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Exception from informed consent for emergency research: Consulting the trauma community

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Abstract

BACKGROUND—Research investigating the resuscitation and management of unstable trauma patients is necessary to improve care and save lives. Because informed consent for research is impossible in emergencies, the Federal Drug Administration has established an Exception from Informed Consent (EFIC) Policy that mandates “community consultation” as a means of protecting patient autonomy. We hypothesized that the trauma community represents a heterogeneous population whose attitudes regarding EFIC and willingness to participate in emergency research are influenced by status as a patient, family, or geographic community member.

METHODS—In the context of an upcoming trial, trauma patients as well as family and community members were asked to rank statements regarding EFIC and willingness to participate in emergency research using a 5-point Likert-type scale. Higher total scores reflected a more positive attitude regarding EFIC (range, 4–20; neutral = 12) and willingness (range, 21–105, neutral = 63). The influence of demographics, education, and interpersonal violence were evaluated by Kruskal-Wallis and Mann-Whitney U-tests ($p < 0.05$).

RESULTS—Overall, the 309 participants (trauma patients, $n = 172$; family, $n = 73$; community, $n = 64$) were positive about EFIC (median, 16; interquartile range, [IQR], 14–18) and demonstrated high willingness scores (median, 82; IQR, 76–88.5). EFIC and willingness were not influenced by age, sex, race, or education. Victims of interpersonal violence and their family members had lower EFIC scores than those with other mechanisms (median [IQR], 16 [14–18] vs. 16 [13–16]; $p = 0.04$) but similar willingness. Although EFIC scores were similar between groups,

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AUTHORSHIP

C.A.S., J.A.I., S.G., and P.R. designed this study. C.A.S., J.A.I., L.M.S., and N.T. contributed to data collection. C.A.S., D.H., and S.S. performed data analysis. C.A.S., J.A.I., D.H., S.G., S.S., J.P., and P.R. prepared the article.

DISCLOSURE

The authors declare no conflicts of interest.

trauma patients had significantly lower willingness than family (median [IQR], 74 [68–77] vs. 77 [70–85]; $p = 0.03$) or community members (median [IQR], 76 [70–84]; $p = 0.01$).

CONCLUSION—Trauma patients, families, and the geographic community expressed a high degree of support for EFIC and willingness to participate in emergency research, although support was influenced by injury mechanism and group status. Consultation efforts for emergency research should extend beyond the geographic community to include trauma victims and their families.

LEVEL OF EVIDENCE—Epidemiologic, level III.

Keywords

Emergency research; EFIC; consent; community

Trauma surgeons need valid evidence to assure patients, families, and the society that patients with life-threatening injuries receive safe and effective interventions. Given the physiologic complexity of trauma, the best way to demonstrate therapeutic benefit and safety is through human subject research. Ideally, such clinical research should only be conducted when the patient has had the opportunity to carefully evaluate the risks and benefits and can provide informed consent before enrollment.¹ In trauma, however, many research questions concern the initial resuscitation and management of unstable patients who, by virtue of their injuries, are incapable of providing informed consent. Moreover, identifying potential subjects a priori or their legally authorized representatives (LARs) in a timely fashion may not be practical in most circumstances.^{2,3}

Conducting emergency research, therefore, poses a substantial ethical challenge: how to balance respect for human autonomy with the potential for medical progress. Recognizing this potential conflict, the Federal Drug Administration (FDA) established an Exception from Informed Consent (EFIC) policy in 1996.⁴ Under the most current guidelines, emergency research using EFIC may only be conducted in unexpected, life-threatening circumstances where (1) the patient is incapacitated, (2) available treatments are unproven or unsatisfactory, (3) the proposed intervention may benefit the patient directly, and (4) the therapy must be initiated before consent from the LAR is feasible. To further safeguard patient autonomy, the FDA requires several other protective measures including the mandate for “community consultation” (Table 1).⁵

The FDA requirement of community consultation, however, remains poorly defined and variably interpreted by both researchers and institutional review boards (IRBs).^{6–15} Because each potential emergency research protocol draws on a uniquely different “community,” it is essential that researchers consult with the “community” from which the subjects will be drawn to truly engage in the consultation process. While defining the community of interest may be the most obvious first step, it is perhaps one of the most challenging requirements of emergency research.¹⁶

Defining the trauma community may be particularly challenging. Geographically, patients may come from local neighborhoods, or they be transported a great distance. The community members may themselves be diverse group of patients, family, friends and

neighbors—each with a different experience of the traumatic event as well as different races, religions, socioeconomic backgrounds, and exposure to violence. The unique experience of being a patient or family member may also provide an important perspective on research that involves the trauma population. We hypothesized that attitudes regarding EFIC and willingness to participate in emergency research would be influenced by demographic variables including status as a patient, family, or geographic neighbor in the trauma community.

