Attitudes of Emergency Department Patients and Visitors Regarding Emergency Exception from Informed Consent in Resuscitation Research, Community Consultation, and Public Notification

Katie B. McClure, MD, Nicole M. Delorio, MD, Mary D. Gunnels, PhD, MS, Maria J. Ochsner, Michelle H. Biros, MD, MS, Terri A. Schmidt, MD, MS

Abstract

Objective: To assess public views on emergency exception to informed consent in resuscitation research, public awareness of such studies, and effective methods of community consultation and public notification. Methods: A face-to-face survey was conducted in two academic Level I trauma center emergency departments (EDs) in Oregon and Minnesota from June through August 2001. Results: Five hundred thirty people completed the survey, with an 82% response rate. The mean age of the respondents was 41 years (range 18–95) with a standard deviation of 14.5; 46% were female and 64% white. Most (88%) believed that research subjects should be informed prior to being enrolled, while 49% believed enrolling patients without prior consent in an emergency situation would be acceptable and 70% (369) would not object to be entered into such a study without providing prospective informed consent. Informing and consulting the community as a substitute for patient consent in emergency research was thought to be reasonable by 45% of the respondents. Most respondents would prefer to be informed about a study using emergency exception from informed consent by radio and television media (42%). Two hundred fifty-eight respondents (49%) stated they would attend a community meeting; the less educated were more likely to attend than those with college degrees (OR = 0.53; 95% CI = 0.33 to 0.85, p = 0.008). However, only 5% knew of ongoing studies in their community using emergency exception from informed consent. Conclusions: Most respondents disagreed with foregoing prospective informed consent for research participation even in emergency situations; however, many would be willing to participate in studies using emergency exception from informed consent. Most respondents would not attend community meetings, and would prefer to rely upon the media for information. Very few were aware of emergency exception from informed consent studies in their community. This suggests that current methods of community notification may not be effective. Key words: public opinion; emergency exception; informed consent; resuscitation research; community exception. ACADEMIC EMERGENCY MEDICINE 2003; 10:352–359.

Advancing the science of medicine often requires the use of human subjects. In the past, medical research subjects were entered into studies without their consent. For example, the Tuskegee syphilis trials enrolled a group of African American men with syphilis and withheld treatment in order to study disease progression. These men were entered into the study without their knowledge. In order to protect the rights of research subjects, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was formed in 1974 to review federally sponsored research. They developed the Belmont Report, which articulates the ethical principles that require subjects to receive and comprehend information about the study, and enroll voluntarily. The Department of Health and Human Services (DHHS) subsequently has required that informed consent be obtained before any conventional or experimental therapy may be administered to any person involved in federally funded research. The Food and Drug Administration (FDA) also requires informed consent for any research that is used to support or approve of a new drug or device. Most institutional review boards (IRBs) apply the same criteria to non-federally funded research as well.

The ethical issues surrounding resuscitation research are complex, because researchers must balance the potentially competing need to advance knowledge in this crucial area with the rights of individual...
research subjects. Under most circumstances the primary protection of the subjects' rights in research has been prospective informed consent prior to enrollment in a research study. However, many emergency medicine and acute resuscitation research questions concern the initial management of unstable patients whose critical illness or injury renders them unable to give prospective informed consent for research.

While this research is ethically challenging, it is vital because no effective therapies exist for a number of life-threatening conditions. For example, despite what the lay public seems to believe, survival from out-of-hospital cardiac arrest remains low, with estimates ranging from 3% to 15% in the United States. There seems to be a public misconception that current therapies are adequate and well studied. The public's misperception may affect public willingness to be involved in resuscitation research.

In November 1996, the FDA and the DHHS developed regulations to allow research to be performed with emergency exception from informed consent in certain emergency research circumstances. These mandates were developed with little to no prospective public input. The federal regulations require that the research subject be in a situation that is acutely life-threatening, and for which currently available treatments are untested or believed to be unsatisfactory. The potential subject must be unable to consent because of the acute clinical condition, and there is not time within the proposed therapeutic window to contact the legally authorized representative (as defined by the state in which the research is being conducted) to obtain prospective consent. Further, the possibility must exist that the subject will directly benefit from participation in the study. These regulations require community buy-in for proposed research and, therefore, additional protective measures have been mandated. These include public notification and community consultation concerning the appropriateness of conducting the study within that particular community. The community, with this consultation, does not have veto power over the study, does not substitute for the patient to provide consent, and does not provide “community consent” for the study. Instead, its role is to provide IRBs with concerns, suggestions, and questions that may not have been considered. The regulations do not provide specifics on what constitutes community consultation and public notification.

