Redesigning Documentation for Informed Consent in Medical Experimentation
(Technical Project)

Adequacy of the Informed Consent Process in Properly Serving the Black Community
(STS Project)

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction

Informed consent is a necessary ethical and legal requirement vital to healthcare and the field of medicine. However, the process of informed consent in medical research and procedures has been a point of contention both throughout history and now for many reasons, one being its unethical reputation with minority communities. My research projects will address the disconnect between the informed consent process and minority communities, particularly Black and Hispanic communities. While informed consent in theory has positive intentions, its execution has failed to consistently and properly serve the people it intends to help.

Informed consent is a process that takes place before a patient undergoes a medical procedure or research study. Its purpose is to inform the patient of all aspects of a potential study or procedure they may engage in, so they are able to make an educated, voluntary decision to participate or not (Nijhawan et al., 2013). The two primary actors in informed consent are the patient and the healthcare practitioner, who plays the role of the educator. The Joint Commission, a national healthcare-organization accreditation organization, requires documentation of every step of the informed consent process, with five essential elements: "(1) the nature of the procedure, (2) the risks and benefits and the procedure, (3) reasonable alternatives, (4) risks and benefits of alternatives, (5) and assessment of the patient's understanding of elements 1 through 4" (Shah et al., 2023, p.1).

While the process is meant to maintain a patient's autonomy and make an educated, informed decision, it often fails to meet this obligation. Physicians overall receive limited training on how to conduct the informed consent process, they may be operating on a condensed time window, or have external demands preventing thorough conduction. A research study found that the first four elements required in documentation only appeared in consent forms 26.4% of

the time ("Quick Safety 21", 2022). One study conducted by the *American Journal of Surgery* investigated the degree of understanding of different aspects of the informed consent process by potential patients. The results of the experiment provided sufficient evidence that more attention needs to be placed on patients' understanding of information presented to them, the amount of information presented, and the understanding of benefits and risks of the surgery (Falagas et al., 2009). If patients are not adequately informed about a possible medical procedure they may take part in, it can lead to a host of serious consequences. These consequences range "from low patient satisfaction with care, increased patient regret, poor adherence to treatment plans, both underuse and overuse of the health system, and patient litigation against medical practitioners" (Sherman et al., 2021, p.2).

While these are general shortcomings of the informed consent process, even more arise when it comes to minority communities. Unique culture-specific values and beliefs may influence the decisions made by members of these communities during the process. These differences manifest in language barriers, role of gender and family in decision-making, socioeconomic status, and historical distrust of medical researchers (Halkoaho et al., 2016).

In order to address these issues, my technical project will be the formation of an app that improves upon the current informed consent documentation, while embedding key cultural factors that have stood as barriers to certain groups. My STS topic will address the relationship between informed consent and the Black community in Charlottesville. It will explore the history of informed consent in connection with the Black community, and how it has impacted the modern medical field. I will then explore the ways in which this history, in combination with the history of racial tension in Charlottesville, has contributed to the treatment of the Black community when it comes to medical procedures.

Technical Topic

As it currently stands, the process of informed consent fails to meet the required standards laid out by the Joint Commission. It is quite simple for healthcare providers to cut corners or leave crucial aspects off of documentation either intentionally or unintentionally. Many participants sign informed consent documentation without a full understanding of risks, benefits, or process of the procedure. The other serious issue with current informed consent documentation is that it is not accessible to all people. As discussed in the introduction, cultural differences among ethnic groups impact their perspective, comprehension, and attitude toward informed consent.

In the last decade, awareness of shortcomings of the consent process has increased, leading to new technologies to remediate some of these issues. One technology to combat this issue is an interactive platform that allows patients to hear, read, and view the study and consent documentation at their own pace. This system was facilitated on an iPad which researchers found to improve overall satisfaction and comprehension compared to the standard paper consent form (Rowbotham et al., 2013). Rather than a long document filled with technical jargon, this technology opts for a more simple, direct presentation of information. This includes an introduction video, the consent form, and then a quiz to assess comprehension with immediate feedback. While this technology is a step in the right direction, it is limited in its ability to serve those from cultural backgrounds that are more often overlooked.

