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Patient-centered outcomes research in emergency care: opportunities, challenges and future directions

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Abstract

The Patient-Centered Outcomes Research Institute (PCORI) was established by Congress in 2010 to promote the conduct of research that could better inform patients in making decisions that reflect their desired health outcomes. PCORI has established five national priorities for research around which specific funding opportunities are issued: 1) Assessment of Prevention, Diagnosis and Treatment Options, 2) Improving Healthcare Systems, 3) Communication and Dissemination Research, 4) Addressing Disparities, and 5) Improving Methods for Conducting Patient-Centered Outcomes Research. To date, implementation of patient-centered research in the emergency care setting has been limited, in part because of perceived challenges in meeting PCORI priorities such as the need to focus on a specific disease state or to have planned follow up. We suggest that these same factors that have been seen as challenges to performing patient-centered research within the emergency setting are also potential strengths to be leveraged to conduct PCORI research. This paper explores factors unique to patient-centered emergency care research and highlights specific areas of potential alignment within each PCORI priority.

Introduction

As part of the Patient Protection and Affordable Care Act of 2010, Congress authorized the establishment of the Patient-Centered Outcomes Research Institute (PCORI). In addition to supporting research aimed at advancing science, PCORI has a unique focus of aiming to provide patients, providers and the public with information they need to make decisions that reflect their desired health outcomes.

PCORI's approach to research is fundamentally and radically patient centered. PCORI aims to improve patient care and outcomes through funding patient-centered comparative effectiveness research (CER), a research approach that engages patients, caregivers, and the broader healthcare community throughout the entire research process, from topic and question generation through to planning, conducting, interpreting, and disseminating research findings.

Emergency care, including Emergency Medical Services (EMS) and Emergency Departments (EDs), represents a key intersection with healthcare systems, especially for patients requiring intensive resources. Over 136 million patients seek care annually in America's EDs.¹ The scope of emergency care necessarily involves coordinating systems of care to support the health of the public: matching patients across a region and population with the right health resource at the right time in the right place is vital to a successful emergency care system.

Emergency medicine (EM) is also unique in its committed passion to meet the needs of any patient, regardless of when or where those needs occur. EDs are staffed by a relatively small number of healthcare providers capable of managing a wide range of diseases and care issues. EM is a 24/7 practice that provides a safety net for patients with acute unscheduled health care needs that develop after hours as well as for the uninsured and other vulnerable populations.

PCORI has identified five high priority areas for research as a result of patient and community engagement activities, advisory panels, and consultation with their Board of Governors and Methodology Committee.² These five PCORI National Priorities for Research are included in Table 1, and Table 2 shows examples of recently awarded PCORI contracts within each research priority.

Challenges in Conducting PCOR in the Acute Setting

There are several challenges to conducting patient-centered outcomes research (PCOR) in the emergency setting that have limited its implementation to date. PCOR prioritizes research that focuses on treating a specific disease state, yet patients treated in the ED often lack a clear diagnosis. Additionally, as patients seek acute care on an as-needed basis, instead of regular scheduled appointments as often occurs in the outpatient care setting, there is a lack of defined follow up for many patients. Finally, the substantial racial, ethnic, and socioeconomic diversity of patients and providers in the ED setting, and the need for providers to make cognitively efficient decisions to ensure safety of the entire population of

ED patients seeking care at a given time, pose challenges to communication and delivery of high quality, empathic emergency care.

Despite these challenges, there are several areas of alignment between emergency care delivery and PCORI National Priorities for Research. These areas of alignment deserve attention, as there is significant potential benefit to performing PCOR research with patients and caregivers seeking treatment in the ED or another acute care setting. Patients with undifferentiated diagnoses at the time of presentation to an ED provide a unique opportunity to compare the effectiveness of various diagnostic, treatment, communication, and longitudinal follow-up strategies as well as various approaches to optimize transitions of care. The wide range of patients visiting EDs across the US also provides access to a full, and representative, range of socioeconomic status, race and ethnicity, age, gender, insurance coverage, pre-existing chronic illnesses, and linkage to primary care and subspecialty outpatient systems.

