

Tuskegee Syphilis Study of 1932–1973 and the Rise of Bioethics as Shown Through Government Documents and Actions

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One government source regarding clinical trials is Clinicaltrials.gov (<https://clinicaltrials.gov>), which is available to health information seekers as a resource to find information about past, current, and recruiting clinical trials. Currently, if you participate in a clinical trial you are required to provide your “informed consent.” This means you have been informed of the risks, benefits, purpose of the study, and your rights. This information is provided to you so that you, as the potential participant, can make an informed decision before deciding whether or not to participate. If you work with or in research, you will become very familiar with the term IRB, which stands for “Institutional Review Board.” An IRB is a panel intended to oversee the entire scope of one or more medical research studies including protecting the rights and welfare of human research subjects. Although it may seem like common sense that these two things are necessary, there was a time when they did not exist. A new approach to bioethics and the regulation of clinical trials and medical studies using living human subjects came about from public and governmental outrage over one study, known as the Tuskegee Syphilis Study. By looking specifically at this case, which led to the rise of bioethics at the federal-government level in the 1970s, the origin of IRBs and informed consent as they relate to medical studies and human subjects will be illuminated. The issues of IRBs, informed consent, and bioethics are important in the library and information science community because we often interact with a public that is impacted by the policies and regulations related to these issues. In addition, we are the very researchers, or hold relationships with researchers, that are held to the strict standards set in place by IRBs and bioethics in general.

Syphilis

Let’s go back to the 1920s. Syphilis had an incidence rate higher than that of gonorrhea, typhoid, diphtheria, or pertussis.¹ It was not as deadly as some other diseases but did cause damage—some permanent—or death.² Syphilis is a sexually transmitted disease (STD) caused by a bacterium but can also be transmitted from a pregnant woman to her unborn child.

Symptoms of syphilis are not always apparent even now, and they were less so in the 1920s, when it was often referred to as “bad blood,” especially in the African American community. Symptoms can look like other illnesses, but syphilis usually follows stages that can last for weeks, months, or years. Syphilis can be transmitted during stage one, stage two, or the early latent stage of the disease. In addition, even if you receive treatment once, you are still at risk of being reinfected if you come into contact with the bacterium that causes syphilis again. “Syphilis is a disease with an acute span of about 2 years and with chronicity which may persist throughout the life span. Most of its lethal and crippling manifestations occur during the first 15 to 20 years of the chronic period.”³

Choosing Macon County and the Start of the Tuskegee Study

Syphilis in Macon County, Alabama, was chosen as a study topic for the following reason,

In the late 20’s various of the foundations began their studies of health conditions in the south which were to eventuate in the development of local health units. One of the most striking findings in the early surveys

of disease prevalence was the high rate of syphilis among the majority of the Negro groups studied. In one of the study areas (Macon County, Ala., home of Tuskegee Institute) initial efforts at control of syphilis were followed by further moves on the part of the United States Public Health Service to bring diagnosis and treatment to the population. With the finding of high prevalence of syphilis in the survey and with certain other factors apparent in the community it became evident that it might be possible to institute in this region a prospective—in contrast to a retrospective—study of the results of untreated syphilis in the Negro male. Such a study was needed to assist in the planning and execution of the national venereal disease control program which was then being planned for a later time.⁴

In addition, that area had the highest syphilis rate in the United States at the time. It was thought that syphilis in African Americans had different manifestations than in whites. Initially, the U.S. Public Health Service and Tuskegee Institute created this study to monitor syphilis for six to eight months. The Tuskegee Institute and the African American professionals from there, were involved to help build relationships with the study population. The U.S. Public Health Service and Tuskegee Institute planned on having a syphilitic group and a control group and wanted to monitor health differences between the two groups. To get as much information as possible about the study participants, autopsies were also intended to be performed on all study participants. To recruit appropriate participants, they used fliers beginning in the fall of 1932. The fliers advertised a new health program and promised free blood tests and free treatments for “bad blood” in addition to free meals, free physicals, and free burial insurance. Approximately 600 black men initially signed up, 399 with syphilis and 201 without. Recruitment was not active after 1933, but participants were added when other participants moved away or were lost. Participants that were enrolled in the control group at the beginning of the study also contracted the disease during the study. There are not exact numbers regarding the total number of participants because records were not exact.⁵