My technical project is the creation of an application that not only homogenizes the informed consent process but is also embedded with unique cultural aspects. Since a key issue with current informed consent documentation is that it differs greatly from physician-to-physician and is often missing crucial information, creating an app that contains all required

information will alleviate this. Furthermore, this technology takes the burden off of the healthcare practitioner and relies less on their competency of informed consent in guiding the patient to make an educated decision. The question I seek to answer is: How can the informed consent process be remodeled to properly serve people of all cultural backgrounds?

This app would build off of the technology listed above as it will be administered via iPad and follow a similar structure of an introductory video to the research study or medical procedure, then the consent form. However, I would like to incorporate several quizzes throughout, instead of just one at the end. The introductory video will include the title of the study, the name(s) and affiliations and of the primary investigator(s), background on the procedure or research, and selection criteria. The informed consent portion will include the purpose of the study, subject selection criteria, study procedures, potential risks, discomforts, and benefits, cost (and compensation for study), timeframe, future use of data (when applicable), and confidentiality ("Elements of Informed Consent", n.d.). Actors used in the introductory video will feature people of all different ethnicities, as one barrier that has discouraged racial minority groups from participating in research studies and medical procedures is a lack of representation (Halkoaho et al., 2016). Seeing people on screen who look like them may ease any anxiety they have surrounding the procedure or study.

The data for this application will be supplied by the Joint Commission, and ethics research codes such as Nuremberg Code, The Declaration of Helsinki, and The Belmont Report, on which the principles of informed consent were established (Nijhawan et al., 2013). It will also utilize research on Black and Latino communities' experiences with the informed consent process to eliminate any cultural biases or concerns these communities have voiced over the years that have been ignored. Additionally, research studies on the intersection between culture

and informed consent will be an extremely helpful resource to ensure the application fully and accurately captures cultural aspects. Some of these aspects include cultural knowledge and perspectives of mental health, rural vs urban upbringing, apprehension and mistrust of researchers, strangers, and/or white people, and low proficiency in English or English as a second language (Halkoaho et al., 2016).

To test the app, my sample will include members of the Charlottesville community from all ages and cultural backgrounds. If the app is successful, I would expect to see similar quiz scores across the board, and roughly even numbers of people from racial minority groups agreeing to participate in the sample procedure or research study as those in the majority after using the app.

STS Topic

The ethical and legal obligation of informed consent was born from several instances of medical patients' autonomy being disregarded and disrespected during the 20th century (Bazzano et al., 2021). The principles of autonomy and right to bodily integrity are the heart of informed consent, however they have not been experienced by all people. The issue of nonconsensual medical procedures and overall mistreatment from the healthcare system is particularly prominent in the Black community (Baptiste, et al., 2022). Historically, Black people have not found the same positive treatment regarding informed consent as other racial groups. These unethical research practices are the foundation on which some of the most important medical advances were established.

The first documentation dates back to the 1840's where three teenage African American girls, Anarcha, Betsy, and Lucy, non-consensually received multiple (some more than 30) gynecological procedures without anesthesia under the hand of surgeon Dr. James Marion Sims.

Dr. Sims invented the vaginal speculum from these experiments with little critique or backlash for his methods. Other more well-known examples include the story of Henrietta Lacks, an African American woman who visited John Hopkins Hospital for treatment for vaginal bleeding as a result of cervical cancer. As she lay dying, her cells were removed from her body without her permission, creating the first cell line to survive outside of the body. Her cells, known as HeLa cells, have provided treatment for a host of diseases such as polio, HIV, and several types of cancer (Nisbet et al., 2013).

Due to this history, as a collective, Black people are more apprehensive toward experimental medical procedures, and there are still instances of their rights being disregarded to this day. Since Black people are overall less likely to participate in research studies, there is less data to work with and it is therefore harder to make population-specific conclusions from clinical trials (Campell, 2021). Years of this mistreatment has become systemically engrained into the healthcare system and has led to a strained relationship between the field of medical research/experimentation and the Black community.

