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Editorial

History of Research Ethics

The Tuskegee Study of Untreated Syphilis in the African American Male is the longest nontherapeutic experiment on human beings in medical history. Begun in 1932 by the United States Public Health Service (USPHS), the study was purportedly designed to determine the natural course of untreated latent syphilis in some 400 African American men in Tuskegee, Macon County, Alabama. The research subjects, all of whom had syphilis when they were enrolled in the study—contrary to the "urban myth" that holds "black men in Alabama were injected with the virus that causes syphilis"—were matched against 200 uninfected subjects who served as a control group. The subjects were recruited with misleading promises of "special free treatment," which were actually spinal taps done without anesthesia to study the neurological effects of syphilis, and they were enrolled without their informed consent. The subjects received heavy metals therapy, standard treatment in 1932, but were denied antibiotic therapy when it became clear in the 1940s that penicillin was a safe and effective treatment for the disease. When penicillin became widely available by the early 1950s as the preferred treatment for syphilis, this therapy was again withheld. On several occasions, the USPHS actually sought to prevent treatment. The first published report of the study appeared in 1936, with subsequent papers issued every four to six years until the early 1970s. In l969, a committee at the federally operated Center for Disease Control decided the study should continue. Only in 1972, when accounts of the study first appeared in the national press, did the Department of Health, Education and Welfare (HEW) halt the experiment. At that time, 74 of the test subjects were still alive; at least 28, but perhaps more than 100, had died directly from advanced syphilis. An investigatory panel appointed by HEW in August 1972 found the study "ethically unjustified" and argued that penicillin should have been provided to the men. As a result, the National Research Act, passed in 1974, mandated that all federally funded proposed research with human subjects be approved by an institutional review board (IRB). By 1992, final payments of approximately $40,000 were made to survivors under an agreement settling the class action lawsuit brought on behalf of the Tuskegee Study subjects[1,2]. In the late 1950s, thalidomide was approved as a sedative in Europe; it was not approved in the United States by the Food and Drug Administration (FDA). The drug was prescribed to control sleep and nausea throughout pregnancy, but it was soon found that taking this drug during pregnancy caused severe deformities in the fetus. Many patients did not know they were taking a drug that was not approved for use by the FDA, nor did they give informed consent. Some 12,000 babies were born with severe deformities due to thalidomide. U.S. Senate hearings followed and in 1962 the so-called "Kefauver Amendments" to the Food, Drug and Cosmetic Act were passed into law to ensure drug efficacy and greater drug safety. For the first time, drug manufacturers were required to prove to (FDA) the effectiveness of their products before marketing them.[3] In 1944-1980s the U.S. government sponsors secret research on the effects of radiation on human beings. Subjects were not told that they were participated in the experiments. Experiments were conducted on cancer patients, pregnant women, and military personnel. In 1956-1980 Saul Krugman, Joan Giles and other researchers conduct hepatitis experiments on mentally disabled children at the Willowbrook State School. They intentionally infected subjects with the disease and observed its natural progression. The experiments were approved by the New York Department of Health.[3]

There are several reasons why it is important to adhere to ethical norms in research. First, norms

promote the aims of research, such as knowledge, truth, and avoidance of error. For example, prohibitions against fabricating, falsifying, or misrepresenting research data promote the truth and avoid error. Second, since research often involves a great deal of cooperation and coordination among many different people in different disciplines and institutions, ethical standards promote the values that are essential to collaborative work, such as trust, accountability, mutual respect, and fairness. For example, many ethical norms in research, such as guidelines for authorship, copyright and patenting policies, data sharing policies, and confidentiality rules in peer review, are designed to protect intellectual property interests while encouraging collaboration. Most researchers want to receive credit for their contributions and do not want to have their ideas stolen or disclosed prematurely. Third, many of the ethical norms help to ensure that researchers can be held accountable to the public. For instance, federal policies on research misconduct, conflicts of interest, the human subjects protections, and animal care and use are necessary in order to make sure that researchers who are funded by public money can be held accountable to the public. Fourth, ethical norms in research also help to build public support for research. People are more likely to fund research project if they can trust the quality and integrity of research. Finally, many of the norms of research promote a variety of other important moral and social values, such as social responsibility, human rights, animal welfare, compliance with the law, and health and safety. Ethical lapses in research can significantly harm human and animal subjects, students, and the public. For example, a researcher who fabricates data in a clinical trial may harm or even kill patients, and a researcher who fails to abide by regulations and guidelines relating to radiation or biological safety may jeopardize his health and safety or the health and safety of staff and students.[4]

Codes and Policies for Research Ethics

Given the importance of ethics for the conduct of research, that many different professional associations, government agencies, and universities have adopted specific codes, rules, and policies relating to research ethics.

Nuremberg Code: On December 9, 1946, when an American military tribunal opened criminal proceedings against 23 leading German physicians and administrators for their willing participation in war crimes and crimes against humanity. Among the charges were that German physicians conducted medical experiments on thousands of concentration camp prisoners without their consent. Most of the subjects of these experiments died or were permanently crippled as a result. As a direct result of the trial, the Nuremberg Code was established in 1948, stating that “The voluntary consent of the human subject is absolutely essential,” making it clear that subjects should give consent and that the benefits of research must outweigh the risks. Although it did not carry the force of law, the Nuremberg Code was the first international document which advocated voluntary participation and informed consent. [5]

Declaration of Helsinki.: In 1964, the World Medical Association established recommendations guiding medical doctors in biomedical research involving human subjects. The Declaration governs international research ethics and defines rules for “research combined with clinical care” and “non-therapeutic research.” The Declaration of Helsinki was revised in 1975, 1983, 1989 and 1996 and is the basis for Good Clinical Practices used today. Issues addressed in the Declaration of Helsinki include: [6]

- Research with humans should be based on the results from laboratory and animal experimentation
- Research protocols should be reviewed by an independent committee prior to initiation
- Informed consent from research participants is necessary
- Research should be conducted by medically/ scientifically qualified individuals
- Risks should not exceed benefits

The Belmont Report[7]: Carrying out its charge, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research prepared the Belmont Report in 1979. The Belmont Report in 1979 attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. The Report is a statement of basic ethical principles and guidelines that should assist

in resolving the ethical problems that surround the conduct of research with human subjects. The Belmont Report established three basic ethical principles – respect for persons, beneficence and justice – which are the cornerstone for regulations involving human subjects.

CIOMS[8]: The International Ethical Guidelines for Biomedical Research Involving Human Subjects, sometimes informally referred to as CIOMS Guidelines, is a set of ethical principles regarding human experimentation created in 1993 by CIOMS and updated in 2002. The 21 guidelines (15 in the original report) address issues including Informed consent, standards for external review, recruitment of participants, and more. The Guidelines are general instructions and principles of ethical biomedical research.

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