NIH Public Access
Author Manuscript
Prehosp Emerg Care. Author manuscript; available in PMC 2010 August 20.

Published in final edited form as:
Prehosp Emerg Care. 2009 ; 13(2): 160–168. doi:10.1080/10903120802708852.

Emergency Medical Service Providers' Attitudes and Experiences Regarding Enrolling Patients in Clinical Research Trials

Terri A. Schmidt, MD, MSMaria Nelson, BAMohamud Daya, MDNicole M. Delorio, MDDenise Griffiths, BSPontine Rosteck, EMT-P
Department of Emergency Medicine, Oregon Health & Science University (TAS, MN, MD, NMD, DG), American Medical Response, Northwest (TAS, PRSSSS)

Abstract

Objective—The purpose of this study was to evaluate Emergency Medical Services (EMS) providers' attitudes and experiences about enrolling patients in clinical research trials utilizing the federal rules for exception from informed consent. We hypothesized that Emergency Medical Technicians (EMTs) would have varied attitudes about research using an exception from informed consent which could have an impact on the research.

Methods and setting—Since January 2007, the EMS system has been participating in a randomized, multicenter interventional trial in which out-of-hospital providers enroll critically injured trauma patients using exception from informed consent. A voluntary, anonymous, written survey was administered to EMS providers during an in-service. The survey included demographics and Likert-type questions about their experiences with and attitudes towards research in general, and research using an exception from informed consent for an out-of-hospital clinical trial.

Results—The response rate was 79.3% (844/1067). Most respondents, 93.3%, agreed that “research in EMS care is important.” However, 38.5% also agreed that individual EMTs/paramedics should maintain the personal right of refusal to enroll patients in EMS trials. Fifty-four percent of respondents agreed with the statement that “the right of research subjects to make their own choices is more important than the interests of the general community.” In response to statements about the current study, 11.3% agreed that “the study is unethical because the patient cannot consent” and 69.2% responded that they would personally be willing to be enrolled in the study before they were able to give consent if they were seriously injured. Those who had not enrolled a patient into the study (681 respondents) were asked their reasons: 76.8% had not encountered an eligible patient or did not work for an agency that carried the fluid; 4.3% did not have time; 4.1% forgot and 1.1% stated that they were opposed to enrolling patients in studies without their consent.

Conclusion—The majority of EMS personnel in one community support EMS research and this specific out-of-hospital clinical trial being conducted under an exception from informed consent. Potential barriers to enrollment were identified. Further study in other systems is warranted to better understand EMS provider perspectives about exception from informed consent research.

Keywords

paramedic attitudes; EMS research; research ethics; consent in research

Address correspondence and reprint requests to: Terri Schmidt MD, MS, Department of Emergency Medicine, CDW-EM, 3181 SW Sam Jackson Park Road, Portland OR 97239, schmidtt@ohsu.edu.

NIH-PA Author Manuscript
NIH-PA Author Manuscript
NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

Introduction

The evidence to support many of the standard treatments utilized by Emergency Medical Services (EMS) providers is limited.[1] Most of the evidence is based on either "best practice" or observational science, and interventional trials are rare. One of the goals of EMS should be to improve patient-care protocols, particularly for conditions that lack adequate proven treatments. Research is necessary to provide objective data, but any interventional research places individual subjects at risk.[2,3] While most existing research has been done in the hospital setting, many interventions must be administered early in order to reduce mortality and improve functional outcomes.[4,5] Therefore, research based solely on in-hospital interventions may fail to detect effective treatments that would be life-saving if administered earlier in the course of disease. To address these scientific issues, EMS providers can be called upon to enroll subjects into out-of-hospital interventional trials.

Recently, several large networks such as the Resuscitation Outcomes Consortium (ROC),[6,7] Pediatric Emergency Care Applied Research Network (PECARN)[8] and Neurologic Emergencies Treatment Trials (NETT) have been formed to attempt to answer important scientific questions in EMS through out-of-hospital, randomized, controlled clinical trials. These networks design studies that expect EMS providers to enroll subjects and initiate a study protocol, but little is known about EMS providers' attitudes and experiences with out-of-hospital research.