The FDA subsequently developed a guidance document giving some suggestions on what constitutes community consultation and public notification, but no data are available regarding whether these suggestions are broadly known, are realistic, or are practical. In addition, there is no information yet available about public views or understanding of the process of applying the exception from informed consent for emergency research and their role in the safeguards required for such research to go forward. The FDA has recognized a need to “evaluate the impact of the rule on enabling research on unconscious subjects as well as its impact on the acceptance of this type of research by society.” They note that community consultation and notification are new to clinical trials.

Although much has been written about the ethics and experience researchers have had with waiver of consent, little has been written about public opinion of the process. Smithline and Gerstle surveyed public willingness to be involved in research without consent in 1996, and found that willingness depended on income and the perceived risk of harm. However, this research occurred before the rules were implemented. The purpose of our study was to assess current public views on emergency exception from informed consent in resuscitation research, to test awareness of ongoing studies requiring exception from informed consent, and to identify effective methods of community consultation and notification.

METHODS

Study Design. This was a survey of adult emergency department (ED) patients and visitors designed to assess their knowledge, attitudes, and opinions about exception from informed consent and the regulatory mandates required to perform research studies using the Final Rule for exception from informed consent. The IRBs of both study sites approved this survey study prior to its execution.

Study Setting and Population. Trained research assistants administered a face-to-face survey to a convenience sample of adult patients and visitors in the waiting areas of EDs of the Hennepin County Medical Center and the Oregon Health & Science University from June through August 2001. Both hospitals are Level I trauma centers and are actively involved in research. The two survey sites were chosen in part because both communities have ongoing research projects involving waiver of consent as sites for the Public Access to Defibrillation Study (PAD), a multicenter national trial that is currently enrolling subjects using emergency exception from informed consent. The survey was administered in Spanish or English. Subjects were excluded if they did not speak one of these languages, or were younger
than 18 years of age. The survey was conducted on all days of the week, and during all shifts.

**Survey Content and Administration.** The survey was designed to assess knowledge of studies related to exception from informed consent, attitudes about the ethics of such studies, and willingness to participate (survey can be found online at [www.aemj.org](http://www.aemj.org)). Some questions were based on Smithline and Gerstle’s previous study. A pilot test was conducted, and some questions were revised as appropriate. Attitudes were assessed using Likert scale responses as well as two hypothetical situations.

**Data Analysis.** Data were entered into a Microsoft Access (version 9.0, Microsoft Corp., Redmond, WA) database and translated into SPSS (version 11.0, SPSS Inc., Chicago, IL) for analysis. A random sample of 15% of data entries were rechecked for errors with none found. Descriptive analyses of demographic characteristics were first performed (rates, frequencies, proportions). We then performed multinomial logistic regression methods to test associations between predictors (selected survey attitude and knowledge questions) and outcomes (ethical and personal participation in research). Common statistical tests were used to measure significance and association (Pearson chi-square, Pearson $r$). For purposes of analysis, the five-point Likert scale (strongly agree, agree, neutral, disagree, strongly disagree) was collapsed to agree, neutral, and disagree. An $\alpha$ level of less than 0.05 (one tail) was considered significant.

**Internal Consistency.** Five questions asked the respondent whether he or she personally would be willing to participate in research. Each question asked about willingness to participate under slightly different circumstances. Using Chronbach’s alpha, reliability analysis was performed on these questions to examine whether they were related to each other and were measuring a particular characteristic. Generally, the acceptable level of reliability for measuring the same characteristic is 0.80. This measure was selected because we were using ranked data measurements (not categorical data). There was an assumption that the data had a bivariate normal distribution.

### RESULTS

A total of 530 people completed the survey (332 in Oregon and 198 in Minnesota). One hundred twenty people were approached but were unwilling to participate, for a response rate of 82%. The mean age of the respondents was 41 years (range 18–95). Table 1 displays the demographics of the population. There were statistically significant differences for gender, education, and ethnicity.

