and Patient Centered

In addition to focusing on trials that are patient centered, PCORI is interested in funding pragmatic trials. Although clinical trials remain the gold standard in conducting research, they only come in two flavors: explanatory and pragmatic. Most studies conducted today remain explanatory, which means they test an intervention under ideal circumstances. Pragmatic studies, on the other hand, test interventions in real-world settings. As a result, pragmatic trials have greater generalizability and are more likely to be successfully disseminated.

Our session, "Pragmatic and Patient-Centered: Clinical Trials Done Differently," featured three clinician-investigators, a patient partner, and a PCORI program officer. The purpose of the session was to discuss three different approaches, as demonstrated by the projects presented, to designing and conducting a trial that is pragmatic and patient centered. Speakers discussed successes and challenges to engaging patients and stakeholders in all aspects of research and in how to

successfully develop stakeholder relationships. Time was allotted for questions and answers to discuss attendees' experiences with and questions about patient-centered research and pragmatic studies. Key insights are presented below:

- Cynthia Chuang, MD, MSc, Penn State College of Medicine, discussed the MyNewOptions Study, a PCORI-funded trial to reduce unintended pregnancies through an online reproductive life planning tool. She discussed the impact her patient partners and community advisory board had in improving her research design during the early phases of the study.
- Elizabeth Jacobs, MD, MAPP, University of Wisconsin School of Medicine and Public Health, shared her PCORI-funded study Peer-to-Peer Support to Promote Aging in Place. She described some of the challenges of conducting a patient-centered trial in multiple locations and how stakeholders played an important role in shaping her trial.
- Stephen Hwang, MD, MPH, University of Toronto, discussed the At Home/Chez Soi Study. This randomized controlled trial of scattered-site housing focused on mental health supports for individuals who were homeless and had mental illness. He brought with him Ms. Susan Gapka, a dedicated campaigner for social justice, who served as a People with Lived Experience Advisory Member to the study. Ms. Gapka described how she was able to work with investigators in ensuring the

study remained patient centered throughout the trial.

- Diane Bild, MD, MPH, senior program officer in the Clinical Effectiveness Research Program at PCORI, discussed how PCORI funding differs from other funding mechanisms. She also described the different funding mechanisms within PCORI, including those focused on improving PCOR methodologies; health care systems; communication and dissemination; assessment of prevention, diagnosis, and treatment options; and addressing disparities. She also mentioned a call for large pragmatic clinical trials (i.e. funding five-year studies for up to \$10 million).

Incorporating PCOR to Develop Learning Health Care Systems

PCORI was established by Congress in 2010 to close the gaps in evidence needed to improve key health outcomes, identify critical research questions, fund patient-centered comparative effectiveness research, and disseminate those results. PCORI articulated five national priorities: 1) assessment of prevention, diagnosis, and treatment options; 2) improving health care systems; 3) addressing disparities; 4) communication and dissemination research; and 5) accelerating patient-centered outcomes research. All research programs ideally adhere to best practices in the planning, design, and conduct of every research project for the findings to be reliable and worthy of adoption.

The PCORI Methodology Report provides baseline requirements and
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a framework for those best practices. The report includes vignettes that illustrate different ways in which good study methodology makes a difference to patients and their care. These include stories of patients' experiences navigating choices and weighing options and examples of published studies that capture the impact of good methodology.

PCORI criteria for funding includes:

- *Patient centeredness.* Is the proposed research focused on questions and outcomes of specific interest to patients, their caregivers, and clinicians?
- *Burden.* Is the condition or disease associated with a significant health burden in the US population?
- *Potential for improving health care practice.* What is the likelihood that this research will change clinical practice or clinical decision making?
- *Timeliness.* Are potential projects associated with this topic likely to be accomplishable within a three-to-five year time frame? Would new information generated by research be likely to have an impact in practice?

Systems, not just individual providers, need to listen, learn, and improve, too. PCORI is seeking applications to study the comparative effectiveness of alternate features of health care systems, innovative technologies, incentive structures, and service designs that optimize the quality, outcomes, and/or efficiency of care. Health care systems may encompass national, state, and local health environments; organization and/or practice settings; family

and social supports; and the individual patient.

Most hospitals and health systems focus on patient engagement because of their mission to deliver high-value care despite potentially negative economic consequences. For many, the goal is to get meaningful reports of performance at an individual physician or patient level segmented by shift or day of week. These reports are being used by hospitals and physician groups who know that they need to meet patients' needs in order to maintain market share. Regardless of how contracts will look a few years from now, if health care providers do not have patients, they will not be successful.

