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Trauma patients, community say they support exception from informed consent research

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Traumatic injury – including car accidents, gunshot wounds, and stabbings – is the leading cause of death for people younger than 40 years old in the United States, but despite the toll of these injuries, few emergency medical interventions considered to be the standard of care for these injuries have been rigorously studied in clinical trials, because patients and their families are typically unable to consent to participate in research. A new study from the Perelman School of Medicine at the University of Pennsylvania sought to examine peoples' willingness to be enrolled in these types of studies under the federal provisions that allow patients with time-sensitive illnesses and injuries to be part of clinical trials without their express consent. The study revealed that those surveyed expressed high levels of approval and willingness to be part of these types of trials, both for themselves and their family members and friends. The findings provide important clues for increasing the number of studies aimed at improving care for this patient population.

The study is published this month in the Journal of Trauma *and* Acute Care *Surgery*.

"We're trying to advance care and really change the mortality rates associated with these injuries, but we will never really be able to do that until we can apply the scientific method," says the study's lead author, Carrie A. Sims, MD, MS, an assistant professor and the director of Research in Penn Medicine's division of Traumatology, Acute Care

Surgery, and Surgical Critical Care. "We don't have all the answers, but we can get closer by conducting more of the same rigorous studies that have led to improvements in care for diseases from cancer to cardiovascular disease."

Since many trauma patients are unconscious and unable to consent to be part of a clinical trial, this research must be conducted under the Food and Drug Administration's Exception from Informed Consent (EFIC) regulations, which were established in 1996. These stipulations, designed to protect patients, govern how physicians can ethically study time-sensitive conditions like traumatic injuries and illnesses including cardiac arrest and stroke. All of these scenarios require instant medical intervention, without the typical discussion of the risks and benefits associated with participation in a study which would typically comprise the informed consent process.

Instead, the EFIC guidelines call for a community consultation and notification process to make the target community aware that the research will be taking place, including information on how to opt out of the study. But progress in trauma and other disciplines has been hampered by the difficulties of conducting research under these regulations, partly because it can be difficult to define the intended patient population and engage with them during the consultation process. While research on a condition such as epilepsy would call for meeting with patient advocacy groups dedicated to that particular illness, EFIC research for traumatic injuries – which, in the case of things such as car accidents, can strike anyone at anytime – presents more challenges.

To obtain more insights about how EFIC research may be perceived by prospective patients and the community at large, the Penn Medicine team studied the community consultation process associated with an upcoming Penn trial known as AVERT Shock, which will investigate the effect of using the hormone vasopressin during resuscitation of patients

who have lost a large amount of blood. The team conducted interviews with 309 Hospital of the University of Pennsylvania trauma patients and their families, as well as members of community organizations and churches in the neighborhood surrounding the hospital, in West Philadelphia.

The overwhelming majority of the participants – more than 95 percent – supported the need for more trauma research, and indicated that the AVERT Shock Trial was an important study to perform. When queried on the appropriateness of enrolling patients if neither they nor a legally authorized representative could provide consent, 67 percent of participants agreed it would be acceptable to enroll a family member, 77 percent said it would be OK to enroll them personally, and 84 percent said it would be acceptable to enroll a member of their community. These results are in contrast to previous studies that show much lower support for research conducted under EFIC regulations. Only 63 percent of those interviewed, however, agreed that it was important to involve the community in making decisions on behalf of potential patients.

"We see the community consultation process required for EFIC research as serving an important educational need in our trauma community – by engaging with members of the public on these issues, we are able to provide information about these injuries as well as the specific trials we are planning, which helps to improve support for our research efforts," Sims said. "We recognize that our patients are especially vulnerable, having been injured with no warning or knowledge of the medical care they will require, and we are eager to find ways to provide comfort and information that can help people during these frightening experiences."

The AVERT Shock Trial is designed to improve the standard of care for the 10 percent or so of trauma patients whose tremendous blood loss puts them at the highest risk of dying as a result of their injuries. The study, slated to begin this spring, will compare the use of normal saline –

the standard practice during resuscitation of trauma victims who have lost a substantial amount of blood – with infusions of vasopressin, a hormone that's necessary to maintain blood pressure. Sims and her team will explore whether using vasopressin during resuscitations improves patient outcomes, by cutting complications, requiring less blood products during recovery, or boosting survival rates. The findings may also provide a way to preserve the blood supply, which is often a limited resource, especially for certain blood types.

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