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religion, educational level, and ethnicity between the two states. Three hundred twenty-six (62%) were patients in the ED, with the remainder comprised of family and visitors. One hundred seventeen (22%) respondents stated that they personally had been involved in medical research, and 27 (5%) stated that they were aware of at least one study currently being conducted in their community that allowed subjects to be enrolled prior to obtaining consent. The difference between those surveyed and the general ED population for race was within 8% for all races listed. With respect to gender, those surveyed exactly matched in Oregon. There was a difference of 10% in Minnesota, where more males were surveyed than that state’s general ED population.

Knowledge and Attitudes about Resuscitation Medicine. When asked a general question about research, 485 (93%) agreed that ongoing emergency research is important [25 (5%) neutral; 15 (3%) disagree]. When asked about chance of survival after cardiac arrest, 324 (61%) believed there was a 50% or greater chance of survival, while 200 (38%) believed there was a less than 50% chance of being incapacitated. Further, 372 (72%) agreed that current medical treatment for people whose heart has stopped is effective [114 (22%) neutral; 33 (6%) disagree] and 421 (81%) agreed that current treatment for people seriously injured and bleeding is effective [74 (14%) neutral; 26 (15%) disagree] (Figure 1). There was no association between a person’s belief that treatments for cardiac arrest and serious injury are effective and the person’s belief that there are times when enrolling research subjects prior to consent in an emergency situation is ethical.

Views on Exception from Informed Consent and Personal Willingness to Participate in Studies. In our population, 463 (88%) agreed with a general statement (not mentioning exception from informed consent) that research subjects should be informed prior to being enrolled in a study [33 (6%) (neutral); 29 (6%) disagree]. When asked a specific question about enrolling subjects in an emergency situation, 181 (34%) agreed that enrolling patients without prior consent in an emergency situation would be acceptable [73 (14%) neutral; 272 (52%) disagree] and 399 (70%) personally would be willing to be entered into a study prior to obtaining consent if it were important to learn about the treatment for a condition that currently has no good treatment [70 (13%) neutral; 86 (16%) disagree]. However, when posed two case scenarios, only 253 respondents (49%) would be willing to be entered into a study testing new therapies for serious bleeding and 316 (62%) would be willing to be entered into a study assessing the efficacy of public access to defibrillation (Figure 2). Whites were more willing to participate in the defibrillation study (OR = 0.64; 95% CI = 0.41 to 0.99, p = 0.046).

The respondents were asked two further questions about their willingness to participate in research without giving prior consent. In the first question, they were asked whether they would be willing to

![Figure 1. Survey questions assessing attitudes about resuscitation research.](image-url)
A hospital in your community is interested in determining if there is a better way to treat life-threatening bleeding than the standard therapy of replacing it with a salt water solution. They devise a new fluid that closely resembles blood. They believe that this could help in patient survival.

If I were in a serious accident, bleeding, and in shock, I would be willing to be entered into the study before giving consent.

- Disagree: 39.5%
- Neutral: 12.1%
- Agree: 48.5%

If my heart stopped and I collapsed, I would be willing to be entered into this study before giving consent.

- Disagree: 27.0%
- Neutral: 11.5%
- Agree: 61.5%

**Figure 2.** People were asked to respond to the two case scenarios above.

participate if the risks were minimal (such as having a blood test). In this case, 392 respondents (75%) were willing [44 (8%) neutral; 88 (17%) unwilling]. In the second case, the risks were described as more than minimal, such as receiving a new drug. In this case, 259 (50%) were willing to participate [97 (19%) neutral; 166 (31%) unwilling] (Figure 1). For both of these questions, Oregonians were more willing to agree to participate than Minnesotans (p < 0.0001).

A multinomial logistic regression model was developed using gender, race, religion, educational level, and insurance status. In this model, nonwhites were less likely to agree with the statement, “I personally would be willing to be in a study if it were important to learn about the treatment for a condition that currently has no good treatment” (OR = 0.34; 95% CI = 0.22 to 0.52, p < 0.001). Nonwhites also were less likely to agree with a statement that, “There are times when it is so important to learn about a potential new treatment that it would be okay to enroll patients in a study before they were able to give consent” (OR = 0.60; 95% CI = 0.39 to 0.93, p = 0.022) (Figure 1). There was no association between gender, religion, educational level, or insurance status and these two questions. In the same model, only gender was associated with the more general statement that subjects should be informed before being entered into a study (OR = 0.42; 95% CI = 0.18 to 0.95, p = 0.038).