Because obtaining informed consent from individuals experiencing life-threatening conditions is not always possible and the legally authorized representative (LAR) is often not available in a timely manner,[9] these trials are frequently conducted using the Food and Drug Administration (FDA) rules for emergency research which involves an exception from informed consent.[10,11] Others have reported such resuscitation research may be ethically and legally conducted under the current regulations, but requires substantial effort, financial resources, and personnel. Further, these studies are challenging to implement because of the regulatory burdens imposed and the need to obtain approval from multiple Institutional Review Boards (IRBs).[12,13] Nichol et al. also reported that introduction of these FDA rules was associated with a decrease in the number and proportion of published cardiac arrest studies that were conducted in the United States.[14] There have been reports of public attitudes toward research using the exception from informed consent.[15,16] We have previously studied the attitudes and experiences of the public[17] and IRB members.[18,19] regarding such research, but have not considered the attitudes and opinions of EMS providers about their role in these studies.

The purpose of this study was to evaluate the attitudes as well as experiences of EMS providers about participation in clinical research trials with emphasis on the enrollment of patients using the federal rules for exception from informed consent.

Methods

Study Design

This was an anonymous, voluntary written survey of paramedics and emergency medical technicians (EMTs) in the 4-county Portland, Oregon metropolitan region (Clackamas, Multnomah, and Washington counties in Oregon, and Clark County, Washington). This study received approval from the Oregon Health & Science University (OHSU) IRB.

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

Setting

The majority of the EMS system in the area is a dual-response system consisting of a non-transporting, fire-based first response and transporting private ambulances. The fire first response vehicles are staffed by EMT-Basics, EMT-Intermediates and paramedics, while the transporting ambulances are staffed with at least one paramedic. The region includes urban, suburban and rural areas including remote, frontier regions.

Since January 2007, EMS providers in the Portland metro area have been enrolling subjects in an out-of-hospital, multi-center, double blinded, randomized, controlled trial (ROC HS) comparing hypertonic saline, hypertonic saline with dextran, and normal saline in the treatment of traumatic shock and head injury. The transporting agencies enroll most patients and administer study fluid; the majority of the fire first response agencies do not carry the study fluid, but all paramedics in the system have been trained on the study protocol. The study is being conducted using an exception from informed consent, and community members were offered the option of opting out of the study by requesting a “No Study” bracelet. Seven hundred and twenty-one bracelets had been distributed at the time of this survey.

Population

All paramedics who work in the EMS system were required by their medical directors to attend an annual in-service in either December 2007 or January 2008. Some EMTs also attended. The survey was administered during these in-services which were offered ten times over 6 weeks. One or more of the authors was present at each of these in-services and provided a 3--5 minute overview of the purpose of the study and its anonymity.

Survey development

A written survey including demographic information and 5-point Likert scale questions (strongly agree, agree, neutral, disagree, strongly disagree) was modified from previously used surveys.[17,18] The survey (Appendix) was pilot tested on 24 paramedic students and modified based on the feedback from the respondents.

Analysis

Survey responses were entered in to a Microsoft Office Access 2003 database; 5% were double- checked for accuracy. For purposes of analysis, the 5- point Likert scale was collapsed to three categories: agree, neutral, disagree. Descriptive statistics were used to tabulate responses to survey questions. Pearson chi- square test was used for sub-group analyses; a p value of $< .05$ was considered significant. Database management and statistical analysis was performed using Stata (version 9.0, Stata Corporation, College Station, TX).

Results

Demographics

Surveys were returned by 844 of the 1067 attendees at the in-services, an overall response rate of 79.3%. Most respondents were paramedics [93.3% (769/833)] while 5.4% (45/833) were EMT- intermediates and 2.8% (19/833) were EMT-basics. The majority [666/801 (83.1%)] were male with a mean age of 37.3 years (range 20--62 years). Race was reported as white by 86.5% (700/809) of respondents. Employment status was as follows: 49.6% (398/802) non- transporting fire department; 41.9% (336/802) private transporting ambulance, 5.0% (40/802) transporting fire department and 3.4% (28/802) unspecified other. They reported a mean of 14.0 years working in EMS (range 0.5--40 years).

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

Attitudes toward the need for EMS research

Most respondents, 92.8% (778/838), agreed that “research in EMS care is important” (2.6% [22/838] neutral; 4.5% [38/838] disagree). At the same time, 57.0% (475/834) agreed that “current treatment for cardiac arrest is effective” (27.5% neutral [229/834]; 15.6 % [130/834] disagree). Regarding trauma, 40.2% (336/835) agreed that “current methods of resuscitation after severe traumatic injury are adequate” (34.7% [290/835] neutral; 25.0% [209/835] disagree).

