Commentary

BEFORE and during World War II, medical professionals already knew that their duties incorporated the historical virtue of being committed to preserving their patients' health and protecting them from harm. Physicians who were serving in prison settings were expected to apply most of the same standards of ethical duty to their patients who were prisoners. Much of the experimentation in the guise of "research" that was performed on prisoners by Nazi physicians was inexcusable, and not just because it was done on imprisoned people. It was unethical because prisoners were not treated as patients or even as people, but rather as expendable objects of unscientific experimental interest. Likewise, in the United States, the continuation of the study of untreated syphilis in black Southern farmers became inexcusable in the 1960s. At that time, the researchers were still deceitfully recalling their subjects for repeated blood and cerebrospinal fluid sampling in the guise of "treatment" for "bad blood." Those researchers involved in the Tuskegee case also inappropriately prevented some of their black subjects from entering the military, because they knew that subjects who enlisted would be given penicillin, which would cure or alter the natural course of their syphilis.[1]

We should understand that the chronological context of the experimentation with ketamine on prisoners in early-1960s Michigan prisons was such that the term "bioethics" was not even in common use. Ethical physicians were guided in their actions by ancient codes for conduct. The meaning of patient "consent" to medical procedures was also in evolution. During the first half of the 20th century, when a patient consulted a physician, they expected that the physician would make all the decisions. The idea that the patient was the locus for medical decision-making was developed in the 1970s and later. Before that time, physicians were taught to routinely use coercion and manipulation of information to gain patients' agreement to medical treatments. This was thought to be for patients' own good, and paralleled the role of parents controlling the choices of their children.

In Dr. Domino's original report, we see that the prisoners were described as volunteers. We must assume that the prisoners gave some degree of consent to the experiments, but we can surmise that some coercion was used and that their consent was most certainly not an informed consent that would meet today's intricate standards for written consent to participate in medical research. Prisoners were probably coerced with privileges and by using limited descriptions of what would happen to them if they were exposed to dose-ranging research with ketamine. It is possible that prisoners would have volunteered to become research subjects for the testing of ketamine even if they had known that some of them would endure brachial arterial lines or tracheal intubation, and all would be exposed to a drug with then-unknown psychologic effects of unknown duration.

The medical ethical principle that we now understand as "respect for patient autonomy" was transgressed in Dr. Domino's work. However, "respect for autonomy" was not clearly defined in 1965. Clear understanding of researchers' obligations to their human subjects was achieved only after the development in the 1970s of federal regulations, published in 1981.* Many physicians and researchers felt that those federal regulations were so strict that medical research would be severely constrained. However, because the federal regulations guided the awarding of government research funding, the regulations became quickly understood and applied. The federal regulations required the assembly of Institutional Review Boards, which were tasked with the evaluation of all research involving human subjects. The federal regulations are applied to research funded from any source, not just from government funds.

In the final analysis, we must decide whether Dr. Domino's research met what were in 1965 reasonable understandings of medical ethics. The Nazi experimentation clearly transgressed basic understandings of the role of physicians, and even transgressed the rules of engagement for ethical warfare as it was understood in the 1930s. The Nuremburg trials and convictions of physicians who experimented on unconsenting prisoners confirmed that those physicians acted as criminals, not just as unethical physicians. The results of their inexcusably cruel studies should not be publicized or used for any purpose. Although not in the same category as the Nazi experimentation, the Tuskegee study

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* Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects, United States Department of Health & Human Services. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm. Accessed June 11, 2010.

design included deceitful recruitment and retention of subjects, and its results will therefore always be tainted.

Where does Dr. Domino's research fit on the scale of ethical acceptability? Their human subjects were volunteers who were given some information about the basic reasons for the research. The prisoners' medical welfare was meticulously monitored during exposure to ketamine. The prisoners were protected from harm during anesthesia and recovery. All of these characteristics make Dr. Domino's research ethically acceptable for its time, and therefore worthy of continued retention in the research literature.

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Reference

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