Design of a Pulse Oximeter for Neonates

Analysis of Technological Failure of Ventricular Assist Devices for Women in Healthcare

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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

Education, gender, employment, income, and other factors heavily influence the physical health of an individual. These factors also affect how individuals interact within the healthcare system from their initial diagnosis, nutritional planning, and other preventive care methods to treatments that they could pursue and medicines they have access to. Another significant part of healthcare most often forgotten is the technologies that are present which influence what treatment options and medicines are available. Yet, most of these technologies only create better health outcomes for certain populations while leaving others with neutral or worse health outcomes.

Within the technical project, I will improve upon the currently existing design of pulse oximeters for neonates in lower to middle-income countries to address existing issues that prevent adequate diagnosis and treatment. Because both technological and social factors have contributed to the inadequacies within current pulse oximeters for various populations, it is necessary to understand how technical and social factors influence technology that is created to serve certain populations adequately. I will draw on the Science Technology and Society (STS) framework of User Configuration (UC) to investigate how the process of technology design has created a discrepancy for women in healthcare where they are harmed or have worse healthcare treatment outcomes in comparison to men and will focus specifically on the medical design of Ventricular Assist Devices (VAD).

Failing to attend to both technological and social challenges will leave the issue unresolved because the existing social dynamics within healthcare influence the tools that are developed, and these tools dictate the treatment outcomes within healthcare. Because creating new healthcare tools is socio-technical in nature, both technical and social aspects must be considered. Thus, I will elaborate on a technical project that describes a pulse oximeter that is

more suitable for neonates and an STS project that examines the greater propensity for women to be left out of the design process due to implicit biases in end-user assumptions within the case of VADs. By learning about the way technology is shaped by the configured user in mind during the design processes, I can then understand how to ensure the device addresses every user of the device once it is deployed instead of the user that was in mind during the design process.

Technical Project Proposal

Currently, the leading contributor towards infant mortality rate is pneumonia, which accounts for 28-34% of deaths globally (Wardlaw et al., 2006). Normal treatment for pneumonia consists of measuring oxygen saturation levels within the blood through the use of a pulse oximeter, and giving supplementary oxygen to the patient if oxygen saturation levels are low (Cutuli et al., 2021). However, the device does not have consistent accurate measurements of oxygen saturation for infants due to the influence of motion artifacts in the data that are created by the erratic movements of infants (Dormishian et al., 2023). This aspect, in addition to others, makes the industry standard for a pulse oximeter inadequate for diagnosing infants in lower-income countries, which inhibits the correct treatment with oxygen saturation in resource-constrained settings.

Some pulse oximeters have been developed to address the unique challenges neonates, newborn children to five years old, pose and the market found within lower-income countries. The first modification in design is changing the clip design of a pulse oximeter to a bracelet to address the smaller fingers that neonates have which would result in a reduction in motion artifacts. However, most bracelet designs are single-use and have a higher cost in comparison to a standard pulse oximeter (*6000CN Neonatal Cloth Disposable Oximeter Sensor - Medical Mega*, n.d.). The LifeBox Foundation attempted to address the motion artifacts by developing a

smaller clip that would fit snug on a neonate's finger, calibrated the design to ensure accurate measurements are taken even with the presence of motion artifacts, and made the pulse oximeter reusable (*Pulse Oximetry Use and Pneumonia*, n.d.). Still, there are negatives present with the design, with the cost being 10 times higher than a standard pulse oximeter and the measurements taking a longer time to give an accurate reading, which would be detrimental within emergency situations.

These devices address parts of the problem, but don't address the multitude of various design needs created by the patient population and the market that the design can exist within. These two constraints create a wide variety of design specifications that sometimes work in tandem and at other times work contrary to each other. A new device must be created which can encapsulate the various design requirements to ensure that the device can be used adequately in the setting that it should operate within.

The aim of the project is to build a pulse oximeter that reduces the influence of motion artifacts, reduces the time necessary for measurements, is low cost, and is specifically designed for the unique physical design specifications neonates pose. By addressing these variety of factors, we ensure that nurses can use the device appropriately in low-resource settings, which would help improve healthcare outcomes for neonates in lower-income countries.

This project will be executed by creating various designs to understand how the device could attach to the specifications of a neonate, add a calibration feature for motion artifacts, and include other potential modifications such as a warming feature that would make neonates more receptive to the device. Through iterations within testing, the device will hopefully be calibrated towards the skin colors of interest for lower-income populations. Then, with a durability and cost savings analysis we'd aim to reduce the cost.

