# Understanding Ethical Challenges in Medical Education Research

Robert L. Klitzman, MD

## Abstract

Rapidly advancing biomedical and electronic technologies, ongoing health disparities, and new online educational modalities are all changing medicine and medical education. As medical training continues to evolve, research is increasingly critical to help improve it, but medical education research can pose unique ethical challenges.

As research participants, medical trainees may face several risks and in many ways constitute a vulnerable group. In this commentary, the author examines several of the ethical challenges involved in medical education research, including confidentiality and the risk of stigma; the need for equity, diversity, and inclusion; genetic testing of students; clustered randomized trials of training programs; and questions about quality improvement activities. The author offers guidance for navigating these ethical challenges, including the importance of engaging with institutional review boards. Academic medical institutions should educate and work closely with faculty to ensure that all research adheres to appropriate ethical guidelines and regulations and should provide instruction about the ethics of medical education research to establish a strong foundation for the future of the field.

Research on medical education will become increasingly important. Given the potential sensitivity of the data collected in such research, investigators must understand and address potential ethical challenges as carefully as possible.

Research is increasingly critical to help improve medical education as it continues to evolve, but medical education research can pose unique ethical challenges. Rapidly advancing scientific discoveries and technologies; ever-rising health care costs; increasing specialization; widening social, economic, and health disparities; and needs for expanded health care access are all changing medicine and, thus, medical training. Online education, electronic medical records, and social media are also affecting both the content and format of learning. These varied transformations pose not only medical but psychological, social, institutional, pedagogical, ethical, and policy challenges. Research can examine these problems and lead to effective solutions, but studies can also raise ethical questions.

Please see the end of this article for information about the author.

Correspondence should be addressed to Robert L. Klitzman, Columbia University, 1051 Riverside Dr., Mail Unit #15, New York, NY 10032; telephone: (646) 774-6912; email: rlk2@cumc.columbia.edu.

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## Sensitive Data in Medical Education Research Require Strong Ethical Guidelines

Studies that explore critical barriers and facilitators in education and the best ways to address these often require the collection of sensitive data, leading to questions about whether and how ethical guidelines and regulations apply. Researchers might have access to sensitive information about learners when probing, for example, how different types of trainees best learn about various rapidly evolving topics; which pedagogical methods are most effective in teaching diagnosis, treatment, and prognostication of diseases; which methods are most effective in teaching both the art and science of medicine; and what strengths and weaknesses various teaching methods, including online versus in-person modalities, have for various learners.

Medical education research must also examine how often mental health problems (e.g., burnout, depression and anxiety, or substance use and abuse) arise for students and trainees, and what predictors and effects of mental health difficulties may exist (e.g., which students are most prone to burnout). Longitudinal studies are needed to assess what factors related to medical education and training may be associated with resilience or difficulties later in medical practice (e.g., medical errors or malpractice), as well as what interventions can help reduce such problems and build resilience and how effective such interventions are. Yet, sensitive data about learners' mental health must be handled ethically.

Given ongoing disparities in health care, medical education research should also investigate possible conscious and unconscious biases and prejudices among providers and trainees—another category of sensitive data—related to race, ethnicity, sexuality, gender identity, or other dimensions of patients' personal identity.

## Types of Ethical Challenges

Studies related to medical education need to follow basic ethical principles of autonomy, beneficence, nonmaleficence, and justice. These studies thus need to consider key elements, such as informed consent, fair selection of participants, equipoise, potential benefits, minimization of risks, and attention to social justice concerns. Adhering to these ethical principles is vital in all medical education research, but unique challenges can emerge in several areas, as described below.

As research participants, medical trainees in many ways constitute a vulnerable group. They face stressful, grueling conditions in the learning environment

and provide unpaid labor during their training. Medical trainees experience higher rates of mental health symptoms than does the general population. A 2020 study showed that 11.1% of medical students at one school had suicidal ideation and 58.2% had symptoms of depression.[1] Given historical patterns of bias and discrimination, individuals from groups that have been underrepresented in medicine may confront additional institutional obstacles and consequent stresses. Researchers investigating medical education need to be acutely aware of these vulnerabilities.