PATIENTS AND METHODS

Our study was conducted in the context of community consultation for an upcoming trial investigating the use of vasopressin during the resuscitation of hemorrhagic shock (AVERT Shock Trial).^{17,18} After obtaining IRB approval, trauma patients and family members at an urban Level I trauma center were asked to participate in a semistructured interview before discharge. Using a convenience sample, interviews were conducted during 6 months, including weekends. Patients (and family members) older than 18 years identified as “ready for discharge” were invited to participate. Patients with moderate-to-severe traumatic brain injuries and those with psychiatric disorders requiring inpatient evaluation were excluded, although their families were invited to participate. During the interview, details of the AVERT Shock Trial and its use of EFIC were explained. In addition to collecting demographic data, participants were asked about their experiences with clinical research, the importance of emergency research, opinions about consent, reason for hospital admission, and exposure to life-threatening trauma requiring blood transfusion. Using a modified version of the Clinical Research Involvement Scales,¹⁹ participants were asked rank statements regarding EFIC in the context of the AVERT Shock Trial and their general willingness to participate in emergency research using a 5-point Likert-type scale (1 = strongly disagree to 5 = strongly agree). Four questions investigated attitudes regarding EFIC and 21 assessed willingness to participate in emergency research. Higher total scores reflected a more positive attitude.

In addition, community-based organizations in the neighborhood surrounding our Level I center were contacted and invited to host a focus group. Focus groups were moderated by a professional facilitator and observed by IRB members. A research team member was also present to address questions. In addition to describing the details of AVERT Shock, discussions were directed at their knowledge and perception of emergency research, their opinion of the EFIC policy, and suggestions for conducting the proposed research. Following the discussion, participants completed the survey tool used by patients and family members.

Data were entered into a Microsoft Excel database (2007, Microsoft Corp., Redmond, WA) and imported into SPSS (version 19.0, SPSS Inc., Chicago, IL) for analysis. Data were analyzed using χ^2 and Kruskal-Wallis tests as appropriate with a two-tailed significance set at $p < 0.05$. For χ^2 tests found to be significant in analyses that contained more than two groups, pairwise comparisons were performed using z test of proportions with Bonferroni's correction. Reliability analyses were performed to examine the internal consistency of the EFIC and willingness scores.

RESULTS

Of the 336 subjects invited, 309 completed the survey for a 92% response rate. Participants included 172 trauma patients, 73 family members, and 64 community members. Community members attended one of six focus groups sponsored by a Baptist church, a mosque, three community organizations, and a recreational center. The three groups (patients, family, community) did not differ in age, religion, or educational level. Significant differences in sex, race, and employment status were present (Table 2). Patients were significantly more likely to be male (65%), white (20%), and unemployed/disabled (56%).

There were no significant differences in previous experience with medical research. Roughly 20% had previously participated in a clinical study, and only 4% to 6% had been asked to consent on behalf of another person (Table 3). When asked who would be the best person to consent on their behalf for an emergency research trial, the majority (93–96%) listed a family member. If that person were unavailable, community members were significantly more likely to indicate a religious leader (45%), another family member (28%), or a community leader (16%). Patients and family members were divided in their responses. Roughly one third listed “doctor” as their second choice, while another third stated that it would not be proper for anyone other than a family member to consent on their behalf.

Subjects did not differ with regard to their experience with trauma resulting in significant blood loss (Table 3). Although most participants either “agreed” or “strongly agreed” that trauma was a significant concern in their community (85–92%), community members were statistically more likely to endorse this concern. The overwhelming majority of participants supported the need for more research in trauma (95–99%) and indicated that the AVERT Shock Trial was an important study to perform (95–99%).

