Thesis Project Portfolio

Developing Wearable Headband for Enhancing Slow Wave Sleep in Older Adults

(Technical Report)

Investigating Normalizing Bias in Cochlear Implant Regulations

(STS Research Paper)

An Undergraduate Thesis

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Sociotechnical Synthesis

My STS research and technical project both involve medical devices, in particular the way in which they are either designed or regulated. In my technical project, I will be focusing on developing a wearable headband device to aid with memory retention in patients with Alzheimer's disease, primarily older adults. In my STS project, I will be analyzing the historical bias within FDA regulations which affect cochlear implants to understand how these have impacted the social and cultural development of deaf people. The wearable headband device will ultimately be subjected to approval by the FDA before reaching patients, as all medical devices are. As cochlear implants have a long history of regulation by the FDA, they may provide further insight into potential gaps in regulation which may impact emerging medical devices. Regulation of both these devices will have an indirect effect on the development of communities within marginalized groups of society: older adults and deaf people.

My technical project is the development of a wearable headband device that reads electroencephalogram (EEG) signals from the brain to identify the slow-wave sleep (SWS) and emit pink noise during this stage to amplify slow-wave activity (SWA). This device prioritizes targeting the root cause of Alzheimer's disease to improve patient condition, rather than targeting only the side effects. The goal of this project was to develop a comfortable headband device that is able to effectively improve memory retention without impeding sleep. In order to do this, form factors were created on Autodesk Fusion 360 for prototypes of the device that minimized coverage of the head to maintain comfortability while also covering the necessary locations for EEG data collection. Stress testing was done to ensure durability of the device and evaluate the individual structure of each design. In addition to the form factors, demos were created for both an audiometer and mobile application to be later integrated with the data collected by the device. The audiometer aimed to gauge patient hearing by calibrating pink noise stimulation and the

frequency of tones that each individual patient can hear. The mobile application provided location for the sleep and stimulation data to be centralized, while allowing for users to provide design feedback as well. A survey was also conducted on the project to gain feedback on user interface and usability of all three aspects of the project.

My STS paper explores the various complexities surrounding normalizing biases in the regulation of cochlear implants (CIs). Although CIs are classified as assistive devices, they are not fully accepted by those within the deaf community and are difficult to access based on various social factors such as race, age, and socioeconomic status. Primarily, this paper argues that the aforementioned biases are not incidental, but are embedded within the technological and regulatory parameters that affect CI deployment. In order to identify the root of these biases, a literature review was conducted of relevant regulatory materials surrounding CIs. The Food and Drug Administration (FDA) regulatory guidelines for Class III medical devices, eligibility criteria for CI recipients, and premarket approvals were examined to reveal how these regulations may reflect broader societal biases that favor hearing norms. These regulations were examined from the perspective of care ethics in order to analyze how these regulations tie into the ethical dimensions of CIs, which may be responsible for the emphasis on 'fixing' deafness through technology. Key findings of the literature review included that current regulations point to a “one size fits all” approach to CI administration, as CIs are not required to be tested for use based on racial differences during clinical trials. Moreover, clinical trials may be circumvented entirely via 510k submissions and PMAs, and are rarely tested on pediatric patients despite doctor recommendations that CIs be implanted at as early of an age as possible. Accounting for these gaps, care ethics calls for a revision of these regulations in order to reflect a broader

understanding of deafness, as well as increase informed consent processes, and promote partnerships with deaf communities to provide more equitable approaches to CI use.

Through both of these projects, I gained insight into both the development and regulatory sides of medical devices. My technical project allowed me to better understand the design process of a wearable device, as well as consider how modifications to design would impact both safety and usability. I was able to integrate my STS research into potential areas where the device I was developing in my technical project could be impacted, in particular in terms of which patients would be able to comfortably use the device outside of just older adults. My STS research allowed me to understand the complexities of device regulations and how these could severely impact the patients who are allowed to use them, and broaden my view on how these implications can be changed in order to advocate for these patients. The STS paper was essential in understanding why holistic approaches to regulating medical devices are necessary in order to allow greatest possible benefit to the patients.