### Confidentiality and risk of stigma

Trainees may face breaches of confidentiality and may be subject to stigma as individuals and as members of particular groups. Data, especially if collected and stored online, can be shared accidentally, stolen, hacked, and/or insufficiently de-identified. Researchers studying whether certain factors (e.g., age, gender, socioeconomic status, race, ethnicity, sexual orientation, or disabilities) affect different trainees' educational or psychological experiences, stresses, or needs require the collection of sensitive data that could fuel stigma and discrimination. Various groups of students might, for instance, be found to have higher rates of burnout or fare less well in medical school (e.g., related to disabilities, socioeconomics, or other factors). One could argue that researchers should not publish such findings, but the benefits may outweigh the risks because enhanced attention to such problems could lead to additional support or ameliorative interventions for vulnerable groups. Importantly, researchers should be careful to anticipate and minimize any possible risks that might occur from publishing data that could potentially harm any group of students.

### Needs for equity, diversity, and inclusion

The ethical principle of justice also highlights needs for equity, diversity, and inclusion (EDI) in medical education research. From 2002 to 2017, the percentage of African American and Latino medical students increased in the United States, but at a rate less than their age-matched counterparts in the U.S. population as a whole, leading to increased underrepresentation.[2] Several recent studies of medical students have failed to assess race or ethnicity.[1,3] Medical education researchers should seek to ensure EDI in participant recruitment, sampling, data collection, and analyses. Trainees who are members of vulnerable groups may be wary of participating in research due to fears of stigma or discrimination. Researchers may thus need to address these concerns, establish trust, and develop ways of ensuring adequate representation in studies.

### Genetic testing of students

At some schools, students have been asked to collect, test, and analyze their own genetic samples to better understand and appreciate techniques, implications, and questions involved in genetic testing.[4] Such classroom exercises, and research on their effectiveness, can pose ethical concerns. Students may find themselves in the difficult position of learning that they are at risk of serious diseases (e.g., breast cancer or Huntington disease) without having undergone any prior genetic counseling. They may also share their results without considering the potential consequences. Instructors and researchers should be aware of these possible ethical concerns and fully inform students of the conceivable risks.[4]

### Clustered randomized trials of training programs

Debates have raged over how resident duty hours should best be structured. Do longer shifts increase continuity of patient care and thus improve clinical outcomes and trainee education? Or, conversely, do they increase physician errors due to fatigue? Would shorter shifts reduce physician fatigue and, thus, errors? Or would they lead to more "hand-offs," disrupting beneficial continuity of care and thereby worsening clinical outcomes?

Several years ago, 2 groups of researchers conducted clustered randomized trials (CRTs), assigning training programs to 1 of 2 types of on-call schedules and assessing patient mortality by program type.[5–7] These trials sparked controversy because the investigators did not obtain informed consent from the trainees or the patients. The researchers argued that obtaining informed consent was not feasible.[7] If some patients chose not to participate, for instance, the hospital would find it very difficult, if not impossible, to arrange for care for those patients in the middle of the night, when only 1 intern and/or resident might ordinarily be assigned to cover each ward. Similarly, to allow some trainees to opt out of these experiments would be very difficult because situations could arise in which the intern and resident assigned to a particular ward on a given shift did not both agree to participate (i.e., one might agree and the other might not). This would make the data difficult, if not impossible, to analyze, requiring researchers to separate clinical outcomes by those patients whose trainees partially or fully participated or did not participate at all.

Controversies arose over whether the ethical principle of equipoise existed in these CRTs—whether, at the start of the study, there was no reason to think that one arm of the study was clearly better than the other. Critics contended that longer on-call hours would lead to more harm to patients, including possible patient deaths, and that the studies were therefore unethical. Yet, data have been published suggesting that no differences exist overall in patient mortality between the 2 structures of on-call shifts—that is, the potential advantages and disadvantages of longer and shorter shifts canceled each other out.[8] Such considerations however, will remain important for any ongoing research related to these issues. Future studies might similarly use CRTs to assess other ways of altering trainee on-call shifts or other aspects of medical education. When using this study design, consent of patients and trainees should be waived only after careful consideration, for compelling scientific reasons, when it is clearly not practicable and risks are minimal. Before implementing different shift structures, researchers must also first examine other retrospective data to help ensure that equipoise indeed exists.

