Trauma Surgery & Acute Care Open

Community of trauma care partnering with stakeholders to improve injury outcomes: focus group analysis

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ABSTRACT

Introduction Engaging trauma survivors/caregivers results in research findings that are more relevant to patients' needs and priorities. Although their perspectives increase research significance, there is a lack of understanding about how best to incorporate their insights. We aimed to capture stakeholder perspectives to ensure research is meaningful, respectful, and relevant to the injured patient and their caregivers.

Methods A multiphase, inductive exploratory qualitative study was performed, the first phase of which is described here. Virtual focus groups to elicit stakeholder perspectives and preferences were conducted across 19 trauma centers in the USA during 2022. Discussion topics were chosen to identify patients' motivation to join research studies, preferences regarding consent, suggestions for increasing diversity and access, and feelings regarding outcomes, efficacy, and exception from informed consent. The focus groups were audio recorded, transcribed, coded, and analyzed to identify the range of perspectives expressed and any common themes that emerged.

Results Ten 90-minute focus groups included patients/caregiver (n=21/1) and researchers (n=14). Data analysis identified common themes emerging across groups. The importance of trust and preexisting relationships with the clinical care team were the most common themes across all groups.

Conclusion Our findings reveal common themes in preferences, motivations, and best practices to increase patient/caregiver participation in trauma research. The project's next phases are distribution of a vignette-based survey to establish broad stakeholder consensus; education and dissemination activities to share strategies that increase research engagement and relevance for patients; and the formation of a panel of patients to support future research endeavors.

Level of evidence Level IV.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ It is clear that stakeholder perspectives increase research significance, but there is a lack of consensus on how best to incorporate their insights into study design.

WHAT THIS STUDY ADDS

⇒ This study is the first of its kind, engaging patients and caregivers to discuss how to ensure that trauma research is meaningful, respectful, and relevant to the injured patient and their families. The importance of trust and preexisting relationships with the clinical care team pervaded the data across all groups.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE, OR POLICY

⇒ Our findings reveal common themes in preferences, motivations, and best practices that may influence participation in trauma research. In the next phases of this project, we will distribute a vignette-based survey in an effort to establish broad stakeholder consensus, provide education, and conduct dissemination activities to share strategies that increase research engagement and relevance for patients.

INTRODUCTION

Injury is the leading cause of death for all persons aged 1 to 44 years in the USA and accounts for approximately 30% of all intensive care unit admissions.[1 2] Injuries result in varying degrees of disability that can lead to significant social and economic consequences,[3 4] including a reduction in quality of life due to significant physical and/or cognitive dysfunction.[5–10] Caregivers of those with long-term disability also face significant challenges including depression, mental health disorders, stress, and frustration, contributing to higher rates of alcohol and substance abuse, and worse overall physical health than non-caregiver counterparts.[11–20]

During the past half century, the need to improve trauma care through research has been increasingly recognized. In 2016, the National Academies of Science, Engineering and Medicine (NASEM) called for a nationally integrated, military–civilian trauma research action plan to achieve zero preventable deaths and disability after injury (ZPDD report). They also recommended the establishment of a National Trauma System focused on continuous quality improvement and increased federal support for trauma research. To date, that system remains undeveloped.

Engaging survivors and their caregivers as partners results in research more relevant to patients'

needs and priorities. It is clear that stakeholder perspectives increase research significance, but there is a lack of consensus on how best to incorporate their insights into study design. We aimed to describe and define stakeholder perspectives in a way that ensures research is meaningful, respectful, and relevant to the injured patient and their caregivers.

METHODS

In June 2021, with the assistance of a Eugene Washington PCORI Engagement Award—The Community of Trauma Care: Partnering with Patients and Caregivers to Improve Trauma Care—the Injury Research Engagement Project (I-REP) was established. In 2022, I-REP performed a multiphase, inductive exploratory qualitative study to elicit stakeholder perspectives and preferences. The Strengthening the Reporting of Observational Studies in Epidemiology guidelines were used to ensure proper reporting of methods, results, and discussion (online supplemental 1).

