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Community Attitudes towards Emergency Research and Exception from Informed Consent

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Abstract

Objective—To determine public attitudes towards emergency research, exception from informed consent (EFIC) and a specific proposed clinical trial using EFIC.

Methods—As part of a planned community consultation activity, a survey was conducted at a popular public venue. Participants answered demographic questions and then were asked their opinions on specifically described consent circumstances in emergency research, including the proposed EFIC trial. Multiple logistic and linear regression were used to determine respondent characteristics associated with specific attitudes.

Results—1901 surveys were completed, The majority of respondents supported emergency research (88%) and the concept of surrogate consent by a legally authorized representative (78%). The concept of EFIC was less well supported (35%) but the application of EFIC was more accepted, especially when EFIC was applied to the respondent themselves (51%). The community believed the proposed EFIC study was acceptable (82%); a minority had concerns but most were related to patient safety and not to EFIC. Respondents with less education and lower incomes were less likely to express opinions about the consent and research concepts described.

Conclusions—emergency research and the proposed EFIC trial is supported in this community. The concept of EFIC is less well supported but is more acceptable when a specific trial is described or when respondents consider EFIC for themselves. Specific respondent characteristics are associated with attitudes about research; this can assist in development of meaningful community consultation activities.

Keywords

Emergency research emergency exception form informed consent; community consultation

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Conflict of interest statement

Dr. Biros serves as a member of data and safety monitoring committees on industry and federally funded research related to critical care. Dr. Biros is the principle investigator for the University of Minnesota Hub of the Neurological Emergencies Treatment Trials (NETT) Network. This involvement would not influence the research presented here. The remaining authors also have no financial or personal relationships that would influence or bias this work.

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1. Introduction

One of the regulatory requirements for research using the emergency Exception from Informed Consent (EFIC) is community consultation with members of the community in which the research is to be performed and members of the community of potential research subjects if those communities are not the same. The nature, content and intensity of community consultation is not completely prescribed by federal regulations, in order to allow site specific application. However , community consultation must include a two- way communication, in which the communities are educated to the content of the EFIC study, and the meaning and need for EFIC .

Although community consultation is not meant to provide community consent or disapproval, the IRB is required, in its deliberations on the proposed EFIC study, to consider questions and concerns from members of the communities. In preparation for a national EFIC trial of pre-hospital interventions for status seizures, we developed a community consultation plan together with our IRB to reach a broad base of the general population of our state (the community in which the research is to be performed) , as well as specific community members at risk for the disease under investigation (the community of potential research subjects).

The current study was directed towards a broad population of Minnesotans. In addition to specific discussion of the planned EFIC trial, we also hoped to assess public attitudes towards research in general and emergency research in particular. We wanted to determine respondent characteristics associated with specific attitudes or understanding about research. We hoped to use this information to determine effective methods of community engagement for future EFIC research trials.

2. Methods

This was a survey of persons visiting the emergency medicine display located in the University of Minnesota education building at the Minnesota State Fair . Data were collected on three afternoons and evenings for a total of 13.5 hours, during August 2008. About 16,000 persons walk through the education building each day of the State Fair. It is a common location for the performance of surveys and health screening examinations. This study was reviewed and approved by the IRB at the University of Minnesota and the Human Subjects Research Committee at Hennepin County Medical Center. Because of its voluntary and anonymous nature , informed consent was waived. However, a cover page was included with the survey tool that provided an overview of the purpose of the study, details of the proposed EFIC trial, and contact information should questions subsequently arise.

The survey consisted of three parts; part one asked for demographic information, previous research exposure/ involvement and whether or not respondents knew of anyone (including themselves) who had experienced seizures. Part two described the proposed pre-hospital study that would enroll seizing patients using EFIC. Respondents were queried about questions or concerns about the study, whether they believed it was valuable for our community, and whether EFIC enrollment would be personally acceptable for their own enrollment. Part three asked about the acceptability of research under various circumstances such as with or without surrogate consent, or with or without the possibility of direct patient benefit.

