Wearable Headband for Enhancing Slow Wave Sleep in Alzheimer's Patients
(Technical project)

Studying Liability Policies of Medical Devices and the Importance of Safety Considerations in Device Making
(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:

In current healthcare, medical devices play an important role in offering diagnostic and therapeutic capabilities that improve patients' quality of life. While medical devices offer many benefits to the healthcare field, they also pose inherent risks that must be carefully considered to ensure patient safety. It was found that "[f]rom 2008 to 2017, the FDA received more than 5.4 million reports of complications, failures or other problems blamed on medical devices" (Keller, 2023, p. 6) and that all types of medical devices caused 1.7 million injuries, highlighting that this is a prevalent and serious problem. Medical devices can have various levels of risks, with the Food and Drug Administration (FDA) categorizing devices based on severity of harm into three levels: medical device-related deaths and serious injuries, non-serious adverse events, and events without reported harm (Food and Drug Administration, 2016). Understanding and enacting steps to mitigating risks is essential. There are four commonly adopted steps to mitigating risks: identifying the risk, assessing the risk, developing a response to the risk, and controlling the risk response (Kheir et al., 2022). Additionally, it is important to consider accountability among a variety of groups such as hospitals, manufacturers, and device users in cases of medical device failure. To research this I will reference various literature reviews on liability and how medical device risks play a role in these policies. Through understanding potential risks that medical devices pose, I can research liability policies related to hospitals and medical device manufacturers.

Specifically, I will be focusing on robotic technology in the healthcare field and liability frameworks involving this device. Robotic surgery involves using robotic technology to assist in surgeries. In most cases, this is through a controller that the surgeon will use to have a robotic arm mimic the movements of a surgeon's hand and perform surgery. With this there are many

potential risks involved especially if there is device failure. Understanding the risks involved and the liability frameworks that have been put in place to protect against these risks is necessary to answer my sociotechnical research question.

In my technical project, my team and I will be developing a wearable headband for Alzheimer's patients to enhance slow wave sleep through acoustic simulation to aid in memory retention. As with any medical device, this wearable headband poses various potential risks to the user as it is used throughout the night while sleeping. In my STS project, I will primarily be focusing on robotic surgery. The sociotechnical research question that I will be addressing is what liability frameworks are in place when using robotics for surgery to ensure accountability among hospitals and device manufacturers? I will be focusing on hospital and robotic surgery manufacturer liability policies as well as safety considerations. Additionally, I will do a thorough literature review on the background and opinion of robotic surgery overtime to depict the problem at hand. The research I conduct on the liability frameworks in place to mitigate risks will aid in the development of safety considerations while designing and testing the device.

Technical Topic:

Dementia is a neurodegenerative and progressive disease, with Alzheimer's being the most common type affecting two thirds of dementia patients (Kumar et al., 2022). The primary symptoms of Alzheimer's are memory loss over time and impaired behavior. There are no known cures and current treatments focus on the side effects of Alzheimer's such as depression, agitation, and sleeplessness (National Institute on Aging, 2023). Research has shown that Alzheimer's patients exhibit decreased slow wave activity (SWA) and spend less time in the non-rapid eye-movement (NREM) stage of the sleep cycle (Lee et al., 2020). Slow Wave Sleep

(SWS) is a restorative stage of sleep that aids in memory consolidation and plaque clearance. SWS has known to "help flush toxic, memory-impairing proteins from" (Benson, 2019, p. 3), but with age there is a dramatic decrease in SWS. This is concerning due to the important role that SWS plays in memory and growth. Acoustic stimulation has been found to stimulate SWS in patients with mild cognitive impairments (MCIs) which in turn has resulted in increased memory retention and recall. Some studies have shown that acoustic simulation can improve sleep and memory retention. A study by NIH concluded that "acoustic stimuli offer diverse possibilities to influence sleep and can lead to desired but also undesired sleep manipulations" (Cordi, 2021). It was found that acoustic simulation can be conducted through pink noise which is a constant ambient sound with lower frequency and deeper pitch compared to white noise; this allows for filtering of higher frequency sounds which can disturb sleep, thereby inducing a constant phase of sleep (Robinson, 2022).

The technical question that I will be answering is: how do we design a wearable headband device that is comfortable, accessible, and does not impede normal sleeping habits while mitigating the risks involved with this device? The primary objective of this device is targeting memory retention in Alzheimer's disease patients through a wearable headband that identifies SWS stage through reading brain waves via EEG and delivering acoustic stimulation via pink noise to amplify the SWS signals. A closed-loop EEG system will be developed through acoustic simulation which will be conducted by measuring brain activity through electroencephalography (EEG) and inputting this data into a Machine Learning (ML) algorithm. This ML algorithm will then time the delivery of specialized sounds to the user which in turn will stimulate the brain and enhance slow wave activity (SWA). This closed-loop EEG system will be tested, and consistency checks will be performed on live EEG readings to validate the

functionality of the program and model through comparison of algorithm accuracy to previously staged data. Additionally, this device is intended to be worn during sleep and contains electrodes and wireless hardware so multiple design specifications will be considered during the development. Firstly, the device should be comfortable and wearable and not impede normal sleeping habits. Additionally, the device should be simple enough for older patients to effectively place on themselves. Most importantly, due to the use of electrodes safety, consistency, and efficacy should be considered throughout the developmental process. Finally, we will develop a supplementary mobile application for patients to provide feedback on the design and use of the device including comfortability, durability, accessibility, and ease of use to make further improvements on future designs. The deliverable for this technical project will be a comfortable and wearable headband which will provide acoustic simulation to the user during sleep will enhance SWS and improve overall memory retention.

