The Tuskegee Study: A Lesson in Ethics

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Chapter 1

The Tuskegee Study of Untreated Syphilis

By 1926, the prevalence rate of Syphilis in the reproductive age population was 35 percent and it was being seen as a major health problem. To address this, an aggressive treatment approach was started in 1929 that included mercury and bismuth. Unfortunately the treatment required months, had toxic and sometimes fatal side effects, and only yielded a cure rate of less than 30 percent (CDC, 2011). Syphilis, the disease referred to as “the great mimic,” (Menikoff, pg. 321, 2008) had the ability to imitate the symptoms of many other diseases, as well as change its symptoms over the course of long periods of time. It produced three distinct stages of infection including primary, secondary, and latent stages.

Given this, the researchers had very good reason to want to learn more about the disease and the consequences of being infected (Menikoff, 2008). With the onset of the economic depression in 1929 and the cuts made to the development projects in 1931 it was decided by Clark and Vondelehr to follow men who were left untreated (due to lack of funds) to demonstrate a need for a treatment program (CDC, 2011). Over a 40 year period, from 1932 to 1972 (Brant, 1978) as joint effort between the Public Health Service and the Tuskegee Institute, the initiative called the “Tuskegee Study of Untreated Syphilis in the Negro Male” conducted a study/experiment on 600 African American males 399 of which had syphilis and 201 who did not.

Originally predicted to last six months (Brandt, 1979), the study was conducted without the informed consent of those involved (CDC, 2011). In fact the participants of the study were never actually told that they were participating in an experiment (Brandt, 1978). Instead participants were told that they were being treated for “bad blood;” a colloquialism used to
describe multiple conditions including syphilis, anemia, and fatigue. However those affected with the disease did not receive the proper treatment needed to cure them. They only received free medical exams, meals, and assistance with burial insurance (CDC, 2011).

The reason for not telling the participants that they were infected with Syphilis was intentional. Researchers wanted to minimize the likelihood that participants would seek or receive treatment for the disease. This was evident even when the study began, as researchers were aware of existing treatments to reduce symptoms, such as arsenic compounds (Menikoff, 2008) and that every major textbook of syphilis, even at the time of the Tuskegee Study’s inception advocated the treating of syphilis (even its latent stage) (Brandt, 1978). However, they still withheld treatment and did not provide this information to the participants (Menikoff, 2008).

By 1934, the first papers from the study demonstrated the health effects of untreated syphilis. The first major paper was published in 1936 (CDC, 2001) with subsequent papers published every four to six years through the 1960s (Brant, 1978). The 1936 paper received much criticism due to the fact that there was no awareness as to whether the participants were being treated or not. Researchers sought the assistance of local physicians and the decision was to follow the participants until death without treating them (CDC, 2011).

By the 1940s, with the development of an effective treatment of Syphilis, the study was still being conducted and participants were still not treated (CDC, 2011). Information regarding treatment options and diagnosis were intentionally withheld (Menikoff, 2008), despite the widely accepted practice and use of penicillin to treat syphilis. Participants were also not informed of nor could they seek treatment from the United States Public Health Service’s Rapid Treatment Centers established to treat syphilis (CDC, 2011). In addition to withholding information, during
the forty years of the experiment, the United States Public Health Service (USPHS) worked to ensure that participants did not receive treatment from other sources (Brandt, 1978).

The USPHS prevented many men from seeing physicians who could have treated them (CDC, 2011) and the USPHS even met with groups of local African American physicians, as far back as 1934, to ask for their cooperation in not treating the men. Lists of participants were distributed to the Macon County physicians along with letters from the USPHS that the participants be referred back to the USPHS if they sought treatment or care. In fact when the Alabama Health Department took a mobile venereal disease (VD) unit into Tuskegee in the 1940s, they were warned by the USPHS to not treat the participants of the study.

