IMPROVING THE DOPPLER ULTRASOUND FETAL HEART RATE MONITOR FOR MULTIPLE GESTATION PREGNANCIES

AN ANALYSIS OF THE TYLENOL MURDERS OF 1982 THROUGH THE ACTOR-NETWORK THEORY FRAMEWORK

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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

As medical advancements continue to influence healthcare outcomes worldwide, the gap between technological promise and actual performance has direct societal repercussions. A particularly poignant example lies in devices designed to monitor the heart rates of fetuses. Twin and triplet pregnancies present unique challenges, including increased risk of fetal distress and premature deliveries. These issues are further exacerbated when Doppler ultrasound (US) fetal heart rate (fHR) monitoring devices fail to successfully track multiple heartbeats simultaneously (Hamelmann et al., 2018). This shortcoming hinders prenatal care, as accurate heart rate data helps to inform the decisions that healthcare providers make to ensure healthy fetal development (Van Mieghem et al., 2022). Consequently, mothers of twins or higher order pregnancies are left with inferior prenatal care compared to those with singletons, posing risks to the health trajectories of their babies.

Additionally, existing heart rate monitors can interfere with medical procedures such as the administration of epidurals due to their positioning, since they wrap around the mother's lower back (Sanchez & Riveros Perez, 2023). During a University of Virginia Labor and Delivery unit shadowing, a patient also stated that the heart monitor was "very uncomfortable." This discomfort was due to the need for nurses to "press down hard" on her abdomen to obtain a proper reading.

An efficient monitoring system could make a tremendous difference in the medical care that a mother and her babies receive even before birth, as well as decrease the adverse postnatal outcome gaps between singletons and higher order pregnancies. I will build upon the current fHR design to create a novel monitor that addresses the aforementioned concerns by being compatible with epidurals and by being able to accurately monitor more than one fetal heartbeat.

To comprehensively address this issue, it is necessary to build an approach that both advances the technical design of fHR monitors and helps us to better understand the socio-technical influence that shapes their usage and trustworthiness.

Because both technical and social factors contribute to the effectiveness of fHR monitors, it is necessary to understand how technical and social factors work together to affect the success or failure of healthcare products. To provide context and deeper insights, I'll also examine the 1982 Tylenol murders using the actor-network theory (ANT), a tragic consequence that also resulted from a medical design flaw. This comparison of two oversights in the biomedical realm will highlight the importance of anticipating design vulnerabilities, the necessity of trust in medical products, and the effects that technological failures have across society.

In what follows, I elaborate two related research proposals: first, a technical project that describes this improved fHR design, followed by a Science, Technology, and Society (STS) project that examines this network, using the Tylenol murders as a case study. The insights derived from the STS portion will inform the design and implementation of the technical proposal. By understanding societal concerns and historical pitfalls, I will build a new monitor that ensures maximum trust and adoption among patients.

Technical Project Proposal

Fetal heart rate monitoring is a crucial aspect of prenatal care; it enables healthcare professionals to diagnose abnormal heart rate patterns in the fetuses and intervene promptly if need be. Doppler ultrasounds are the current *de facto* standard device for fetal heart monitoring in mothers because they are less invasive than internal fetal scalp electrodes (Hamelmann et al., 2018). These devices consist of external transducers that are held in place on patients by belts

that wrap around the abdomen (Umana & Siccardi, 2023). They leverage the Doppler effect, which describes how reflected ultrasonic sound waves change in frequency when they encounter moving artifacts, such as red blood cells. This phenomenon provides a noninvasive way to detect movement of blood within the baby (Magee, 2020).

Improved fetal surveillance through methods such as heart rate monitoring are associated with better outcomes for infants (Alfirevic et al., 2015). Although constituting only a small percentage of all births, twins and higher order pregnancies account for 13% of preterm deliveries and 14% of neonatal deaths (Alexander et al., 1998). Signal loss with fHR monitors is particularly prevalent in cases involving twins, largely due to the high rate of preterm birth among multiples (Ayres-de-Campos et al., 2015). These statistics emphasize the growing need for appropriate fetal monitoring of multiples in order to bridge the mortality disparity. The established benefits of monitoring, coupled with the need for improved surveillance, drive the motivation to improve the current design.

Additionally, the current fHR system struggles with instances of maternal-fHR overlap. Misinterpretations of these readings by clinical staff, especially in instances where the mother has an elevated heart rate, can have potentially fatal consequences (Maude et al., 2014). In the context of twin or higher-order pregnancies, accurate heart rate monitoring is even more complicated. The device must differentiate not just between the maternal heartbeat and that of a fetus, but also among multiple fetal heartbeats (Neilson et al., 2008). If the monitor can't locate both fetal signals, a scalp electrode is typically placed on the foremost baby for discrimination. However, these internal monitors, which involve rupturing membranes, increase the mother's risk of infection. Therefore, no solution ensures precise monitoring for multiple gestation pregnancies (Ayres-de-Campos et al., 2015).

Inaccurate fHR interpretation and misidentified fetal distress can result in unnecessary obstetric interventions, increasing risks for the mother and fetuses (Ayres-de-Campos et al., 2015). Such disruptions may elevate the mother's anxiety, affecting her overall experience. Additionally, they have the potential to diminish her trust in the medical team's expertise (Maude et al., 2014).

Given these shortcomings, it's imperative to develop a more effective Doppler ultrasound device. The current design obstructs epidural administration and even more notably, struggles to accurately distinguish between multiple fetal heartbeats. With this in mind, the primary objective of our technical project is to improve the accuracy of a fHR monitor for multiple gestation pregnancies, ensuring optimal functionality while also maximizing the comfort and safety of the pregnant individual.

