VIEWPOINT

Ethical Considerations in the Development of the Flexibility in Duty Hour Requirements for Surgical Trainees Trial

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Editorial

In February 2016, the results of the Flexibility in Duty Hour Requirements for Surgical Trainees (FIRST) Trial were released[1] amidst controversy. Participating general surgical residency programs were randomized to either a control arm, which adhered to current Accreditation Council for Graduate Medical Education (ACGME) duty hour requirements, or an intervention arm, which relaxed many duty hour restrictions while still adhering to the 80-hour work week. Critics of the trial questioned the ethics of its design and conduct. Public Citizen, a consumer watchdog group, and the American Medical Student Association, filed a complaint with the Department of Health and Human Services regarding the study's unethical nature. They contended that the FIRST Trial was misclassified as nonhuman subjects research, involved unacceptable risk for the residents in the intervention arm, and failed to satisfy informed consent requirements.[2] While these complaints represented an oversimplified view of the relevant issues, they highlighted the need to discuss the inherent ethical complexities of this trial. These issues, which are not unique to the FIRST Trial and could arise in future randomized studies testing institutional policy changes, include (1) institutional review board (IRB) determination, (2) assessment of equipoise, and (3) informed consent.

IRB Determination

The trial was granted a waiver by Northwestern University's IRB office, which determined that the study did not meet the definition of human subjects research. This decision represented the end result of multiple conversations between the study team, leaders of the IRBs at Northwestern University and other participating sites, and independent bioethicists. Several considerations informed the IRB's study determination, including the definition of trial participants and the nature of the data collected.

Fundamental to the conception of the trial as nonhuman subjects research was how the study participants were defined. Were the trial subjects the patients, the residents, or the institutions? Although the trial objectives were to examine the effect of duty hour restrictions on patient safety and resident education (seemingly implicating residents and/or patients as the subjects), the institutions were the true "participants" given that they were the units of randomization, that the policy changes were enacted at the institutional level, and that institutional officials were the ones who had to agree to trial participation. When a study is deemed nonhuman subject research, IRB review is not indicated because the IRB is charged with monitoring human subjects research. Instead, it is the institution's responsibility to make decisions regarding training, professional development, and service delivery that is consistent with their own mission. As such, participation in the FIRST trial had to be sanctioned by the institutions' Designated Institutional Official on behalf of the Graduate Medical Education (GME) committee, Chair of Surgery, Program Director, and American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) Surgeon Champion. Participation in the FIRST Trial was viewed as being akin to other institutional policy changes (eg, changes in nursing shifts or regulations regarding concurrent surgical procedures), which do not typically require IRB review or patient and/or staff consent. Importantly, it was noted that the ACGME duty hour policy changes in 2003 and 2011 did not require consent of residents or patients.

Particular to this policy change was the accompanying research initiative to evaluate the resultant differences between the 2 study groups. As per the Common Rule, human subjects research takes place when (1) data are obtained through intervention or interaction with a living individual or (2) identifiable private information regarding that individual is obtained.[3] Neither of these conditions were fulfilled. Patient outcome data came from the ACS NSQIP, a quality program in which the trial hospitals were already participating, meaning the trial simply analyzed previously existing data. Data regarding resident perceptions could not be traced back to individual residents because they were gathered from deidentified surveys administered during the annual American Board of Surgery In-Training Examination (ABSITE), a test taken by all general surgery residents across the nation, irrespective of study participation.

Institutional review boards at other sites concurred with the Northwestern IRB's study determination. Because nonhuman subjects research is not required to be submitted for IRB review, submission of a separate IRB application at participating sites was optional if the institution concurred that the study was nonhuman subjects research.[4] Other participating residency programs submitted the study protocol to their local IRB office and also received a determination of nonhuman subjects research. The trial underwent a full review as human subjects research at only 1 program, which wanted to go beyond the national study protocol by capturing additional aspects of the trial's effects on their residents.

Establishing Equipoise

Duty hours have been the focus of intense debate for decades, fueled by mixed results from mostly retrospective sources. While some argued that tired residents would cause more medical errors, results of multiple systematic reviews, including one performed by the ACGME, concluded that the 2003 duty hour reforms may be associated with worse patient outcomes, particularly for surgical patients.[5] Studies of the 2011 duty hour reforms showed no change in patient outcomes.[6,7] Moreover, systematic reviews suggested increased concerns regarding resident training,[2] with mixed results with respect to resident well-being.[5,8] While it was possible that duty hour regulations fulfilled their original intent (improving patient safety and resident education), it was just as possible that these regulations resulted in unintended harm to patients (due to increased patient handoffs) and diminished educational opportunities for residents.[2] Given this equipoise in the medical literature and the concerns throughout the surgical community regarding the effect of duty hour policies on patient outcomes and resident training, a randomized trial was deemed necessary and appropriate by the groups charged with oversight of duty hours and surgical resident training (the ACGME, American Board of Surgery, and the ACS). Not only was there equipoise, but the suggestions of worse patient care and resident education created a need to study this issue.

Informed Consent

While some suggest that residents should have been consented, important pragmatic issues made this infeasible. The cluster-randomized trial design required all surgery residents within a given program to adhere to the same training model. A single resident could not opt out because differential scheduling would not be practical at the individual program level. Residents were not without voice, however; their opinions were elicited by many program directors, and approval from each site's GME committee was necessary to participate. Patient consent was also a pragmatic issue because millions of patients would have to provide consent across 151 hospitals.

The ultimate risk to residents and patients was determined to be low because the trial required residents to work 80 hours or less per week, have 1 day free per week, and take calls no more than every third night. Thus, residents were not working more total hours, but rather adjusting when those hours were worked, within the confines of the 80-hour rule, for reasons related to patient care and resident education. Similarly, patient safety was guarded closely by the trial's data safety monitoring board.

Conclusions

The FIRST Trial is a study of policy change, not of interventions at the level of the individual, and thus may not readily fit our traditional conception of research ethics. However, the potential for harm to residents and/or patients were carefully weighed in discussions with stakeholders, ethicists, and the organizations charged with oversight of medical education. These groups, along with the surgical community at large, overwhelmingly supported the trial and the manner in which it was conducted, including the largest organization of surgical residents. These issues will continue to be relevant as more cluster-randomized trials are undertaken to study quality and safety issues.

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