The Tuskegee Syphilis Study

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Table of Contents

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The Tuskegee Syphilis Study</td>
<td>2</td>
</tr>
<tr>
<td>Introduction and Overview</td>
<td>2</td>
</tr>
<tr>
<td>2. Human Rights Protections Today</td>
<td>5</td>
</tr>
<tr>
<td>Respect for Persons</td>
<td>5</td>
</tr>
<tr>
<td>Beneficence and Nonmaleficence</td>
<td>6</td>
</tr>
<tr>
<td>Informed Consent</td>
<td>6</td>
</tr>
<tr>
<td>The Nuremberg Code</td>
<td>7</td>
</tr>
<tr>
<td>Institutional Review Boards</td>
<td>8</td>
</tr>
<tr>
<td>3. Summary and Recommendations</td>
<td>10</td>
</tr>
<tr>
<td>References</td>
<td>13</td>
</tr>
</tbody>
</table>
Chapter 1

The Tuskegee Syphilis Study

Introduction and Overview

The Tuskegee Syphilis Study is one that will go down in history as one of the worst instances of maltreatment and manipulation of human beings. The way the study was conducted demonstrated a blatant disregard for human rights and violated many principles of morality and public health ethics. There were many things that went wrong with this study and today there are various protections and documents in place to help prevent this type of unethical treatment from happening again. The formation of the Belmont Report and the Nuremberg Code help to protect basic human rights against this type of manipulation and cruelty from happening again. These documents help to clarify boundaries between researchers and their study participants to respect the rights of the individual.

The Tuskegee Syphilis study, officially titled the “Tuskegee Study of Untreated Syphilis in the Negro Male,” began in 1932 in Macon County, Alabama and ran its course until 1972. Developed in collaboration with the Public Health Service and the Tuskegee Institute, the study was originally intended to record the natural history of syphilis with the hope of finding treatment for black people. At the time when the study began, syphilis was recognized as a major health problem and there was not a known treatment for it. The study included six hundred black men in total: 399 with syphilis and 201 without (U.S. Public Health Service Syphilis Study at Tuskegee, 2013). The participants agreed to participate in the study under the premise of receiving free medical exams, free meals on the days they were in the clinic, free rides to and from the clinic, and burial insurance in exchange for their participation; something that many of these poor and illiterate black men could not otherwise afford. They understood they were being
treated for “bad blood,” a term that included ailments ranging from syphilis, anemia and fatigue and were enticed by the benefits offered for participation (About the USPHS Syphilis Study, 2014).

At first glance, one may think this study sounds beneficial and justified. However, there were many things that went wrong and were unjust over the course of the forty years the study was run. First of all, it was discovered that while the participants had agreed to be examined and treated, they never really understood the study or its real purpose. The men had been manipulated and the researchers omitted information regarding the study and its purpose and never gave the participants a chance to have what we now know as informed consent. The participants were also never given a chance to end their involvement with the study (U.S. Public Health Service Syphilis Study at Tuskegee, 2013).

In 1945 penicillin became accepted as the preferred form of treatment for syphilis. Unfortunately this treatment was withheld from the study participants. The study continued for an additional twenty seven years without these men ever being offered this effective treatment. In fact, efforts were even made to hinder the participants from receiving penicillin. In 1947 there were also “Rapid Treatment Centers” established by the United States Public Health Service (USPHS) designed to treat syphilis, but again the study participants were not treated (U.S. Public Health Service Syphilis Study at Tuskegee, 2013). Not only were the men repeatedly withheld treatment, but they were told they would receive treatment if it became available while the researchers blatantly lied to these men.

Eventually news broke of the way the study was being run in 1972 and there was an outcry from the public. This led to the development of an Ad Hoc Advisory Panel consisting of professionals from medicine, law, religion, labor, education, health administration, and public
affairs fields to review the study. After revision, the panel concluded that the study was ethically unjustified and suggested that the study be stopped immediately, at which point a month later the Assistant Secretary for Health and Scientifics affairs declared the end of the Tuskegee Study. The following summer, a $10 million lawsuit was filed on the behalf of the participants and their families. This lawsuit also led to the Tuskegee Health Benefit Program (THBP) development to provide lifetime medical benefits and burial services to still living participants and their families (About the USPHS Syphilis Study, 2014).