When asked to rank their support of six statements related to the EFIC policy as it pertained to the AVERT Shock Trial, participants were generally supportive (Table 4). If a LAR could not be contacted, 67% of participants agreed that it would be acceptable to enroll a family member in this study without consent; 77% indicated that it would be acceptable to enroll them personally, and 84% believed that a member of the community could be enrolled. Eighty-five percent agreed that it would be acceptable to conduct the AVERT Shock Trial in their community. Only 63% agreed that it was important to involve the community in making decisions on behalf of potential patients.

Although most subjects supported the use of EFIC, there were statistically significant differences in the degree of support. Community members tended to be more supportive of EFIC as it pertained to family members and themselves but less supportive of enrolling others without consent. They were also more emphatic regarding the importance of involving the community (Table 5).

Based on the average interitem correlation, Cronbach’s α was 0.8 for EFIC score and 0.9 for willingness, indicating an excellent degree of internal consistency. Of note, question 7 and question 9 were excluded from the willingness score because of lack of internal consistency.

Three factors were found to influence the degree of positive support for EFIC: race, admission following interpersonal violence, and the participant's opinion regarding the importance of the AVERT Shock Trial (Table 6). Participants also endorsed factors known to positively influence willingness to participate clinical research with a median willingness score of 82 (interquartile range, [IQR], 76–88.5). Family members had statistically higher willingness scores, as did those who believed in the importance of conducting the AVERT Shock Trial (Table 6).

DISCUSSION

Although traumatic injury remains the leading cause of death for people younger than 40 years, very few of the “standard” interventions used to treat critically injured patients have been rigorously investigated and only a handful of clinical trials have used EFIC.^{20–24} Our study investigated trauma community attitudes about emergency research and the use of EFIC in the context of the upcoming AVERT Shock Trial.

Overwhelmingly, the trauma community we consulted considered the AVERT Shock Trial an important study that could be acceptably conducted in their community. Importantly, the key concept of enrollment without consent was endorsed by most participants. Surprisingly, subjects in our study were more supportive of enrolling a community member without consent than they were in applying EFIC to either themselves or a family member. In contrast, previous investigators have noted reluctance on the part of participants to assume responsibility for supporting EFIC on behalf of others.^{25,26} In a survey study of 1,901 community members, Biros et al.²⁷ found that only 35% supported using EFIC in emergency research. Support increased to 70%, however, when respondents were asked to evaluate emergency research in the context of their own care. Participants in our study may be more supportive of implementing EFIC as applied to the general community because while they universally perceive trauma research as important, they felt less strongly that they would personally benefit from care associated with emergency research (Table 5).

Our community consultation process may have also had a positive influence on the community's support of emergency research. Public disclosure and consultation activities that actively educate and engage participants have been shown to positively influence attitudes about EFIC research.^{7,28,29} Moreover, educating the community about the need for the proposed research and the lack of effective lifesaving therapies may also improve the community's perception of EFIC.²⁵ Our use of focus groups and semistructured interviews served to facilitate a dialogue in which the trauma community learned more about hemorrhagic shock, the lack of effective therapies, and the specifics of the AVERT Shock Trial. In addition, the research team was able to solicit views and recommendations from the trauma community. Although the community does not need to “approve” the study, the process of consultation is valuable in that the community is able to serve more as “partners rather than simply as subjects.”⁹

As hypothesized, the demographics, experiences, and attitudes of our trauma community varied depending on group assignment. When compared with trauma patients, community members were significantly more likely to be female, African American, and employed.

Although age, sex, education, and income previously have been shown to influence attitudes about emergency research, these factors did not impact either the EFIC or willingness scores in our study.^{25,27,30,31} While race was found to be statistically significant, African American and white subjects both reported high EFIC and willingness scores that were not statistically different.

Group assignment was also associated with differences in willingness but not in the composite EFIC score. When compared with trauma patients, community members were more likely to believe that trauma was a serious concern in their community, felt more strongly that trauma research should be performed, and were more likely to believe that their community would directly benefit from trauma research. Importantly, community members were also more likely to believe in the importance of consulting the community before initiating the AVERT Shock Trial. When individual question regarding EFIC and willingness were analyzed, community members were significantly more positive than patients in their support of EFIC research. They were, however, significantly less likely to endorse this type of research on behalf of their community. This reluctance to provide “consent” on behalf of strangers may stem from an altruistic desire as a community leader to protect the public, or it may represent a more democratic notion in which the community derives its authority from the will of its individual members.