Respondents were also asked who should be allowed to make decisions about participation in EMS research: the EMS medical director, the EMS agency and/or individual EMTs/ paramedics. The majority of respondents, 73.4% (611/833), agreed that “the EMS medical director should be able to decide if the agency will participate in protocols that direct EMTs/ paramedics to enroll patients in research trials” (16.0% [133/833] neutral; 10.7% [89/833] disagree). In addition, 57.7% (482/836) of respondents agreed that the EMS agency should be able to decide about participation in research trials (19.4% [162/836] neutral 23.0% [192/836] disagree).

Finally, 38.5% (320/831) agreed that individual EMTs/paramedics should maintain the personal right to refuse to enroll patients in EMS research (23.8% [198/831] neutral; 37.7% [313/831] disagree).

The ethical conduct of research

Sixty-one percent (507/835) of respondents agreed that “investigators involved in medical research will act in the patient's best interest” (30.9% [258/835] neutral; 8.4% [70/835] disagree). In addition, 49.9% (417/835) of respondents agreed that “there are enough safeguards in place to assure that research is done in an ethical manner” (37.0% [309/835] neutral; 13.1% [109/835] disagree).

Attitudes toward exception from informed consent

When responding to the general statement, “There are times when individual rights should be limited for the benefit of public health”, 46.4% (388/836) agreed (29.6% [247/836] neutral; 24.0% [201/836] disagree). Fifty-four percent (454/834) of respondents agreed with the statement that, “the right of research subjects to make their own choices is more important than the interests of the general community” (29.9% [249/834] neutral; 15.7% [131/834] disagree). Similarly, 52.4% (438/836) agreed with the statement that, “there are times when it is so important to learn about a new treatment that it would be okay to enroll patients in a study before they are able to consent” (20.9% [175/836] neutral; 26.7% [223/836] disagree).

Moreover, in response to a specific statement about the ROC HS study, 11.3% (91/806) of respondents agreed that this study is unethical because the patient cannot consent (31.1% [251/806] neutral; 57.6% [464/806] disagree). Further, 69.2% (678/835) of respondents agreed that they would personally be willing to be enrolled in the hypertonic saline study before they were able to give consent if they were seriously injured (16.7% [129/835] neutral; 14.1% [118/835] disagree).

We also compared responses based on years of EMS experience and training level (paramedics versus non- paramedics). Respondents with 2 years of experience or more were more likely to agree with the statement, “there are times when it is so important to learn about a new treatment that it would be okay to enroll patients in a study before they are able to consent” (65.1% versus 46.2% Chi2 $p = 0.01$) There were no differences based on training level.

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

Barriers to enrollment in EMS research studies

Regarding the hypertonic saline study which at the time of the survey had enrolled just over 100 subjects, 14.5% (122/844) of the respondents reported having enrolled at least one patient. Those who had not enrolled a patient were asked their reasons which are summarized in Table 1. While none of the respondents reported not entering a patient in the study because the patient was wearing a “No Study” bracelet, 8 (1.1%) reported that they had not enrolled a patient because they were ethically opposed to enrolling patients in studies without consent. Finally, 1% (8/844) of the respondents reported having been on an EMS call (for any complaint) where the patient was wearing such a bracelet.

Discussion

To our knowledge this is the first study evaluating EMS providers' beliefs and how these providers can affect the ability to conduct out-of-hospital interventional trials. We found that while the vast majority of EMS providers (93%) agreed that EMS research is important and most believed that research investigators act in the patients' best interest, some expressed concerns about enrolling subjects when consent is not obtained. Further, barely half of respondents agreed that there are enough safeguards to assure the ethical conduct of research. We did not explore respondents' reasons for their response but note that many respondents were “neutral”. Respondents to this survey differed from IRB members who report that the current regulations provide enough protections.[19] One explanation might be that they are unaware of the existing safeguards including the FDA regulations that require scientific equipoise, community consultation, public notification and a safety monitoring board. In the past, EMS research may have been done without these safeguards.[20] Education of the EMS community regarding these safeguards may need to be included as part of the preparation for such studies.