The survey was not previously validated but had been tested for readability and understanding with 38 undergraduate students (data not included). Based on their assessment of the survey, no modifications were made. Categorical responses were available for demographic and personal characteristic questions; for questions asking for opinions , a five point Likert scale was used (1= strongly agree, 3= no opinion , 5= strongly disagree).

Surveys were distributed by trained research associates (RAs) under the supervision of the research study team (i.e., the PI and research coordinators) Respondents completed the survey in writing; the RAs were available to read the survey to the respondents if so desired. Questions about the survey, the seizure study and EFIC were encouraged, and directed to the research team.

Among other demographic information, respondents were asked to identify their religious denominations. Because of the small number of respondents classifying themselves into specific non- Christian denominations, the demographic category for religions was collapsed for analysis into Christian (Catholic and protestant denominations) and non - Christian (Buddhist , Muslim, Jewish).

Data were analyzed using SAS 9.1 (SAS Institute Inc., Cary, N.C., USA). Bivariate analyses were evaluated with chi-square tests for proportions, student's t-test for comparing means, and correlation coefficients for evaluating the associations between two continuous or approximately continuous variables. For multivariate analyses, where the dependent variable was dichotomous , we performed a logistic regression and for all others we used linear regressions

3. Results

One thousand nine hundred and one persons participated ; the demographics of the respondent group are shown in Table One. All responses were self- reported; classification as rural or urban was based on zip codes and state definitions. The distribution of ages ,educational levels, and household incomes are listed in Table Two. Thirty five per cent of respondents knew someone who or themselves had experiences seizures.

Fifteen percent (n= 290) had previously participated in a research study and 8 % (n= 154) had previously refused to participate .The reasons for participation or refusal are listed in Table Three. One hundred and fifty respondents (8.1 %) had previously provided consent for someone else (a minor or other vulnerable relative) to participate in research.

Overall, respondents were supportive of medical research, and 88 % indicated that they believed research in emergency care was important (9 % had no opinion). Those with more education were more favorable towards emergency medical research (p= .0090); those with a higher income and those who previously participated in research tended to be more supportive (p= .0575 and .0642, respectively).

The attitudes of respondents towards various consent concepts and associated respondent characteristics are show in Table Four. Respondents supported the concept of surrogate consent for research participation ; 78 % agreed or strongly agreed that it is acceptable for family members to provide consent for research participation when they themselves could not. Even when told that there would be no direct benefit from their enrollment into a research study, 65 % still would allow their family members to provide surrogate consent on their behalf.

Enrollment into emergency research without prospective consent was less strongly supported. When no specific study was described, only 35 % of respondents agreed or strongly agreed that it is acceptable to enroll patients into emergency research studies without consent (Table four). If the respondents were told that the proposed EFIC research offered a direct benefit to the patient, 41 % agreed or strongly agreed that the research was acceptable without consent; older persons agreed less often (p= .0391). If the EFIC study did not offer direct benefit but might help future patients, 38%% were supportive or strongly supportive. No specific demographic characteristic was associated with being supportive of research in this

circumstance; those who were older or with more education tended to be less supportive ($p = .0573$ and $p = .0901$ respectively).

However, when the respondents were asked if it was acceptable that they personally be enrolled in an emergency EFIC research study when they themselves were too sick to give permission, 51 % agreed or strongly agreed . Table four shows respondent characteristics associated with specific attitudes on a persons' own enrollment into an EFIC trial.

Related to the proposed EFIC seizure study , a large majority (82 %) of respondents believed the study was valuable for our community. Respondent characteristics associated with specific attitudes regarding the proposed trial are shown in Table five. Overall, only 3 % of respondents had specific questions about the proposed EFIC trial. A number of themes emerged from among the questions and concerns stated by respondents ; these are categorized in Table Six.

The IRB was informed of the results of the survey and considered the survey responses as an adequate community consultation . No changes in the protocol or material related to EFIC were required by the IRB based on the results of the survey. The survey informed the development of public notification material; specific details of the protocol were expanded.

