Ethical considerations in education research in emergency medicine.

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COMMENTARY

Ethical Considerations in Education Research in Emergency Medicine

Chadd K. Kraus, DO, MPH, Todd Guth, MD, Derek Richardson, MD, Bryan Kane, MD, and Catherine A. Marco, MD

Abstract

The 2012 *Academic Emergency Medicine* consensus conference on education research in emergency medicine (EM) addressed various issues, including that of ethics in medical education research for EM. Education research in EM is essential to patient care and safety, and with recent advances in simulation and the advent of the Milestones project, it will become even more vital. Education research in EM is guided by the same principles that guide the ethical conduct of all human subjects' research: respect for persons, beneficence, and justice. Regulatory provisions and widely accepted ethical standards provide a framework for research in EM education; however, special considerations exist for education research. To ensure patient and trainee safety and to maintain the integrity of new knowledge, ethical considerations should remain at the forefront of EM education research. For EM education researchers, recognition of the vulnerability of residents, medical students, and others as research subjects is paramount. This article fills an important gap by outlining the principles guiding education research in EM, exploring the ethical challenges and approaches to education research, and offering a framework and future directions for the ethical conduct of education research in EM.

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Education research in emergency medicine (EM) is essential to patient care and safety. Over the past decade, EM education research has developed significantly, with evaluations of high-fidelity simulation training, the development of medical education fellowship training and a focus on sharing and implementing best practices in EM training. The Council of EM Residency Directors (CORD) defines EM education research as "scientific investigation designed to furnish new knowledge relating to emergency medicine education."[1] The goal of EM education research is to define how to most effectively and efficiently prepare competent and compassionate emergency physicians (EPs) in the cognitive, procedural, and professional competencies outlined in the Accreditation Council for Graduate Medical Education (ACGME) core competencies and elucidated in the Model of the Clinical Practice of Emergency Medicine.[2]

The recently released EM Milestones highlight the central role of providing objective measures of effective, feasible, and accountable education in EM.[3] Evaluating the progression of learners through specialty-specific milestones might result in the identification and remediation of learners who require additional professional development.[4] However, maximizing the potential of the milestones for producing well-trained EPs will depend on rigorous scientific evaluation of educational interventions, programs, and curricula. Investigations of how to best meet the objectives of the milestones for residents in training will be a priority for EM research in the near future.

Education research in EM is guided by the same principles that guide the ethical conduct of all human subjects' research: respect for persons, beneficence, and justice. Regulatory provisions and widely accepted ethical standards provide a framework for research in EM education. Education research in EM poses unique challenges, due in part to the uncontrolled clinical environment, unpredictable case mix, and extensive variety of the requisite skill set of the EP.

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ETHICAL PRINCIPLES

The first modern codification of the ethical principles that guide human subjects' research principles can be found in the Nuremberg Code, released in 1947 after World War II. The principles of the Nuremberg Code are summarized in Table 1.[5] The code seeks to protect subjects from undo suffering, injury, and death. It also seeks to ensure that the subject who enrolls in, and continues to participate in, research does so in an informed way and of his or her own free will.

In 1948, the Declaration of Geneva was the first modern delineation of the obligations of physicians to society. These obligations were combined with the protection of research subjects in the Declaration of Helsinki, first released in 1964 and subsequently updated six times, with the latest revision released in 2008.[6] While the Nuremberg Code contains many of the same concepts, what sets the Declaration of Helsinki apart is that it was an attempt by physicians to regulate human subjects' research.

Despite these advances in medical research ethics, the Tuskegee syphilis study was continued in the United States until 1972. In part a response to that tragic chapter in American history, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created in 1974. The Commission published its report in 1979. This report, commonly known as the Belmont Report, sets forth three basic ethical principles and outlines their application: 1) respect for persons, 2) beneficence, and 3) justice.[7] These principles are fundamental to all human subjects' research, including medical education research.

