

A NOVEL STAKEHOLDER ENGAGEMENT APPROACH FOR PATIENT-CENTERED OUTCOMES RESEARCHⁱ

Katherine K. Kim, PhD, MPH, MBA
Assistant Professor
Betty Irene Moore School of Nursing
University of California Davis
Sacramento, CA

Background: The engagement of patients and others stakeholders is a critical element in the design of patient-centered outcomes research (PCOR) studies. The Patient-Centered Outcomes Research Institute (PCORI) puts forth four principles of patient and stakeholder engagement: 1) reciprocal relationships—clear roles and decision making; 2) co-learning—understanding by researchers and stakeholders of research process and patient-centeredness; 3) trust, transparency, and honesty—inclusive and honest communication; and 4) partnership—valued time and contributions. However, methodology for patient and stakeholder engagement in research governance is in a nascent stage of development. Research governance includes both the operationalization of network policies and the determination of research priorities. The objective of this study was to develop a methodology for a PCOR-based, purposefully-designed, research governance approach which was demonstrated in pSCANNER: patient-centered SCALable National Network for Effectiveness Research, a stakeholder-governed, distributed clinical data research network of 21 million patients.

Methods: PCORI engagement principles were applied to the development of network policies and determination of research priorities. Stakeholders were engaged in groups via conference calls and online focus groups, as well as one-on-one follow up calls. Three primary venues for engagement were developed: 1) stakeholder advisory boards (SABs) that were involved in planning and development the governance activities and refining policies; 2) stakeholder research prioritization expert panels that set research priorities using an online, modified Delphi method, a deliberative and iterative approach to attaining consensus with discussion and statistical feedback. The panels consisted of patients, clinicians and researchers in three conditions: weight management/obesity (WMO), heart failure (HF), and Kawasaki disease (KD); and 3) a stakeholder engagement team of staff who implemented the activities.

Results: 46 unique stakeholders comprised of 20 patients/patient advocates and 26 clinicians were engaged in the SABs, supported by a stakeholder engagement team of 11 PIs and staff at varying times during the study. Each principle was manifested in several ways including policy documents, flexible logistical arrangements, educational materials, open decision-making processes, rigorous and transparent determination of research priorities, and equitable compensation for participation.

Implications: Advantages of designing research governance activities with attention to PCOR principles include potential for meaningful participation of patients, and interaction among diverse stakeholders who might not typically work together. This study represents one of the first to demonstrate PCOR-principled, purposefully-designed, approach for research governance that may serve as a model for other researchers interested in research networks and patient-centered outcomes research.

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