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Medical Ethics
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Human Research

Human research is the systematic, scientific investigation that can be either interventional or observational and involves human beings as research subjects. Interventional meaning that there is an actual clinical trial held, and observational meaning that researchers do not have actual human participants. Human research is an ongoing process and it has been around for many years, but it was not always classified is as "human research". In 500 BC there was the first experiment to resemble a clinical trial; in the 1800s there was the first appearance of a placebo; in 1964 there was the declaration of Helsinki and that brings us to now where patient centric clinical trials are held. The purpose of clinical trials is to understand the physiology of diseases and try to find potential treatments.

Even though human research has been going on since 500 BC, it took much longer to pass any laws to protect the participants. It was not until 1964, with the Declaration of Helsinki that participants had any laws protecting them from the researchers in clinical trials. Up until then researchers had the ability to perform almost any study on a participant of the clinical trial, and more often than not it did not matter if the researcher had the participants consent. The Declaration of Helsinki states, "The health of my patient will be my first consideration", and "A physician shall act in the patient's best interest when providing medical care." This made it so the participants of clinical trials could not be treated as a disposable object, and made the physicians accountable for how they were treating the people in their study. The rules and regulations put into place have made clinical trials exponentially safer for the people participating in them.

Since human research has been going on for such an extended period of time, there are two conflicting moral demands that have arisen from the use of clinical trials. First is rights

based moral theory, which states that humans should not be treated as ends within the means; they should be treated as ends within themselves. This means that you cannot do whatever you want to a patient to achieve results that will be beneficial in the log run. The second moral theory is utilitarianism, which states that what is right, is in the best interest for the greatest number of people. After looking the negative aspects of cases throughout history there are still many positive things that came from them, mainly the laws and regulations that are in place now to protect the participants of clinical trials. I agree with the utilitarianism view and I am going to argue in favor of human research, because despite all of the negative aspects; in the long run, human research will help more people than it will harm.

During the Nazi regime during World War II, the Germans horribly mistreated people in concentration camps. They conducted experiments to see the effect of head injuries, immunizations, sterilization and many other things. These experiments were strewn with ethical issues. People were not told what was going to happen to them, they were not able to drop out of the experiment if they no longer wanted to be in it, and the researchers did not care at all about the participants well being. Between 1945 and 1949, all of the people who participated in the unethical research, mainly Nazi officials, were put on trial. The set of 13 trials was called the Nuremberg Trials, the most well known trial is called the Trial of Major War Criminals, which was held from November 20th, 1945 to October 1st, 1946; during this trial 24 people were indicted. After the trials were over the Nuremberg Codes were written and established.

The U.S Public Health Service in conjunction with the Tuskegee Institute conducted the Tuskegee Syphilis study from 1932-1972. The study, that was supposed to take 6 months and lasted 40 years, was called the “Tuskegee Study of Untreated Syphilis in the Negro Male.” There were 399 men in the study who already had late syphilis, and another 201 men who did not have syphilis who were initially enrolled to participate in the study. All of the participants were black men from Macon County, Alabama. The purpose of the study was to record the natural history of syphilis, in order to create a treatment program for African American people. The people Macon county Alabama, specifically the physicians and nurses were aware of the study and were told not to treat the men. The staff and faculty at Tuskegee University were also

involved and made aware of all of the aspects of the study. The only people who were not fully aware of the study in its entirety were the participants. At the beginning of the study the participants were told they would be given free medical exams, free meals and burial insurance. For the inhabitants of Macon County, Alabama, who were not the most affluent people, the promise of free food and free medical examinations was extremely appealing to them.

There were 2 main ethical issues with this study. One, the participants of the study were not fully informed of all of the aspects of the trial. Researchers told the men they were being treated for "bad blood," which was a term researchers used to describe multiple ailments such as syphilis, anemia and fatigue. Two, in the 1940s penicillin became available to the public as a drug that could treat syphilis, but it was not offered to the participants of the study. This caused the men in the study who actually had syphilis unnecessary suffering because they never had the option to leave the study and be given treatment for their disease. The case was deemed to be ethically and morally wrong and was stopped in 1972. Congress held hearings, and a class-action lawsuit was filed on behalf of the study participants. Due to this clinical trial and the hearings after it, the Belmont Report was written and Institutional Review Board was put in place.

From 1963-1966 the Willowbrook Study involved a group of children diagnosed with mental retardation that were being treated at the Willowbrook State Hospital in Staten Island, New York. The children were deliberately infected with the hepatitis virus. Early subjects were fed extracts of stool from infected individuals and later subjects were given injections of more purified virus preparations. The study's purpose was to study the history of the disease when left untreated and to see assess the effects of gamma globulin as a therapeutic intervention. Gamma Globulins are proteins in human blood plasma, which include most antibodies. When the patients were injected, they would have an immediate immune response. Parents were coerced into allowing their children to participate in the study because they were promised to receive free medical care from Willowbrook hospital.

