

Patient-centered outcomes research and the injured patient: a summary of application

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SUMMARY

As trauma surgeons, we focus on the immediate care and needs of the injured patient every day. Historically, trauma and injury research has focused on outcomes such as mortality, complications, and length of stay; and process metrics such as time to CT scan, resuscitation checklist frequencies, or venous thromboembolism prophylaxis rates. These outcomes are perceived by healthcare providers to be important, but patients likely have different perceptions of what outcomes are most important to measure and improve. True patient-centered outcomes research involves the healthcare providers, and the entire team of stakeholders including patients and the community. Understanding the process of stakeholder engagement and the barriers trauma researchers must overcome to effectively enter this field of research is important. This summary aims to inform the trauma research community on the basics of patient-centered outcomes research, priorities for funding from the Patient-Centered Outcomes Research Institute, resources for collaboration around patient-centered outcomes research, and a unique career development and training opportunity for early career trauma surgeons to develop a skill set in patient-centered outcomes research.

INTRODUCTION

'Why are we doing research and what are we hoping to accomplish?' Many researchers would answer this question with a response related to impact. Impact can be measured in multiple ways, one of which is by measuring through the eyes of patients and community stakeholders the outcomes that *they* perceive to be most relevant. This principle is central to doing research that is patient centered. The intent of this review is to discuss patient-centered outcomes research, inform the trauma community about the stakeholders involved in this process, and outline the funding priorities and trauma-related research activities of the Patient-Centered Outcomes Research Institute (PCORI). The following is a summary of innovative patient-centered approaches to trauma and injury research.

The topics to be discussed include:

- ▶ Approaching evidence strategically.
- ▶ PCORI 101: Patient-Centeredness, Stakeholder Engagement.
- ▶ The Transitional Care Evidence to Action Network (TC-E2AN).
- ▶ The PCORI K12 Mentored Career Development Program.

APPROACHING EVIDENCE STRATEGICALLY

Impactful research must be 'implementable'. Programs and interventions that cannot be implemented in real-world settings will not successfully change practice or generate any impact on people's health or lives. Traditional research produces facts and makes recommendations, but often the recommendations lack alignment with patient priorities or are too costly or restrictive to be practically implemented. Patient-centered outcomes research aims to move the design for effective implementation and dissemination of processes and policies upstream in the research development by engaging stakeholders and focusing on outcomes and processes that are prioritized by individuals impacted the most. Clinicians and researchers sit at the intersection of research and policy. It is therefore important to think strategically about making research actionable. To accomplish this, there are multiple facets to consider for the target population; including but not limited to their background, languages spoken, cultural beliefs, religion, and literacy. It is also important to consider the resources available for access to care, transportation, medications, supplies, and social support. In addition, establishing connections with local stakeholders, community leaders, and patients is needed to ensure the research is applicable and relevant.

An example of strategic thinking in interventional design is the 'Coleman Care Transitions Intervention'—one of the most widely disseminated transitional care interventions in practice. This intervention was designed and implemented by Eric Coleman to help improve care for older adults with multiple chronic illnesses by decreasing readmission rates and medication errors that resulted from fragmentation of care.¹ The ultimate goal of this intervention was to improve patient care and to decrease stress on the patient as well as the healthcare system. To achieve impacts within the stakeholder population to which the intervention would apply, these stakeholders were engaged early in the design process. Stakeholders included patients, payers, and policymakers. Unlike traditional research, the goal was to design a study resulting in a policy and procedure in process by the close of the study. One of the tools created assesses hospital-level performance in transitions of care at discharge through a patient survey about how well they felt prepared to care for themselves at home. This has been made part of Hospital Consumer Assessment of Healthcare Providers and Systems.² The development of this intervention illustrates the importance

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Box 1 Patient-Centered Outcomes Research Institute strategic goals

- ▶ Increase quantity, quality, and timeliness of useful, trustworthy research information available to support health decisions.
- ▶ Speed the implementation and use of patient-centered outcomes research evidence.
- ▶ Influence research funded by others to be more patient centered.

of collaboration with stakeholders to ensure the intervention provides value to all parties with meaningful outcomes.