Universally, participants supported contacting a family member to obtain consent for research in emergency situations. The concept of consent by proxy for research was initially introduced in the Declaration of Helsinki and later expanded to include an emphasis on respect for persons in the Belmont Report (1979).^{1,32} Because a family member is the most likely person to know the values and attitudes of the injured patient, it seems ethically appropriate to seek out family for surrogate decision making in emergency situations. Under the EFIC policy, consent for participation, or continued enrollment, must be discussed with the patient’s LAR as early as feasibly possible. In most cases, a parent or spouse is considered the LAR and should be approached first. However, if the LAR is unavailable, federal policy requires that any available family member should be asked whether they object to the patient’s participation. Our research suggests that the mandate to seek out family as surrogate decision makers in emergency research represents an important protection that is widely supported by the trauma community.

If family were unavailable, however, the community and patients/family expressed strikingly different opinions regarding an alternative proxy. Community members were significantly more likely to designate a religious leader or a community member or write in a specific family member. Trauma patients and their families, in contrast, were equally divided between designating a doctor and declaring that consent could only be obtained from a family member. It is important to note that the category “doctor” was not included as an option in the survey. Under the option of “other,” respondents specifically wrote in terms such as “doctor,” “trauma doctor,” and “researcher.” This trust in the medical profession may be directly related to the recent trauma and resuscitation experience.³³ Because trauma patients and family members in our study had just survived an unexpected emergency, they may be more keenly aware of the difficulties associated with emergency care and more likely to trust that their physicians have their best interest in mind.

Trust, however, may not be universal. Patients, and their families, who were admitted following interpersonal violence were statistically less supportive of EFIC than those admitted following nonviolent mechanisms. Experiencing violence shakes one's core belief that the world is safe and victims frequently suffer a loss of trust in people that can continue for years.³⁴ In a recent prospective study of 1,386 trauma patients seen in follow-up, more than 40% of those treated after a violent assault experienced symptoms of posttraumatic stress.³⁵ While it is unclear how many patients or family members in our study were experiencing posttraumatic stress, the recent exposure to violence may have negatively impacted their sense of trust as well as their support of EFIC. Further research investigating the impact of posttraumatic stress on attitudes about emergency research may provide useful insight regarding how to conduct meaningful community consultation with this vulnerable population.

There are a number of limitations to this study. First, this study was performed in context of the upcoming AVERT Shock trial, and attitudes were clearly influenced by the participant's opinion regarding the importance of this particular study. It is unclear if a different study with perhaps less overall support would report similarly high EFIC and willingness scores. Second, while we did find statistical differences between groups in the trauma community, these differences may not necessarily reflect clinically important distinctions. Specifically, because there was such a high degree of support for the AVERT Shock Trial and willingness to participate, statistically significant differences between the groups reflected variations in the degree of positive support rather than any one group expressing disapproval. Again, if there was less support for the AVERT Shock Trial overall, the differences observed between the groups may actually become important distinctions. Third, the opinions of the participants may not reflect the views of the general public. Participants in the focus groups may represent a self-selected group of people with altruistic motives. Similarly, trauma patients and their family members may be more biased toward trusting the medical profession that just saved their lives when compared with the general public. Fourth, although we used a convenience inpatient sample at various times throughout the week, not all admitted trauma patients or their family members were interviewed. The families of patients who died as well as those who declined or who were never contacted may have very different opinions about emergency research and EFIC. In addition, given the face-to-face semistructured nature of the interview, participants may have responded in a way that they thought the researcher would approve. Finally, while both the focus group format and the individual assessment allowed for in-depth questions and dialogue, this method of community consultation was time intensive, with each focus group lasting 1.5 hours to 2 hours and individual patient/family interviews taking 20 minutes to 40 minutes. The potential issue of bias may be mitigated by randomly consulting a larger sample size in a more anonymous fashion. Recently, random digit dialing has been successfully used to investigate community attitudes regarding the use of hypertonic saline in trauma.³⁶ Although this method clearly allows access to a larger population, it is expensive, has a fairly low response rate (33–45%), and may not capture the trauma patient's unique perspective. Further research is needed to determine the optimal balance between individualized consultation and the widespread dissemination of information.