These EMS providers were asked their opinions about the relative importance of public health needs versus personal rights to consent to research. Less than half agreed that “there are times when individual rights should be limited for the benefit of public health” and a majority thought that “the right of research subjects to make their own choices is more important than the interests of the general community.” However, only 11% reported ethical concerns about enrolling patients in the current on-going study in the community using the exception from informed consent and most of the respondents were also personally willing to be enrolled before they were able to consent if they were seriously injured. We cannot entirely explain the general belief that individual rights should not be limited for the public good and the high rate of acceptance of the ongoing study. However, these findings are similar to those we previously reported a study conducted in an ED and its waiting room. In that study, most people responded that research should never be conducted without consent, but they also responded that they would personally be willing to be in such studies.[17]

Injury and cardiopulmonary arrest both cause significant morbidity and mortality. In the United States, unintentional injury is the most common cause of death in persons aged 1--44 years, and diseases of the heart continue to be the most common cause of death overall.[21] Although national estimates of cardiac arrest differ, the proportion of cardiac deaths associated with out-of- hospital cardiac arrest is large and the survival rate remains poor.[22] Despite this, 57% of our respondents thought that treatments for cardiac arrest were effective and over 40% thought that treatment for trauma was effective. It is interesting to note that although the survival rate for cardiac arrest remains low, more re- sponders believe that current out-of-hospital treatment is effective. This could be because EMS providers are unaware of the clinical course after the patient arrives at the hospital; in our area, EMS providers do not routinely receive patient outcomes. This falsely elevated perception of treatment success may cause providers to think that such research is less important, as they

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

may be aware of the need for improved treatments and may partially explain the responses to questions about public health needs. Since many EMS providers believe that current treatments are adequate, they do not necessarily recognize a public health need for improvements. Again, this may be an area where education of EMS providers is warranted.

Barriers to research

There are many potential barriers to performing EMS research.[23] In this study, we explored reasons that an EMT had not enrolled an eligible patient in the study that was being conducted in our area. The most common reasons for not enrolling an eligible patient included not being exposed to a study patient, not having enough time and not remembering these studies. Time constraints and forgetting, leading to missed enrollments, could impact a study. For example, EMS personnel may not enroll their sickest patients because they are "too busy" or become distracted, leading both to lost enrollments and selection bias. Patient care is the priority of EMS personnel so enrollment of patients in a study must be made part of the patient care protocols to be successful, and researchers must consider how to best incorporate the study into the patient care algorithms and treatment priorities when designing studies. Study protocols must be simple and integrated into current care practices as much as possible. At the same time, EMS providers will likely need frequent reminders and visual cues to remember ongoing studies.

As part of the community consultation and public notification process, the public in the community were offered the opportunity to opt out of the ROC HS study by obtaining a bracelet. Little is known about the opt- out process and what, if any, effect it will have on the ability to enroll subjects in studies.[24,25,26] The Portland ROC site has had requests for over 700 bracelets, the highest number of any of the ROC sites (unpublished data). The reason for the number of bracelet requests in this area is unknown and was not explored in this study. There were no cases where respondents to this survey reported a patient was not enrolled because he or she was wearing a "No Study" bracelet. However, eight respondents did report being on at least one call in which they recalled someone was wearing a bracelet. This suggests that EMS providers in our system recognize the bracelets, but to date patient opt-out has not altered trial enrollment. This finding may be of interest to the FDA in response to their request to know more about the protections offered by opt-out mechanisms.[24]

Eight respondents reported that they did not enroll a patient because of ethical concerns about studies using exception from informed consent, and five respondents did not enroll a patient because of concerns about the safety of this particular study. Although this represents less than 1% of the respondents to the survey, these represent potential study enrollments that may have been missed. For the small number of EMTs who have ethical concerns about these studies, this also raises an ethical dilemma. EMTs practice under physician medical direction and protocols, yet 40% of our respondents believe that an individual EMT should maintain the right to refuse to enroll patients in EMS research. When conflicts arise between the personal beliefs of the individual EMT and his or her medical direction, how should these conflicts be resolved? Certainly, individual counseling and education should be considered. It may be that some EMTs do not understand the federal guidelines for exception from informed consent in emergency research and further training would resolve the issue.