PCORI 101: PATIENT-CENTEREDNESS STAKEHOLDER ENGAGEMENT

In 2010, the US Congress authorized PCORI as an independent research institute focusing on patient and stakeholder engagement to improve healthcare delivery and patient outcomes, and to help patients make *informed* healthcare decisions.³ The mission of PCORI is to help people, ‘make informed healthcare decisions, and improve 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’.³ It is governed by a 21-member Board of Governors that is representative of the healthcare community, with an overarching goal of focusing on impact on care rather than pure generation of knowledge (box 1).⁴ PCORI funds Comparative Clinical Effectiveness Research, categorized into five priority domains, with the ultimate goal to better inform patients to make healthcare decisions (box 2).⁴ Patient-centered outcomes research engages patients and other stakeholders throughout the research process, seeking to answer real-world questions about what works best for patients based on their circumstances and concerns. Patient and stakeholder engagement up front facilitates design of processes and interventions that minimize barriers to implementation and are more likely to have impact. Understanding who the key stakeholders are is paramount in the engagement process. These stakeholders can include a broad range of individuals—payers, clinicians, caregivers, family members, purchasers, policymakers, industry training institutions, patients, caregiver advocacy organizations, hospitals, and health systems. Patient-centered outcomes research requires engagement with all of these stakeholders as ambassadors in collaboration with scientists.

Patient-centered outcomes research projects are evaluated using a number of factors when being considered for funding from PCORI. Of primary importance is stakeholder engagement and impact. The study needs to have the potential to fill critical gaps that address stakeholder needs and generate actionable evidence

Box 2 Patient-Centered Outcomes Research Institute (PCORI) research priority domains

- ▶ Assessment of prevention, diagnosis, and treatment options.
- ▶ Improving healthcare systems.
- ▶ Communication and dissemination research.
- ▶ Addressing disparities.
- ▶ Accelerating patient-centered outcomes research and methodological research.

to help patients make healthcare decisions. A project cannot be too complex or too expensive for real-world delivery systems. In terms of comparative clinical effectiveness research, consider the example of transitional care, where hospital versus community-based transitional care is compared. Which one works better for whom and when? In this example, the patient, clinician, and family all assess the data according to their perspective on need for transitions of care, and each party describes which approach will work better for them and for what reason(s). It is necessary to take into account the perspective of each of these groups to have a product that is practical and implementable for all parties: patient, caregiver and provider. These types of questions require large study populations to be properly powered to address the heterogeneity of treatment effect via subgroup analyses.

A number of additional factors are evaluated in prioritizing funding decisions. A study must have the potential to be adopted into clinical practice and to improve delivery of care and patient outcomes. In addition to practicality, scientific merit of the study design is evaluated to ensure that the research is valid and sufficient to meet the study goals. Scientific merit is often evaluated in traditional research designs. Rather than focusing solely on traditional, highly controlled experimental studies, PCORI has funded a number of patient-centered research designs, including pragmatic trials, natural experiments, and adaptive trials with novel designs—all of which are highly focused on patient-centered outcomes. A patient-centered research design looks at a set of outcomes and what those outcomes mean to the patients as stakeholders, as the metrics of what the different stakeholders care about may diverge. This potentially makes the outcomes different for each participant, but focusing on the convergence of these differences facilitates implementable research. Patient-centered research requires a final criterion unique to PCORI—patient and stakeholder engagement as partners throughout the entire process, from study design through dissemination and implementation. This final and unique criterion is often sufficient alone to compete for PCORI funding, as the Institute funds engagement awards that train investigators and study teams how to develop or better form these communities needed to complete community engagement and patient-centered outcomes research.

TRANSITIONAL CARE RESEARCH AND THE TC-E2AN

Transitional care research is one of the most widely funded types of patient-centered outcomes research, and focuses on encounters, time points, or transitions between different care settings or between different clinicians. Examples of this include discharge from the hospital to home, to a nursing facility then to home, or home into a primary care or follow-up clinic, or back into an acute care facility. Factors impacting transitions in care can negatively impact patients and lead to harm. Patients can become overwhelmed and vulnerable to adverse outcomes, unnecessary readmissions or use of hospital-based resources, medication errors, and poor quality of life during these transitions, particularly if they have multiple comorbidities or require follow-up with more than one specialist after hospital discharge. PCORI has a particular interest in research investigating which approaches are optimal for improving transitional care. Since it launched the TC-E2AN in 2015, PCORI has invested \$120 million in 26 projects that address differing approaches to optimizing transitional care across a diverse set of disease processes and populations.⁵

Recognizing common themes across disease processes and populations that emerged from these transitional care projects, the PCORI TC-E2AN was developed in 2015 to foster collaboration and discussion about best practices and shared

Table 1 Current Transitional Care Evidence to Action Network trauma-related projects