CONCLUSION

Trauma patients, their families, and the surrounding geographic community expressed a high degree of support for the AVERT Shock Trial, EFIC, and emergency research in general. Although injury mechanism and group status were found to have a significant influence on EFIC and willingness scores, their impact merely changed the degree of positive support. By allowing participants the opportunity to ask questions and provide direct feedback to the research team via focus groups and semistructured interviews, the trauma community became “partners” in the research process. This method of community consultation may have contributed to the overwhelming support of the AVERT Shock Trial. Future consultation efforts for emergency research in trauma should consider using community participatory methods that extend beyond the geographic community to include patients and their families.

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TABLE 1**Summary of 21CRF50.24—EFIC Requirements for Emergency Research**

Subjects may receive the experimental therapy without consent only if all of the following conditions are met:

- 1 Available treatments are unproven or unsatisfactory.
- 2 The research cannot otherwise be performed to determine whether the therapy is safe and effective.
- 3 It is not feasible to obtain informed consent from the subject or the subject's legal representative, and there is no reasonable way to identify potential subjects prospectively.
- 4 Participation in the research holds out the prospect of direct benefit to the subjects.
- 5 The risks and benefits of the experimental procedure/treatment are reasonable compared with those associated with the subject's medical condition and standard therapy.
- 6 The proposal has been reviewed and approved by the IRB.

Additional protections include the following:

- 1 Consultation with the community and public disclosure of the study design, including risks and benefits, before initiation of the study.
 - 2 The establishment of an independent data and safety monitoring board during the study.
 - 3 Public disclosure of study results upon completion of the study.
 - 4 FDA review and approval of the protocol design and study information.
 - 5 An attempt to contact the subjects LAR within the therapeutic window before enrollment if at all feasible. The subject's LAR must be informed of the subject's inclusion as soon as feasible and asked for consent. If the LAR is not reasonably available, a family member must be approached as soon as possible and asked whether he or she objects to the subject's participation in the clinical investigation.
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TABLE 2

Demographics of the Study Population

Variable	All Participants (N = 309), n (%)	Patients (n = 172), n (%)	Family Members (n = 73), n (%)	Community (n = 64), n (%)	p
Male sex ^{**†}	162 (52)	111 (65)	23 (32)	28 (44)	<0.001
Age, y					
18–24	64 (21)	38 (22)	15 (20)	11 (17)	0.337
25–34	57 (18)	35 (20)	16 (22)	6 (9)	
35–49	83 (27)	46 (27)	18 (25)	19 (30)	
50–64	76 (25)	35 (20)	19 (26)	22 (35)	
65	29 (9)	18 (10)	5 (7)	6 (9)	
Race					
African American ^{**†}	191 (62)	96 (56)	39 (53)	55 (87)	<0.001
White ^{**†}	102 (33)	69 (20)	28 (38)	5 (8)	
Other	16 (5)	7 (4)	6 (8)	3 (5)	
Religion					
None	55 (18)	27 (16)	16 (22)	12 (19)	0.116
Judeo-Christian	203 (66)	118 (69)	46 (63)	39 (61)	
Islam	40 (13)	24 (14)	7 (10)	9 (14)	
Other	11 (3)	3 (1)	4 (5)	4 (6)	
Declined	2 (1)	0 (0)	0 (0)	0 (0)	
Education					
Some high school	37 (12)	24 (14)	7 (10)	6 (9)	0.657
High school graduate	128 (41)	75 (44)	28 (38)	25 (39)	
Some college or technical school	82 (27)	44 (26)	21 (29)	17 (27)	
College degree	39 (13)	19 (11)	10 (14)	10 (16)	
Professional degree	23 (7)	10 (6)	7 (10)	6 (9)	
Employment status					
In school	18 (6)	11 (6)	4 (5)	3 (5)	<0.001
Part time ^{**†}	41 (13)	11 (6)	13 (18)	17 (27)	
Full time ^{**††}	111 (36)	54 (31)	36 (49)	21 (33)	

Variable	All Participants (N = 309), n (%)	Patients (n = 172), n (%)	Family Members (n = 73), n (%)	Community (n = 64), n (%)	p
Unemployed/disabled ^{*†}	137 (44)	96 (56)	20 (27)	21 (33)	
Declined	2 (1)	0	0	2 (3)	

χ^2 test was used to evaluate significance of variables between groups. Significance further analyzed with pairwise comparisons reported at $p < 0.05$ following z test of proportions with Bonferroni's correction.

^{*} Patient versus community.

[†] Patient versus family.

[‡] Family versus community.