The project coordinating center collaborated with the American Trauma Society's (ATS) Trauma Survivors Network (TSN) and the Health Alliance for Violence Intervention (HAVI). The ATS conceptualized and established the TSN in 2008 to help trauma centers provide the support and services patients and their families need during their recovery from serious injury. ATS has expanded to 181 hospitals internationally. Hospital-based violence intervention programs (HVIPs) have existed in the USA for more than 20 years. In 2009, the National Network of HVIPs was established, fostering hospital and community collaborations to advance equitable, trauma-informed care and violence intervention and prevention programs. To date, more than 60 member programs exist at trauma centers nationally.

Recruitment

HAVI and ATS TSN coordinators recruited sites to provide trauma survivor referrals to participate in the focus groups. Researcher and clinician participants were recruited through emails from colleagues of the research team and via the project coordinating center, STN, and ATS newsletters. All potential participants were consented to participate in the study by the ATS TSN coordinator. Patients and caregiver received a US$100 gift card for participating in a focus group.

Focus groups

Virtual focus groups to elicit stakeholder perspectives and preferences were conducted by coinvestigators with extensive focus group and trauma support group facilitation experience, using an interview guide that was developed for this project. Both facilitators were also trauma researchers with experience coordinating and conducting clinical trials. Patient/caregiver focus group participants were prompted to consider challenges related to giving informed consent during hospitalization, including caregiver concerns when asked to provide consent as a legally authorized representative (LAR). Discussion topics included 'meaningful, patient-centered outcomes', ways patients/caregiver would like to engage in research, the importance and challenges of collecting long-term outcomes data, exception from informed consent (EFIC), and consideration of the meaning of comparative effectiveness research (CER). Research professionals were asked to discuss challenges and best practices when recruiting and engaging with patients during all phases of their treatment and recovery. Questions/prompts were open-ended. The focus groups were audio recorded, transcribed, coded, and analyzed to identify the range of perspectives and common themes.

Analysis

After initial data review, two team members (AN, KJ) developed a code book with 17 categories based on interview topics and additional concepts that arose. Seven research team members used this guide to code the transcripts, with each transcript coded by two different team members. AN reviewed the coded data for discrepancies, which were addressed through negotiated consensus (AN, KJ).[21] Coding fragments relevant to each theme were extracted from individual transcripts and merged into a single Excel file with one tab for each code. This dataset was again analyzed by the team for consistency, clarity, and re-coding.[22] Each tab was then summarized into a smaller list of bullet points; and finally, all summarized points were merged into one summary document. This process identified the range of motivations, preferences, suggestions, concerns, influences, and experiences present in the data.

RESULTS

Six TSN and two HAVI sites referred trauma survivors for the focus groups, and researchers from 12 trauma centers participated (see stakeholder demographics in table 1). Ten 90-minute focus groups including patients (n=21), a caregiver (n=1), and researchers (n=14) were conducted. Discussion topics were chosen to identify patients' motivation to join research studies; preferences regarding consent; suggestions for increasing diversity and access; and feelings regarding outcomes, efficacy, and EFIC. The focus group transcriptions yielded more than 200 pages of data. Data analysis identified common themes emerging across groups (table 2).

Motivation to participate in research

The motivation to participate in research was evaluated from all participants' perspectives. The caregiver or LAR often reported that they did not have the bandwidth to think about research unless they knew the injured patient—their loved one—was stable. This intuitively makes sense, as many trauma patients are critically ill. Other key motivating factors for participating in research included a prior background in healthcare, trusting the healthcare and/or research team, and having a personal interest in research or the research topic, specifically.

We categorized patients' motivations to participate by the common themes of altruism, new knowledge, own status, and research perspective. Patients expressed a desire to participate in research if they thought the study could have a positive impact on others and if their participation could help expand medical knowledge to make an impact. Patient participants frequently expressed frustration with how difficult it is to get answers to their medical or prognostic questions and saw research as an opportunity to engage with healthcare and research teams as a 'partner'. Similar to the caregiver, patients often could not even consider contributing to research, despite their altruistic nature and desire for new knowledge, until they resolved feelings regarding their own medical situation, especially in the setting of an uncertain prognosis.