Finally, there are many important treatment decisions and conversations that happen with patients in the acute care setting. Patients may be asked to make life-changing decisions regarding their care over the course of minutes or hours, potentially relying solely on the information that their providers communicate to them during this time period. This discussion requires rapid development of trust between patients, their physician and the healthcare team; it highlights the importance of developing and testing dissemination and communication strategies to best acknowledge patient-important outcomes and to facilitate alignment between patients' values and preferences and their emergency care plan.

In the sections below, we explore specific areas of alignment between emergency care research and each of these five research priorities.

Alignment between Current PCORI National Priorities and Opportunities for Emergency Care Research

1) Assessment of Prevention, Diagnosis and Treatment Options

This research priority is closely aligned with PCORI's stated purpose to "help patients, clinicians, purchasers, and policy makers make better-informed health decisions by 'advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions.' " Proposals within this area are intended to employ CER that is designed to provide information that would inform critical decisions that are currently made in the absence of sound evidence about the comparative effectiveness of at least two alternative approaches. These "alternative approaches" can be diagnostic methods or options, screening, or interventions, and can focus on either prevention or treatment. The efficacy or effectiveness of the alternative strategies must be known, or the comparator must be a generally accepted practice currently occurring despite insufficient evidence supporting its use. Although usual care may be the most relevant comparator in a given study, it must be clearly specified (e.g., guideline-based usual care).

This priority area is broad-based: some PCORI Funding Announcements (PFAs) within the area identify specific clinical services or patient populations, such as the PFA to assess treatment for multiple sclerosis³, while others are more general funding announcements (similar to parent R01s at NIH) that are open to any clinical service or patient population.⁴ For these general PFAs, examples of potential services of interest to compare include but are not limited to: prescription drugs and biologics, surgical or other interventional procedures, techniques for disease screening, vaccinations and other approaches to prevent disease, counseling and behavioral interventions, complementary and integrative services, rehabilitation services, or diagnostic tests and procedures.

There are many areas of potential alignment between emergency care research and this PCORI research priority. Emergency providers assess, diagnose, treat, and make efforts to prevent or limit the sequelae of disease on a daily basis. EMS personnel and emergency clinicians are often the first point of contact for a patient with a potential emergent condition, and serve as the safety net for after-hours care and for a diverse population of patients who may otherwise have limited or no access to health care. This role in the health system allows emergency care researchers to compare the effectiveness of alternative approaches to assess and diagnose potential acute or exacerbations of chronic illness in a diverse population of patients. Although other medical specialties may have ready access to specific cohorts of patients based on the type of specialty care provided (e.g., neurologists caring for patients with multiple sclerosis), emergency care providers are charged with the challenge of rapidly assessing patients with an extensive range of possibly serious or life-threatening illness, making an early diagnosis when possible, and instituting empiric treatment to minimize morbidity and mortality. In fact, the core competencies for emergency medicine are based largely in physicians' ability to properly develop differential diagnoses and assess signs and symptoms of patients rather than treat specific diagnoses.⁵ This emphasis on early and rapid assessment, diagnosis, and treatment of undifferentiated patients is a core aspect of EM and well-positions emergency care researchers to propose impactful CER studies that are well-aligned with this research priority.

2) Improving Health Care Systems

This PCORI priority seeks to “study the comparative effectiveness of alternate features of healthcare systems (e.g., innovative technologies, incentive structures, service designs) intended to optimize the quality, outcomes, and/or efficiency of care for the patients they serve”. Grants funded in this portfolio explore a wide range of care delivery efforts from the patient's perspective including telehealth interventions, home-based health services, and many other innovative shifts in how healthcare gets delivered. This research priority provides an enormous opportunity to define how patients want to receive acute unscheduled care and to test the innovation that is occurring in the healthcare marketplace. There is also synergy within this portfolio with the delivery system reform initiatives that are central to the current Department of Health & Human Services efforts recently outlined by the Secretary of Health.⁶ While emergency care represents only a modest proportion of the delivery system, it has been referred to as the “hub of the enterprise”, as it connects many domains of healthcare delivery. To date, relatively little attention has focused on how emergency care can be better integrated into the evolving healthcare delivery system.⁷

