The Tuskegee Syphilis Study

Introduction

Although experimentation on human subjects has long been understood to be fraught with serious ethical concerns, little was done to develop national and international guidelines and regulations with regard to such research until the end of World War II. Populations that were frequently victimized by involuntary or coerced participation in potentially dangerous experiments included prisoners and insane asylum inmates. Due to popular recognition of the need to test new medical treatments, defenders of the rights of such powerless individuals found little political interest in outlawing these practices. However, the atrocities committed by Nazi doctors in the name of medical experimentation, as revealed during the Nuremberg war crimes trials, raised international consciousness about the need for an acceptable code for medical research.

The result was the promulgation in 1947 of the Nuremberg Code. This document was drafted by an international panel of experts on medical research, human rights, and ethics. It focused on the requirement for voluntary consent of the human subject and the weighing of the anticipated potential humanitarian benefits of a proposed experiment against the risks to the participant. The Code served as the initial model for those few public and private research and professional organizations that voluntary chose to adopt guidelines or rules for research involving human subjects.

In the ensuing years occasional media publicity called attention to continuing questionable biomedical and behavioral research practices. In 1972 the Tuskegee Syphilis Study, described in the case study below, became a cause celebre due to the thorough and dramatic Associate Press story written by reporter Jean Heller. Congressional hearings took place in 1973 and the following year Congress passed legislation creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commissioners included prominent experts and scholars in the fields of medicine, psychology, civil rights, the law, ethics and religion. In 1979 they published *Ethical Principles and Guidelines for the Protection of Human Subjects of Research,* which is commonly referred to as "The Belmont Report." This document presents a well-developed ethical framework for the exploration of the issues associated with the use of human beings as the subjects of research. More comprehensive than the Nuremberg Code, it defined the boundary between accepted therapeutic practice and experimental research, and proposed the following three basic principles to guide in the evaluation of the ethics of research involving human subjects

Respect for Persons

> This principle incorporates the convictions that individual research subjects should be treated as autonomous agents, and that persons with diminished autonomy (such as prisoners or inmates of mental institutions) are entitled to protection.

Beneficence

> Research involving human subjects should do no intentional harm, while maximizing possible benefits and minimizing possible harms, both to the individuals involved and to society at large.

Justice

> Attention needs to be paid to the equitable distribution within human society of benefits and burdens of research involving human subjects. In particular, those participants chosen for such research should not be inequitably selected from groups unlikely to benefit from the work.

The Belmont report has greatly influenced the codes and regulations regarding human subjects research that have since been established in the United States by federal and many state governments, universities, professional organizations and by private research institutions, as well as similar codes and regulations elsewhere in the world.

Background

Syphilis was a widespread but poorly-understood disease until shortly after the turn of the century. Two of the principal steps forward were the isolation of the bacterium associated with syphilis in 1905, and shortly thereafter, the development of the Wasserman reaction to detect the presence of syphilis through a blood test.

Still, much about the disease and its progress remained unknown. Due to this lack of understanding many cases were incorrectly diagnosed as syphilis, while in other cases patients who would now be recognized as victims of the disease were missed. As the etiology of the disease was better understood, it became increasingly urgent to understand its long-term effects. The early treatments that predated the discovery of penicillin involving the use of such poisons as arsenic and mercury were dangerous, and sometimes even fatal. Thus, it was vital to learn about the likelihood that the disease itself would result in serious physical or mental disability in order to make sure that the potential benefits of treatment exceeded the risks.

One long-term study had been carried out in Oslo, Norway. This had been a retrospective study, going over the past case histories of syphilis victims then undergoing treatment, and had been undertaken on an exclusively white population.

In the early 1930s, the U.S. Public Health Service (PHS) began a program aimed at controlling venereal disease in the rural South. The Julius Rosenwald Fund - a philanthropic organization that was interested in promoting the welfare of African-Americans, provided the funds for a two-year demonstration study in Macon County, Alabama where 82% of the residents were African-Americans, most of whom lived in poverty and had never seen a doctor. A principal aim of this study was to determine the incidence of the disease in the local population, while training both white and African-American physicians and nurses in its treatment. When the results revealed that 36% of the Macon County African-Americans had syphilis, which was far higher than the national rate, the Rosenwald Fund, concerned about the racial implications of this finding, refused requests to support a follow-up project

The discovery of the fact that the incidence of the disease was higher among African-Americans than among whites was attributed by some to social and economic factors, but by others to a possible difference in susceptibility between whites and non-whites. Indeed one Public Health

Service consultant, Dr Joseph E. Moore of Johns Hopkins University School of medicine proposed that *Syphylis in the negro is in many respects a different disease from syphilis in whites.*

Case

In 1932 the PHS decided to proceed with a follow-up study in Macon County. Unlike the project supported by the Rosenwald Fund, the specific goal of the new study was to examine the progression of *untreated* syphilis in African-Americans. Permission was obtained for the use of the excellent medical facilities at the teaching hospital of the Tuskegee Institute and human subjects were recruited by spreading the word among Black people in the county that volunteers would be given free tests for *bad blood,* a term used locally to refer to a wide variety of ailments. Thus began what evolved into "The Tuskegee Study of Untreated Syphilis in the Negro Male," a project that would continue for forty years. The subject group was composed of 616 African-American men, 412 of whom had been diagnosed as having syphilis, and 204 controls.