A "Health Literate Care Model," which endorses health literacy as a cultural value modeled by leadership and integrated into all aspects of planning and operations, has been proposed. To succeed, organizations must build longitudinal partnerships with patients and community partners to drive ongoing management of chronic conditions and utilization of preventive care services and to improve long-term quality and cost outcomes. Encouraging patients' participation in decision making through simple interventions can potentially help patients become more engaged and informed. Clinical information systems provide real-time reminders about needed services during patient visits, help track care delivered to different populations, and assist with planning future care. Community partners encourage patients to connect with resources in their communities as well as offer insights into the social determinants of health and health literacy.¹

PCORNet Big Data Studies

The PCORNet Big Data Studies session, led by Joan Neuner, MD, and featuring Gary Rosenthal, MD, Cynthia Chuang, MD, and patient researcher Jim Uhrig, PhD, provided an introduction to PCORNet focused on the clinician and clinician-educator wishing to get more involved in research. The session began with an introduction to PCORNet, the national Patient-centered Clinical Research Network, and covered the PCORI vision to improve upon weaknesses of research that is too "slow, expensive, and unreliable," doesn't answer questions that matter most to patients, and is unattractive to clinicians and administrators. PCORNet initially funded 29 clinical data research networks and patient-powered research networks and now has representation in every US state. The session then focused on examples from PCORNet sites, with Dr. Chuang outlining how her PaTH Network has been working to engage patients in their research. Dr. Joan Neuner presented information about the Greater Plains Collaborative extending from Minnesota to Texas and led by the University of Kansas and University of Iowa. She discussed the collaborative process involved in working with 11 institutions to develop a study of breast cancer patients in the Greater Plains Collaborative. Dr. Uhrig, a patient researcher in PaTH, presented his experience with interstitial pulmonary fibrosis and his perceptions of how patients can help focus research questions. Finally, Dr. Rosenthal outlined opportunities for clinicians to become involved in research, discussing both the intellectual and practical challenges in doing so and calling for creative solutions such as relative value

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unit (RVU) credit from academic institutions for clinicians who enroll patients in research.

Patient Engagement

Patient participation is the cornerstone of PCOR and its focus on improving health care. It is critical that patients and other key stakeholders are integrated into the planning of studies, how the protocols are carried out, and the analysis and dissemination of study results. The PCORI engagement principles are founded in reciprocal relationships, co-learning, trust, transparency, and honesty and are the framework for patient engagement in research.

Our patient engagement workshop at the SGIM annual meeting in Toronto highlighted the benefits, challenges, and rewards of engaging patients in research. The session focused on patient participation from both the perspective of the patients/family members and from researchers to emphasize the necessity of relationship building and trust.

- Clarissa Hoover of FamilyVoices shared her experiences as a family caregiver to highlight the essential nature of fostering relationships where safety is assured and vulnerability is

supported by the entire team.

Empowering patients and family members to ask questions, to be respected as different but equally important, and to be involved in the decision-making process was emphasized in her discussion.

- Dawnmarie Harriot of Working for Change described the necessity of getting the right people onto the team and recognizing and addressing pitfalls and external challenges as a caucus. She underscored the benefits of working with people with lived experience as a means to both improve the research question and the potential outcomes.
- Jeffrey Whittle, MD, MPH, Medical College of Wisconsin, described his unique experiences working with Veteran's service organizations to recruit and engage patients in mental health research. Dr. Whittle emphasized the need to develop personal contacts, to learn about and accept organizational culture, and to recognize that the institutional review board and other academic "expectations" may not be widely understood or recognized by the community.
- Jennifer Thomas from the Institute for Educational Leader-

ship described her unique experiences as both a patient and advocate working with youth on development and leadership. She noted that young people frequently need additional support, that access needs to be viewed with an open lens, that patient participation may need to include monetary support, and that the patient voice is key for engagement.

- Our session was concluded by Shivonne Laird, PhD, MPH, program officer for the Eugene Washington PCORI Engagement Awards Program. Dr. Laird described PCORI goals and process while highlighting recently funded projects. She closed the loop by discussing and reinforcing fundamental themes raised by speakers when describing their experiences and research activities.

Reference

1. Koh HK, Brach C, Harris LM, Parchman MC. A proposed 'health literate care model' would constitute a systems approach to improving patients' engagement in care. *Health Affairs* 2013; 32(2):357-67.

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