Published in final edited form as:

Crit Care Med. 2014 February ; 42(2): 451–453. doi:10.1097/CCM.0b013e3182a51f37.

Studying Community Consultation in Exception from Informed Consent Trials

Clifton W. Callaway, MD, PhD

University of Pittsburgh Department of Emergency Medicine

Keywords

Informed Consent; Ethics; Resuscitation; Traumatic Brain Injury

Some readers may not remember a crisis 20 years ago when a moratorium on emergency care research was pronounced in the United States (1). Federal regulatory bodies reviewed the practice of enrolling unconscious patients into clinical research without informed consent using various justifications, such as “deferred consent,” “implied consent,” and “retrospective consent.” (2) These justifications were deemed to conflict with the principle of subject autonomy as set out in the Declaration of Helsinki and the Nuremberg Code (3,4). Ongoing trials were halted, and institutional review boards (IRBs) were directed to approve no new trials of more than minimal risk without prospective consent (5).

The moratorium decreased the number of trials on resuscitation from the United States for at least a decade relative to trials in other diseases (6,7). Other countries subsequently developed regulatory angst over emergency care research (8). Many young investigators doing clinical resuscitation science left the field during the moratorium to develop careers studying other conditions that allowed more traditional informed consent. One wonders what would be the state of clinical resuscitation science today had the moratorium never occurred.

Dedicated scientists, including several authors of a study in this issue (9), worked with federal regulators to develop our current framework for conducting acute care research: Exception from Informed Consent in Emergency Situations (EFIC). EFIC was announced in 1996 along with Guidance for IRBs and investigators (10). Among the multiple criteria for use of EFIC, the hallmark requirement is notification and consultation with the communities in which research will be conducted. While more burdensome than the prior doctrines, EFIC does provide a well-vetted regulatory basis for conducting acute care research. Finally, after 20 years, the pace of clinical resuscitation and emergency care research has resumed the upward trajectory it enjoyed in the early 1990s.

Correspondence: Clifton W. Callaway, MD, PhD Department of Emergency Medicine University of Pittsburgh 400A Iroquois Building 3600 Forbes Avenue Pittsburgh, PA 15230 callawaycw@upmc.edu Phone: 412-647-9047.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Community consultation serves many functions in EFIC. Most importantly, consultation provides community members with representative autonomy to accept or reject participation. In an ideal situation, every community member would hear about and consent to potential participation in a trial prior to that trial commencing. In practice, the consultation process needs to achieve at least a meaningful, representative sample whose opinions reflect those of the actual subjects who are enrolled.

There is a paucity of research comparing the validity of different consultation techniques for EFIC (11). This research is essential for investigators to keep pace with society. Past trials with EFIC used consultation techniques suggested by the original Guidance: focus groups, community meetings, advertisements with call-in numbers, and so forth. However, the world has changed dramatically since the writing of the Guidance. In 1993, the World Wide Web was new, there were more landlines than cell phones, there was no social media, and text messaging was just invented. Patients did not search the Internet to learn about their disease or treatment options. Today, these asynchronous modalities for dissemination of information and measurement of public opinion are more the norm than town-hall meetings. Some groups have called for a greater measure of judgment in choosing to use any or all of these techniques to interact with communities (12).

In the present study, investigators embedded a study about community consultation within the approval process for a trial of progesterone for traumatic brain injury to be conducted with EFIC (www.clinicaltrials.gov: NCT00822900). Importantly, this study compares the responses that are generated when interactive methods (e.g. in-person meetings with an investigator presentation) or less-interactive methods (e.g. surveys handed out) are used for community consultation.

This study notes that public opinion in some individual events was not in favor of EFIC in general or even of personal enrollment in this trial in particular. Nevertheless, the overall average of responses favors EFIC and personal enrollment in the trial. This clinical trial is now ongoing even in the communities that had strong negative responses. Such an approach is consistent with a purely democratic philosophy: majority opinion decides the fate of the community. However, it may be worth further philosophical and ethical debate on this conclusion. Should more protection be provided for members of the community with minority opinions? That approach would be consistent with the protectionist stance towards minorities that we adopt in other aspects of public life.

Another function of community consultation is allowing the investigator to share responsibility with the community for subjects who are hurt in a trial or who are upset after the trial. Adverse outcomes are much easier to defend and accept for situations and risks that “everyone knew about” and “most people thought were a good idea.” The validity of this function requires that risks were adequately disclosed to the community participants.