**Community Consultation.** Subjects were asked to respond to the statement, “Informing the community before doing a study without consent is not necessary,” and 38 (73%) disagreed with this statement [92 (18%) agree; 51 (10%) neutral]. However, informing the community and consulting the community as a substitute for patient consent in emergency research was believed to be reasonable by 235 (45%) of the respondents [83 (16%) neutral; 208 (40%) disagree]. Oregonians were more likely to agree with this statement than Minnesotans (OR = 0.37; 95% CI = 0.24 to 0.57, p < 0.001). The survey asked respondents to pick as many potential methods of informing the community as they endorsed (Figure 3). While 258 respondents (50%) stated they would attend a community meeting, respondents with less education were more likely to attend than those with college degrees (OR = 0.53; 95% CI = 0.33 to 0.85; p = 0.008). People who believe there are enough safeguards in place to ensure that research is done in an ethical manner also were more likely to agree that for some studies it would be reasonable to do research without consent after informing the community (OR = 0.57; 95% CI = 0.43 to 0.73, p < 0.001).

**Internal Consistency.** Reliability analysis was performed to examine internal consistency among the five questions about willingness to participate in research, based on the average inter-item correlation. Chronbach’s alpha was 0.69.

**DISCUSSION**

Our study was designed to look at the views on emergency exception from informed consent in resuscitation research of ED waiting room occupants. Smithline and Gerstle reported their survey prior to implementation of the current regulations. Because of the requirement for community consultation and public notification in the Final Rule, the community has been granted an advisory role in resuscitation research protocols using the emergency exception from informed consent. It is not clear whether this role is understood by investigators or by the community itself. We, therefore, thought it was important to study public opinion now that the regulations have been used in several studies.

We asked five questions about willingness to participate in research without consent. These questions varied the circumstances to include research that involved both minimal risk and higher risk. The questions also varied the seriousness of the medical condition. Chronbach’s alpha for these questions was 0.69. This suggests an association between these measurements of personal participation in research yet, as expected, is not within the acceptable range of reliability for measuring a single characteristic. This implies that the respondents were consistent in their beliefs, but their willingness to participate in research involving emergency exception from informed consent would vary depending on the circumstances.

In general, the respondents strongly endorsed the importance of obtaining informed consent, including
informed consent in emergency research. However, most respondents did not agree with a statement that there are times when it is so important to do research that it can be done prior to obtaining consent. On the other hand, we found that most people would be willing to be enrolled into a study using exception from informed consent. This suggests that people are uncomfortable with the idea of emergency exception from informed consent, but would ultimately participate to advance medical knowledge. This willingness to participate varied with the circumstances. For example, people were more willing to participate in a study of public access defibrillation than one of a blood substitute for trauma patients, both actual studies that have used emergency exception from informed consent. We also found that the majority of people were more willing to participate if the risks were minimal; when the risks were described as more than minimal, such as receiving an experimental drug, they were less willing to participate. This is in consistent with the findings of Smithline and Gerstle. We also used case-based examples in our survey (Figure 2) to help elucidate the issues surrounding exception to informed consent. This, coupled with the consistency in the two surveys done to date, suggests that those surveyed had an understanding of the issues.

There were some differences in responses based on ethnicity. Nonwhites were less likely to believe that there are times when it is appropriate to do studies prior to obtaining consent. They were also less likely to be willing to participate in studies that use exception from informed consent. This may be due to a mistrust of researchers, based on previous investigations involving vulnerable populations (particularly ethnic minorities), in which no consent was obtained. This finding could have important implications in designing studies in certain communities. Special efforts to reach out to diverse populations may be necessary when designing studies using the exception from informed consent and appropriate community consultation and public notification.