The researchers' perspectives focused more on best practices for approaching the patient and caregiver, and how their methods may impact potential participants' motivation to be involved. Many researchers felt that patients were more likely to consent to a study if first approached by the care team (eg, a care team physician introduces the research team to facilitate trust but does not participate in the consent process). The researchers stressed the importance of separating the care team and the research team to avoid perceived conflict of interest.

Table 1 Stakeholder demographics

Patient/caregiver variables	Participant (n=22)
Age (years)	22–65
Race	► Mostly Caucasian ► 4–5 non-white
Recruitment method	► 6 TSN ► 2 HAVI
Mechanism of injury	► MVC ► HBC ► Bike ► Infection ► Fall from tree ► Skiing/fall ► Ped struck
Injuries	► Ortho ► AKA/BKA ► SCI ► TBI ► Many internal injuries ► Many years of sx/rehab
Time since injury	4 months to 25 years
Researcher variables	**Participant (n=14)**
Credentials and current practice (researchers only)	► Fellow ► Early–mid–late career professionals ► MD clinical only ► MD clinical and bench research ► PhD ► RN research manager/ clinical research coordinators

N=number of participants.
AKA, Above knee amputation; BKA, Below knee amputation; HAVI, Health Alliance for Violence Intervention; MVC, Motor vehicle crash; SCI, Spinal cord injury; Sx/Rehab, Symptoms/rehabilitation; TBI, Traumatic brain injury; TSN, Trauma Survivors Network.

Table 2 Perspectives and common themes

Topics of discussion	Themes
Motivation to participate	► Altruism ► New knowledge/perspective ► Own health status ► Recognition of benefits of giving back
Consent preferences	► Timing ► Researcher's approach/characteristics ► Focus on altruistic nature ► Trust/respect
Increasing diversity and access	► Use of native language ► Researcher characteristics ► Building relationship with patient/family ► Additional resources—virtual options, financial incentives, transportation, meals, child care ► Accessible, welcoming environment ► Respect towards participants time
Patient outcomes	► Sense of progress ► Improvement ► Return to pre-trauma baseline ► Regaining independence ► Mental health
Efficacy	► Trust ► Preexisting relationships ► Transparency, honesty—clear description of research process, data collected
Exception from informed consent	► Want for explanation of study aims and potential risks ► Fear of receiving less effective study arm ► Complex topic to understand

Consent preferences

Informed consent is required for many types of research just as it is required for a surgical procedure. Best practices regarding the researcher's approach and barriers were discussed (table 3). All focus group participants expressed the importance of coordination and timely implementation of the initial research approach and consent, recommending the researcher wait until the patient has achieved stability and the LAR is in a mindset to comprehend the discussion. Participants also expressed the value of: (1) having an experienced coordinator who is well versed in the study and who communicates with compassion and sincerity, (2) ensuring patient access to the principal investigator or other research staff for support and to answer additional questions, (3) avoiding coercive language, and (4) emphasizing the participant's important contribution to science and future patients. Other best practices include ensuring that the research question is relevant to the patient, that participation does not impede recovery, and that access to additional medical care or information is a benefit of participation.

Increasing diversity and access

The participants discussed the importance of including diverse populations in research for broad applicability of the results. The patients and caregiver recommended offering research materials in their native language or the use of an interpreter during in-person contact with the research team. They additionally suggested having research team members who look like the population of interest to build further rapport. A focus on building a relationship with participants after they leave the hospital will make it easier for patients and caregiver to participate. Reminders about how continued participation is part of the recovery process were also found to be important to participants.

A patient's lack of resources can make it difficult to keep in touch, so providing a phone or offering home visits or telehealth options to increase communication opportunities and patient follow-up were offered as suggestions. It can be difficult getting patients to return for data collection due to work, family constraints, financial difficulties, and time required. Systems support such as financial incentives; providing transportation, meals, and childcare; and paying for parking may additionally support patients' and caregiver's efforts to participate in research follow-up. The stakeholders expressed the importance of a clean, accessible, and welcoming office. They recommended that researchers be respectful of the participants' time and honest from the beginning about the research process and potential participation burden.