Even those drafted by the Army were prevented from receiving treatment. In 1941, multiple participants were drafted and were to begin antisyphilitic treatment, but the USPHS intervened supplying the draft board with a list of 256 names they were requesting to have excluded from treatment; the draft board complied. Despite the USPHS efforts, by the early 1950s many of the participants secured some treatment independently and by 1952 approximately 30 percent of the participants had received some penicillin, although only about 7.5 percent had received an adequate dose. As a result of the efforts of the USPHS to ensure the non-treatment of the participants, many died a painful death, became permanently blind, mentally ill, or produced children who were born with congenital syphilis (Brandt, 1978).

Unfortunately, the study continued without criticism through the 1950s, and most of the 1960s while participants continued to go untreated. In 1968 an ethical concern was raised about the study by Peter Buxtun and others. It is even on record that Dr. James B. Lucas, Assistant Chief of the Venereal Disease Branch, stated in reference to the study that “nothing learned will prevent, find, or cure a single case of infectious syphilis or bring us closer to our basic mission of
controlling venereal disease in the United States,” but he still recommended the study to be continued “along its present lines” (Brandt, pg. 11, 1978). As a result, the need for the study was reaffirmed in 1969 by the CDC with the support of the local American Medical Association and National Medical Association (CDC, 2011). Consequently, instead of the study actually justifying new or continued treatment for African Americans, doctors and public officials watched as 400 men in Alabama died in a scientific study/experiment based on unethical methods that produced no new information about syphilis (Brandt, 1978).
Chapter 2

Cause for Concern

Finally, in 1972 an Associated Press story about the study raised awareness and cause for public concern. This interest and concern lead to the Assistant Secretary for Health and Scientific Affairs to appoint an interdisciplinary advisory panel to review the study (CDC, 2011). The panel named the Tuskegee Syphilis Study Ad Hoc Advisory Panel (Menikoff, 2008) consisted of nine members from the following disciplines: medicine, law, religion, labor, education, health administration, and public affairs (CDC, 2011). The panel was asked to determine 1) if the study was justified at the time it began, and should it have continued after penicillin became widely available; 2) if the study should be continued, and if not, what is the best way to terminate the study that was respectful to the participants; and 3) if existing policies to protect the rights of patents participating in the health research, conducted or supported by the agency, were adequate and effective and what improvements could be implemented (Menikoff, 2008).

The panel issued their final conclusions in 1973 (Menikoff, 2008). They found that the study was “ethically unjustified” reporting that although men agreed to the examination and treatment freely, there was evidence that the participants were misled and not informed of the study’s real purpose. In fact, they were not given all of the required facts to provide informed consent, were never given adequate treatment for the disease (even when the drug of choice, penicillin, was identified in 1947), and were never given the option to quit the study (CDC, 2011). The panel also determined that the benefit of the study was very little when compared to the associated risks to the participants. After their review in October of 1972, the panel advised that the study be stopped (CDC, 2011).
The panel was also and was “rather damning of the then-existing policies to protect human research subjects” (Menikoff, pg. 314, 2008). Finding that the Tuskegee Syphilis Study was not an isolated in its research practices, the panel believed that the review of the study only surfaced unresolved problems associated with studies and experiments on human beings. They believed these issues to be ongoing in many fields including such disciplines such as medical, psychological, sociological, educational, and legal (Menikoff, 2008). The panel also expressed that their initial determination (to protect human research subjects) was a current and widespread problem and was not surprising, as there was much congressional activity in the form of hearing and bills focusing on the regulation of experimentation. There were also many experiments raising ethical questions during the previous decade regarding other studies such as the “injection of cancer cells into aged patients at the Jewish Chronic Disease Hospital in Brooklyn, the deliberate infection of ‘mentally retarded children with hepatitis at Willowbrook,’ the development of heart transplantation techniques the enormous amount of drug research conducted at American prisons, the whole-body irradiation treatment of cancer patients at the University of Cincinnati, the advent and spread of psychosurgery, and the Tuskegee Syphilis Study itself” (Menikoff, pg. 314, 2008).

