

Attn: PCORI Input

Patient-Centered Outcomes Research Institute
1701 Pennsylvania Avenue, NW, Suite 300
Washington, DC 20006

March 15, 2012

Re: PCORI's National Priorities for Research and Research Agenda

On behalf of the Improvement Science Research Network (ISRN), I am pleased to submit these comments on the Patient-Centered Outcomes Research Institute's *Draft National Priorities for Research and Research Agenda, Version 1*. The ISRN is a one of its kind, hospital-based research network, funded by the National Institutes of Health, which is focused on improvement science. The primary mission of the ISRN is to advance the scientific foundation for quality improvement, safety and efficiency through transdisciplinary research addressing healthcare systems, patient-centeredness, and integration of evidence into practice (www.ISRN.net). With over 200 individuals and organization members, the ISRN focuses on improving quality and safety of patient care through the conduct of multisite healthcare quality improvement research. All projects conducted within the ISRN are centered on four stakeholder-generated priorities in this field including coordination and transitions of care, evidence-based quality improvement and best practice, high performing clinical microsystems and microsystem approaches to improvement, and learning organizations and culture of quality and safety

Following the ISRN's strategic planning to build a supporting infrastructure, an early target was set to establish a consensus on high-priority research, development processes, and evaluation needs to guide the field of improvement science. Since the ISRN aims to promote a national program of research to advance what is known about improvement strategies, it was deemed essential to identify high priority research as part of the early stages of the infrastructure development. The ISRN believes that, by making substantial progress in these high priority areas over the next 3 to 5 years it will contribute significantly to field of improvement science in order to improve patient outcomes.

The Improvement Science Research Networks Comments consist of two sections: (1) General comments that address the overall vision and intent of the PCORI National Research Priorities; (2) A comparison and contract to the research priorities established by the ISRN; (3) General comments on the content within the research agenda; and, (4) Concluding remarks.

General Comments

In general, the priorities stress the need for patient centered research; we urge you to sharpen the focus of the study of patient outcomes through T3 and T4 research focusing on contextual variables at the system, microsystem, and patient level that affects the implementation and sustainment of evidence-based interventions. For example, a clear limitation of disease-specific

research is the lack of patient input and perspective in the delivery of care. The patient, as a consumer, is a valuable stakeholder that should be included in research aimed at redesigning care to be truly patient-centered.

As a whole, the five priorities identified in this draft will yield the evidential base that providers, patients and stakeholders need to improve the quality and safety of patient care. PCORI's five priorities parallel the four ISRN National Research Priorities, which will be discussed below in more detail.

The ISRN supports PCORI and endorses the consensus building used to draft the proposed research priorities and bring together organizations that represent key stakeholders in patient centered research. Patient centered research resonates with the ISRN and the proposed research agenda aligns with the ISRN's mission and national priorities.

The ISRN's programs of research focus on **T3-T4 research, translating evidence into practice and to the community**. If PCORI is able to support research that transcends the entire translational science continuum, outcomes can be translated to the population (patient, families, caregivers and provider) for improved quality of patient care.

The ISRN supports the priority to improve diagnostic and treatment options for patients and improve overall prevention, screening and monitoring of conditions. This priority, if studied to its full capability, has the potential to help improve overall satisfaction and quality of life for a large population in the US.

The ISRN emphatically supports the priority to improve healthcare systems. Explicitly stated in our mission, the ISRN aims to advance the scientific foundation for improving quality, safety and efficiency in addressing healthcare systems. In fact, the ISRN's first three landmark network studies are centered on healthcare systems and the respective microsystems within the hospital setting. The first study, [Small Trouble, Adaptive Responses \(STAR-2\): Frontline Nurse Engagement in Quality Improvement](#) aims to examine the types and frequency of first order operational failures that nurses detect during their work shifts. This study is currently being conducted over 14 hospitals across the country, engaging approximately 850 nurses over 20 days to self-detect operational failures that prevent them from providing timely patient care. Other studies include the [impact of cognitive load on medication administration errors](#) across 10 hospitals distributed nationally using trained observers to follow nurses and document 840 medication administrations focusing on interruptions, distractions and procedural failures during medication administration. The third study incorporates the Department of Defense designed [TeamSTEPPS protocol](#), implementing evidence-based systems improvements in teamwork and communication skills among members of the health care team to improvement patient outcomes.