As a result of broader shifts in both the population and in healthcare delivery, there is a growing challenge to manage acute conditions and acute exacerbations of chronic conditions in the US.⁸ Important demographic shifts include both the aging of the population and the growing number of Americans living with multiple chronic conditions. The management of increasingly isolated and medically fragile patients requires that systems be in place in order to manage the predictable exacerbations of their chronic conditions. Healthcare delivery changes include the transition from an inpatient-centered to an outpatient-centered system of care, patient preferences about how and when to receive care, and an overall shift to understanding healthcare to be a consumer good. Indeed, fewer than half of acute care visits are managed by primary care providers, with almost a third managed by emergency physicians (despite the fact that they make up less than 5% of providers).⁹

Patients are confronted with many choices when they are sick, injured, or scared. Tremendous recent growth in urgent care centers, retail clinics, and other nontraditional care settings has both complicated this landscape and created opportunities for patients to match their needs to the resources that best fit them. Much of the focus in this area has been focused on improving value by decreasing cost. This PCORI portfolio represents an important opportunity to include the patient's perspective on what defines high quality acute care, and could perfectly complement the cost-driven agenda currently dominating innovation in this area.

3) Communication and Dissemination Research

This funding priority represents another opportunity for emergency care researchers and practitioners to consider PCOR.¹⁰ PCORI's approach to improving patient centered outcomes through communication and dissemination research can be viewed from two distinct, but overlapping, perspectives. The first perspective stems from the mission to communicate and disseminate the results of comparative effectiveness and PCOR to key stakeholders, namely patients, caregivers and providers. This approach aligns well with the disciplines of implementation and communication sciences. The second perspective seeks to specifically use the tools and methods of comparative effectiveness and PCOR to evaluate the best approaches to communication and dissemination of health information. Both perspectives are woven into PCORI's aim to advance patient centered outcomes by improving communication and dissemination of potential benefits and harms of various diagnostic and therapeutic decisions faced by patients and their care teams.

PCORI emphasizes patients' personal characteristics, conditions and preferences in making informed healthcare choices.¹¹ Often overlooked, however, are the profound influences of the environment where patients and providers communicate with each other. Similarly, the urgency and time sensitive nature of emergency-related clinical conditions is likely to impact the communication of evidence and consequently subsequently impact important patient centered decision-making. Emergency conditions and emergency care environments pose unique challenges and opportunities to implement and evaluate communication and dissemination strategies for engaging patients. Successful programs for studying communication approaches related to emergency care and emergency conditions are ongoing and include the study of cardiopulmonary resuscitation educational techniques for

family members of patients with acute cardiac conditions¹² and the use of visual decision aids tailored toward communicating adverse event risk for ED patients with chest pain.¹³

PCORI defines dissemination as “the active and targeted approach of spreading evidence-based interventions to potential adopters and the target audience through determined channels using planned strategies. The goals of dissemination research are to increase the reach of information, motivation, and ability of patients, caregivers, and providers to successfully use and apply evidence.”¹⁴ From this perspective, studies comparing the use of different approaches to disseminating emergency care-related clinical care guidelines, particularly those that focus on patient centered outcomes or efficient use of resources¹⁵, are aligned with PCOR dissemination priorities.

In summary, patients who seek emergency care differ from those who get set care in other settings—often they are more socially vulnerable, have more complex disease severity, and have less access to primary and specialty care. For these populations, there is great opportunity to study how to best disseminate and communicate nuanced health information from a patient-centered perspective, without the benefit of longitudinal therapeutic relationships and with the task of time critical nature of many aspects of emergency care.

4) Addressing Disparities

With this research priority, PCORI seeks to facilitate patient-focused research to identify and address disparities to improve healthcare outcomes. The Centers for Disease Control Health Disparities and Inequality Report defines health disparities as “differences in health outcomes between groups that reflect social inequities”.¹⁶ Emergency medicine is uniquely well-positioned to conduct patient-centered research to address these healthcare disparities and identify patient-preferred outcomes due to the 1) diverse patient population and medical conditions in the ED; 2) proportion of ED patients that experience barriers to healthcare; 3) role of the ED in the spectrum of healthcare delivery; and 4) demonstrated ability of emergency medicine to conduct CER across patient populations and disease states.