The efficacy and efficiency of the design will be evaluated on three fronts. Primarily, it has to still be accurate to the degree of current FDA requirements, which is +/- 2% of oxygen saturation values in comparison to arterial blood saturation gas values (Health, 2022). Secondly, nurses and doctors should find that it moves the needle for the treatment of neonates and that they would recommend this device over other devices. Lastly, the cost should be affordable, which will be defined as $11.5, which was calculated through a cost analysis of pulse oximeters in the U.S. and salaries within the U.S. (*Usual Weekly Earnings of Wage and Salary Workers Third Quarter 2023*, n.d.) compared to lower-income countries (Hub, n.d.).

STS Project Proposal

A ventricular assist device (VAD) helps pump blood from the lower chambers of the heart to the rest of the body (Atti et al., 2022). It provides mechanical respiratory for patients with heart failure while they're waiting for other treatment options such as a heart transplant (*Do Medical Devices Negatively Affect More Women Than Man?*, n.d.). Both women and men have similar lifetime risks for Heart Failure, which would suggest both sexes have the same demand for a VAD (*Sex Differences in Heart Failure*, n.d.). There is also evidence that even though women and men have different pathophysiology regarding heart failure, women might benefit as much or more with mechanical circulatory support devices (Dayanand et al., 2021). Thus, it could be assumed that VADs address the needs of both sexes and ensures that women's heart failures issues could be adequately treated by a VAD.

However, in a study done on next-generation VADs, the health treatment outcomes were different between men and women. Specifically, there were higher rates of stroke within women compared to men, respectively 18% vs 6%, and in addition there were increased rates of bleeding

and infection among women compared to men (*Do Medical Devices Negatively Affect More Women Than Man?*, n.d.). Also, in most medical images illustrating how VADs operate within the human body, all images are of men without any images of how the device operates within women are shown (*Ventricular Assist Devices (VAD)*, n.d.). Examining the health outcomes of medical devices can illuminate the implicit biases engineers and the medical field have as their normal end user. VAD is not the only medical device that has this implicit bias within the design. The International Consortium of Investigative Journalists conducted a report on how out of 340,000 people injured by medical devices, 67% were women (*Report: More Women Harmed by Medical Devices than Men - MassDevice*, n.d.). By looking at how VADs are created in the early stages of product creation and how women are underrepresented in clinical trials, the device could be suited for male bodies leading to the discrepancies in treatment outcomes.

Drawing on the Science Technology Framework of User Configuration, I argue that the designers of healthcare technology, specifically VADs, have embedded the idea that men exist as the normal end user for their design without consideration for other users. The theory of User Configuration has been developed by Steve Woolgar, a British sociologist, and has been expanded upon by Linday Christina, Nelly Oudshourn, and Trevor Pinch. User Configuration states that technology is a script that engineers create, and users are constrained by the original engineer's design since they can only act with the technology within the confines of the script created by the engineer (Woolgar, 1990). The key concept I will be using within the idea of User Configuration is the concept of configured user. A configured user is the user that a designer takes into consideration when building the design. The idea of who the configured user is might be driven by implicit or explicit biases (Woolgar, 1990). As a result, a design that is not "user friendly" indicates a mismatch between the intended user and the configured user. And for

women, most medical devices, and specifically the VAM, haven't taken into consideration women as the end user. This leads to negative treatment outcomes due to the mismatch of intended design. To support my argument, I will be analyzing evidence from articles on National Women's Health Network that illuminate how women are hurt by medical devices, research papers that illuminate how women are left out of data collection, and comparisons of men and women's physiology and seeing if patents of VADs take into consideration the physiological differences.

Conclusion

The deliverable for the technical problem discussed in the paper will be a pulse oximeter that can be used for neonates in low resource settings adhering to a variety of design requirements posed by neonates and the market found within lower-income countries. The STS paper will strive to address how current healthcare practices do not take into consideration the variety of users who use medical devices, in this case, specifically women for VADs. This will be addressed by using User Configuration to illuminate how the intended user informs the technical design process and what we should do to ensure that we can create medical devices to treat every patient that device is intended to be used for. The STS project informs the technical project on what considerations should be taken within the design process to ensure the pulse oximeter truly addresses the vulnerable population of neonates in lower-income countries instead of being unable to treat a subset of neonates based on gender, disability, or skin color. There is a need to look at social dynamics, since social dynamics influence implicit biases about the intended user, and this influences how the technology is created for an end user influencing what type of health outcomes are present for society. By identifying how technology is shaped to treat

different populations by keeping the end user in mind, we can create a more just and equitable society regarding health outcomes.

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