Implementation, dissemination, and sustainment of evidence-based improvements fit well within T3 and T4 research. Translation of evidence to the provider and community requires efforts from both the funding organization and the researcher. Additionally, this process involves dissemination of evidence-based best practices to improve decision by both the provider and patient. Research that compares the effectiveness of dissemination strategies is warranted. The ISRN supports the efforts to disseminate study results to not only providers and patients, but also caregivers and all stakeholders.

The ISRN supports the priority of addressing healthcare disparities. As indicated, disparities persist in this country based on race/ethnicity, gender, location, socio-economic status and many other factors that are yet to be studied. By prioritizing research to address health disparities, these obstacles can be overcome.

The ISRN applauds PCORI for the priority on research methodology. Not only is the study of PCOR important, but the methodology used in this study is of utmost importance. Transdisciplinary methodologies that are centered on comparative-effectiveness need to be better integrated within PCOR as the standard randomized control trial has shown to be ineffective in most studies. Previous reports indicate that a moratorium be placed on RCTs and alternative methodologies, such as stepped-wedge or orthogonal design, be embedded into research design to increase the generalizability of results specific to healthcare systems and minimize confounding variables that vary from hospital to hospital and patient to patient.

The ISRN has a centralized focus on research methodologies through its annual conferences, the Improvement Science Summit. As a research methods conference, the [Improvement Science Summit](#) builds the science foundation for improving healthcare. This conference has provided attendees the resources needed to study improvement strategies centered around the priorities on improvement science.

The ISRN also has developed a research infrastructure that may prove to be beneficial to PCOR through the **Improvement Science Research Network Coordinating Center**. In the Coordinating Center, there is a team of PhD level researchers and support staff that have developed electronic data capturing systems, an administrative core and a research core to conduct multisite, hospital based, projects. The data capturing system was designed as an expandable database is available for secondary analysis.

Comparison and Contrast to the Research Priorities of the ISRN

The ISRN used consensus building to identify a national set of research priorities. A number of sources were used for this process including environmental scans of major concerns in healthcare, reviews of professional and scientific literature, research priorities for quality and patient safety established by other entities (e.g., World Health Organization), a targeted stakeholder survey, and a RAND Delphi process with the ISRN Steering Council (members of which represented a wide array of stakeholders). Multiple points of information and multiple iterations of consensus building were used to assure that the Research Priorities merit high attention.

The ISRN commends PCORI for focusing the priority on improving healthcare systems, to non-physician healthcare providers, specifically nurses. Nurses are the frontline in quality care within the acute care setting. It is often the case, particularly in the hospital setting, that services, resources and decision making are tailored around the physician; however, when analyzing the time spent engaging in patient care, it is the nurses that spend more time in delivering patient care. Furthermore, allocation of resources (space, people, and time) within hospital units is the responsibility of the nurse administrator. To not include nursing in PCOR would be an absolute weakness and the ISRN supports PCORI prioritizing the use of nurses in patient centered research. The following ISRN Research Priorities align closely with the PCORI priority on improving healthcare systems.

A. COORDINATION AND TRANSITIONS OF CARE—this category emphasizes strategies for care improvement to care processes in specific clinical conditions. At this time, care coordination and transitions of care are the key clinical focus.

Priority topics for the ISRN are (1) to evaluate strategies and methods to assure coordination and continuity of care across transitions in given clinical populations and (2) test and refine methods of handoffs and other strategies to assure safe, effective, and efficient transitions in given clinical populations.