The ED serves a wide variety of healthcare roles, ranging from providing life-saving care to critically ill and injured patients, to performing complex evaluations of high-risk patients, facilitating non-elective admissions, and providing acute care for individuals who cannot access healthcare in other settings.¹⁷ The ED is a critical link in the chain of healthcare service provision; it is the conduit between primary care, specialty care, mental health services, and the hospital. By providing care to an extremely varied patient population across the full spectrum of disease states, emergency care researchers are positioned to successfully evaluate and compare patient-centered interventions across diverse populations.

The ED provides care for “all comers”, including at-risk patients unable to access healthcare elsewhere. The ED is the “safety net” and for some patients the ED is the only source available to access healthcare.¹⁷ Although the ED serves patients across the full socioeconomic spectrum, ED patients are more likely than the average American to report psychosocial vulnerabilities such as poverty, housing instability, and a lack of social support. They more frequently experience physical, medical, and social barriers to outpatient healthcare, ranging from insurance to mental illness to substance use to transportation

difficulties. These barriers increase their risk for poor physical, psychological, and social health outcomes as well as inequities in health care.^{18–23} Both ED physicians caring for these populations and ED patients themselves are uniquely positioned to work together to identify patient-centered strategies to overcome these barriers and improve healthcare outcomes.

The variety of patient types and disease states encountered in the ED is a particular strength of emergency care research. The diverse clinical population and the acute treatment component of emergency care provide an ideal setting to compare interventions across patient populations and to identify best care practices within various populations with a focus on reducing or eliminating disparities between groups. Moreover, this CER may be conducted using established, successful emergency care research networks to address the disparities that persist in healthcare service delivery and outcomes.

5) Accelerating Patient Centered Outcomes Research and Methodological Research

This priority area is focused on “improving the nation’s capacity to conduct patient-centered outcomes research, by building data infrastructure, improving analytic methods, and training researchers, patients and other stakeholders to participate in this research”. There are a number of topics within this area that are especially relevant to the ED setting, including the priority to develop methods to: engage and empower patients, incorporate hard to reach populations, increase the efficiency of data sources commonly used for PCOR, develop large clinical data networks or registries, and research how to develop patient-centered outcomes in systematic ways.

As discussed in the sections above, there is no place in the healthcare system where a higher number or more diverse set of patients are evaluated and treated per square foot than the ED. Patients arrive with complaints that cover the full spectrum of acuity, are both acute and chronic in nature, and require both immediate as well as ongoing treatment. Patients who have no desire to regularly engage with healthcare still likely have occasional reason to come to the ED, and thus the ED offers opportunity to reach otherwise hard to reach populations.

Additionally, establishment of a means of routinely screening and engaging ED patients in PCOR-related studies is highly feasible and offers the potential for rapid enrollment of significant numbers of patients into a variety of studies. Standard procedures can also be set in place to consent patients during their ED evaluation for future contact, thus facilitating the development of large-scale patient registries for future research. With development of these methods, EDs can serve as a primary portal through which a diverse group of patients can be identified for PCOR.

In addition, emergency medicine research is inherently pragmatic and focused on the entire patient, not just a specific disease or symptom. While research agendas of national institutes are often driven by a specific disease, this disease-specific focus raises the risk of missing inclusion of broader patient needs and priorities.

Future Directions and Opportunities for Conducting PCOR in the Acute Setting

Emergency care is uniquely positioned to perform impactful and necessary PCOR. The national movement towards developing a more patient-centered healthcare system necessitates better understanding of patient experiences within all parts of the healthcare system. Emergency patients are united by the “illness experience” of deciding to seek acute unscheduled care. The ED is an ideal venue for performing PCOR in the “real world”, offering opportunity for engaging a broad range of patient conditions and demographics in large-scale, pragmatic clinical trials.