Patient outcomes

When asked about outcomes from a research initiative that would be meaningful to them, the participants reported that a

Table 3 Best practices and barriers

Consent best practices	
Include healthcare team	► Provide clinical update before proceeding with research update ► Ensure clinically a 'good time' for patient to participate and to engage family
Frame the consent discussion	► 'Here is what we do understand and what we don't understand…and what we hope this study will help us figure out'
Barriers to best practices	
Mistrust in science	► Foster a connection with LAR/patient; listen carefully and do not rush
Negative hospital experience	► Enlist support from relevant departments and address concerns before proceeding with request for engagement
Critically ill patient	► Ensure clinically a 'good time' for patient to participate and to engage family
Interpersonal dynamics (researcher–provider)	► Approach clinical staff with gratitude; include staff/clinicians in development of implementation processes

LAR, legally authorized representative.

sense of progress, improvement, or getting closer to their pre-trauma self are the preferred outcomes, and ultimately, regaining independence and mental health tranquility. Patients reported that it is difficult for them to measure effectiveness since their only point of comparison is their pre-injury self.

Perceptions related to trust

The importance of trust and preexisting relationships with the clinical care team pervaded the data across all groups. Patients and caregiver felt previous negative experiences with the medical field or prior research studies would discourage participation. The stakeholders felt that negative experiences during the current hospital stay, even if unrelated to direct medical care or research, may affect participation since those experiences eroded trust. A patient gave an example of sitting in the emergency department hallway for hours. Despite receiving great care later, his entire perspective on the experience was overshadowed by that initial very negative experience.

Trust must be earned. To build trust, the researcher should display transparency and honesty and provide a clear description of the research process. In practice, this includes sharing details regarding the process expectations, data and specimens being collected, contact information of team members for follow-up questions, and information regarding the anticipated impact of the treatment. The research team should approach patients in an empathetic and respectful manner. The researcher should be calm and knowledgeable, should display professionalism in the chaos of trauma, and should be educated about the experience of the patient/caregiver. Trust may be enhanced by including a trauma survivor on the research team or engaging staff with personal experience/familiarity of the topic being studied.

Exception from informed consent

In 1996, the Federal Drug Administration (FDA) established EFIC.[4] EFIC is a set of federal regulations implemented when conducting a clinical trial to inform best practices in an emergency. EFIC allows patients to be treated as part of research studies under special and rare circumstances. It can only be used in life-threatening emergencies, when there is a possibility for direct benefit to participants and when consent is not possible.[23] These regulations include utilizing a process known as community consultation. The requirement for community consultation is one of the special protections provided whenever an EFIC is granted for emergency research. It serves as a 'vehicle to listen to the community's interests and concerns, to address ethical issues, and to communicate information about the research to the community'.[4 24] EFIC studies help researchers perform trials with significant societal benefit that would otherwise be unattainable, but one must maximize the extent to which these studies respect patient concerns and experiences.[5]

The patients and caregiver preferred that a physician explain any EFIC study in detail to ensure full understanding of the aims and possible side effects. They expressed fear of being assigned to the less effective treatment arm. The researcher should ensure clarity over the assignment process and downsides of not receiving 'standard treatment'. Overall, the researchers found EFIC studies difficult to explain and the concept hard for the patients and caregiver to understand.

DISCUSSION

Patient and caregiver engagement in all aspects of research, including the preparatory, execution, and translation phases,[25] improves the significance and relevance of the research. Ultimately, increased transparency of research activities promotes better adoption of the evidence into practice.[26]

This study is the first of its kind, engaging patients and caregivers to discuss how to ensure that trauma research is meaningful, respectful, and relevant to the injured patient and their families. The importance of trust and preexisting relationships with the clinical care team pervaded the data across all groups. Surgeons often build trust within seconds of meeting a patient or their family member. They present their interpretation of the patient's clinical problem and their recommendations. Even though research is often presented in a similar manner—introductions followed by information and next steps—it may not be met with the same level of understanding and trust, perhaps because it is often interpreted by patients and caregivers as negative. One example from a patient was that they did not want to be part of a science experiment, as one of the focus groups discussed