Project name	Principal investigator, institution—location
Improving Transition from Acute to Post-Acute Care Following Traumatic Brain Injury—The BRITE Study	Jeanne Hoffman, PhD, University of Washington—WA
A Patient-Centered Approach to Successful Community Transition After Catastrophic Injury	Michael Jones, PhD, Shepherd Center—GA
A Comparative Effectiveness Trial of an Information Technology Enhanced Peer-Integrated Collaborative Care Intervention for US Trauma Care Systems	Douglas F Zatzick, MD, University of Washington—WA
Does Care Management Help Patients Recover from a Serious Injury?	Douglas F Zatzick, MD, University of Washington—WA

<https://www.pcori.org/topics/transitional-care/network>

lessons learnt. The projects TC-E2AN focuses on are all related to patient-centered research on transitional care—specifically aimed to reduce readmissions, improve patient experience, and meet the needs prioritized by stakeholders. Funded projects across the network currently focus on cardiovascular disease, chronic obstructive pulmonary disease, kidney disease, mental health, sickle cell disease, medically complex patients, and trauma/injury.⁵

Four of currently funded TC-E2AN projects focus on trauma and injury. All of these studies specifically address high-risk trauma patients who are particularly vulnerable during transitions in care (table 1).⁵ The topics of these studies include care transitions after

spinal cord injury and traumatic brain injury. In addition, they are evaluating the impact that different resources—such as case managers or constant cellphone access to a care team—have on mental health and well-being after discharge.⁵ These studies, in combination with those projects related to other disease processes, can provide insight into ongoing comparative effectiveness research in the trauma community to improve patient-centered outcomes after injury—particularly around aspects of transitional care that focus on patient-centeredness, patient experience, and complex systems of care.

Box 3 Learning Health Systems Centers of Excellence, K12 grant recipients

- ▶ Northwestern University*
- ▶ Kaiser Permanente Washington Health Research Institute
- ▶ Vanderbilt University*
- ▶ Indiana University School of Medicine*
- ▶ University of Minnesota*
- ▶ Oregon Health and Science University*
- ▶ Children's Hospital of Philadelphia*
- ▶ University of California Los Angeles*
- ▶ Albert Einstein College of Medicine*
- ▶ University of Pennsylvania*
- ▶ University of California San Francisco*

<https://www.pcori.org/news-release/ahrq-and-pcori-announce-awards-support-next-generation-learning-health-system>

*Institutions associated with American College of Surgeons-verified trauma centers.

THE AHRQ/PCORI K12 MENTORED CAREER DEVELOPMENT PROGRAM

Recognizing a lack of training and career development opportunities that focus on patient-centered research, AHRQ and PCORI jointly announced funding for K12 Mentored Career Development Awards in 2018 to train emerging Learning Health Systems (LHS) Researchers. A Learning Health Researcher is defined as an individual who is embedded within a health system and collaborates with its stakeholders to produce novel insights and evidence that can be rapidly implemented to improve the outcomes of individuals and populations, as well as health system performance.⁶ These K12 Mentored Career Development Awards, which total \$40 million over 5 years across 11 institutions, are designed to establish LHS Centers of Excellence and to train the next generation of clinical and research scientists to conduct patient-centered outcomes research within these LHS centers. This workforce training initiative focuses on developing skill sets such as stakeholder engagement, embedded research, implementation science, pragmatic trials, adaptive designs, and hybrid trials. By embedding research into LHS centers and healthcare delivery systems, these programs will facilitate research that will become impactful more quickly.

In the first year, 40 trainees were funded. The plan is to fund a total of 92 scholars in the first 5 years. Each institution receives \$800 000 for each project and is required to train half of their awardees from external centers. Projects incorporate PCORI methodology standards and are required to address how patient-centeredness, engagement, and health disparities will be incorporated in the training plans. Ten of the 11 sites are university based and are affiliated with American College of Surgeons (ACS)-verified trauma centers or pediatric trauma centers (box 3),⁷ and could potentially facilitate integration of LHS approaches to trauma patients and systems.

SUMMARY

Patient-centered outcomes research is a unique study approach that uses stakeholder engagement to define and improve processes and outcomes in a meaningful way. To conduct research in this domain, investigators need to consider a unique set of criteria and approaches that incorporate patient engagement, implementable programs, scientifically valid patient-centered research designs, and community engagement throughout the entire research process. Investigators have successfully competed for funding from PCORI and completed patient-centered outcomes research related to trauma and injury, particularly centered on care transitions. The TC-E2AN provides a platform for collaboration and idea sharing and includes sites that have successfully completed projects specific to trauma and injury. Mentored Career Development Awards that focus on patient-centered outcomes research exist in universities affiliated with ACS-verified trauma centers and provide infrastructure to train the next generation of trauma and injury researchers with an interest in LHS and patient-centered research.

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