Respect for persons is the principle that acknowledges the autonomy of individual persons, including those with diminished autonomy, to make informed decisions. Physicians in training potentially have diminished autonomy to consent to participation in research, especially in situations when the investigator is also the program director or supervising faculty. Beneficence is the principle to do no harm, minimizing risks, and maximizing benefits to research subjects. In EM education research, the harm to the subject (that is, the resident or student) could include the denial of an educational opportunity, the effect of which might be felt by the physician in training as well as his or her future patients. Justice is the principle that guides the fair selection of research subjects and can be assured if all residents are afforded an equal opportunity to participate in the study.

The Belmont Report also seeks to differentiate between the practice of medicine and research.[6] The practice of medicine involves well-intentioned therapy undertaken for the benefit and well-being of an individual patient, while research systematically poses a question or tests a hypothesis with the goal of generating generalizable knowledge. Ultimately the principles outlined in the Belmont Report were systematically codified by the Department of Health and Human Services into the Code of Federal Regulations, Title 45, Part 46 (45 CFR 46), also known as the "Common Rule."[8] This regulation and its four subparts provides the blueprint for federal oversight of human subjects' research in the United States.

The application of the ethical principles presented in the Belmont Report requires that research questions have equipoise (i.e., uncertainty about the benefits and harms interventions under investigation)[9] and that research participation is voluntary and free of coercion or undue influence. The Belmont Report describes coercion as an "overt threat in order to obtain compliance" and defines undue influence as "an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance."[7] In education research, the possibility of undue influence exists from a faculty member conducting research with residents he or she supervises as study subjects.

Together with the three principles outlined in the Belmont Report, voluntariness and equipoise create the context for the informed consent process as codified in the Common Rule and provide guidance for institutional review boards (IRBs). Although education research at some institutions has been viewed as minimal-risk or

Table 1
Directives for Human Experimentation Outlined in the Nuremberg Code

1. Voluntary consent of the subject.
2. Experiment should yield results for the good of society.
3. Experimental design should be designed and based on knowledge from animal studies and the natural history of disease.
4. Experiment should be conducted to avoid unnecessary physical or mental suffering and injury.
5. No experiment should be conducted if there is reason to believe that it will cause injury or death.
6. Risk should not exceed the humanitarian importance of the problem to be solved by the experiment.
7. Preparations and appropriate facilities should exist to protect subjects against the remote possibilities of injury, disability, or death.
8. Experiments should only be conducted by qualified scientists.
9. Subjects are free to withdraw from the experiment at any time.
10. The scientist in charge must be prepared to stop the study at any time if it becomes clear that experiment is likely to result in injury, disability, or death.
Adapted from U.S. Department of Health and Human Services, Office of Research Integrity. Nuremberg Code: Directives for Human Experimentation. Available at: http://ori.dhhs.gov/education/products/RCRintro/c03/b1c3.html[5] (last accessed October 1, 2012).

Table 2
Levels of Human Subjects Research Review by IRBs

Review Type	Criteria for Initial Review
Exempt	Study involves risk not more than encountered in routine, daily life
Expedited	Study involves no more than minimal risk to subjects, AND Falls into defined DHHS expedited review categories (see 45CFR46)
Full review	Study involves greater than minimal risk to subjects (e.g. double-bline, placebo-controlled studies for drug safety)

DHHS = U.S. Department of Health and Human Services; IRB = institutional review board.
*Adapted from U.S. Department of Health and Human Services. Code of Federal Regulations Title 45, Part 46: Protection of Human Subjects. Available at: http://www.hhs.gov/ohrp/archive/irb/irb_chapter6.htm[10] (accessed October 1, 2012).

even exempt from IRB review, the pressures to expand scientific knowledge through medical education research with potentially vulnerable subjects require a reassessment of whether this research is, in reality, minimal risk. As outlined in the Common Rule, human subjects research, including EM education research, can be classified into one of three categories for the purposes of initial IRB review: 1) exempt, 2) expedited, or 3) full review.[8] A summary of these categories is provided in Table 2. The key ethical consideration for medical education researchers is that while most medical education research falls under the exempt or expedited review categories, and may ultimately pose minimal risk for research participants, all medical education research should be submitted for review by the IRB.