This study reports that participants perceive risk differently when presented in different formats. Participants in more interactive settings minimized their estimates of study risk compared to participants in less interactive settings. While this study cannot determine exactly why this difference in perception occurred, it is easy to speculate that investigator

enthusiasm or non-verbal cues about risk-benefit profiles influenced participants in interactive sessions. These differences in risk perception are important, because past critiques of public consultation in EFIC trials focused primarily on whether risks were adequately disclosed (13). The present data might suggest that less interactive methods are a more conservative estimate of public opinion, and might be preferred for providing fair assessment of risk.

We must continue collecting rigorous data about community consultation and other aspects of EFIC. Progress in acute care research depends on having a solid and contemporary ethical basis for conducting research on vulnerable patients who cannot consent for themselves. The present study provides an excellent example of how investigative teams can study and make specific meaningful conclusions about these practices. Similar studies should be embedded in all trials employing EFIC.

Acknowledgments

Dr. Callaway received support from Award Number K12 HL109068 from the National Heart, Lung, and Blood Institute. Dr. Callaway is a site investigator for the Neurological Emergencies Treatment Trial network (U10 NS080371) and the Resuscitation Outcomes Consortium (U01 HL077871). The content is solely the responsibility of the author and does not necessarily represent the official views of the National Heart, Lung, and Blood Institute or the National Institutes of Health.

REFERENCES

1. Olson CM. The letter or the spirit. Consent for research in CPR. *JAMA*. 1994; 271:1445–1447. [PubMed: 8176805]
2. Abramson NS, Meisel A, Safar P. Deferred consent. A new approach for resuscitation research on comatose patients. *JAMA*. 1986; 255:2466–2471. [PubMed: 3701965]
3. Katz J. The Nuremberg Code and the Nuremberg Trial: a reappraisal. *JAMA*. 1996; 276:1662–1666. [PubMed: 8922453]
4. Rickham PP. Human experimentation: code of ethics of the World Medical Association: Declaration of Helsinki. *Br Med J*. 1964; 2:177. [PubMed: 14150898]
5. Ellis, GB. OPRR Reports: Informed Consent--Legally Effective and Prospectively Obtained. Aug 12. 1993 <http://www.hhs.gov/ohrp/policy/hsdc93-03.html>
6. Nichol G, Huszti E, Rokosh J, et al. Impact of informed consent requirements on cardiac arrest research in the United States: exception from consent or from research? *Resuscitation*. 2004; 62:3–23. [PubMed: 15246579]
7. Hiller KM, Haukoos JS, Heard K, et al. Impact of the final rule on the rate of clinical cardiac arrest research in the United States. *Acad Emerg Med*. 2005; 12:1091–1098. [PubMed: 16264080]
8. Sterz F, Singer EA, Böttiger B, et al. A serious threat to evidence based resuscitation within the European Union. *Resuscitation*. 2002; 53:237–238. [PubMed: 12062833]
9. Dickert NW, Mah VA, Biros MH, et al. Consulting Communities When Patients Cannot Consent: A Multi-Center Study of Community Consultation for Research in Emergency Settings. *Crit Care Med*. 2013 in press.
10. 21CFR50.24 - Code of Federal Regulations Title 21. Part 50. Protection of Human Subjects. Section 50.24. Exception from informed consent requirements for emergency research. Oct 2.1996
11. Baren JM, Biros MH. The research on community consultation: an annotated bibliography. *Acad Emerg Med*. 2007; 14:346–352. [PubMed: 17400998]
12. Halperin H, Paradis N, Mosesso V Jr, et al. Recommendations for implementation of community consultation and public disclosure under the Food and Drug Administration's "Exception from informed consent requirements for emergency research": a special report from the American Heart Association Emergency Cardiovascular Care Committee and Council on Cardiopulmonary,

Perioperative and Critical Care: endorsed by the American College of Emergency Physicians and the Society for Academic Emergency Medicine. *Circulation*. 2007; 116:1855–1863. [PubMed: 17893277]

13. Grassley C. Americans should not be on a game show in U.S. emergency rooms and ambulances. *Am J Bioeth*. 2010; 10:9–10. [PubMed: 20945261]