The government has since taken even more steps to try to provide consolation to the study participants and families. In 1995 the THBP expanded to not only include medical benefit coverage but also health benefits and in 1996 President Clinton gave a public apology on behalf of the country. Tuskegee University National Center for Bioethics in Research and Health Care also hosts annual commemorations of the presidential apology and opened a Bioethics Center. The Centers for Disease Control and Prevention (CDC) also hosted a commemoration at Tuskegee called Commemorating and Transforming the Legacy of the United States Public Health Service (USPHS) Syphilis Study (About the USPHS Syphilis Study, 2014).

While the government has taken several steps to improve the situation, all of these violations of public health ethics contributed to a completely unjustifiable and unfathomable amount of pain and suffering for those affected. Their suffering was morally inexcusable as the knowledge gained from the study was minimal compared with the risks and pain they were exposed to through the study. Following the public outcry surrounding the discovery of the way the study was run, the federal government was forced to take a closer look at ethical and moral protections regarding human research. This set into motion the development of new documents to protect human rights against moral breaches like in the Tuskegee study from happening again.
Chapter 2

Human Rights Protections Today

Thankfully today there are various documents and principles designed to protect human rights and individuals’ involvement in research studies. Some of these principles include respect for persons, beneficence and nonmaleficence, and informed consent. The Nuremberg Code also outlines boundaries between researchers and participants and Institutional Review Boards also help to ensure experiments are being run with respect to human rights.

Respect for Persons

The principle of respect for persons has four main components. The first is autonomy which means that individuals are allowed to be self-governing. This includes the right to refuse unwanted treatment and be left alone which is essentially a liberty right. If this idea had been applied to the Tuskegee Study individuals would have been able to opt out of the study at any time if they so wished. The second element is truth telling. This element implies that those in positions of authority are required to be honest in all they do. The element of truth telling falls under the premise that dishonesty is a form of disrespect to persons. If participants were told the truth about the Tuskegee study and its purpose they may not have chosen to continue their participation. The third component of respect for persons is confidentiality which requires those in authority (like researchers) to keep confidential what they learn about participants and only share information on a need to know basis. The final element of respect for persons is fidelity which binds researchers to keeping their word and acting as promised. One can see how if the researchers gave promised treatment to participants many of the moral breaches that occurred could have been avoided (Burke & Friedman, 2011).
Beneficence and Nonmaleficence

The term beneficence means to “act with charity and kindness (Burke & Friedman, 2011).” Nonmaleficence is defined as “refraining from actions that aggravate a problem or cause other negative results (Burke & Friedman, 2011).” These principles aim to weigh relative benefits to costs or potential harms with regard to a positive duty of providing as much benefit to a population as possible. These principles essentially hold public health officials accountable to acting in the best interest of populations and individuals involved. Both principles are at opposing ends of a continuum and hold public health officials and researchers accountable to both doing no harm while also providing as much benefit as possible (Burke & Friedman, 2011). One can clearly see how if the researchers in the Tuskegee Syphilis Study had applied these principles of beneficence and nonmaleficence then many ethical breaches could have been avoided and the study could have actually benefited the participants instead of causing undue harm.

Informed Consent

Perhaps one of the most important protections for individuals today is the construct of informed consent. The concept of informed consent draws from the principles of individual and patient autonomy and basic human rights (Rao, 2008). The idea behind informed consent is that a participant is able to make an informed decision pertaining to his or her health. There are several communications that need to occur between a researcher or health care provider and an individual for an informed consent to happen. There needs to be a discussion concerning the nature of the decision and/or procedure or study, reasonable alternatives presented, relevant risks, benefits and uncertainties to all options need to be presented and understood, and there needs to be an assessment of the patient’s understanding of these discussions. All health care
interventions, whether patient to provider or researcher to study participant are legally required to have informed consent (De Bord, 2014). A person may be subject to punishment for battery or physical assault if they so much as touch or treat another person without permission (Rao, 2008). The idea of informed consent assumes that an individual understands the implications of their involvement with a healthcare intervention and that they’ve received adequate information pertaining to the options available to make an informed decision for themselves free of coercion or outside influence.

There are a couple exceptions to obtaining full informed consent. One example includes instances where an individual does not have the decision making capacity and has a proxy or surrogate decision maker for them. Another example is if an individual lacks the time to make an informed decision or find a proxy and their treatment is potentially lifesaving but time sensitive. In other rare circumstances a patient may waive consent or designate a trusted love-one to make health decisions for him or her (De Bord, 2014). In the context of a research study, a participant may not know whether they are receiving a placebo or a treatment in order to accurately measure the effect of a treatment, but they should have informed consent that they may receive one or the other and that they will be unaware which option they get.