4. Discussion

As part of community consultation targeting the population in which our planned EFIC trial will take place, we surveyed a large number of persons at a popular public venue, the Minnesota State fair. For the most part, the demographic characteristics of the study population reflect those of the state (Table One). Given the similarities between the state and study populations, we believe the opinions we gathered provide a reasonable representation of public attitudes of Minnesotans towards research. However, because of the relatively homogenous study group, we cannot generalize our findings to other specific population subgroups within the state, such as the growing population of ethnic and racial minorities. While the State fair data is valuable to discern public attitudes about research, EFIC and the proposed EFIC seizure study , it may be incomplete in other circumstances, such as for research involving an acute illness or injury that targets a different specific population (for example, trauma in young adults in Minnesota).

Our data suggest an overall support of emergency research. This is consistent with other studies of public attitudes towards emergency research (1,2). Our respondents also were supportive of the proposed EFIC seizure study. Only a small number of respondents had questions or concerns about the proposed seizure trial, and most were related to clinical issues , such as patient safety, the drug approval process, and the study design . However, a quarter of those with concerns or questions were concerned about research ethics and/or EFIC . Concerns about patient safety and the risk- benefit ratio were commonly expressed by survivors of sudden cardiac death interviewed by Dickert, et. al (2) ; less concern was expressed related to randomization or the exception from consent. These concerns must be acknowledged and addressed by investigators, even if they represent a minority of concerns. Community consultation activities might be more able to engage the public to support the research process if detailed discussion and education about the clinical aspects of the proposed study are included, as well as research ethics and EFIC. This is further suggested by the observation that support of these research concepts was more apparent when more details were available (ie. the specific study was described), and when it was known that a direct patient benefit was possible from study enrollment. Triner, et.al., (3) also found more acceptance of EFIC among emergency department (ED) patients when the concept was described in the context of a specific trial. Richardson et.al., (4) found that focus group participants with negative attitudes about EFIC were strongly supportive of EFIC research trials described in specific scenarios. Longfield et.al, (5) reported that only 35 % of attendees to at community meetings supported

the concept of research without consent in emergency circumstances, but 82% believed a described EFIC trial was valuable in the community.

The concept of EFIC itself was not as well supported among our respondents as other consenting circumstances. It is interesting to note that EFIC was less supported when respondents were asked to assume responsibility for deciding on the acceptability of EFIC for others, as compared to EFIC for themselves. McClure et. al, (6) found that only 49 % of a surveyed ED population (n= 530, including 198 in Minnesota) supported the concept of EFIC, but 70 % felt it was acceptable that they themselves be enrolled in an EFIC trial. Kasner et.al.,(7) found similar results in neurology patients. McClure has suggested that this phenomena may represent a simultaneous desire of patients to protect the public and an altruistic attitude towards those with critical illness and injury (6). The reluctance to support EFIC for others may also reflect uneasiness of an individual to speak on behalf of strangers. Careful consideration of what constitutes acceptable community representation needs to be included in the development of a community consultation plan (4) .

Certain respondent characteristics were associated with support or lack of support for the consent concepts included in the survey. For example, those with higher education or incomes were favorably inclined or tended to be favorable towards research in general and EFIC in particular, whereas those with less education and who were older were not supportive. In addition, we observed that women tended to be less supportive of many of the research concepts. Similar gender differences have been described (3). Although the gender difference in attitudes among our respondents did not usually reach statistical significance, we believe it is an important practical observation, since women often are the medical decision makers for their families. This information may be useful in planning the content and intensity of community consultation activities, to ensure that adequate time and effort is devoted to those groups with less support or understanding of these complex topics.

We also found that certain respondent characteristics were associated with the response of “no opinion” regarding research and consent concepts. This response could represent uncertainty, a lack of adequate information , or reluctance to state an opinion. Regardless, the characteristics of this group are key to community engagement in the research process. In almost all questions we asked, those who responded with “no opinion” were, or tended to be, those with lower incomes and less education. In many types of community consultation activities, such as the use of pre-existing meetings, individuals with no opinion might not be recognized. Analyzing only the responses of those who voice an opinion during community consultation activity might lead investigators and IRBs to a biased impression of the acceptability (or lack of acceptability) of the research within the entire community . Discerning why some persons have no opinion (ie. they don’t understand the concept being described), might address the adequacy of the community consultation activity itself.