The participants were never explained the true nature of the study. Not only were the syphilitics among them not treated for the disease -- a key aspect of the study design that was retained even after 1943 when penicillin became available as a safe, highly effective cure -- but those few who recognized their condition and attempted to seek help from PHS syphilis treament clinics were prevented from doing so.

Eunice Rivers, an African-American PHS nurse assigned to monitor the study, soon became a highly trusted authority figure within the subject community. She was largely responsible for assuring the cooperation of the participants throughout the duration of the study. She was aware of the goals and requirements of the study, including the failure to fully inform the participants of their condition and to deny treatment for syphilis. It was her firm conviction that the men in the study were better off because they received superior medical care for ailments other than syphilis than the vast majority of African-Americans in Macon County.

The nature of the Study was certainly not withheld from the nation's medical community. Many venereal disease experts were specifically contacted for advice and opinions. Most of them expressed support for the project. In 1965, 33 years after the Study's initiation, Dr. Irwin Schatz became the first medical professional to formally object to the Study on moral grounds. The PHS simply ignored his complaint. The following year, Peter Buxtin, a venereal disease investigator for the PHS began a prolonged questioning of the morality of the Study. A panel of prominent physicians was convened by the PHS in 1969 to review the Tuskegee study. The panel included neither African-Americans nor medical ethicists. Ignoring the fact that it clearly violated the human experimentation guidelines adopted by the PHS in 1966, the panel's recommendation that the Study continue without significant modification was accepted.

By 1972, Buxtin had resigned from the PHS and entered law school. Still bothered by the failure of the agency to take his objections seriously, he contacted the Associated Press, which assigned reporter Jean Heller to the story. On July 25, 1972 the results of her journalist investigation of the Tuskegee Study of Untreated Syphilis in the Negro Male were published. The response to Heller's revelations was broad-based public outrage, which finally brought the Study to an immediate end.

Issues

Significant questions of ethics and values raised by this case

- An explicit requirement of the Tuskegee study was that the subjects not receive available treatment for a debilitating disease, a clear violation of normal medical practice. Would any study involving human subjects that violated normal medical practice necessarily be unethical?
- The Tuskegee victims were not informed -- in fact they were deliberately misinformed -- about the nature of the study in which they were participants. A basic guideline for human subject research, specified in both the Nuremberg Code and the Belmont Report is the requirement of informed consent. What would have constituted informed consent in the case of the Tuskegee Study? If such informed consent had been obtained from the subjects, would this remove all questions about whether the Study was ethical?
- In what sense were the premises and the practices of the Tuskegee study racist? An important question to explore when examining accusations of human rights violations or of prejudicial behavior is whether the standards being applied are those of the time the action took place, and if not, whether this should affect any judgement about the ethics of the situation. (Conforming to official social standards does not necessarily imply that you are behaving in an ethical manner. Most people would consider the medical experiments of the Nazi Doctors to be unethical even though they conformed to the principles spelled out in the Nazi ideology imposed on Germany by the Third Reich.)
- Eunice Rivers, the African-American nurse who played a vital role by befriending the Tuskegee Study participants and assuring their cooperation has justified her support for the project in terms of the fact that the attention that she and the other medical staff gave to the men was more than a non-enrolled, poor, Macon County resident was likely to receive. If you had been in her place, do you think you would have come to the same conclusion with regard to the ethical choices available to you.
- Ordinarily, one would not think of the media as the proper instrument for enforcing public morality. They had that role here, but should they have?
- The political reaction to the Tuskegee revelations was largely responsible for establishing the committee that wrote the Belmont report, which set guidelines for experimentation on human subjects. These guidelines have been the basis for regulations, usually enforced by human subjects research panels, at most public and private institutions that conduct such research. Is this likely to assure that all future research on human subjects will be conducted in a manner that raises no ethical concerns?
- The Belmont Report proposes three criteria for the evaluation of human subjects research, *respect for persons*, *beneficence* and *justice*, as described above in the introductory section. In what ways does the Tuskegee Study fail to conform to each of these criteria.
- In experiments on infants, it is obviously impossible to obtain the informed consent of the subject. This is also true in experiments on senile individuals. Does this mean that ethical considerations preclude using such subjects in any experiment?

Further reading

For a medical report on the Study summarizing the first thirty years of subject observation

- "The Tuskegee Study of Untreated Syphilis: the 30th year of observation," by D.H. Rockwell et al., *Arch. Intern. Med.*, 144, pp 792-798, 1964.

Recent books about the Tuskegee Study include

- *The Tuskegee Syphilis Study*, by Fred D. Gray (Montgomery, AL: Black Belt Press, 1998).
- *Bad Blood. The Tuskegee Experiment*, by J. H. Jones (: Free Press, 1993).

For more information on the ethics of experimentation on human subjects read

- "The Belmont Report," by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, OPPR Reports, NIH, PHS, HHS , April , 1979.
- *The Nazi Doctors and the Nuremberg Code*, by G. Annas and M. Grodin, (New York: Oxford University Press, 1992).

For a report on recent revelations concerning unethical experiments that exposed many human subjects to nuclear radiation see

- "Radiation: Balancing the Record," by Charles C. Mann, *Science*, 263, pp 470-473, January 28, 1994.