### Questions about quality improvement activities

Concerns arise, too, regarding studies that faculty feel constitute quality assurance or quality improvement projects rather than research per se. Federal regulations explicitly state that a few types of projects are exempt from needs for institutional review board (IRB) approval, providing certain criteria are met.[9] For instance, projects that are designed to study, evaluate, or improve a federal public benefit or service program

solely to enhance its performance, or that seek only to improve the quality of services at an institution, rather than constitute research involving human participants, also do not require IRB review if they meet the regulations' definitions of the relevant terms.[9] The regulations define "research" as a "systematic investigation … designed to develop or contribute to generalizable knowledge."[9] At many institutions, faculty members first self-assess whether an activity fits this categorization. If faculty sense ambiguity regarding the need for IRB review, they should consult with their IRB. If they do not do so and are found later to have erred in their assessment, they bear full responsibility. Hence, it is best to check with the IRB if there is any doubt. Many academic institutions seek to embed IRB review into their culture and encourage investigators and research staff to consult with the IRB routinely, especially if any ambiguities may exist. Uncertainties can arise, for instance, regarding quality assurance or quality improvement activities, as well as secondary or biospecimen analyses. IRBs regularly conclude that numerous submitted protocols do not in fact constitute "human subjects research," but at many institutions, this determination is the purview of the IRB, not the researchers. Researchers may feel that submitting a protocol to the IRB is onerous or can take too much time. But they should be aware that the desire for expediency may in fact bias them, which makes independent review essential.

Distinctions between quality improvement/quality assurance and research may seem straightforward, but errors and controversies have emerged. For example, in 2003, researchers at Johns Hopkins University (JHU), in conjunction with 67 hospitals, supported by a federal grant, prospectively carried out an intervention to test hypotheses that a simple 5-item checklist, which included handwashing, would reduce infections associated with insertion of arterial catheters.[10] The JHU IRB decided that the research constituted quality improvement and was thus exempt from review at 67 hospitals, mostly in Michigan, and that informed consent was not needed. Yet these researchers then published the results, suggesting that the investigators saw the data as contributing to generalizable knowledge—thus constituting research. The federal Office for Human Research Protections (OHRP) subsequently rebuked the investigators and the JHU IRB.[11] The IRB could presumably have determined that it could review the study on an expedited basis and waived consent. This case raises several controversial issues but illustrates how a project can be designed to improve quality of care at institutions and *also* constitute research, such that IRB review may be needed.

Medical educators may routinely collect data from students in the course of normal educational activities (e.g., course evaluations) and consequently attempt to analyze and publish these, feeling that these can contribute to generalizable knowledge. Yet, these educators may not have obtained IRB review when needed, and scientific journals may refuse to publish the findings as a result. Faculty should hence consider in advance whether the activities in which they are engaging might be considered research involving human participants and thus require interaction with an IRB. Again, if it seems ambiguous, engaging with the IRB early on can ensure sound ethical practices.

## Guidance

The key ethical principles articulated above can improve ethical rigor and regulatory adherence in medical education research. Autonomy and respect for persons are crucial, and, hence, informed consent of trainees may be needed and should be as robust as possible.

Researchers should also ensure that their studies follow the principle of beneficence by providing benefits for individual participants, for science, and/or for society more broadly and that these benefits are sufficient to outweigh potential risks, threats to autonomy, and justice concerns.

To follow the principle of nonmaleficence, researchers need to minimize risks, taking cautions regarding data collection and reporting and considering whether the reporting of data might stigmatize certain groups. Data might still be reported, but investigators need to be sensitive to these issues and seek to minimize all potential harms.

As mentioned earlier, the principle of justice requires that studies avoid unfairly burdening any particular group and that they include diverse samples. Investigators must consider unique pressures and added stigma that certain groups of learners may face (e.g., related to race, ethnicity, disability status, or mental health issues) and take measures to minimize such potential harms.