In this work, we explore stakeholder perspectives regarding motivations to participate in trauma research, consent preferences, ways to increase diversity and access, patient outcomes, efficacy, and processes around EFIC. The trauma patients who participated were primarily motivated by altruism, a desire to partner with the research team and to attain an increased feeling of certainty around their diagnosis. LARs were motivated by past experiences in healthcare, trust in the treatment team, and the clinical stability of their family member at the time. Many motivating factors in the trauma patient population are similar to those identified by contemporary studies of other healthcare populations, though the impact of a patient's clinical status has not yet been investigated. To date, there has been little evaluation of how patients think about the LAR and EFIC processes and how that might affect their participation in research, particularly within communities of color. Some articles on approaches to

community consultation for EFIC education suggest that social media can be used to reach targeted populations.[27 28] Additionally, loss to follow-up is prevalent among research subjects in the trauma population.[29] Not only does this issue serve to magnify the health outcome disparities that are noted after trauma[30] but the phenomenon has significant implications for the ability to conduct high-quality research with valid and appropriate outcomes measures beyond the index injury or hospitalization.

This study has limitations, primarily it is a small, convenience sample that may not be representative of all patients, caregivers, and researchers as well as the possible Hawthorne effect. The focus groups were composed of stakeholders (patients, a caregiver, and researchers) in addition to the trained facilitators. It is possible that participants were influenced by the other participants' responses or by observing the trained facilitators. We intentionally kept the focus groups small and did not invite other study staff to limit this observation bias.

CONCLUSION

Our findings reveal common themes in preferences, motivations, and best practices that may influence participation in trauma research. In the next phases of this project, we will distribute a vignette-based survey in an effort to establish broad stakeholder consensus, provide education, and conduct dissemination activities to share strategies that increase research engagement and relevance for patients. We will also establish a panel of patients to support future research endeavors. Future studies are needed to improve EFIC processes and educational materials, as this concept was difficult for researchers to explain and patients/caregiver to understand.

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Competing interests AN: Inova Fairfax Hospital (Employee)—Received grant funding -from PCORI-American Trauma Society (Board member)—Received grant funding from PCORI. KJ: American Trauma Society (Employee)—Received grant funding from PCORI. PB: Coalition for National Trauma Research (Employee)—Received grant funding from PCORI. MAP: Coalition for National Trauma Research (Employee)—Received grant funding from PCORI. RD: Health Alliance for Violence Intervention (Board member). RK: NIH—Payment to institution-DOD—Payment to institution-Air Force—Payment to institution—Royalties for being Associate Editor Trauma textbook-Teaching ATLS—Payment-Honorarium for speaking at Detroit Trauma Symposium—Payment-Service on NIH and DOD grant review panels—Payment-EAST for giving Scott Frame Memorial Lecture—Payment-Cellular Therapeutics in Trauma and Critical Care—Payment-AAST strategic retreat—Payment-WTA-CNTR-Deputy editor J Trauma Acute Care Surgery-Associate editor Trauma Surgery Acute Care Open-Receipt of blood product used in pre-clinical study ERH: PCORI-AHRQ-NIH/NHLBI-CNTR (Board member)-NBCA (Board member)-Editor in Chief, TSACO—Paid DMS: PCORI—Grant-NIH—Grant, Site PI-Air Force—Grant-CNTR/DOD—Grant-NHTSA—Grant-CSL Behring, LLC—Participation in DSMB-Payment for honoraria—Austin Trauma and Critical Care Conference, University of Cincinnati, University of Arizona, University of Texas Southwest/Parkland-Meeting travel—ACS/ASA Health Policy Scholarship, ACS Clinical Congress, EAST Strategic/Tactical Retreat-Patent—Method and Apparatus or Monitoring Collection of Physiological Patient Data-Leadership roles—Past Present EAST, board member EAST, Examiner ABS, Program Committee member/Algorithm Chair WTA, Vice Chair Trauma, Burns, SCC ABS, Geriatric Content Lead ACS ATLS.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the Coalition for National Trauma Research (CNTR). The project coordinating center obtained Institutional Review Board approval to conduct the study. This protocol was reviewed and approved by WCG WIRB (IRB Protocol #: 20215168). Participants gave informed consent to participate in the study before taking part.

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