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Med-Mal Matters

The value of informed consent

In December 1946, an American military tribunal tried German physicians and administrators for their participation in medical crimes against humanity. The defendants were accused of conducting experiments on prisoners in concentration camps without consent. Of course, many of the prisoners died or were maimed by these experiments.

In response to these atrocities, the Allied powers drafted the Nuremberg Code, which states voluntary consent from participants in any human experimentation is absolutely essential, and the benefits of the research must outweigh the risks.

The principles expressed in the Nuremberg Code have been codified in federal statute and regulation in the years since World War II. But this wouldn't be the last time informed consent in medical experiments became a topic of national discussion.

From 1932 to 1972, the U.S. Public Health Service conducted a research project, known as the Tuskegee Syphilis Study, on low-income African-American men. Four hundred of the subjects had contracted syphilis, but they were not informed of the infection or offered penicillin treatment when it became available. The study continued until the 1970s and was stopped only after it was publicized.

The uproar over Tuskegee led to the creation of a commission that issued what is known as the Belmont Report, a discussion of the basic ethical principles necessary to protect human subjects during medical experiments. The report states that participants must give knowing, voluntary consent; the value of the knowledge to be gained must outweigh the risks to the participants; and there must be fair procedures for the selection of participants.

Currently, two almost identical experiments — designed to study the effects of "extreme sleep deprivation" on resident physicians — are considered "highly unethical" and fail to comply with basic regulatory requirements for the protection of human subjects, according to the American Medical Student Association and the nonprofit consumer rights advocacy group Public Citizen.

The studies are the Individualized Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education (iCOMPARE) trial and the Flexibility in Duty Hour Requirements for Surgical Trainees (FIRST) trial.

In both studies, rules limiting duty hours for internal medicine and surgical residents, respectively, were relaxed or eliminated to determine if patient mortality went up and if resident quality of life went down.

Under the iCOMPARE study, participating institutions received waivers on resident duty hour restrictions from the Accreditation Council for Graduate Medical Education (ACGME). Internal medicine residents at 63 programs were then selected via "cluster randomization" to a control group or an experimental group.

The control group would follow the current 16-hour duty-shift cap, which ACGME enacted in 2011 to protect not only patients but also residents from a demonstrated increase in the risk of sleep-deprivation-connected harms, including needle sticks, exposure to blood-borne pathogens and post-shift auto collisions. The experimental group, on the other hand, had a "flexible" schedule that allowed shifts of unlimited duration, potentially reaching 30 hours or more.

The FIRST study uses the same design. Surgical residents assigned to the experimental group are subject to 24-hour shifts with potentially unlimited additional hours for rounds or other clinical and nonclinical tasks. They also receive less time off between shifts.

According to the AMSA and Public Citizen, these studies violate the basic tenets of ethical experimentation published in the Belmont Report and federal regulations. For instance, the studies do not allow for informed consent from either patients or residents. Because they use "cluster randomization," the studies assign residents to a group by program and not individually. The only way to opt out is to refuse to accept an offer from an "experimental intervention" residency program.

Residents are at least informed of the studies; patients are not. According to the AMSA and Public Citizen, the patient subjects enrolled at experimental group hospitals are exposed to a greater than minimal risk of medical errors from the longer shifts allowed for medical and surgical residents.

Additionally, the studies are not designed to provide information that will outweigh the risks, according to the AMSA and Public Citizen. For instance, the studies are unblinded and do not require participating programs to follow any set schedule. Hospitals that implement few or no changes to duty hours will skew the results, making it more likely that a finding of no difference in outcomes between the two patient groups will be inaccurate.

Indeed, one of the outcome measures is patient mortality. The very fact that the investigators do not know if more patients in the experimental group will die is conclusive evidence, according to the AMSA and Public Citizen, that increased risk of medical errors and death exist and therefore require full, knowing consent by patients. ■

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