The panel then continued to provide a comprehensive gap analysis of the system for protecting research subjects (Menikoff, 2008). The following month, the Assistant Secretary for Health and Scientific Affairs announced the end of the study (CDC, 2011); only 74 participants were still alive (Brandt, 1978). In 1973, a class-action lawsuit was filed on behalf of the participants and their families and in 1974 a settlement agreement was reached. The settlement included an amount of $10 million along with the establishment of the Tuskegee Health Benefit Program (THBP) to provide lifetime medical benefits and burial services to all living
participants. This settlement established the Tuskegee health Benefit Program (THBP) (CDC, 2011). Additionally, within one year of the report, Congress passed the National Research Act of 1974, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The commission authored the Belmont Report providing the foundation for the regulations subsequently adopted to protect research subjects (Menikoff, 2008).

In 1975, wives, widows, and children of participants were added to the THBP and the Centers for Disease Control and Prevention (CDC) were given responsibility for the THBP. In 1995, health benefits as well as medical benefits were added to the plan, (CDC, 2011). However all of this did not make up for what has been described as “one of the most horrible scandals in American medicine in the 20th century” (Brandt, 1978). Finally, on May 16, 1997, in the East Room of the White House, President Bill Clinton issued a formal apology (Thomas, 2013) on behalf of the Nation (CDC, 2011) saying:

*The United States government did something that was wrong, deeply, profoundly, morally wrong. To the survivors, to the wives and family members, the children and the grandchildren, I say what you know: No power on earth can give you back the lives lost, the pain suffered, the years of internal torment and anguish. What was done cannot be undone. But we can end the silence. We can stop turning our heads away. We can look at you in the eye and finally say on behalf of the American people, what the United States government did was shameful, and I’m sorry* (Thomas, 2013).

In 1999, the Tuskegee University National Center for bioethics in Research and Health Care hosed their 1st Annual Commemoration of the Presidential Apology. In 2001, the President’s Council on Bioethics was established. Currently it is operated by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention division of the CDC. As of 2011 there were 15 children of participants receiving medical and health benefits through the THBP. The
final participant passed away in January of 2004 and the final spouse passed away in January 2009 (CDC, 2011).
Chapter 3
Ethics and Regulation

The Tuskegee study was designed to provide information and insight regarding the natural course of syphilis until death. While little was learned about syphilis as a result of this study, much was learned about ethics; “more was learned about the nature of scientific inquiry than the nature of the disease process” (Brant, pg. 13, 1978). From the inception of the study until its end, there were many ethical considerations that needed to be evaluated by a regulatory entity. Looking at the study in historical context and realizing that there was an “essentially racist nature” (Brandt, pg 12, 1978) occurring in Alabama during the 40-year long experiment should raise a question in the mind of those providing oversight. In this case, the study revealed the “persistent belief within the medical profession about the nature of blacks, sex, and disease,” (Brandt, pg. 12, 1978), believing that “blacks were promiscuous and lustful” (Brandt, pg. 6, 1978). Given their beliefs, the researchers demonstrated an obvious lack of concern for the community, as they continued to place the community at risk of a communicable disease for many decades (Brandt, 1978).

Other areas of concern were with the regulators as there was regulation and awareness of the study throughout its entirety. The USPHS itself decided to extend the experiment in the summer of 1933 and was widely reported for almost half a century (40 years) without any significant protest from the medical community or governmental entity. In fact the USPHs sent physicians to Tuskegee every few years to evaluate the study’s progress. There was never any question of morality, ethics, or usefulness of the experiment; nor was there any serious scrutiny. There was a serious injustice committed by those involved with the study and the degree of deception was inexcusable. Greater vigilance was needed to assess the processes, as well as the
professional behavior of those involved. Science is not value free, and the impact to human beings should have been considered first (Brandt, 1978).