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Table 1

Current PCORI funding opportunities based on the National Priorities for Research and Research Agenda

Research Priority	Description	Examples of Applicability to Emergency Care
Assessment of Prevention, Diagnosis and Treatment Options	This line of research aims to provide new information for patients about the comparative effectiveness, benefits, and harms of various diagnosis and treatment options.	Decisions about evaluation pathways for undifferentiated ‘‘chest pain’’
Improving Healthcare Systems	The goal of this agenda item is to provide evidence regarding the quality, efficiency, and patient-centered outcomes associated with various methods of healthcare delivery.	Examining the relative efficiency of telehealth for triage before the ED
Communication and Dissemination Research	This line of research strives to elucidate best practices for communication between patients and clinicians, between researchers and patients, and between researchers and clinicians; ultimately, the goal is to improve patients’ and caregivers’ ability to make informed decisions about evidence-based care.	Assessing best practices for communicating discharge instructions
Addressing Disparities	Research proposals in this area specifically address creating evidence for vulnerable and otherwise under-studied groups. Foci include socioeconomic, racial, ethnic, and other minority groups, as well as patient groups that may experience systemic barriers to care (e.g., mental illness, geriatrics, rare diseases).	Examining the evidence behind psychiatric triage protocols for minority populations
Improving Methods for Conducting Patient-Centered Outcomes Research	This research focus of PCORI looks at addressing methodological gaps in patient-centered research.	Testing concept mapping as a means of identifying patient priorities for ED transitional care plans

Table 2

Contemporary examples of recently funded PCORI contracts relevant to emergency medicine

Principal Investigator	Organization	Project Title	Funding Announcement	Year Awarded
Katherine Deans, MD	Research Institute at Nationwide Children's Hospital	Randomized Controlled Trial of a Patient Activation Tool in Pediatric Appendicitis	Assessment of Prevention, Diagnosis, and Treatment Options	2013
Erik Paul Hess, MD, MSc	Mayo Clinic	Shared Decision Making in the Emergency Department: The Chest Pain Choice Trial	Assessment of Prevention, Diagnosis, and Treatment Options	2012
Erik Paul Hess, MD, MS	Mayo Clinic	Shared Decision Making in Patients of Children with Head Trauma: Head CT Choice	Assessment of Prevention, Diagnosis, and Treatment Options	2013
Erik Paul Hess, MD, MS	The Society for Academic Emergency Medicine	Shared Decision Making in the Emergency Department: Developing a Patient-Centered Research Agenda	Engagement Award Meeting and Conference Support	2015
Sophie Lanzkron, MD, MHS	Johns Hopkins University	Comparing Patient Centered Outcome in the Management of Pain between Emergency Departments and Dedicated Acute Care Facilities for Adults with Sickle Cell Disease	Improving Healthcare Systems	2014
Lisa Iezzoni, MD	Massachusetts General Hospital	Acute Community Care to Avoid Unnecessary Emergency Department Visits	Improving Healthcare Systems	2015
Donna Lynne Carden, MD	University of Florida	An Emergency Department-to-Home Intervention to Improve Quality of Life and Reduce Hospital Use	Improving Healthcare Systems	2013
Adil Haider, MD, MPH	Brigham and Women's Hospital	Patient-Centered Approach to Collect Sexual Orientation/Gender Identity Information in the Emergency Department	Addressing Disparities	2013
Sean Collins, MD	Vanderbilt University	GWTG Interventions to Reduce Disparities in AHF Patients Discharged from the ED (GUIDED HF)	Addressing Disparities	2015
David Reed Flum, MD, MPH	University of Washington	Comparing Outcomes of Drugs and Appendectomy	Pragmatic Clinical Studies and Large Simple Trials to Evaluate Patient-Centered Outcomes	2015

Principal Investigator	Organization	Project Title	Funding Announcement	Year Awarded
Kristin L Rising, MD, MS	Thomas Jefferson University	Concept Mapping as a Scalable Method for Identifying Patient-Important Outcomes	Improving Methods for Conducting Patient-Centered Outcomes Research	2015
Benjamin Abella, MD MPhil	University of Pennsylvania	CPR Education for Families of Cardiac Patients before Hospital Discharge: Comparing Methods for Real-World Dissemination	Communication and Dissemination Research	2015

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