Another suggestion that has been made in our EMS system is individual providers, like the public, should have the option to opt out of participation in these clinical trials but they would need to declare their intent to opt out before the time of an individual call, preferably before the study begins enrolling patients. Any such plan would need to assure that for every potential study participant, someone on the scene was able and willing to enroll the subject,

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

to avoid potential selection bias. In a system with multiple paramedics on each call this could be considered. In most, systems, it would be problematic and would risk selection bias. Another solution may involve enhanced education and experience with research for EMS personnel since we did find that respondents with more experience were more likely to believe that it is okay to enroll subjects in research before obtaining consent. EMS providers who have more experience may have an understanding of the importance of and realities of doing EMS research. Research methodology, evidence-based medicine and the ethics of research should also be included as part of a paramedic's educational training.

Limitations

While we have a high response rate, we do not know if the views of the people who did not respond were significantly different from those who did. Further, our survey provides the opinions of EMTs and paramedics in one geographical region and the results may not generalize to other areas. In particular, the opinions of these EMTs and paramedics may be affected by their personal experiences with the out-of-hospital studies that have been done in this system or local publicity related to the studies in the local area. We also cannot generalize to other communities since EMS systems differ across the nation. Our system has a large number of paramedics at each scene and most of the care is rendered by these advanced level providers that have more training than basic level providers.

Conclusions

Many challenges exist to performing high quality out- of-hospital prospective, clinical research trials. This study showed that most EMS providers in this community agree that research, and specifically, this research project being conducted under an exception from informed consent is important. However, a minority of EMS providers did express concerns. Further study in other EMS systems to determine if other EMS providers have similar views would be helpful. It is important that investigators better understand the concerns, if any, of EMS providers in their community and incorporate educational messages to EMS personnel that address these concerns, both before and during trial implementation.

Acknowledgments

We want to thank all of the EMTs and paramedics who work in our system for their response to our survey. We also want to thank Chris Koppenhafer for help with the database and data entry. Maria Nelson is supported by the Oregon Clinical and Translational Research Institute (OCTRI), grant number UL1 RR024140 from the National Center for Research Resources (NCRR), a component of the National Institutes of Health (NIH), and NIH Roadmap for Medical Research.

Appendix: Survey Questions

Dear EMTs/paramedics

We are hoping you will take a few minutes to complete the following survey. Our team is interested in medic opinion on conducting research without informed consent, and your experiences with the Hypertonic Saline trial in particular. Your responses will remain completely anonymous. Your participation is voluntary.

Thank you in advance for helping us better understand the EMT/paramedic perspective on these types of studies. What is your highest level of certification?

□ EMT-B

□ EMT-I

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

□ EMT-P

If you are not an EMT, please check this box---and return the survey. You do not need to fill out the rest of the questions.

Please share your ideas about medical research in the following questions:

1 Research in EMS care is important.

□ Strongly disagree □Disagree □ Neutral □ Agree □ Strongly Agree

2 There are times when individual rights should be limited for the benefit of public health.

□ Strongly disagree □Disagree □ Neutral □ Agree □ Strongly Agree

3 Investigators involved in medical research will act in the patient's best interest.

□ Strongly disagree □Disagree □ Neutral □ Agree □ Strongly Agree

4 The right of research subjects to make their own choices is more important than the interests of the general community.

□ Strongly disagree □Disagree □ Neutral □ Agree □ Strongly Agree

5 Current methods of resuscitation after severe traumatic injury are adequate.

□ Strongly disagree □Disagree □ Neutral □ Agree □ Strongly Agree

6 Current treatment for cardiac arrest is effective.

□ Strongly disagree □Disagree □ Neutral □ Agree □ Strongly Agree

7 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 are able to consent.

□ Strongly disagree □Disagree □ Neutral □ Agree □ Strongly Agree

8 There are enough safeguards in place to assure that research is done in an ethical manner.

□ Strongly disagree □Disagree □ Neutral □ Agree □ Strongly Agree

9 EMTs/paramedics should have the individual right to refuse to enroll patients in EMS research.

□ Strongly disagree □Disagree □ Neutral □ Agree □ Strongly Agree

10 The EMS medical director should be able to decide if his agency will participate in protocols that direct EMTs/paramedics to enroll patients in research trials.

□ Strongly disagree □Disagree □ Neutral □ Agree □ Strongly Agree

11 The EMS company/agency should be able to decide if its EMTs/paramedics will participate in protocols that direct EMTs to enroll patients in research trials.

□ Strongly disagree □Disagree □ Neutral □ Agree □ Strongly Agree

12 I personally would be willing to be enrolled in the Hypertonic Saline trial before I was able to consent if I was seriously injured.