The current regulatory system for protecting research subjects “owes a great deal” (Menikoff, pg. 314, 2008) to the governmental response and disclosure of what occurred in the Tuskegee Study. The current system largely based on a set of federal regulation, generally operates under the “Common Rule” a term to describe (Menikoff, 2008) the United States Health and Human Services (HHS) regulations, 45 CFR part 46, subpart A, published in 1991 and codified in separate regulations by 15 Federal departments and agencies including the Department of Agriculture (7CFR Part 1c); Department of Energy (10 CFR Part 745); National Aeronautics and Space Administration (14 CFR Part 1230); Department of Commerce, National Institute of Standards and Technology (15 CFR Part 27); Consumer Product Safety Commission (16 CFR Part 1028); Agency for International Development (22 CFR Part 225); Department of Housing and Urban Development (24 CFR Part 60); Department of Justice, National Institute of Justice (28 CFR, Part 46); Department of Defense (32 CFR Part 219); Department of Education (34 CFR Part 97); Department of Veterans Affairs, Office of Research Oversight and Office of Research and Development (38 CFR, Part 16); Environmental Protection Agency, Research and Development (40 CFR Part 26), Department of Health and Human Services (45 CFR Part 46); National Science Foundation (45 CFR Part 690); and Department of Transportation (49 CFR Part 11) (HHS, n.d.). There are three other federal departments/agencies that adhere with all subparts of 45 CFR part 46 including the Central Intelligence Agency (Executive Order 12333, paragraph 2.10), Department of Homeland Security (6 U.S.C. section 112), and the Social Security Administration (42 U.S.C. section 901).
The HHS regulations, 45 CFR part 46 also include three additional subparts. Subpart B adds additional protections for pregnant women, human fetuses, and neonates; subpart C adds additional protections for prisoners; and subpart D adds additional protections for children. Each agency includes in their chapter of the Code of Federal Regulations (CFR) section numbers and language identical to those of the HHS codification at 45 CFR part 46, subpart A. The Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance and any human research conducted or supported by each federal agency or department is governed by those regulations. The final judgment as to whether particular activity the agency or department conducts or supports is covered by the Common Rule falls to the agency/department head (HHS, n.d.).

This set of regulations has substantial influence over most human subject research and set the requirements that researchers must meet before conducting a study involving human subjects. In particular, the proposed subjects must receive adequate information so that they can make informed choices about participation including that they can only be enrolled in a study after freely and voluntarily providing their informed consent (explained in more detail later in this report). The rule(s) also includes that there be an appropriate balance of the risks and benefits to the participants and society from conducting the study. Regulations must also include an Institutional Review Board (IRB), composed of at least five members with differing or various backgrounds. The IRB is responsible for reviewing and determining whether a study conforms to the regulations. Major research institutions in the United States are able to have one or more IRBs, they are also able to hire one independently of their institution (Menikoff, 2008).

Every year in the United States, thousands of IRBs review research studies and the types of research are not limited to only include biomedical research. Consistent with the findings of
the Tuskegee Syphilis Study Ad Hoc Advisory Panel’s 1973 Report that identified that biomedical research is not the only type of problematic research, the regulations are not limited to a particular type of research. The definition of research is broadly defined when research involves human subjects, but dose recognized that not all research requires the same level of scrutiny. The regulations allows for certain types of research such as those involving surveys or questionnaires to be exempt from most of the requirements. The low-risk research such as this is only required to comply with the less-specific ethical principles included in The Belmont Report (Menikoff, 2008). Additionally, “several non-HHS federal departments and agencies have additional regulations in place for research involving special populations or for human subject research in general” (HHS, n.d.).

Informed consent is paramount when considering participation in any human study. Informed consent is more than a participant signing a consent form, but it is a process of communication that is “both an ethical obligation and a legal requirement spelled out in statutes and case law in all 50 states” (AMA, 2013) of the United States. At the core of informed consent is the “overarching ethical consideration” of patient autonomy. The Code of Medical Ethics for the American Medical Association (AMA), explains that physicians must provide full disclosure of relevant information to their patients to ensure the patients’ rights of self-determination, bodily integrity, and to protect his or her “voluntariness” in the healthcare decision making process. Additionally, this is codified by the Centers for Medicare and Medicaid Services (CMS) and is interwoven in their conditions of participation. Reasons for this are to ensure patients to participate in the development and implementation of his or her plan of care with the responsibility falling to the physician to ensure that the patient can exercise this right by allowing he or she (or their legally authorized representative) to make their own decisions about treatment
after the physician respectfully, and sensitively discloses any relevant information to the individual in a manner the individual understands.