The human research trials listed above are extreme examples of the horrors of human research. The cases depict the results of lack of consent, lack of care for the patient and the use of coercion. In each case the patients were treated as if they were not human beings at all, but

rather a test subject that was disposable. Due to cases like the ones mentioned above, we now have laws and regulations put into place that prevent clinical trials being harmful to the participants. The Nuremberg Codes, the Declaration of Helsinki, the Belmont Report and the Institutional Review Board all came from these trials. The Nuremberg Codes, Declaration of Helsinki and the Belmont Report were all documents that stated how the doctors performing the research had to treat the participants. It made it so the participant had to have fully informed consent before the start of a clinical trial, the participant would be able to leave the trial at any time is they deemed it was no longer in their best interest to be there, and the doctor could only perform a trial if it was in the best interest of the participant. There were also many other implications the research party had to follow in order to have an ethical clinical trial. The Institutional Review Board is a committee that has been designed to approve, monitor and review research that deals with human subjects. Since there is an outside source approving and overseeing the clinical trial in its entirety, there is even less of a chance that the researchers or physicians leading the trial will mistreat the participants. The only reason why human research is regulated so strictly today is because of these cases that happened in the past. While it is horrible that people had to suffer back then, due to their suffering, people today are much safer. If it wasn't for those documented cases, who knows if we would be where we are today when it comes to human research. The only way to change is to make mistakes and learn from them. Since these regulations have been passed, there have been many clinical trials that have been beneficial and did not harm the participants in the process.

Many clinical trials are currently being held to try and find cures for deadly diseases. All of these clinical trials are being carried out according to the laws and regulations that protect the participants. Safe regulated trials have been going on since the laws were originally passed and we have learned copious amounts of information from them. For example, there are trials that are conducted to try and find a vaccination for malaria. Malaria is a difficult disease to find a vaccine for because there are many different strands of the disease. The process to conduct a clinical trial for malaria is very heavily regulated and may take up to 25 years. First the vaccination goes through a research and development phase, and then there is a period of testing on animals. Next there are human trials. The first human trial phase is only 50-100

participants, to observe the specific immune responses of a small group of people. Next there is phase 2 where the participant pool gets larger and finally phase 3 where the participant pool is large enough to be able to observe the effects of the vaccination on many people with diverse backgrounds and different environmental factors. While there is not a vaccination for malaria yet, clinical trials are ongoing and no one is being harmed in the process. The clinical trial process for the malaria vaccine is similar to that of HIV/ AIDS, Ebola and Hepatitis C. It would be impossible to do testing and try to find vaccinations for these diseases if we could not test and see their effects on humans.

We have vaccinations around today that we take for granted, such as those for measles, mumps and rubella. At one point they were viruses that would kill people and there was not anything doctors could do about it. In 1964 there was a clinical trial held in Great Britian for a vaccination to protect against the measles. There were about 50,000 children that participated in the study. The parents gave consent for their children and the study was a double blind study, meaning that both the participant and the doctor did not know who was being placed in the control group and who was not. There were three groups in this particular study one group received a killed and live vaccine, the second group to receive the live vaccine only and the third group to receive no vaccine at all. No matter which group the child was put in, it was clear due to the results of the study that the vaccination could produce a significant decrease in the number of measles cases in Great Britain. This case shows that it is possible to conduct a clinical trial and follow guidelines that ensure the safety of the participants while still achieving the desired result. We are still reaping the benefits from the findings of this trial today. All children are vaccinated against measles, mumps and rubella at a very young age, to try and prevent them from getting the diseases.

The cases mentioned above are important milestones in the history of medical ethics. While it may seem that the cases were all negative because of the mistreatment of humans, they eventually lead to very important laws and regulations that were passed. The laws were passed on the behalf of those who suffered during a clinical trial. If we wouldn't have had these cases, where people made mistakes and were more interested in their research than the well being of their research subjects, then we would not be where we are today in human research.

The laws that were passed, such as the Nuremberg Codes, Belmont Report and the Helsinki Declaration wouldn't have been a topic of conversation if it weren't for these monumental clinical trials. The few cases mentioned above are cases that are widely known and recognized as horrific for the people involved, so that being said, you cannot just glance over them when you are talking about human research. Trying to talk about human research as a topic that is wholly right or wholly wrong is almost impossible. There is a gray area where people can see both a good and bad side to each human research case and everyone needs to look at all of the aspects in order to make an informed decision. The unethicality of some cases is painfully obvious, but the laws that come from them help more people today than they hurt years ago. The safety of the people participating in clinical trials today outweighs the harm that was done. There are a countless number of clinical trials that are being held, all of which are following the guidelines put in place in order to ensure human safety. Therefore, in my opinion saving many lives, while harming significantly fewer makes human research trials ethically acceptable.

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