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Experiential Ethics

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From HeLa to Hip Replacements: Is American Patient Consent Ethical?

The system of healthcare in America has long been surrounded with ethical questions and criticisms. One area where this is especially prevalent is with regard to patient consent. Allowing individuals to make informed choices about their health and the care they receive is a crucial element of a good healthcare system and society. However, the American healthcare system has a long and complicated history surrounding patient consent, and ethical dilemmas in this area persist today. This paper aims to explore the ethicality of the current system of patient consent in America and what potential reforms would improve it. To do this, the issue will be examined through the ethical lenses of justice and autonomy, as well as considering historical events that have played important roles in determining the current rules and regulations that govern patient consent in American healthcare.

One of the first major examples of patient consent being violated in American healthcare is the story of Henrietta Lacks. Henrietta Lacks was a young African American woman who sought treatment for cervical cancer in the 1950s at the Johns Hopkins Hospital in Baltimore, Maryland. As part of her treatment, cancerous cells were taken from her cervix and, unbeknownst to her, given to a cancer researcher. This researcher soon noticed that her cells, named HeLa, had a remarkable ability to grow and reproduce, making them excellent for use in research (Nott). Henrietta died in October 1951, only ten months after she initially sought treatment, but her cells long outlived her, as many companies were founded that sold the HeLa cell line. These companies made large profits from the production and distribution of these cells,

but none of the profits were ever given to the Lacks family, and concerns from the family about the use and proliferation of Henrietta's cells were largely ignored (Nott). These concerns were largely ignored until the release of the book *The Immortal Life of Henrietta Lacks* in 2010, which brought a larger public awareness to the issue and started a debate about the ethics of the HeLa cell line and what compensation was owed to the Lacks family.

Looking at the HeLa cell story through the justice lens, there are a few clear points where Henrietta was denied fair and equal treatment by the American healthcare system. The first point where this occurred was in the racist societal structure of the 1950s, as Henrietta was African American which prohibited her from receiving care at many hospitals. The Johns Hopkins Hospital was one of the few that would treat her, and even then she was treated in a "colored ward" (Nott). Because of this, her options for care were already more limited than a white woman in her position would face, showing that she was at a disadvantage and more likely to have her right to informed consent violated simply because of her race.

Additionally the justice lens is useful to consider when looking at the response of society to the concerns from the Lacks family about the use of HeLa cells. The family was not even made aware of the existence and use of the HeLa cell line until 1975, and then their concerns were ignored. Furthermore, family medical records and genetic information were published in the 1980s, subjecting the family to a large invasion of their privacy and causing them additional undue stress (Skloot). From a justice perspective, this treatment is not fair and compounds the problems that were already caused from the taking of the HeLa cells without consent. Race is also an important factor, as it is difficult to imagine that a white family would have faced this same level of complete disregard for their complaints and such large intrusions into their privacy.

Another ethical perspective on the HeLa story is to look at it through the lens of autonomy. When patients are denied the right to choose what happens with their genetic and biological material, they lose part of their autonomy, as they are losing the right to decide what happens to their body. Even though Henrietta lived in a time when it was not customary or required to ask for consent to take biological material from patients, it doesn't mean that her autonomy wasn't violated. This violation only continued and extended to her family, as they were subjected to the publishing of their health and genetic information without their consent more than thirty years after Henrietta's death. Clearly, autonomy is an important consideration in patient consent and is necessary in order to ensure an ethical system where the decisions of individual patients are respected.

In the years following the harvesting of the HeLa cells, major improvements in patient consent were made and codified. One of the most significant laws that addressed these concerns is the Common Rule, which governs all human subjects research. This law, originally passed in 1991 and updated in 2018, created a framework for institutions to monitor research that involves human subjects, and also mandated compliance with these regulations in order for institutions to receive federal funding (Bazzano et al). As part of this law, it is also mandatory for institutions to obtain and document informed consent from all participants in their research (HHS.gov). This is a major improvement that would have altered the outcome of Henrietta's story, as she would have been aware of the harvesting of her cells and would have had to give her express written consent in order for them to be kept and used in research.