The Nuremberg Code

The Nuremberg Code was developed in response to the moral and ethical violations that occurred during the Tuskegee Syphilis Study to help prevent a similar situation from happening again and protect basic human rights. The code details a respect for voluntary participation in research, true informed consent, and the researcher’s ethical responsibilities to ensure the welfare of their participants. The Nuremberg Code warrants that “the voluntary consent of the human subject is absolutely essential (The Nuremberg Code, 2005)” The code elaborates on what
informed consent entails stating that the individual must not be influenced by any form of “force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion (The Nuremberg Code, 2005)”. This consent also must include the individual’s knowledge and understanding of “the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment (The Nuremberg Code, 2005).”

The Nuremberg Code also details that the experiment in consideration must have the potential to yield rewarding results to better society that cannot be acquired in other ways and that are not random and unnecessary in their nature. The Nuremberg Code also aligns with the principles of beneficence and nonmaleficence in that it mandates that all experiments should be conducted in a way that avoids as much as possible any unnecessary physical and mental suffering or distress, and also that “the degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment (The Nuremberg Code, 2005).” The code also details that participants should be able to end their participation in an experiment at any time if they wish to do so.

**Institutional Review Boards**

To help ensure that scientific experiments and studies are being conducted in an ethical manner, Institutional Review Board’s (IRB’s) must be established. These IRB’s help to ensure that human subjects and their rights are being protected and they are committees comprised of scientific and nonscientific members that are independent of the researchers. State laws require IRB’s to be established by the government for all research involving human subjects. Federal
regulations govern who can be a part of these committees to help prevent bias and conflicts of interest in their review (Burke & Friedman, 2011).
Chapter 3

Summary and Recommendations

Summary

The Tuskegee Syphilis Study is a prime example of moral and ethical breaches of human rights. Experiments like this emphasize the need for laws and regulations governing and protecting basic human rights to avoid future instances of such terrible disrespect of the human kind. While we cannot change the past, we can absolutely learn from it and apply these lessons learned to have a better future for all of us. Researchers and individuals must abide by principles like informed consent, the Nuremberg Code, beneficence, respect for persons and nonmaleficence. We must use our integrity, ethics, and morals as a guide to conduct respectable and beneficial research.

Discussion and Recommendations

If I were to have had any say in the study, I would have used my conscience as a guide. The old adage “treat others how you wish to be treated” is a good guide. I don’t believe that one can do bad and feel good about it; at least I cannot. I also don’t believe that any of these researchers would have liked to be treated the way they treated their participants. I would like to believe that at least the majority of people working in the public health field do so because they care about the greater good improving people’s health, not harming it.

I would have been upfront, open, and honest about the study and all procedures and information surrounding it. I would have conducted it abiding by the regulations that exist now in accordance with the Nuremberg Code and principles of informed consent, nonmaleficence and beneficence and respect for persons.
I don’t see the idea of waiving consent for some areas of clinical investigation to be a good thing. It’s hard to imagine that the benefit of doing so could outweigh the potential risks and cons. I also believe that we need to actually learn from our past mistakes to make better decisions in the future. If we were to waive consent I feel that it would open up the door again for some human rights to be potentially violated or compromised and I personally would rather not take that risk. I can’t imagine that the expense would be worth any potential gain from doing so. I also believe that it absolutely could open up the door to taking advantage of vulnerable populations again. In a society where there is already distrust of the government because of past mistakes, we cannot take the risk of reinforcing that distrust with making the same mistakes again. While I believe that most people are good in nature, unfortunately not everyone can be trusted to act ethically and morally which is why we need to have governmental regulation today and paternalism. I feel more comfortable with potentially over regulating this issue as opposed to under regulating it if it means that human rights are being protected. I don’t believe that there is any benefit that can justify violating a human being’s rights like they were in the Tuskegee Syphilis Study. I also don’t believe that waiving consent would be ethically acceptable with documents like the Nuremberg Code and Belmont Report in place. Why were they even developed if they were just going to be disregarded? They serve a purpose and that purpose needs to be trusted, respected, and adhered to.

Regarding public health ethics, I think it is imperative that a more consistent and overarching code of ethics be developed to help govern public health entities. It seems as though there are several recommendations and documents available pertaining to ethical principles and guidelines, but not necessarily a generally agreed upon document that all public health professionals must abide by. Unfortunately ethical and moral issues tend so have somewhat of a
gray area and can be somewhat subjective in certain instances, and I believe that the formation of a document to address and manage some of these more gray areas would be beneficial.
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