The men tended to be sharecroppers who were poor and illiterate and had never had any proper medical care. The men were never told what the study involved, were never told that they would not receive adequate treatment for syphilis, and were not given the option of leaving the study. In addition, positive participants were not specifically told that they had syphilis or that that was the specific disease being studied. In 1936,

the decision was made to follow the study participants until their death. They also continued the decision to not provide any treatment for syphilis. This practice continued even when it was discovered in the 1940s that penicillin was a safe and effective treatment for the disease. The U.S. Public Health Service established treatment centers for syphilis but made sure that study participants were not treated. Study doctors went as far as to prevent participants from receiving this treatment from other doctors. In the case of George Key, even when he moved to California and Massachusetts, he was still tracked as a study participant and not given the appropriate treatment. Similarly, Ernest Hendon was tracked by study doctors when he relocated to Ohio.⁶ One other issue with this type of study was that the study did not consider the effects of the disease and lack of treatment on wives, partners, children, unborn children, families, and local communities of the study participants.

When ongoing continuation of the study was evaluated under multiple supervisors, it was deemed that the benefits of continuation outweighed the benefits of ending the study. Patient welfare was not taken into consideration. Even as late as 1969, a committee with the Center for Disease Control decided to continue the study until all study participants had died and been autopsied.⁷

End of the Study, Advisory Panel, and Civil Case

The study continued until 1972 and ended for several reasons. The most prominent and the first chronologically was when one of the investigators associated with the study, Peter Buxtun, leaked information to an Associated Press reporter. This is after he had voiced his concern to the director of the U.S. Division of Venereal Disease, which was a branch of the U.S. Public Health Service, and was ignored. A news article was published on the front page of the *New York Times* on July 26, 1972, under the headline “Syphilis Victims in U.S. Study Went Untreated for 40 Years.” “Officials of the health service who initiated the experiment have long since retired. Current officials, who say they have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.”⁸ This publication immediately raised concerns both internally in the Department of Health, Education, and Welfare, which now oversaw the study, as well as in Congress. Merlin K. DuVal, the Assistant Secretary of Health, created the Tuskegee Syphilis Study Ad Hoc Advisory Panel. DuVal tasked the panel with three tasks:

- Determine whether the study was justified in 1932 and whether it should have been continued when penicillin became generally available.
- Recommend whether the study should be continued at this point in time, and if not, how it should be terminated in a way consistent with the rights and health needs of its remaining participants.
- Determine whether existing policies to protect the rights of patients participating in health research conducted or supported by the Department of Health, Education, and Welfare are adequate and effective and to recommend improvements in these policies, if needed.⁹

On November 16, 1972, a memo from DuVal, was sent to the Director of the Center for Disease Control. This memo called for the termination of the “Tuskegee Study.”¹⁰ The decision was based on information from the Ad Hoc Advisory Panel and noted that additional information would be forthcoming regarding next steps. Besides in-depth answers to the three specific tasks they were assigned, a few summary conclusions were also raised:

1. There was no evidence of informed consent.
2. There was known risks to human life and transmission of the disease during the time of the study.
3. There was evidence that those from the control group that developed syphilis were moved to the syphilitic group and it is not clear if those participants received treatment.
4. The study was deemed ethically unjustified in 1932 (Based on hindsight from 1973).
5. This type of study would never be repeated.
6. The scientific pluses of the Tuskegee study were hugely overshadowed by the violation of basic ethical principles.
7. Congress should establish a permanent body to regulate, at a minimum, all federally funded research involving human subjects.¹¹

On July 24, 1973, an individual civil case was filed on behalf of study participant Charlie Pollard by lawyer Fred D. Gray. Gray was known for his civil rights work with Martin Luther King Jr., Claudette Colvin, and Rosa Parks. *Pollard v. United States* alleged violations of both federal and state law.¹² The case was based on violations of wrongful death statutes, deprivation of life and liberty, and involuntary servitude. The case was expanded to a class-action lawsuit and broadened to include both remaining study participants as well as family members of deceased participants. The case was settled for \$10

million dollars, which is equal to about \$60 million in 2019. As part of the settlement, the Tuskegee Health Benefit Program was also created.