While HeLa cells may have been one of the first well-known examples of the American healthcare system violating patient consent, it is far from the only one. This violation of consent continues even today, as patients often consent to medical procedures with new technology that

they do not fully understand the risks of. Furthermore, these risks are often downplayed by doctors who can receive significant financial compensation from the companies that sell this new technology. One example of this is presented in the documentary *The Bleeding Edge*, which tells the stories of patients harmed by medical devices. In the documentary, an orthopedic surgeon named Steven Tower decides to receive a cobalt hip replacement because of their supposed benefits for people with an active lifestyle. However, soon after undergoing the surgery, he begins to suffer a host of negative health effects that he eventually determines to be caused by cobalt poisoning from the hip implant. After doing further research, he determines that many of his own patients are being harmed by this type of hip replacement, and brings his concerns to the FDA. One of his major complaints is that he wasn't informed of all of the potential risks of the implant, and he is a surgeon himself so if he didn't understand the risks it is highly unlikely that average patients are able to give their informed consent for the procedure.

Looking at this case through the lens of justice, it is easy to see that the system of patient consent is not fair in regards to background knowledge. If an orthopedic surgeon can be misinformed about the risks of a procedure he does himself, it is evident that just about anyone would lack the necessary information to make an informed decision about whether or not the benefits outweigh the risks of this surgery, especially when there are other, safer options available, such as traditional hip replacement surgeries. When considering the autonomy lens, this situation shows how important informed consent is to maintain individual rights. This is because severe negative health effects caused by something that a person didn't give full informed consent to isn't fully the responsibility of the person, so it violates their autonomy because they are being subjected to negative health effects from something not entirely in their control.

From these examples, it is evident that the American system of patient consent needs improvement. While many improvements have been made since the days of Henrietta Lacks, there are still major areas that need to be addressed. Even though the current system of informed consent in medicine would require Henrietta to give consent for her cells to be harvested, she still would not be able to profit from her cells. This is due to the legal ruling in *Moore vs. Regents of the University of California*, which held that discarded biological material from patients is not their personal property and that they have no rights to any share of the profits from the sale of commercial products or research derived from their cells (Nott). This is one potential area for improvement in the American healthcare system, as it seems unjust that patients have no right to their own genetic material, especially when it can be so profitable. Additionally, this seems to violate the autonomy of patients, because biological material is unique to each individual, and losing control over that is losing control over a person's body and identity.

Another area where patient consent could be improved is in the marketing of new medical devices to patients. From the hip replacement example, it is clear that patients are not always informed of all the risks of a procedure before they undergo it. Additionally, as evidenced by this example, FDA approval of a medical device does not always mean it is safe or free from side effects. One potential improvement would be to lengthen the FDA approval process for new devices, as well as work to reduce corporate influence on the process, as companies have a large financial interest in getting their products approved as soon as possible, even at the expense of safety. Finally, working to make doctors less susceptible to pressure from companies to recommend their devices over other existing options would help ensure that patients are presented with all of the information so that they are able to make the most informed decision that is best for their health.

In conclusion, the American system of patient consent has improved since the days of Henrietta Lacks, but there are still lots of reforms that could be made in order to ensure that patients have the most possible control over their health. The recent dialogue about Henrietta Lacks shows progress in that America is finally discussing these issues, and hopefully solutions will be found to right the historical injustices faced by the Lacks family and others. Additionally there are still major problems in patient consent, especially in regards to medical devices that are potentially unsafe. There are a few potential solutions to these problems, such as working to reduce corporate influence over FDA regulators and doctors, as well as ensuring doctors present unbiased information to their patients about all available treatment options. The current system of patient consent in America is much more ethical than it was in the 1950s, but there is still much more improvement that needs to be made in order to ensure that the system is fair to all patients and that patient autonomy is protected.

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