The process of informed consent must also be documented as a process, one that occurs to provide the authorization or agreement to undergo a specific intervention. In the medical field the communication process of informed consent is described by the American Medical Association (AMA) as follows: the physician performing the treatment/or procedure (not a designated representative) should disclose and discuss the diagnosis, purpose, risks and benefits, alternatives, risk and benefits of alternatives, and risks and benefits of not receiving the treatment or undergoing the procedure. They also explain that the patient should have the opportunity to ask questions and seek more information to better understand what is being communicated and to make an informed decision regarding their decision to proceed or refuse part or all of the treatment and/or procedure (AMA, 2013).

Given the right of Informed Consent, it appears that in some cases there may be some conflicting ethical considerations when it comes to autonomy and beneficence. In this situation, autonomy is when an individual has the right to make decisions regarding their own health care (Kotaska, 2011) if they are competent to do so. Their choice must also be made without coercion or undue influences from others (Faith, n.d.). Beneficence is the imperative to do what is in the best interest of the patient (Kotaska, 2011). Ethical issues arise when the patient’s autonomous decision conflicts with the physician’s obligation to do what is in the patient’s best interest (UCSF, 2011).

One of the associated issues with a physician acting in the best interest of a patient is that there may be disagreements over what is actually best for the patient and for their quality of life. Additionally the historical “paternalistic approach,” believing that the “doctor knows best,” is not
a sufficient argument to override the patients’ wishes (SCCO, 2005). In cases where the physician truly believes that the patient’s decision is not in their best interest (e.g., a recipient of triple bypass surgery continues to smoke, or a patient with a pneumonia refuses antibiotics) if the person has the capacity to understand their choice the physician must respect the choice of the patient (UCSF, 2013). If a patient lacks the decision-making capacity, the physician should be guided by the patient’s best interests and not by autonomy, especially if the patient requests interventions that may be more harmful than beneficial, or when the patient requests interventions whose benefit can only be seen by the patient (UCSF, 2013).

As part of the research process, informed consent is even more than a conversation; it is an ongoing dialogue of sorts that must educate potential subjects to ensure they can truly make an informed decision about their participation. Consent for research must also be given freely (without coercion), and there must be a clear understanding of what a subjects participation includes. The process begins during initial contact and continues for the duration of the study and all information presented through advertisements, recruitments, pre-screening solicitations, must all be understandable to the subjects and contribute to their understanding of their participation and the nature of the research.

To ensure understanding, medical terminology should be avoided and education and explanations provided in common language (preferably an 8th grade reading level or lower), as well as be presented in the language understood best by those who are being recruited, considered, and selected for participation in the study. The consent discussion should also take place far enough in advance to all potential subjects time to review and reflect on the potential risks, benefits, and possible discomforts associated with their participation in the study. Multiple mediums of communication will also help to promote understanding such as advertisement,
information sheets, letters, discussions, listing of frequently asked questions, and one-to-one conversations. All materials should be provided in advance and encouraged by researchers for potential subjects to take them home to review in further detail.
Chapter 4

Recommendations, Summary, and Commentary

It is the opinion of this writer that things could have been handled much differently regarding the Tuskegee Syphilis study. It is the recommendation of this writer that the researchers demonstrate respect for their subjects regardless of who they are and the situation they are in. It is recommended that they do so through the following recommendations: be honest with the public and their participants continually educating them of the actual purpose of the study; seek participants who truly wanted to participate; explain to those interested in participating the nature of their condition and why they are being chosen to volunteer for the study; time limit the study and adhere to the timeframe; allow and encourage participants to have the ability to end their participation at any time; set milestones for the study and if the results are not meeting the milestones, end the study; allow the study to evolve and change as more is learned about the study; continually inform participants about treatment options and either provide them with treatment, help them to access treatment, and always explain the risks and benefits associated with receiving and not receiving treatment; have a unbiased and interdisciplinary team provide regular oversight and direction, and regular recommendations; use an institutional review board to review the study prior to starting the study; and make every effort to minimize risk to the participants, researchers, and the community.