During slavery, Black women were perceived as more masculine, pain resistant, and stronger than white women. At the same time, they were also seen as weaker, less capable, and less competent (Campbell, 2021). While not as overt, these ideals are still embedded in the governing systems of society. Particularly in the healthcare sphere, these views of Black women often cause doctors to either prescribe more or less medication than necessary or perform procedures with an irregular amount of anesthesia. One modern example of the way informed consent fails to serve Black people is the paradox of overmedicalization and medical neglect when it comes to cesarean section operations for Black women. Viewing Black women through this distorted lens has led physicians to present informed consent in such a way that the women

are not aware of every possible risk (Campbell, 2021). This is fueled by the underlying racist assumption that Black women can handle whatever is thrown at them.

To support my investigation of the failure of informed consent to serve the Black community, I will evaluate informed consent as an infrastructure, as done by Susan Leigh Star (1999) in *The Ethnography of Infrastructure*. Her core argument is that infrastructure is interwoven into political, social, and cultural contexts, and is directly tied to ethnographic studies (Star, 1999). Approaching informed consent as an infrastructure will help me to understand every aspect of society that it influences. The influence of informed consent is not constrained to the field of medicine as demonstrated by the ways it has harmed the Black community. I will be able to gain a more holistic perspective of its shortcomings by understanding the intersection between informed consent and the political, social, and cultural contexts it has altered. I will also use a book by Star and Geoffrey C. Booker titled *Sorting Things Out* to support my research. The authors define classifications, "the scaffolding of information infrastructures" (Bowker & Star, 2000, p.1). They argue that the modern world is shaped by categories or classifications, and these classification systems shape worldviews and social interactions. I would apply this work to understand medical experimentation as a classification system. This will help me understand both the advantages and suffering it has produced in the modern world. Lastly, I will use Ruha Benjamin's *Race After Technology: Abolitionist Tools for the New Jim Code* to understand how emerging technologies related to informed consent may consequently "reinforce racism and other forms of inequity" (Benjamin, 2019, p. 4). This will help me understand the inequities at play and how to navigate tech development in such a way that they are abolished from the system.

Research Question and Methods

This area of research has garnered growing attention over the years. I would like to build off of it by investigating racial tension in relation to informed consent, specifically in the city of Charlottesville. The question I will ask is: How has informed consent for medical procedures failed to properly serve the Black community in Charlottesville? The relationship between Charlottesville and the Black community is rather muddy and complicated. Events such as Black enslaved laborers building the University of Virginia and the alt-right rally in 2017 exemplify a long-standing, continuous culture of mistreatment and disrespect. For this reason, I would like to research the ways in which this history may have manifested in medical practices.

To develop an answer to this question, I will conduct a literature review. This will encompass both the history and current state of the relationship between the informed consent process and the Black community. I will also conduct a literature review of the racial history of Charlottesville. In relation to the literature review, I will also utilize professional interviews or scientific studies specifically detailing Black people's knowledge, perception, and personal experience with informed consent in medical experimentation. I will also conduct interviews with physicians at the University of Virginia Hospital to understand their knowledge of and experience with the informed consent process. I would like to know if they receive education about informed consent and any guidance regarding conducting informed consent. I would also like to gauge a sense of their knowledge of the socioeconomic rifts and racial issues in the Charlottesville community. Specifically, I would like to know if they have received any guidance in carrying out medical procedures given the racial history in Charlottesville. Both Black and non-Black physicians will be interviewed to evaluate the way racial differences may influence knowledge, approach, and compassion regarding these topics.

Conclusion

For my technical topic I will create an app that not only standardizes the informed consent process, but also incorporates key cultural differences that once stood as barriers. This app will ensure that necessary requirements are not left off of documentation, it takes the burden off of the healthcare provider, increases patient comprehension, and is easy to understand for all users. For my STS topic, I will investigate the ways in which informed consent in medical procedures has failed to properly serve the Black community in Charlottesville. The hope is that this research will be utilized by people working in the University of Virginia hospital, and other hospitals in Charlottesville to improve the informed consent process for the Black community.

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