

Medical ethics and human subjects

In at least a dozen experiments humans have been subjected to questionable practices

The Tusgegee syphilis study went on for 40 years before public disclosure forced an investigation. Now the Department of Health, Education and Welfare has decided that the study was unethical, even when it started.

The sterilization of young girls in Alabama, while not a research project, is another case of questionable medical ethics. The Civil Rights Division of the Justice Department and the Senate health subcommittee are investigating charges that as many as 11 minors may have "undergone involuntary sterilization operations."

These highly publicized incidents "may give the erroneous impression that such procedures raising ethical questions are rare and involve only bizarre procedures. . . . This is not the case," say Robert M. Veatch and Sharmon Sollitto of the Institute of Society, Ethics and the Life Sciences in Hastings-on-Hudson, N.Y. In the June Report of the Hastings Center, they cite 11 studies they believe raise disturbing questions.

The studies were selected from a collection of 43 questionable experiments that have been published in responsible medical journals or professional proceedings since 1966. No names are mentioned but all the studies were performed in the United States or with funding from the United States.

The first three involved "grave risks to subjects." In one, nine normal female patients were given injections of epinephrine in an attempt to produce arrhythmia or abnormal heart beat. Those conducting the experiment admitted that such a procedure is hazardous, but they said, "informed consent cannot be obtained in a study of this type." In a second study, blood samples had to be taken from patients who had had both of their kidneys removed, some as recently as two weeks prior to the experiment. The ten subjects had to be transfused "in anticipation of blood loss due to repeated sampling." By the third day, "all subjects were clinically dehydrated." A third study involved giving LSD to 24 subjects in order to study long-range changes in personality, attitudes, values, interests and performance. No mention was made to the subjects of possible personality changes.

Four experiments involved risks to incompetent or incarcerated subjects. Nine children suffering from asthma were intentionally subjected to doses of

antigens known to produce asthmatic attacks. In another experiment, 48 children suffering from blood diseases were subjected to dual-site bone marrow withdrawals. The study pointed out that such procedures "involve physical and psychological problems" for children.

In prisons or mental institutions, the quality of consent, even if it is obtained, is questionable. At a maximum security facility for the criminally insane, 90 patients were "used in an exploratory study to determine the effectiveness of succinylcholine as an agent in behavior modification." The drug causes temporary muscle paralysis, including inability to breathe.

Another experiment in operant conditioning was reported by an American psychiatrist working at a mental hospital in Vietnam. Chronic male patients (mostly schizophrenic) were offered freedom if they proved they could work. Of 130, only 10 volunteered to work. The rest were told they needed treatment and were given electroconvulsive shock. After a few treatments, most of the men decided to work. A similar experiment was then tried on 130 women. Even after each had received 20 treatments, only 15 were willing to work. Shock treatments were discontinued and food was withheld for periods of up to three days. The patients were eventually cured and went to work tending crops for the Green Berets.

In a placebo experiment, 91 of 130 children with bronchial asthma received injections of buffered saline instead of medication. This ineffective treatment lasted in some cases for 14 years. Neither the children nor their parents knew an experiment was going on. In an experimental birth-control program, 262 women had megestrol acetate capsules implanted in their forearms to test the long-term contraceptive effectiveness of the drug. This experiment produced 48 unwanted pregnancies. In a study involving legal and psychological risks, 332 patients in a voluntary psychiatric hospital were subjected to urine analysis for drug use. No consent was obtained and the patients did not know what the test was for. In a final experiment, 41,119 patients enrolled in a group health plan were given a test for pain tolerance as part of their regular checkup. They were subjected to as much pain as they could stand but did not know they were

part of an experiment.

These examples, say Veatch and Sollitto, indicate the need for mechanisms for consent and review which give greater assurance that the rights and interests of subjects will be protected. The procedures now available, they say, are inadequate. In peer review, for instance, it is the peers of the researchers not the peers of the subjects who are asked to evaluate the ethical acceptability of the proposed research. Conclude the Hastings Center researchers: "The immediate establishment of a governmental committee to formulate rigorous procedures to ensure reasonable informed consent and review is the minimum that is called for."

This week, after testimony from the family involved in the Alabama sterilization case, the Senate health subcommittee began consideration of a bill that would strictly control medical experimentation. In a similar case, judges in Detroit ruled this week that psychosurgery may not be performed on prisoners or mental patients confined against their will. □

Infant mortality in the

In spite of the United States' high standard of living and medical sophistication, newborn death rates are shamefully high. And they are getting worse. Several years ago 13 countries had lower infant death rates than the United States. Now 15 countries do.

The Institute of Medicine of the National Academy of Sciences has now issued a study that offers unprecedented insights into the causes of deaths among American newborns. The study is based on records of 140,000 births in New York City in 1968. It relates demographic, social and medical factors to differences in the medical services needed and received by pregnant women. The study was headed by David M. Kessner, professor of community medicine at Georgetown University.

The study's findings underscore the marked influence of social risks, medical risks and prenatal care on infant survival. Social risks include minimal education, having many