TABLE 3

Experience and Attitudes Regarding Emergency Research and Trauma as a Function of Trauma Community Subgroups

Variable	Patient (n = 172), n (%)	Family (n = 73), n (%)	Community (n = 64), n (%)	p
Previous participation in clinical research	36 (21)	14 (19)	16 (24)	0.694
Given permission for others to participate in clinical research	10 (6)	3 (4)	4 (6)	0.830
If you were a victim of trauma and could not consent, who would you want to consent for you to participate in emergency research?				
Family member	160 (93)	70 (96)	60 (94)	0.039
Community leader/member	10 (6)	2 (3)	0 (0)	
Religious leader	2 (1)	1 (1)	4 (6)	
If your family were not available, who would be the best person to consent for you to participate in emergency research?				
Family member ^{*†}	13 (8)	2 (3)	18 (28)	<0.001
Community leader/member [*]	6 (3)	3 (4)	10 (16)	
Religious leader ^{*†}	20 (12)	5 (7)	29 (45)	
Friend	19 (11)	12 (16)	5 (8)	
Doctor ^{*†}	57 (33)	30 (41)	1 (2)	
Responsible person	5 (3)	1 (1)	1 (2)	
Nobody, it would not be right for someone other than my family to consent for me to participate in this type of research even if it could potentially be helpful to me or save my life. ^{*†}	52 (30)	20 (27)	0 (0)	
Have you or someone you know experienced trauma resulting in significant blood loss and the need for blood transfusions?				
Yes	70 (41)	33 (45)	27 (43)	0.369
No	102 (59)	40 (55)	36 (57)	
Trauma, such as injuries related to violence or accidents, is a serious concern in my community.				
Strongly disagree	2 (1)	0 (0)	3 (5)	0.026
Disagree ^{*†}	11 (6)	2 (3)	0 (0)	
Neutral	13 (8)	4 (5)	3 (5)	
Agree	88 (51)	32 (44)	25 (39)	
Strongly agree ^{*‡}	58 (34)	35 (48)	33 (52)	
More research that could benefit trauma patients should be performed.				
Strongly disagree	0 (0)	0 (0)	0 (0)	0.003
Disagree	0 (0)	0 (0)	0 (0)	
Neutral	2 (1)	3 (4)	3 (5)	
Agree ^{*‡}	117 (68)	38 (52)	27 (42)	
Strongly agree ^{*‡‡}	53 (31)	32 (44)	34 (53)	
Do you think the AVERT Shock Trial is an important study for us to perform?				
Yes	166 (96)	72 (99)	61 (95)	0.279
No	3 (2)	1 (1)	0 (0)	
Undecided	3 (2)	0 (0)	3 (5)	

χ^2 test was used to evaluate significance of variables between groups. Significance further analyzed with pairwise comparisons reported at $p < 0.05$ following z test of proportions with Bonferroni correction.

* Patient versus community.

[†] Family versus community.

[‡] Patient versus family.

TABLE 4**EFIC Questions Regarding the AVERT Shock Trial**

	Disagree, %	Neutral, %	Agree, %
I think it would be acceptable to enroll my family members in this study without consent if they had a traumatic injury resulting in blood loss and I could not be contacted.	20	13	67
I think it would be acceptable for me to be enrolled in this study without my written consent if I had a traumatic injury resulting in blood loss and my legal representative (spouse, children, or guardian) could not be contacted.	13	10	77
I think it is acceptable for a member of my community to be enrolled in this study without consent if they had a traumatic injury resulting in blood loss and their legal representative (spouse, children, or guardian) could not be contacted.	4	12	84
I think it is acceptable for this study to be performed in my community.	4	11	85
I think the opt-out bracelet and online registry is an acceptable way to identify which potential patients do not want to be enrolled in the study.	15	11	74
To perform this type of research, it is important to involve the community in making decisions on behalf of the patients who might be enrolled.	25	13	62