The National Research Act of 1974

As a result of becoming aware, Congress held hearings regarding the Tuskegee Study and bioethics in general. Testimony was heard from Peter Buxtun; Fred D. Gray; multiple Department of Health, Education, and Welfare officials; members of the Tuskegee Syphilis Study Ad Hoc Advisory Panel; study participants; as well as others. It is clear from the testimony of the study participants that they thought that they were receiving appropriate medical treatment as participants of the study.¹³ The result of these hearings was The National Research Act of 1974 that created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission produced multiple reports, of which two were highly influential. The first of these is “Report and Recommendations: Institutional Review Boards.”¹⁴ IRBs were initially created by The National Research Act of 1974 and certain specifics about IRBs are listed in the Title 45 *Code of Federal Regulations* Part 46. “Report and Recommendations: Institutional Review Boards” helped to further define how IRBs should work, how to evaluate if they are working, and how to improve the review process. IRBs are in place to oversee research from an ethical perspective as well as to monitor research to ensure that steps are taken to protect the rights and welfare of human participants. IRBs exist at academic and nonacademic organizations. They review protocols and methods as well as study materials. Most IRBs require documentation in specific formats. They may approve, disapprove, or require modifications to research before it can begin. In addition, they require continuous monitoring during the course of a study. If aspects of a study or the study environment change, an IRB does have the ability to revoke approval of the study. If IRBs had been required during the time of the Tuskegee Study, both the Tuskegee Institute and the U.S. Public Health Service would have had IRBs that would have reviewed the study. Based on given facts and current IRB standards, it is doubtful that the Tuskegee Study would, at any point, have been given approval by an IRB. Even if the study had met all of the requirements of both the Tuskegee Institute and federal IRBs and approval had initially been granted for the study to start, there is no guarantee that there would have been continued approval given the extension of the timeframe and the discovery of a safe and effective treatment for syphilis.

The second influential document created by the Commission is “The Belmont Report: Ethical Principles and Guidelines

for the Protection of Human Subjects of Research.”¹⁵ This document defined three basic ethical principles of respect for person, beneficence, and justice. Respect for persons is the idea that all people deserve the right to autonomy (i.e., the right to make their own choices based on their values, preferences, and beliefs) and included additional protections for those who cannot practice this right because they are “disadvantaged.” As part of respect for persons, researchers should be truthful and without deception. Beneficence is the idea that researchers must “do no harm” and maximize benefits and minimize risks for study participants. Justice is the idea that the benefits and burden of the study must be equally distributed.

“The Belmont Report” also discussed the application of informed consent, risk/benefit assessment, and the selection of subjects of research that somewhat match to respect for persons, beneficence, and justice. Informed consent is based on three main principles: information, comprehension, and voluntariness. Information typically includes items such as the purpose of the study, risks, benefits, procedures, and ability to withdraw. Comprehension has to do with both the manner in which the information is presented and the ability of the subject to understand the information. The researcher has a responsibility to make sure that participants understand their informed consent, especially if they are considered disadvantaged. Lastly, informed consent is only valid if it is given voluntarily. There can be no coercion or undue influence. Risk/benefit assessment requires the researcher to look at data and consider alternative ways to obtain the benefits of a study under consideration. It requires that a researcher consider all options and carefully plan proposed research. It is designed to make sure that research is appropriately designed to maximize benefits and minimize risks. The selection of subjects of research requires that there be fair procedures in the selection of participants for research. This maximizes the application of justice.