It is the opinion of this writer that implementing these changes supports the Common Rule and allows for there to be oversight and direction, as well as and provide a study that is ethical and purposeful. It also demonstrates the integrity of the researchers by showing that they value the lives and opinions of their participants. The Tuskegee Study lost sight of their original plan, they interfered with the course of evolution, essentially played God (by deciding that this
group of men, would die of Syphilis). In the name of Science, they destroyed people’s lives, learned nothing, but still managed to educate a nation that true cruelty can not only exist, but have the support of those who the citizens of the Nation otherwise trusted to protect them.

The changes made by the federal government were necessary, but were overdue. The civil rights of the participants were being violated and society in this case became the criminal. The medical community was guilty of groupthink (a phenomenon that occurs when a highly cohesive group fails to consider alternatives that may effectively resolve dilemmas) and their cruelty was justified all in the name of experimentation; even when those who had the authority to stop the study knew there was no benefit to continuing. It was not until the media started to ask questions, was anything done to address the issue. This begs the question, if there hadn’t been media involvement, would anything ever have been done to address this situation (at Tuskegee or anywhere else) or would those 74 remaining participants have died without ever knowing what was being done to them; and without Tuskegee, would there ever have been such strong policy change to protect future subjects of human research?

The decision to require informed consent on the part of all physicians, human researchers, and Medicaid and Medicare providers holds them to a higher set of ethical standards and considerations that were there during the Tuskegee Study. Informed consent should always be considered even when it contradicts with beneficence. The only time informed consent is contraindicated, is if the person lacks capacity to understand the information. In cases such as these, it is the recommendation of this writer that the patient and seek the informed consent of the legally authorized representative. If a legally authorized representative is not available, then prior to making a treatment decision, the physician should consider the best interest of the individual. Also to ensure that there is ethical consideration on part of the physician, it is
recommended that the physician present the information to an ethics committee or seek a guardian ad litem to provide informed consent. This way there are more than one person reviewing the issues and making final decisions thereby reducing the propensity that the decision is not in the best interest of the individual. There is never a case recommended by this writer where a researcher should consider using a subject who does not have the capability to make their own decisions, or does not have a legally authorized representative to make that decision for them.

The idea of waiving consent for some areas of clinical investigation is not in the best interest of anyone. Doing so will begin the unraveling of the very necessary regulation and oversight needed to ensure the safety of people. If the requirement is removed in any case, it sets precedence for more subjectivity allowing for some to not have to play by the rules. Also, if there were some latitude given for specific circumstances, who would ultimately make the determination to allow for an exemption from informed consent; would there be a panel, would it be one person, and how could you assure that the decision maker has the same ethical opinion as those who would have been able to make that determination for his or herself? Further, it places vulnerable populations more at risk, as was seen with Willowbrook (mentioned previously in this report). If a person already lacks capacity to make decisions, and there is no requirement to receive the informed consent of their legally authorized representative, the Nation could wind up taking a step backwards, leaving vulnerable populations with no voice and no one to speak for them. This is definitely a step backwards in time.

Clinicians and medical researchers are working for the public, their patients, and the benefit of society. Given this, it is never acceptable to give an individual the main points of a study and not provide the detail. If the research is that important isn’t worth the time to ensure
that everything is done correctly. If not, how can there be any legitimacy to their findings? It is already impossible to guarantee the ethics of all professionals; it is only possible to require it, and enforce it. Allowing for more latitude in this area will only create more issues in the long-run.
REFERENCES