It is logistically impossible to consult with or even identify every member of the community in which an EFIC trial is to occur and from which study subjects will be drawn. In fact, the definition of community is itself not always clear to potential research subjects themselves. (4). Many types of consultation have been attempted, with various degrees of community involvement; many believe that community consultation may be one of the most difficult of the EFIC requirements to fulfill (8,9).When public meetings are held, attendance is often low ; Booth et al.,(1) found that , while 65% of interviewed ED patients supported public meetings as a means of community consultation , fewer that 35% stated they would attend such meetings. Public meetings called specifically for community consultation on a proposed EFIC trial also are often poorly attended and may result in biased attendance not representative of the broader community (10). Focus groups provide the opportunity to discuss issues in more detail and more specifically, but may not reflect the feelings of the broader community (11). Recently,

Dickert et. al (2) performed structured interviews of survivors of sudden cardiac death, in order to obtain the perspective of those most intimately involved with a condition that would qualify for EFIC research studies. While this unique approach is perhaps the most relevant to the question of EFIC, it is labor intensive, requires an available and cognitively intact survivor group, and may in fact be biased towards altruism and trust in the medical establishment that ,in fact , saved the lives of the participants.

We chose a survey technique for community consultation to obtain opinions (and identify characteristics of those with favorable , unfavorable and no opinions) from a large representative group in a relatively short time frame. Surveys have been successfully used by others to gather public opinions about emergency medicine research and EFIC . (6,12,13). Random digit dialing has been described as a means of community consultation , using scripts describing the proposed EFIC study and a survey to assess attitudes (14). Survey techniques can potentially reach a broad constituency , but may be subject to responder bias (15). In order to avoid this, we surveyed a large number of individuals but we acknowledge this possibility. If well -crafted, a survey can provide good insight into community attitudes in an anonymous and non - threatening manner. However, we believe that, in order to fulfill the requirement that community consultation be a two -way communication between investigators and the community, surveys must include the opportunity for respondents to state their concerns through open ended questions , coupled with the immediate availability of the investigators to answer questions and address concerns.

The responses obtained to a variety of questions suggest altruistic motives for participation in research. Very few of the respondents who had previously participated in research had done so for concrete benefits, while those who refused did so because it was not convenient to participate. Our respondents were willing to allow themselves to be enrolled in research trials with surrogate consent or with EFIC, even with no direct benefit, but with the potential to benefit others. Altruism has been noted as a motivation for participation and for support of emergency research in many other studies. Survivors of sudden cardiac death would participate in research because of its potential benefit for future patients.(2). Blixen and Agich (16) found that a large majority (83%) of stroke patients were willing to be enrolled into research trials (although half were uncertain about enrollment without informed consent): their motivations were primarily altruistic. Altruistic attitudes, even in the face of risky studies, imply a certain degree of trust towards the research and medical establishment. Most survivors of sudden death ,when interviewed about attitudes towards emergency research ,exhibited trust towards the clinicians , the medical community and the process of scientific review of a proposed research project(2). The public trust is required for in acceptance of all research; with EFIC studies, it is especially important. Public confidence in the research enterprise can be strengthened with thoughtful approaches to community engagement (17,18).

5. Conclusions

Emergency research and the proposed EFIC trial is supported in the community in which the research will occur. The concept of EFIC is better supported when a specific trial is described and when respondents answer for themselves. Specific respondent characteristics are associated with attitudes or no opinions about EFIC and research; with this information, community consultation can be tailored to be more meaningful.