ETHICAL CHALLENGES

The ethical conduct of education research in EM poses several challenges. First, subjects who are trainees are a unique and vulnerable study population because of their role in the institution and their relationship with supervising faculty members. The U.S. Department of Health and Human Services has specifically identified students, and particularly medical students, as a special class of human subjects.[10] As learners, trainees are dependent on their institutions for the resources (e.g., curriculum, clinical experiences, salary, and benefits) to complete their training. Similarly, they are dependent on the evaluation, support, recommendations, and professional network of their trainers for career development and advancement.

The recognition of medical students as a special class of human subjects has not been widely expanded to include physicians in graduate medical education programs. For EM education researchers, recognition of the vulnerability of residents as research subjects is paramount. Residents are a captive research population, but more importantly are the group of learners most affected by changes in curriculum, training requirements, and interventions that evaluate learning outcomes. Despite the rapid growth of education literature (e.g., simulation in EM) there has been little discussion in the literature regarding how to best protect EM residents as research subjects. Therefore, adherence to the fundamental principles of the Belmont Report is crucial in resident-focused medical education research.

In addition to the general ethical principles of human subjects' research that are outlined in the Belmont Report, the issue of informed consent is especially important in medical education research. Informed consent is a process that provides transparency about the research being undertaken and provides the potential research subject with an opportunity to freely choose to participate or not in the protocol. The perception of or actual existence of coercion or undue influence that persuades the trainee to initially enroll or to continue participation as a research subject violates the tenets of autonomy and justice. In addition to this potential conflict of interest, there also exists the possibility that the research subject will expect that participation will be rewarded in the form of strong evaluations or strong recommendations for professional or career advancement or conversely that refusal to participate will be met with punitive measures. As such, a special focus must be placed on the informed consent process, with special attention to the ethical principles outlined above and avoidance of any coercion or undue influence in soliciting participation.

Multiple high-profile examples display the potential for harm to be done to vulnerable learners. Early studies of radioactive thermal burns on skins across racial backgrounds began on students, likewise with early studies of untested hallucinogens and potentially addictive illicit drugs.[11] More recently, medical students participating in surveys of mental health and depression reported concerns of lack of anonymity and professional repercussions for admissions of depression.[12] A survey of osteopathic physicians in training in 2005 found that nearly one-fourth of clinical students believed better grades, recommendations, or other favors would accompany participation in clinical trials.[13] Further concerns of professional coercion and anonymity have been raised not only with biochemical trials, but also with educational endeavors.[14] In the course of research involving residents or other trainees, sensitive information might be discovered that could be damaging to the professional future of the subject. Protections for these subjects must include provisions against inappropriate incentives, blinding subject identities when possible, ensuring that participation is entirely voluntary without repercussions for nonparticipation and, when possible, the avoidance of direct recruitment of subjects by professional supervisors.

Fairness and equity in education are highly valued. Uneven distribution of educational techniques or opportunities would be unethical if some learners receive a

substandard educational experience as a result of the research study, so it is important to ensure the same opportunities for all subjects.[15] For example, residents in a single institution could be randomized to different arms of a protocol for an intervention that teaches a procedure. The residents in the arm of the study that proves to be the more effective intervention could possibly garner an advantage over those subjects in another arm of the same study. A similar situation could occur in residents from different programs enrolled in a multicenter study. Use of a crossover study design is an especially elegant solution to this problem, especially for research being conducted in a single institution. A crossover design mitigates the potential bias of a small sample size and can ensure equal educational opportunities by making each subject his or her own case and control.[16,17]

Another ethical challenge in EM education research is the potential conflict of interest for the faculty member in the dual role of educator and researcher. For these individuals, there exists a tension, and potential conflict of interest, between meeting the challenges of answering a research question and fulfilling the responsibilities of serving as a teacher and mentor.[18] This conflict of interest is potentially problematic, as it is difficult to serve the interests of both the learner and the subject simultaneously. The historic context of the Nuremberg Code applies here, in that the investigator must be willing to stop the study if the conflict of interest might reasonably be expected to harm the subject.