If these concepts had been in place in 1932, the Tuskegee Study would not have taken place as it did. The participants in the Tuskegee Study would have been considered disadvantaged because they were poor, had limited access to health services, limited education, and limited literacy. Because of these factors, they would have needed special protections to make sure that they understood their choices and their ability to make their own decisions. In addition, researchers would have needed to make sure there was no deception and be truthful about the study. After knowing the full facts of the study, participants would have needed to voluntarily join the study and stay in the study. In addition, there would have had to be some form of informed consent, which never occurred. In terms of

beneficence and risk/benefit balance, the Tuskegee Study did not meet the qualifications for beneficence as they did harm and did not seek to benefit the study participant or limit risk for the participants, the families, or the community. It is not clear that the researchers sought out other ways to obtain the benefits that they did through the Tuskegee Study. In the case of justice, the burden was not equal as the burden was strictly on the participants and they did not see any of the benefits. It was also clear that these subjects were chosen for specific reasons that placed a bigger burden on them than was appropriate.

Later Bioethics Commissions

In 1978, Congress created the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.¹⁶ This Commission was different from the previous one in that it was operated through the President instead of through the Department of Health, Education, and Welfare. It also broadened the scope to allow for consideration of more emerging issues, or issues raised at the request of the President. Presidents Clinton, Bush (I), and Obama created bioethics bodies via executive order. It does not appear, at the time of writing, that President Trump has created a commission or council on bioethics.

Official Apology

On May 16, 1997, President Clinton made official remarks in apology to African Americans on the Tuskegee Experiment.

So today America does remember the hundreds of men used in research without their knowledge and consent. We remember them and their family members. Men who were poor and African-American, without resources and with few alternatives, they believed they had found hope when they were offered free medical care by the United States Public Health Service. They were betrayed.

Medical people are supposed to help when we need care, but even once a cure was discovered, they were denied help, and they were lied to by their Government. Our Government is supposed to protect the rights of its citizens; their rights were trampled upon—40 years, hundreds of men betrayed, along with their wives and children, along with the community in Macon County, Alabama, the City of Tuskegee, the fine university there, and the larger African-American community. The United States

Government did something that was wrong, deeply, profoundly, morally wrong.¹⁷

Application for National Register of Historic Places

The National Register of Historic Places recognizes the country's historic buildings, sites, and structures worthy of preservation. Being added to this list marks these buildings, sites, or structures, as important examples of the country's heritage, both positive and negative. "The Tuskegee syphilis study, has come to symbolize the most egregious abuse of authority on the part of medical researchers."¹⁸ In addition, the application also highlights some of the more deplorable acts such as painful and dangerous spinal taps performed without informed permission of the participants and taking blood samples and giving medication at local roadway intersections or in other non-sterile environments. This application called for different types of properties to be added to the National Register of Historic Places. These include cemeteries, medical facilities, residences associated with prominent persons, and "roundup" centers, which include churches and schools. The goal with this application was not just to recognize the negatives of the study but to remember the rural, African American Alabama families that were forever changed by the Tuskegee Study. Though the study is over, generations of Macon County families will be able to show the impact that the study had on changing the face of bioethics in the United States.

Conclusion

The United States has come a long way from the 1920s in Macon County, Alabama. There are now in place protections intended to help protect the welfare of human participants in research. Unfortunately, without up-to-date guidelines about the ever-changing bioethics environment, we may be in a situation in which we are bound to repeat history. Staying current with this environment, not forgetting the past mistakes and transgressions that have occurred, and changing policy as necessary are key to making sure that we do not repeat the past. We will have to pay close attention to new advances in subjects like human genetics, stem cell use, precision medicine, and the use of AI in medicine. Along with advancements in medicine and clinical care comes the need for reciprocal and forward-thinking advancements in bioethics. In looking at the intersection of health information and government documents, there are important areas of legislative history that can teach us as librarians and our library users much about the growth of health research in the United States from both a professional perspective and one that can impact us on a more personal level as well.

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