TABLE 5

Willingness Score

WILLINGNESS Questions	Patient	Family	Community	p
1. I think it would be acceptable to enroll my family members into this study without consent if they had a traumatic injury resulting in blood loss and I could not be contacted.	3.5 (1.1)	3.8 (1.1)	3.8 (1.2)	0.026*
2. I think it is acceptable for me to be enrolled into this study without my written consent if I had a traumatic injury resulting in blood loss and my legal representative (spouse, children, or guardian) could not be contacted.	3.7 (1.0)	4.1 (0.9)	4.2 (1.1)	<0.001*†
3. I think it is acceptable for a member of my community to be enrolled into this study without consent if they had a traumatic injury resulting in blood loss and their legal representative could not be contacted.	4.1 (0.6)	4.2 (0.8)	3.8 (1.1)	0.037*
4. I think it is acceptable for this study to be performed in my community.	4.1 (0.6)	4.2 (0.7)	4.3 (0.8)	0.094
5. I think the opt-out bracelet and online registry is an acceptable way to identify which potential patients do not want to be enrolled in the study.	3.7 (0.9)	3.6 (1.1)	4.1 (0.9)	0.005*‡
Willingness questions				
1. I believe that medical research (in trauma care) is important.	4.4 (0.5)	4.4 (0.6)	4.6 (0.6)	0.005*
2. My participation in a medical study would be a very good thing.	3.9 (0.7)	4.1 (0.8)	4.2 (0.8)	0.025*
3. I or my family would benefit from medical research on trauma.	4.1 (0.7)	4.3 (0.6)	4.4 (0.7)	0.01*
4. My community would benefit from medical research on trauma.	4.0 (0.7)	4.3 (0.6)	4.4 (0.8)	<0.001*†
5. My participation in a medical study on trauma would be more trouble than it is worth.§	2.3 (0.9)	2.1 (1.0)	2.3 (1.1)	0.304
6. Participation in medical study on trauma seems risky.§	2.8 (1.0)	2.8 (1.0)	2.7 (1.2)	0.746
7. I think my doctor would approve of my involvement in emergency research.	3.6 (0.9)	3.9 (0.9)	4.0 (0.8)	0.006*
8. My immediate family is supportive of my involvement in emergency research.	3.6 (1.0)	3.9 (1.0)	3.7 (0.9)	.082
9. If my pastor, imam, or rabbi supported emergency research, I would be inclined to get involved.	3.2 (1.1)	3.3 (1.1)	3.4 (0.9)	0.579
10. My community feels that my participation in emergency research is good.	3.6 (0.8)	3.6 (0.8)	3.7 (0.8)	0.544
11. I like to do good for others.	4.3 (0.5)	4.3 (0.6)	4.7 (0.5)	<0.001*‡
12. Trauma, such as injuries related to violence or accidents, is a serious concern in my community.	4.1 (0.9)	4.4 (0.7)	4.3 (0.9)	0.013*
13. I would benefit from the medical care associated with an emergency study.	4.0 (0.5)	4.2 (0.6)	4.1 (0.7)	0.343
14. More research that could benefit trauma patients should be performed.	4.3 (0.5)	4.4 (0.6)	4.5 (0.6)	0.019*
15. Involving patients in a medical research study without asking their permission first is acceptable in emergency circumstances.	3.4 (1.1)	3.7 (1.1)	3.9 (1.0)	0.009*
16. It is okay to get permission from the family member if a patient cannot give permission themselves to participate in a research study.	4.1 (0.7)	4.2 (0.7)	4.3 (0.8)	0.008*
17. It is okay to enroll patients in emergency research studies if there is no family member present and there is not time to contact anyone.	3.6 (1.1)	3.8 (1.0)	4.1 (0.8)	0.001*
18. It is okay for medical researchers to include me in a study that might help me if I am unconscious or too sick to give permission myself.	3.6 (1.0)	3.9 (0.9)	4.1 (0.7)	0.015*
19. It is okay for my family members to give permission for me to be in a study that might help me if I am unconscious or too sick to give permission myself.	4.1 (0.7)	4.2 (0.8)	4.1 (0.7)	0.257
20. It is okay for medical researchers to include me in a study that might NOT help me but might help future patients if I am unconscious or too sick to give permission myself.	3.5 (1.0)	3.6 (1.0)	3.6 (1.1)	0.292
21. It is okay for my family members to give permission for me to be in a study that might not help me but might help future patients, if I am unconscious or too sick to give permission myself.	3.6 (1.0)	3.7 (1.0)	3.8 (0.9)	0.599
22. It is okay for emergency research that does not ask for patient's consent to be done in my community if the study might help the patient.	3.7 (0.9)	4.0 (0.8)	3.6 (0.9)	0.014‡

WILLINGNESS Questions	Patient	Family	Community	<i>p</i>
23. It is okay for emergency research that does not ask for patient's consent to be performed in my community if the study might help future patients.	3.7 (0.8)	3.9 (0.7)	3.5 (1.0)	0.033 [‡]

Participants ranked each statement using a 5-point Likert-type scale (strongly disagree = 1; disagree = 2, neutral = 3, agree = 4, strongly agree = 5)

Groups compared using the Kruskal-Wallis test. Significant differences underwent pairwise comparisons with adjusted significance of $p < 0.05$ reported.