□ Strongly disagree □Disagree □ Neutral □ Agree □ Strongly Agree

Now please share your views about and experiences with the ROC hypertonic saline study.

13 I had adequate training about this study.

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

□ Strongly disagree □Disagree □ Neutral □ Agree □ Strongly Agree

14 I personally believe this study is unethical because the patient cannot consent.

□ Strongly disagree □Disagree □ Neutral □ Agree □ Strongly Agree

15 This study adds to the burden of EMS workers.

□ Strongly disagree □Disagree □ Neutral □ Agree □ Strongly Agree

16 The protocol is too complicated.

□ Strongly disagree □Disagree □ Neutral □ Agree □ Strongly Agree

17 I have personally enrolled a patient in the ROC hypertonic saline study:

□ YES

□ NO

18 If no, I have not enrolled a patient in the study because: (check all that apply)

□ I have not yet had a patient who met entry criteria for the study.

□ I had a patient who qualified for the protocol, but I did not have time to enroll the patient.

□ The patient qualified for the protocol, but was wearing a “no study” bracelet.

□ I had a patient who qualified but we did not remember to enroll the patient.

□ I am ethically opposed to enrolling patients in studies without consent.

□ I have concerns about the safety of this particular study (Hypertonic Saline).

□ I do not work for an agency that is participating in the study

□ Other

19 Have you ever been on a call (for any complaint) where the patient was wearing a “no study” bracelet?

□ YES

□ NO

Please tell us about your background:

20 What is your age?_____ Years

21 What is your gender? □ Male □ Female

22 How would you describe your race? (check all that apply)

□ Asian/Asian American □ Black/African American □ Caucasian/White

□ Hispanic/Latino □ Native American □ Other:_____

□ Prefer not to answer

23 How many years have you worked in EMS?_____

24 At your primary job, for what type of agency do you work?

□ Private ambulance company

□ Non-transporting public service

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

□ Transporting public service

□ Helicopter service

□ Other_____

25 In which county do you work primarily?

□ Clark □ Clackamas □ Multnomah □ Washington Do you have any other comments you would like to share?

_____

_____

_____

_____

_____

We sincerely thank you for taking the time to complete this survey -- your feedback is important to us.

References

1. Callaham M. Quantifying the scanty science of prehospital emergency care. Ann Emerg Med 1997;30(6):785–790. [PubMed: 9398774]
2. Moscati R. Protection of human subjects in prehospital research. Prehosp Emerg Care 2002;6(2 Suppl):S18–23. [PubMed: 11962578]
3. Sugarman J. Examining the provisions for research without consent in the emergency setting. Hastings Cent Rep 2007;37(1):12–13. [PubMed: 17348255]
4. Weisfeldt ML, Becker LB. Resuscitation after cardiac arrest, a 3-phase time-sensitive model. JAMA 2002;288:3035–3038. [PubMed: 12479769]
5. DeMaio VJ, Stiell IG, Wells GA, Spaite DW. Optimal defibrillation response intervals for maximum out-of-hospital cardiac arrest survival rates. Ann Emerg Med 2003;42:242–250. [PubMed: 12883512]
6. Davis DP, Garberson LA, Andrusiek DL, Hostler D, Daya M, Pirrallo R, Craig A, Stephens S, Larsen J, Drum AF, Fowler R. A descriptive analysis of Emergency Medical Service Systems participating in the Resuscitation Outcomes Consortium (ROC) network. Prehosp Emerg Care 2007;11(4):369–382. [PubMed: 17907019]
7. Brasel KJ, Bulger E, Cook AJ, Morrison LJ, Newgard CD, Tish erman SA, Kerby JD, Coimbra R, Hata JS, Hoyt DB. Hypertonic resuscitation: design and implementation of a prehospital intervention trial. J Am Coll Surg 2008;206(2):220–232. [PubMed: 18222373]
8. The Pediatric Emergency Care Applied Research Network (PECARN): rationale, development, and first steps. Acad Emerg Med 2003;10(6):661–668. [PubMed: 12782530]
9. Dutton RP, Stansbury LG, Hemlock B, Hess JR, Scalea TM. Impediments to obtaining informed consent for clinical research in trauma patients. J Trauma 2008;64(4):1106–1112. [PubMed: 18404082]
10. 21CFR50.24. Protection of human subjects; informed consent-FDA. Final rule. Fed Regist 1996;61(192):51498–51533. [PubMed: 10161558]
11. Morris MC. An ethical analysis of exception from informed consent regulations. Acad Emerg Med 2005;12(11):1113–1119. [PubMed: 16264082]
12. Mosesso VN Jr, Brown LH, Greene HL, Schmidt TA, Aufderheide TP, Sayre MR, Stephens SW, Travers A, Craven RA, We isfeldt ML. Conducting research using the emergency exception from informed consent: The Public Access Defibrillation (PAD) Trial experience. Resuscitation 2004;61(1):29–36. [PubMed: 15081178]