Last, the recent growth of education research in parallel with an increased focus on quality and process improvement initiatives blurs the line between education process improvement and education research. Given the potential risks that students and physicians in training incur as subjects, educational reviews previously classified as quality improvement projects, and thereby immune to IRB review, are now being more closely scrutinized. While a 2008 study found that nearly all medical education proposals were low-risk and therefore considered to be exempt by IRBs, there was a wide range of IRB expectations and a gross misunderstanding of the board's role in research review.[19] Multiple cross-disciplinary recommendations have been made to distinguish educational program development from human subjects research, most of which have found an unclear line between the two.

PROPOSED GUIDELINES FOR MEDICAL EDUCATION RESEARCH

The ethics of medical research are regulated closely at most institutions through IRBs or ethics review boards. While researchers widely agree on the importance of the ethical treatment of research participants involved in clinical research, there is much more variability in the field of medical education research. This variability of opinion stems from the variability of policies across institutions in this country and around the world.[20] Much of this variability exists as medical education research bridges the precarious position between clinical research and social science research. While the World Medical Association's Helsinki Declaration on Ethical Principles for Medical Research Involving Human Subjects provides universally accepted guidelines for clinical research,[6] there is no such standard for medical education research. Medical students and residents are the potentially vulnerable subjects of medical education research and are entitled to the same protections as subjects in any research study. The potential harm to residents and students highlights the need for appropriate standards and guidelines specific to medical education research.

Many medical education researchers have become frustrated with the cumbersome process of forcing medical education research studies into the mold of clinical research guidelines and adapting IRB forms and processes designed for clinical research. Dyrbe and colleagues[19] have called for national guidelines for ethics review in medical education research to promote appropriate protection of learners, while providing a more uniform and a more tailored process for ethics review in medical education research.[19] Ethical review guidelines for medical education research will need to continue to provide protections for the subjects, while improving the efficiency and appropriateness of the ethical review process. Editors of medical education research journals are moving toward requiring formal institutional review of all education research projects prior to acceptance for publication to maintain the highest ethical standards for subjects and thus making the review process more stringent in the future.[20]

The charge for EM education researchers moving forward is to acknowledge that all medical education research should go through an IRB or ethics review board. Researchers should acknowledge the potential for violations of research ethics in the conduct of education research, and to actively seek frameworks, whether through IRBs or other neutral third parties, that can help to uphold those ethical principles intended to protect the most vulnerable human subjects. Investigators will also need to continue to be trained in and exhibit competence in research ethics. The addition of ethics modules in research training programs such as the Medical Education Research Certificate (MERC), offered by CORD in partnership with the Association of American Medical Colleges (AAMC), is a model for such training.[21]

Additionally, it will become increasingly important for EM education investigators to be engaged in the ethics review process at the institutional, national, and international levels. Through active engagement in the review process, medical education researchers can guide implementation of focused ethical reviews of protocols involving vulnerable subjects that are mindful of the risks unique to education research. Medical education researchers, including those in EM, should look to develop medical education specific IRB submission forms and processes that can evaluate the ethics of medical education research.[22] Pugsley and Dornan's ten ethical questions for research involving students has been recommended by ten Cate as a step in this direction.[22,23]

Once proactive, EM education researchers can take the next step in becoming involved in their local IRBs and more effective change for the implementation of a

medical education focused review process can be achieved. Education researchers should also look to build consensus within the specialty of EM and across all medical specialties to establish uniform criteria for the collective medical education community. Until these uniform criteria are available and local IRBs have made them available for use in the ethical review process, medical education researchers should look to use accepted IRB protocols.

Finally, medical education researchers can improve their methodologies and study designs to mitigate the aforementioned ethical challenges. Study design can de-identify subjects so that faculty cannot link individuals to data. For example, subjects can be provided with an anonymous study identification numbers as is standard in research protocols, where personal identification of subjects might be personally damaging. Expanding research to include several institutions mitigates the possibility of identifying specific research subjects in small residency programs or in situations where a specific piece of identifying data (e.g., age) in programs with fewer residents.

CONCLUSIONS

Emergency medicine educators, researchers, learners, patients, and the public all have a vested interest in the ethical conduct of education research. To ensure patient and trainee safety and to maintain the integrity of new knowledge, ethical considerations should remain at the forefront of EM education research.

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