* Patient versus community.

[†] Patient versus family.

[‡] Family versus community.

[§] Questions that were reverse coded when included in the willingness score.

TABLE 6

Univariate Analysis of EFIC and Willingness Scores

Variable	EFIC Score, Median (IQR)	<i>p</i>	Willingness Score, Median (IQR)	<i>p</i>
Group	16 (14–18)		82 (76–88.5)	
Patient (n = 172)	16 (14–16)	0.50	81 (75–84)	0.005
Family (n = 73)	16 (14–19)		84 (76–92.5)	
Community (n = 64)	16 (13–18.75)		83.5 (77–91)	
Sex				
Male (n = 162)	16 (14–17)	0.58	81 (75–87)	0.507
Female (n = 147)	16 (14–18)		82 (76–90)	
Age, y				
18–24 (n = 64)	16 (14–18)	0.466	82 (76–86.75)	0.205
25–34 (n = 57)	16 (14–18)		81 (73.5–86)	
35–49 (n = 83)	16 (14–18)		82 (76–91)	
50–64 (n = 76)	16 (14–18)		83.5 (76.25–91.75)	
65 (n = 29)	16 (13.5–16)		80 (75–84)	
Race				
African American (189)	16 (14–17.5)	0.044	81 (75–86)	0.118
White (n = 102)	16 (15–18)		83 (76–92)	
Other (n = 16)	14 (13–16)		84.5 (75.5–88.5)	
Religion				
None (n = 55)	16 (14–18)	0.339	80 (74.5–88)	0.413
Judeo-Christian (n = 203)	16 (14–18)		82 (75.25–86.75)	
Islam (n = 40)	16 (14–17.75)		81 (75.25–86.75)	
Other (n = 11)	16 (14.25–18)		84.5 (76.75–89.25)	
Education				
Some high school (n = 37)	16 (14–18)	0.50	80 (76–87)	0.314
High school graduate (n = 128)	16 (14–17)		82 (75–86)	
Some college or technical school (n = 82)	16 (14–18)		84 (76–90)	
College degree (n = 39)	16 (13–19)		82 (74–93)	
Professional degree (n = 23)	16 (15–20)		84 (79–91)	
Employment status				
Attending school (n = 18)	16 (13–16.5)	0.649	81 (74.5–89.25)	0.683
Part time (n = 41)	16 (13–19)		84 (76–91.5)	
Full time (n = 111)	16 (14–18)		82 (75–91)	
Unemployed/disabled (n = 137)	16 (14–17)		82 (76–85)	
Previous participation in medical research				
Yes (n = 66)	16 (14–17)	0.367	84 (75–90.25)	0.314
No (n = 243)	16 (14–17)		82 (76–87)	
Given permission for other to participate in medical research				
Yes (n = 17)	16 (14–18)	0.636	84 (70.5–90.5)	0.843
No (n = 292)	16 (14–18)		82 (76–88)	

Variable	EFIC Score, Median (IQR)	<i>p</i>	Willingness Score, Median (IQR)	<i>p</i>
Experience with significant trauma requiring a transfusion				
Yes (n = 130)	16 (14–18)	0.339	82.5 (75.75–90)	0.543
No (n = 178)	16 (14–18)		82 (75.75–86)	
Admitted following violent event				
Yes (n = 76)	16 (13–16)	0.035	81 (73–84)	0.078
No (n = 167)	16 (14–18)		82 (76–89)	
The AVERT Shock Trial is an important study to perform				
Yes (n = 299)	16 (14–18)	0.007	82 (76–89)	0.016
No (n = 4)	13.5 (9–16)		82 (74.5–91)	
Neutral (n = 6)	12 (10–14)		69 (60–77.25)	

Groups compared using the Kruskal-Wallis test. Significant differences underwent pairwise comparisons with adjusted significance of $p < 0.05$ reported.