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References

1. Booth MG, Lind A, Read E, Kinsella J. Public perception of emergency research; a questionnaire. *European J Anaesthesiology* 2005;22:933–937.
2. Dickert NW, Kass NE. Patients' perceptions of research in emergency settings; a study of survivors of sudden cardiac death. *Social Science Medicine* 2009;68:183–191. [PubMed: 19004536]
3. Triner W, Jacoby L, Shelton W, et al. Exception from informed consent enrollment in emergency medical research; attitudes and awareness. *Acad Emerg Med* 2007;14:187–191. [PubMed: 17267533]
4. Richardson LD, Wilets I, Ragin DF, et al. Research without consent; community perspectives from the community VOICES program. *Acad Emerg Med* 2005;12:1082–1090. [PubMed: 16264079]
5. Longfield JN, Morris MJ, Moran KA, Kraugh JF, Wolf R, Baskin TW. Community meetings for emergency research community consultations. *Crit Care Med* 2008;36:731–736. [PubMed: 18091552]
6. McClure KB, Deloio NM, Gunneis MD, Ochsner MJ, Biros MH, Schmidt TA. Attitudes of emergency department patients and visitors regarding emergency exception from informed consent in resuscitation research, community consultation and public notification. *Acad Emerg Med* 2003;10:353–359.
7. Kasner SE, DelGiudice A, Rosenberg S, et al. Who will participate in acute stroke trials? *Neurology* 2009;72:1682–1688. [PubMed: 19433742]
8. Biros MH. Research without consent; current status 2003. *Ann Emerg Med* 2003;42:550–564. [PubMed: 14520326]
9. Baren JM, Biros MH. The research on community consultation; an annotated bibliography. *Acad Emerg Med* 2008;14:346–352. [PubMed: 17400998]
10. Shah AN, Sugarman J. Protecting research subjects under the waiver of informed consent for emergency research; experience with efforts to inform the community. *Ann Emerg Med* 2003;41:72–78. [PubMed: 12514685]
11. Morris MC, Nadkarni VM, Ward FR, Nelson RM. Exception from informed consent for pediatric resuscitation research; community consultation for a trial of brain cooling after in-hospital cardiac arrest. *Pediatrics* 2004;114:776–781. [PubMed: 15342853]
12. Baren JM, Ancietti JP, Ledesma S, Biros MH, Mahabee-Gittens M, Lewis RJ. An approach to community consultation prior to initiating an emergency research study incorporating a waiver of informed consent. *Acad Emerg Med* 1999;6:1210–1215. [PubMed: 10609922]
13. Smithline HA, Gerstle ML. Waiver of informed consent; a survey of emergency medicine patients. *Am J Emerg Med* 1998;16:90–91. [PubMed: 9451323]
14. Bulger EM, Schmidt TA, Cook AJ, et al. The random digit dialing survey as a tool for community consultation for research involving the emergency medicine exception from informed consent. *Ann Emerg Med* 2009;53:341–350. [PubMed: 18824274]
15. Lewis RJ. Community consultation by randomly reaching out to the community. *Ann Emerg Med* 2009;53(3):351–354. [PubMed: 18986733]
16. Blixen CE, Agich GJ. Stroke patients' preferences and values about emergency research. *J Med Ethics* 2005;31:608–611. [PubMed: 16199606]
17. Dickert NW, Sugarman J. Getting the ethics right regarding research in the emergency setting; lessons from the Polyheme study. *Kennedy Institute of Ethics Journal* 2007;17:153–169. [PubMed: 18018997]
18. Richardson LD, Rhodes R, Ragin DF, Wilets I. The role of community consultation in the ethical conduct of research without consent. *Amer J Bioethics* 2006;6:33–35.

Table One

Demographics of Study Population vs Minnesota State

	Per cent of Study population (N = 1901)	Percent of Minnesota population (2006 census) (n= approximately 5 million)
Female gender	65	
White	94	87
Urban	65	65
Christian *	79	84
≥ College	47	42
> \$50 K/ yr	48	Median income= \$52K

(Non- Christians = Buddist, Muslim, and Jewish)

* Christian = Catholic and Protestant denominations

Table Two

Respondent characteristics (n= 1901)

Age distribution(years)	n	%
18-24	255	13
25-34	182	9.4
35-49	551	28.6
50-64	640	33.2
≥65	299	15.5

Education level		
Grade School	29	1.5
Some high school	77	3.9
High School/ GED	272	14.0
Some college	407	20.9
2 yr college/tech degree	217	11.1
4 yr college degree	598	30.7
Grad school/ degree	347	17.8

Yearly household income		
Less than \$10,000	57	3.5
\$10,000- 25,000	92	5.6
\$26,000- 50,000	324	19.8
\$51,000-75,000	374	22
\$76,000- 100,000	342	20.8
> \$ 100,000	451	27.5

Table Three

Reasons for previous participation or refusal of participation in previous research studies