We wondered whether there was a misconception that current resuscitation treatments are effective and how that perception might affect views on future resuscitation research. Most respondents agreed that resuscitation research is important. On the other hand, we found that there were unrealistic ideas about outcome after one’s “heart stops.” The majority of respondents believed that treatments for cardiac arrest are adequate and that there is greater than 50% chance of full recovery. This perception differs from the reality of 3–15% survival to hospital discharge\(^3\) and has
been termed emergency medicine’s “illusion of efficacy.” Although we found no association between belief in the likelihood of survival from cardiac arrest and agreement that it is acceptable to do research without consent, this may make it difficult to convince the public that further research is needed.

In order to evoke the exception from informed consent under the Final Rule, researchers must notify and consult with the community. This is a new process that has never before been required. The methods of such consultation were not stipulated in the rules, which authorize the local IRB to determine what is an appropriate means of notification and what level of involvement is acceptable. This community consultation must be “acceptable to the local community, and at a level of involvement that is appropriate to the project.” Not surprisingly, we found that people who believe that the current safeguards in research are adequate were more likely to support studies using exception from informed consent for research after community consultation.

In the studies that have implemented the exception from informed consent rule, many means of community consultation and notification have been used. These methods have included community meetings, 24-hour telephone hot lines, newspaper and radio advertisements, videotape presentations, posters, and more. Barren et al. proposed an alternate means of community consultation by surveying patients regarding their willingness to be entered into a hypothetical study prior to the beginning of such a study. This consultation does not mean that the community can have direct input on changing the study, but rather allows issues to be raised that may be addressed by the IRB.

One of the purposes of community notification is to increase awareness that a study using exception from informed consent is occurring in the community. Currently, both communities in which this study was undertaken have ongoing studies using the emergency exception to informed consent, and both sites conducted public notification and community consultation prior to initiating these studies. However, only 5% of our population knew of ongoing studies in their community, suggesting that current methods of public notification were not effective.

Although nearly half of the respondents stated they would be willing to attend a community meeting as a method of community consultation, we found that most of our population would prefer to be informed through the media. People with less education were more likely to agree that they would attend a community meeting. Of course, such survey results do not guarantee actual attendance. One study found that in area of 1.5 million people, 25 attended community meetings. This suggests that meetings may serve as a way to consult, but more action is needed to notify the community.

LIMITATIONS

Our study was conducted in ED waiting rooms, and the demographics of our subjects were similar to those of the patients treated in each department. The demographics of the two departments are different with respect to race. This convenience sample may not reflect the views of the general public. Our population consisted of people experiencing some type of acute medical problem, which may or may not be an appropriate group to assess. One could argue that the most appropriate subjects may change with each study. For example, a study looking at trauma resuscitation affects the general public, while a study on cardiac resuscitation may affect only the sickest of the population. Therefore, we believe the most appropriate population to target has yet to be defined and may change based on the study design. Our sample population may have missed the sickest patients due to the need for timely treatment and inability to answer survey questions.

In addition, it is possible that the research assistants who identified subjects in the waiting area introduced bias based on whom they approached. Further, about 19% of those approached chose not to participate, and these people may have been systematically different from those who did. The population was largely white, and only 2% of the surveys were conducted in Spanish. We found some ethnic differences in responses that may need to be explored further in the future. Our sample did not include a sufficient number of nonwhites to further analyze these ethnic differences. Finally, the survey was done face-to-face with the research assistant. It is possible there was a tendency for people to respond in ways they thought the researchers would prefer. For example, the results may overestimate those who would be willing to attend meetings or participate in research.

CONCLUSIONS

In this population, most respondents were uncomfortable with the concept of emergency exception from informed consent for research even in emergency situations; however, many would personally be willing to participate in such studies. This may suggest that people are interested in protecting the public, but are ultimately altruistic in furthering resuscitation research.

We also found that nonwhites were more uncomfortable with emergency exception from informed consent. This suggests that special attention should be paid to addressing concerns of minorities in this type of research.

Less than half of respondents believed that research without consent after community notification is reasonable. Most respondents would not attend community meetings about a proposed study in their
community. They would prefer to rely upon the media for information. Very few were aware of waiver of consent studies in their community, despite the fact that there are ongoing studies. This suggests that current methods of community notification may not be effective.

References

2. Protection of Human Subjects, 45 CFR, part 46, Subpt A.