A central aspect of our project is the phantom gel, which is designed to simulate the varying acoustical impedances of human tissue, offering a controlled medium to observe how sound waves from ultrasounds travel through the body. Specifically, our phantom gel model mimics the layers of human tissue surrounding a typical uterus; it will allow us to test and evaluate our device in a representative environment. One of our primary aims is to develop a non-invasive method to seamlessly generate phantom heartbeats through the integration of microphones into a phantom gel, while avoiding the creation of unintended artifacts.

Then, we will redesign the device for minimal interference with epidural administration, while maintaining its ability to receive data from multiple sources using ultrasound transducers. After creating a prototype, we will assess its comfort and functionality. This evaluation will occur under simulated conditions through a self-testing phase.

We also aim to develop an algorithm that filters and analyzes ultrasound data to identify multiple fetal heart rates. Our approach will begin by using Fourier transforms and filters on open-source data to generate the heart rate measurements. Fourier transforms will allow us to analyze the frequency components of the sound waves, helping us distinguish genuine signals from unwanted artifacts in the ultrasound images. Then, we will develop a signal processing component to separate the maternal from fetal heartbeats. We will improve the existing MATLAB software dedicated to filtering and analyzing the ultrasound data, with a focus on refining the algorithm to more accurately account for varying acoustical impedances of tissues surrounding the uterus. Finally, we will explore different microphone placements within the phantom gel to account for varying fetal positions. By addressing the aforementioned challenges associated with multiple gestation pregnancies through our device, we can ease the concerns of expectant parents, foster their trust in medical professionals, and ensure the best possible care for all.

STS Project Proposal

In medicine, it's essential to understand the relationships between products, the public, and their trust in healthcare institutions. The Actor-Network Theory (ANT) provides a perspective for analyzing these connections, making it particularly valuable when examining incidents such as the 1982 Tylenol murders in Chicago and the factors that lead to Johnson & Johnson's failure (Tauke et al., 2015). ANT studies the activity of network builders, such as Johnson & Johnson, who construct heterogeneous networks of human and non-human actors to solve a problem or accomplish a goal. Initially, the cause of the seemingly random deaths was unknown, but investigators soon found a common thread among the victims: Tylenol ingestion

shortly prior to their passing. These homicides resulted from drug tampering; the suspect allegedly laced Tylenol capsules with cyanide and returned the bottles to pharmacies. This caused nationwide terror and eroded the public's trust in what had previously been a reputable healthcare product (Tauke et al., 2015; Haberman, 2018).

While many attribute the Tylenol murders solely to the actions of a malicious individual, this viewpoint overlooks other factors contributing to Johnson & Johnson's failure. Using this framework, I will argue that Johnson & Johnson's failure was not just due to one person, but a combination of various actors. By limiting the narrative to the actions of just one central actor, we miss a more nuanced understanding of the causes of this tragedy and neglect lessons that could inform future preventative measures. In this case, Johnson & Johnson, a leading pharmaceutical company, acted as a central node in the network that connected various actors, such as consumers, regulatory agencies, the media, and the healthcare community. This network was built on the foundational premise of trust in Tylenol as a safe, effective, over-the-counter (OTC) pain reliever. When the safety of Tylenol was compromised due to criminal tampering, Johnson & Johnson was thrust into the role of a crisis mediator, where they had to navigate the complexities of their network in order to restore public trust.

The goal of the network surrounding Tylenol initially aimed to deliver a healthcare product and to sustain the public's confidence in OTC medications. However, when there was a breach in the network, Johnson & Johnson had to adjust. At the core of ANT is also the concept of "translation," which refers to the moment where relationships between actors converge and become interdependent and a network forms (Callon, n.d.; Cressman, 2009). In my argument, translation serves as a lens through which to examine the reconfiguration of the network that included Johnson & Johnson, media, regulatory agencies, and the public in the aftermath of the

Tylenol crisis. This reconfiguration was necessary for Johnson & Johnson to address their compromised network's primary goal: to re-establish a safe consumer environment and to reconstruct the damaged system of trust. To support my argument, I will analyze evidence from Johnson & Johnson's official statements, the FDA's recommendations, and the Federal Anti-Tampering Act passed by Congress that followed the incidents, as well as articles from major outlets such as *The New York Times* to capture public sentiment from the time of the murders.

Conclusion

The outlined technical project aims to refine sound integration into the phantom gel, yielding a model that mimics human conditions for US testing. This initiative also includes the development of a redesigned attachment mechanism to ensure maternal comfort and to avoid interference with epidural administration, as well as software to correctly identify multiple fetal heartbeats. The STS research paper will inspect the interconnected actors that led to and shaped the aftermath of the Tylenol murders using the ANT framework. Collectively, these projects address challenges in biomedical engineering by balancing both innovation and safety; they both emphasize the trust that society places in medical devices and products. The Tylenol incident shows us the devastating consequences that arise when trust in a medical product is undermined, whether due to malicious tampering or design oversights. This case serves as a potent reminder for my technical project, which emphasizes the importance of designing the fHR monitor so that it is not susceptible to errors that could arise from unintended design flaws that could similarly jeopardize human lives. Drawing insights from the Tylenol case, I am reminded of the gravity of responsibility in biomedical design, and I hope to learn valuable lessons about the importance of

meticulous design and safety considerations as I work to enhance the credibility of the current Doppler US fHR monitor.

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