B. HIGH-PERFORMING CLINICAL SYSTEMS AND MICROSYSTEMS APPROACHES TO IMPROVEMENT—this category emphasizes structure and process in clinical care and healthcare as complex adaptive systems.

Priority topics for the ISRN are (1) determine effectiveness and efficiency of various methods and models for integrating and sustaining best practices in improving care processes and patient outcomes; (2) investigate strategies to engage frontline providers in improving quality and patient safety. Evaluate strategies for preventing targeted patient safety incidents; and, (3) Establish reliable quality indicators to measure impact of improvement and isolate nursing care impact on outcomes.

Though the ISRN is focused on hospital quality and safety, the remaining priorities transcends the spectrum of healthcare and closely aligns with the five priorities proposed by PCORI. By incorporating evidence-based quality improvement and best practices and establishing the healthcare system as a learning organization focused on culture of quality and safety, each of the 5 priorities described by PCORI will be elevated to make the substantial improvement in patient centered care that is intended by this institute.

C. EVIDENCE-BASED QUALITY IMPROVEMENT AND BEST PRACTICE—this category emphasizes closing the gap between knowledge and practice through transforming knowledge and designating and implementing best practices.

Priority topics include (1) evaluate strategies and impact of employing evidence-based practice in clinical care for process and outcomes improvement; (2) determine gaps and bridge gaps between knowledge and practice; (3) transform evidence for practice through conducting systematic reviews, developing practice guidelines, and integrating practice into clinical decision-making; and, (4) develop new research methods in evidence-based quality improvement, including comparative effectiveness research and practice-based evidence.

D. LEARNING ORGANIZATIONS AND CULTURE OF QUALITY AND SAFETY—this category emphasizes human factors and other aspects of a system related to organizational culture and commitment to quality and safety.

Priority topics include (1) investigate strategies for creating organizational environments, processes that support cultures fully linked to maintaining quality, and patient safety in order to maximize patient outcomes and (2) determine effective approaches to developing organizational climates for change, innovation, and organizational learning.

General Comments on Content

When referring to the “patient,” it is important not to forget the extension of the patient that includes the family and caregivers. So many times, the family and caregivers are forgotten in the patient centeredness. Healthcare is a team effort and the healthcare system has not done a good job in keeping the patient centered in the healthcare team. To not include the patient’s family and caregivers in PCOR would result in a large gap in learning the effectiveness of PCOR.

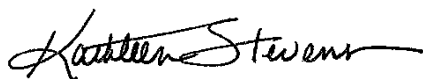
The nine organization represented on page 8 include leaders in PCOR and its understandable that it took great efforts to organize them to receive public input on comparative effectiveness research. Also, it is evident that a great deal of effort was put forth to identify the ten CER priority areas from existing literature as indicated on page 9. What is not evident is the role of patient advocacy groups in the preparation of PCORI research priorities. Again, this is an example of how the patient is forgotten in the healthcare team. In future iterations, it would be advantageous to have patient and caregiver advocates on board when revising the PCOR priorities.

Communication and dissemination research are referenced in two different ways on pages 4, 10 and 18. Page 4 refers to this as simply “Communication and Dissemination” while pages 10 and 18 refer to this as “Communication and Dissemination Research.” Literal readings of the two lead to two different conclusions: communication versus research on communication.

Concluding Remarks

The Improvement Science Research Network appreciated the opportunity to comment on the Patient-Centered outcomes Research Institute’s Research Agenda. We as network stand ready to assist in any way possible and support your efforts in forming a consensus on care that centers on the patient. The field of healthcare is a complex adaptive system that is continuously changing and efforts made through the research supported by PCORI will likely help lead the way in improving the quality of patient centered care. We look forward to future collaborations with PCORI and I welcome you to contact me if you have any questions you may have.

...to the best of our knowledge,



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