Previous participation in research (303 responses from 290 persons)		
	n	%
Personal interest in the topic	156	53.8
Someone asked	135	46.6
Might help others	136	46.9
Might advance science /medicine	122	42.2
Unique personal experience	55	19.0
Financial compensation	44	15.2
Other benefits	34	11.7
Other	17	5.8

Previous refusal to participate in research (184 responses from 154 persons)		
Too much of a time investment	82	53.3
Inconvenient time or place	38	24.7
Concerned about the risk	36	23.4
Information was not clear or complete	33	21.4
Concerned about confidentiality	31	20.1
Insufficient compensation	18	11.7
Other	18	11.7

Table Four

Attitudes towards consent concepts in general and associated respondent characteristics

Concept	Supports*	Does not support*	Has no opinion*
Surrogate Consent is acceptable if the patient cannot give consent	78% of total Higher education (<.0001)	11% of total Non- white (.0230) Older (<.0001)	11% of total Older (.0191) Less education (<.0001)
Surrogate Consent acceptable even if the research study offers no direct benefit to the patient	65% Higher income (.0275) Younger (.0025) More education (.0032) Know of someone with seizures (.0876)	19.3% Women (.0078) Non white (.0109)	15.6% Older (.0457) Less education (<.0001)
EFIC is acceptable for patient enrollment into an emergency research study when no surrogate is available to speak for the patient	35.4% Higher incomes (.0136) Knows someone with seizures (.0287)	46.5% Women(.0758)	18.0% Less education (.0067) Lower income (.0056)
EFIC is acceptable even if the research study offers no direct benefit to the patient	38.1% No characteristics statistically significant	38.1% Older (.0573) More education (.0901)	23.4% Less education (.0035) Lower income (.0002)
EFIC enrollment is acceptable for myself if no surrogates are available to speak for me	51% Previous participation in research (.0483) Knew someone with seizures (.0028)	31.3% Women (.0692)	17.6% Lower income (.0400) Less education (<.0001) Older (.0695)
EFIC enrollment is acceptable for me even if the study offers no direct benefit	46% Higher income (.0704)	34.4% Women (.0704)	19.2% Less education (<.0001) Lower income (.0879)

* numbers in parentheses are p values; % do not always add up to 100 due to rounding

Table Five

Attitudes specific towards the proposed EFIC seizure trial and associated respondent characteristics

	YES*	NO/NO OPINION*
The proposed study is valuable for our community	82% More education (.0233) Higher income (.0607)	4% ; Non - Christians (.0021) Older (.0778) 14% No opinion
EFIC is acceptable for emergency research in our community	74% Higher income (.0092) More education (.0249) Know someone with seizures (.0633)	3.6 % 22.4% No opinion
My own EFIC enrollment in this study would be acceptable	45 % Younger (.0110) More education (.0180)	19 % 35% No opinion
I have questions about this EFIC study	3 % Previous research participation (.0017) Know someone with seizures (.0044) Higher incomes (.0800) Rural (.0885)	97%
I have concerns about this study	10 % Previous research participation (.0598) Non Christians (.0716)	60 % No concerns Higher income (.0212) 30 % No Opinion Older (.0002) Less education (.0247)

* numbers in parentheses are p values; per cents do not always add to 100 due to rounding

Table Six**Written responses ; Questions/ concerns about the proposed EFIC trial**

Do you have Questions ? (n= 27)
On Clinical issues (n=12)
Related to the nature of seizures = 4
Safety issues related to the study drugs/ drug delivery = 3
Potential harm if delayed treatment = 5
On Study design =6
On the FDA and drug approvals = 4
On research ethics/ consent (n= 4)
Why is consent not possible?= 1
When will consent be obtained?= 1
Is this study ethical?=2
Do you have Concerns ? (n = 103)
On clinical issues
Patient safety issues/potential for harm if delayed treatment = 28
Design issues = 34
FDA and drug approvals = 12
Research ethics/ consent (n= 26)
No consent will be obtained = 15
Patients won't be informed until after the fact = 3
No pre-notification about the study= 3
Not obtaining consent is not ethical= 2
Pharma may benefit from the study?= 3