Overall, there has not been a substantial amount of research on the auditory applications of memory retention specifically on older age groups. However, research has shown that overall auditory simulation can improve cognitive performance and memory retention. The use of this device on older patients with impaired memory will yield data that can aid in reducing the effects of Alzheimer's. This device will also provide more information on the effect of acoustic simulation on SWS.

STS Topic:

Robotic surgery is an evolved technology that has made great advancements in the field of medicine. Alongside this there is also a gradual transitioning of public opinion from skepticism to more widespread acceptance and confidence. The premise behind robotic surgery

is to help facilitate the surgery through mimicking the movement of the surgeon's hands as it is remote controlled by the surgeon. One example of surgical robotics is the Green Telepresence Surgery System which was described as a "dexterous manipulator for microsurgery" (George et al., 2018). The earliest concept of this device began in 1986 and eventually became a device that could "improve a surgeon's performance, even beyond human physical limitations" (George et al., 2018). The device works by transmitting the hand motions of the surgeon to the remote robotic arms through hand controllers. Similarly, the Da Vinci Robotic Assisted Surgery Device was another technical intervention created to aid surgeons in conducting surgeries. The Da Vinci robot has four arms, three of which are used to perform surgery with the fourth incorporating a camera. Every move a surgeon makes using the controller is replicated by the robot hands (Bramhe & Pathak, 2022). The device also has certain safety features to ensure proper surgery, including a binocular-like device for the surgeon to see incisions, a LED screen which displays every action, and speaker systems for effective communication amongst staff (Bramhe & Pathak, 2022).

Overtime, robotic surgery has become perceived as a standard of care through devices such as the robotic-assisted laparoscopic radical prostatectomy (RALP) that have been found to have low rates of medical complication compared to traditional surgery (Pessoa et al., 2021). However, there is still skepticism and controversy surrounding the extent to which the medical field should be dependent on surgery. While recently robotic surgery has incorporated many safety features in the design specifications, like with any medical device, robotic surgery can pose risk. One article describes the concern over the role of robotic technologies in the healthcare field and argues that "pediatric patients, their parents, and other caregivers might begin to overtrust robotic technology, possibly resulting in a patient being harmed or the technology

adopted prematurely" (Borenstein et al., 2018). The authors gather evidence to support this argument through surveying parents who have at least one child with a movement disability as the focus of the study is on robotic exoskeletons. The big takeaway from these surveys that supports the key argument is that many parents had concerns not only over their child slipping or falling, but also the skeleton itself hurting the child (Borenstein et al., 2018). While robotic surgery offers a variety of benefits, such as enhanced precision and efficiency, it is crucial to acknowledge the potential risks and ethical concerns surrounding the widespread increase in use. Overall, balancing technological advancements in medicine and patient safety remains important. Understanding public opinion on robotic surgery and parents concern can aid in understanding what liability policies are placed to ensure trust in robotic technology in the medical field. Additionally, it is important to see if changes in public perception have an influence on liability frameworks.

The research question I will be addressing is: what liability frameworks are in place to ensure accountability among hospitals and medical device manufacturers? I will conduct a thorough literature search to investigate liability policies and the potential risks that are associated with robotic surgery. This research will involve examining the policies of specific hospitals and medical device manufacturers as well as analyzing the risks that different robotic surgery devices pose. From the literature search I found information on liability standards for medical robotics and key information, such as that there is a binary distinction in terms of allocation of liability for harm (Pasquale, 2022). The author describes this distinction as "[w]hen…robotics substitutes for a physician, strict liability is more appropriate…[w]hen the same technology merely assists a professional, a less stringent standard is appropriate" (Pasquale, 2022). Additionally, I will read in depth the liability policies of Intuitive

Surgical, the manufacturing company that created Da Vinci Robotic Assisted Surgery Device through their website which has information on legal and safety information. Moreover, I will utilize the regulatory filing that Intuitive Surgical submitted to the FDA on the Da Vinci device. The response to the regulatory filing details the classification of the device and the existing major regulations that will affect the device (Trumbore, 2022).

Conclusion:

In my technical project, the deliverables will be a wearable headband that delivers acoustic simulation to the user to enhance acoustic simulation and a mobile application that will accept user feedback to adjust and improve on future designs. The wearable headband will meet safety and design specifications such as accessibility, feasibility, and functionality. For my STS project, the deliverable will be thorough literature search on the liability frameworks currently in place to ensure accountability among hospitals and device manufacturers. By understanding medical device liability policies as it pertains to robotic surgery, I will be able to utilize this research to aid in mitigating inherent risks pertaining to medical devices during the development of the wearable headband device.

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