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

13. Schmidt TA, Baren JM, Mann NC, Richardson LD. Executive summary: the 2005 AEM Consensus Conference on Ethical Conduct of Resuscitation Research. Acad Emerg Med 2005;12(11):1017–1018. [PubMed: 16264066]

14. Nichol G, Huszti E, Rokosh J, Dumbrell A, McGowan J, Becker L. Impact of informed consent requirements on cardiac arrest research in the United States: Exception from consent or from research? Resuscitation 2004;62(1):3–23. [PubMed: 15246579]

15. Triner W, Jacoby L, Shelton W, Burk M, Imarenakhue S, Watt J, Larkin G, McGee G. Exception from informed consent enrollment in emergency medical research: attitudes and awareness. Acad Emerg Med 2007;14(2):187–191. [PubMed: 17267533]

16. Smithline HA, Gerstle ML. Waiver of informed consent: A survey of emergency medicine patients. Am J Emerg Med 1998;16(1):90–91. [PubMed: 9451323]

17. McClure KB, DeIorio NM, Gunnels 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(4):352–359. [PubMed: 12670849]

18. DeIorio N, McClure K, Nelson M, McConnell K, Schmidt T. Institutional review board members' experiences with exception from informed consent protocols. Journal of Empirical Research on Human Research Ethics 2007;2:23–30. [PubMed: 19385848]

19. McClure KB, DeIorio NM, Schmidt TA, Chiodo GT, Gorman P. A qualitative study of Institutional Review Members' experience with reviewing proposals for exception from informed consent in resuscitation research. J Med Ethics 2006;33:298–293.

20. Richardson LD. The ethics of research without consent in emergency situations. Mt Sinai J Med 2005;72(4):242–249. [PubMed: 16021318]

21. Arias E, Smith BL. Deaths: Preliminary data for 2001. National Vital Statistics Reports 2003;51:1–48.

22. Zheng ZJ, Croft JB, Giles WH, Mensah GA. Sudden cardiac death in the United States, 1989--1998. Circulation 2001;104:2158–2163. [PubMed: 11684624]

23. Nichol G, Huszti E. Design and implementation of resuscitation research: special challenges and potential solutions. Resuscitation 2007;73(3):337–346. [PubMed: 17292525]

24. Department of Health and Human Services Food and Drug Administration, Proposed Rules Sess. Aug 29. 2006 Conduct of Emergency Clinical Research Public Hearing.

25. Anderson A. Emergency trials of blood substitutes skirt ethical questions. Nat Med 2007;13(6): 652. [PubMed: 17554317]

26. Vaslef SN, Cairns CB, Falletta JM. Ethical and regulatory challenges associated with the exception from informed consent requirements for emergency research: from experimental design to institutional review board approval. Arch Surg 2006;141(10):1019–1023. discussion 1024. [PubMed: 17043281]

NIH-PA Author Manuscript

NIH-PA Author Manuscript

NIH-PA Author Manuscript

TABLE 1

Reasons Reported by the 681 People Responding that they had not Enrolled a Patient in the ROC Hypertonic Saline Study.

Reason for not enrolling a patient	Number of respondents who endorsed this reason	Percent of respondents endorsing this reason (n = 681)
I have not had a patient who met entry criteria	446	65.5%
I did not have time to enroll a patient who met entry criteria	29	4.3%
A patient qualified for the study but was wearing a No Study Bracelet	0	0.0%
I had a patient who qualified but did not remember to enroll	28	4.1%
I am ethically opposed to enrolling patients in studies without consent	8	1.1%
I have concerns about the safety of this particular study	5	0.7%
I do not work for an agency that is participating in the study	77	11.3%
Other	62	9.1%

Numbers do not add up to 100% because not all respondents endorsed any reason and more than one was allowed