Thesis Project Portfolio

Developing Wearable Headband for Enhancing Slow Wave Sleep in Older Adults

(Technical Report)

Studying Liability Policies of Robotic Surgical Systems to Ensure Accountability Among Hospitals and Device Manufacturers

(STS Research Paper)

An Undergraduate Thesis

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Sociotechnical Synthesis

Both my technical project and STS research are related to medical devices. My technical project involved creating a wearable headband device to aid with memory retention in Alzheimer's patients. My STS paper focused on analyzing liability policies of robotic surgical systems to ensure accountability among hospitals and medical device manufacturers. Alzheimer's Disease (AD) is a prevalent neurodegenerative disease that affects millions of people; as someone with a close family member with AD, I was motivated to work on this technical project aiming to make a positive impact to those affected by AD. However, as with any medical device, the wearable headband poses various potential risks to the users. Thus, I conducted my research on liability policies related to robotic surgical instruments as this emerging technology with promising benefits was of particular interest to me. Both the wearable headband and robotic surgery pose significant benefits to the healthcare and medical device industry in various ways and understanding the legal frameworks is important for ensuring patient safety and fostering technological innovation.

The technical project that I have been working on throughout this year is a wearable headband device that identifies the slow wave sleep (SWS) stage through reading brain waves via EEG and delivering acoustic stimulation via pink noise to amplify the SWS signals. The primary goal of this project was to design a wearable headband device that is comfortable, accessible, and does not impede normal sleeping habits while delivering acoustic stimulation to enhance memory retention in users. This project was aimed at aiding in memory consolidation in Alzheimer's patients unlike current treatments which primarily manage side effects. The accomplished deliverables for this project were form factors of the device, an audiometer, and a supplementary mobile application. The form factors of the device were created through Autodesk Fusion 360 and stress testing was conducted to acquire quantitative data regarding the structure of the proposed designs. The audiometer portion of this project was created to aid in frequency and decibel calibration of pink

noise stimulation and for users to test the frequency of tones they can hear. Finally, the supplementary mobile application was created for users to provide feedback on the device to the design team. Apart from this, a survey was created and distributed to receive feedback on the form factors and the user interface and usability of the audiometer and supplementary mobile application. Modifications to each of the three components of the project were made based on the feedback we received.

My STS research project focused on the issue of ambiguity regarding legal guidelines in cases of robotic surgery malfunction. Contrary to conventional surgical practices, the use of robotic surgical instruments introduces new variables including the device and the manufacturers, resulting in the need for clear legal frameworks. With the potential consequences of device failures and lack of clarity, this presents a significant barrier to technological innovations. In my paper I argued that currently, liability frameworks for robotic surgical devices distribute accountability among hospitals and device manufacturers, but lack of understanding amongst legal professionals can lead to challenges determining who is at fault in cases of device malfunction. The specific policies that I used in my analysis is product liability for medical device manufacturers and medical malpractice for hospitals and physicians. I analyzed these policies through the lens of Langdon Winner's politics of artifacts framework to determine whether current liability frameworks in place promote or favor specific policies or values. Moreover, I utilized a legal trial involving a robotic surgical device failure to illustrate the complications involved with unclear liability policies through a real-life example. Through my analysis, it was revealed that the greatest consequence of unclear legal frameworks is the potential threat to patient safety. Moreover, the lack of clarity between physician error and technological failures demands a need for understanding and reassessment of legal standards.

Through both my STS research and my technical project, I gained valuable insight into the medical device industry, particularly on the importance of patient safety and advancement of

technology. Working on these projects concurrently allowed me to apply my research on liability policies and medical device risks from my STS research directly to the design process of the wearable headband. This motivated me to place safety considerations as an integral part of the design process in my technical project. Moreover, my STS research on the complexities of legal responsibility in the medical device industry highlighted potential pitfalls that could arise with the headband device, prompting strategies to mitigate risks during the design process. My STS research enabled me to broaden my view on the social and legal implications of technological innovation specifically within the medical industry. This STS paper was overall helpful in providing a holistic view on the medical device industry and the importance of safety considerations during the design process.