Academic medical institutions and their OHRPs should educate and work closely with faculty to ensure that all research adheres to ethical guidelines and regulations. Given the potential ethical challenges discussed above, faculty should receive instruction on both the specific nature of, but also, importantly, the need for, such guidance. Trainees, as potential future researchers, should also receive education on applying ethical principles in research, including in studies of medical education studies. Many students as well as faculty tend to see research outside of biomedical science per se as "soft" and unimportant. Yet, as potential study participants themselves, trainees may be relatively more appreciative and open to the needs for ethical approaches in investigations regarding medical education.

## Conclusions

In sum, medical education research will become increasingly important due to ever-more rapidly advancing biomedical and electronic technologies and ongoing challenges related to health disparities. Given the potential sensitivity of the data collected in medical education research, investigators must understand and address potential ethical challenges as carefully as possible.

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**R.L. Klitzman** is professor of psychiatry and director, Masters of Bioethics Program, Columbia University, New York, New York.

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## Teaching and Learning Moments
# The Outside Looking In

I could count on one hand the number of times I had seen my attendings enter room 509 during my month-long internal medicine rotation.

Room 509 was tucked away at the end of the hallway by the other COVID rooms, with an exterior window facing the other buildings of the hospital complex and a small window in the interior hallway door. The patient within had been there for almost 3 months with complications related to COVID-19, her experience mirroring countless others around the country as she spiraled first toward the ventilator and ultimately long-term tracheostomy, now stuck in the slow process of being weaned off the machine helping her breathe. Every day we would peer through her window on rounds, sometimes making eye contact and exchanging a thumbs up (on a good day), but most often simply reading the machines keeping her alive and discussing how the various numbers looked that day.

And so, every day the unspoken conclusion was the same: Why would we need to walk into her room and put our staff at risk if her numbers are looking better and the plan remains the same?

These moments of physical disconnect may sound all-too-familiar to health care practitioners and families of affected patients around the world during the COVID-19 pandemic. While this distance is undoubtedly painful for patients and their families, it also affects foundational medical training. When the COVID-19 pandemic finally declared itself in early spring of 2020, most students around the country were—as one of my peers put it—*benched* to minimize the spread by eliminating *nonessential* personnel. To many trainees, this was not a surprise. It is something we have felt often during training: that we were more of a burden than a boon, that we were slowing down the doctors we were scheduled to rotate with and learn from—that we were mere outsiders looking in.

And so, every day our unspoken conclusion was the same: Why see patients every day and delay their care if we are able to learn how to interpret the numbers and prescribe the right treatments online?

As the month went along, it became increasingly obvious that what the patient in room 509 required most was human contact and support. The days when she was with a Spanish-speaking staff member for extended periods of time were the days when she succeeded on weaning trials, conversed lucidly with staff and family on the phone, and even gave us a jubilant thumbs up during our daily window-peering. On other days, when she was alone for hours, she showed clear signs of delirium and attempted to pull out her tracheostomy tube, yelling and tossing items around the room in a powerful subconscious cry for human connection and presence. It was clear she longed to be more than "one of the COVID patients on the fifth floor"—more than just "room 509."

And I longed to be more than an outsider looking in.

It is worth noting that what are possibly the most important parts of medical training—experiencing the value of the patient–practitioner relationship firsthand, sharing in patients' and families' grief and suffering, building on-the-ground resiliency for when the next pandemic strikes—were significantly diminished during this past year. Once we begin to move past peering through the window because being in the room is *nonessential*, we may begin to heal the wounds from our shared human experience of COVID-19. Let us have the strength and foresight to never forget that developing the ability to give ourselves to our patients starts in our training—and starts at the bedside.

**Harrison VanDolah, MD**

**H. VanDolah** is a first-year internal medicine and pediatrics resident, University of Arizona College of Medicine–Phoenix, Phoenix, Arizona; email: harrison.vandolah@gmail.com; Twitter: @HarrisonJVDMD.

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