Investigating Normalizing Bias in Cochlear Implant Regulations

A Research Paper submitted to the Department of Engineering and Society

Presented to the Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree

Bachelor of Science, School of Engineering

Devanshi Radadiya

Spring 2024

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

Advisor

Dr. Gerard Fitzgerald, Department of Engineering and Society

Introduction

Cochlear implants (CIs) are devices that are surgically installed into a region above the ear to stimulate the auditory nerve and allow for pseudo-hearing. These devices are commonly used as "corrective" devices for those with hearing disabilities ranging from partial to full hearing loss. Medical devices such as these have been regulated by the Food and Drug Administration (FDA) in the United States since it was established in 1906, and are classified into Class I, II, and III devices based on increasing levels of safety risk. CIs are classified as a Class III medical device due to the need for surgical installation and the associated risk, and have become a common option for partial restoration of hearing (Eshraghi, 2012). It is important to note that there are some ways that regulations for these devices can be manipulated in terms of passing FDA testing, and that even if they are not, these procedures have a significant impact on how CIs are perceived in society as well as how they affect deaf people.

Since CIs were invented in the early 1960s, they have been integrated into society as an assistive technology, and consequently have many intersections with social factors such as race, age, socioeconomic status, and the marginalization of disabilities. Historically, CIs have been negatively regarded in deaf communities as they assume that hearing disabilities are something that needs to be "fixed", while in reality the case is that many deaf people believe that they are able to lead a productive live regardless; this is due to their primary use of American Sign Language for communication, as well as a general culture of self-sufficiency (Erting, 1996). Moreover, CIs cost between $50,000 to $100,000 due to their technological intricacies and required surgery, creating a barrier to access based on socioeconomic status as well ("Duke University", 2023). Finally, even in cases where deaf individuals attempt to use these devices, they are not able to reach full hearing ability, as CIs only restore up to 53.9% of hearing ability at

most (Boisvert, 2020). This leaves deaf individuals stuck between both deaf and hearing culture, bringing into question their impact on the social development of deaf individuals.

These biases can contribute to the marketing of devices which are “normalizing”, meaning they are catered towards helping people from a marginalized social group–those with hearing disabilities–fit in with the “mainstream”, also known as hearing people. From an engineering perspective, it is important to investigate the root of these biases in how CIs are regulated, as regulations are what determines which devices are ultimately able to be used by the public. These regulations include both those set forth by the FDA, as well as criteria put forth for determining CI candidate eligibility. In evaluating gaps within these regulations, future solutions to these issues can be created in order to minimize or prevent marginalizing effects of CIs, and potentially other assistive devices or technologies.

To understand social issues surrounding cochlear implants, it is essential to first understand why “normalizing biases” are such a detriment to society. As stated previously, these biases cause many within society to view the hearing conditions as the standard, while viewing deviations from this as potential deficiencies within an individual. The primary effect of this inherent bias is that there is a general marginalization of deaf people, who then suffer the consequences of being regarded through a somewhat ableist lens rather than self-sufficient individuals. This plays a significant role in how deafness is treated, as researchers who have delved into the “deaf world” have found that viewing deafness through strictly a medical lens is highly detrimental to deaf individuals as it disregards their existing linguistic and cultural contributions (Lane, 1996). Resultantly, deaf individuals who are seeking correction to their hearing may not be receiving the appropriate treatment that they require, as impacts of CI use on their social development are not often considered (Padden & Humphries, 1988).

The most significant impact of CI use is arguably on the social development of children in particular, as the decision to use this device at a young age is left up to the parents of the individual rather than themselves. Both the FDA and medical specialists recommend early implantation of CIs, as this provides a higher likelihood of hearing improvement ("Mayo Foundation", 2019). In combination with these recommendations, the FDA does provide comprehensive information on potential impact on individual life and need for ongoing therapy, with the goal of informing the decision-making process of whether to use a CI ("U.S. Food and Drug", 2020). However, experts have critiqued that blanket statements such as the "need for ongoing therapy" tend to take away from the weight and complexity of this decision and blur the lines of what "informed consent" in decision making is (Sparrow, 2005). This critique is proven to be true after a study found that parents were more inclined to carry on with CI implementation at a younger age based either heavily or entirely on medical advice stemming from CI regulations (Hardonk, 2011). Major consequences of this lack of information prior to implementation were demonstrated in a study done on the self-esteem of children with and without CIs, which found that 68% of the children with low self-esteem were children with CIs who attended deaf schools, further indicating that CIs are likely hindering the social adaptation of deaf people (Percy-Smith, 2008). Lack of social adaptation at a young age may lead to lifelong challenges for deaf people.

Finally, access and long-term support are two overlooked factors in CI regulation. In terms of access to these devices, it was found that socioeconomic status (SES) of trial participants is considered in less than 15% of clinical trials that are required by the FDA (Alegria, 2021). Moreover, testing devices for racial and ethnic bias is not required by the FDA either, leading to a lack of transparency in CI success results (Grant, 2023). These facts likely

contribute to the results of studies done on SES of children who receive CIs, one of which found that despite white children making up 51.1% of patients with severe hearing loss, they accounted for 73% of cochlear implant recipients, while Hispanic, Asian, and black children made up less than 9% each (Stern, 2005). This issue ties into an array of healthcare disparities, such as access to insurance coverage, rehabilitation, and follow-up care, leading to the potential for propagating existing social inequalities (Blume, 2010). Furthermore, post-implantation support which is critical to CI success, such as language services and auditory training, is not ensured by the FDA and provides a major gap in both access and quality of treatment for children in particular, where quick and early language acquisition are critical to social integration (Niparko et al, 2010).

In this paper, I argue that normalizing biases within the criteria and regulations put forth by the FDA are severely detrimental to those with hearing disabilities or impairments as they fail to holistically provide care and access to those who would benefit from CI use. In the methods section, I list the regulations, candidacy criteria, and research on regulation impacts that I will be using. In the literature review section, I highlight the exact gaps within regulations and how they demonstrate a severe lack of care, and in some cases responsibility, on the part of the FDA. Finally, I analyze how these biases place a stronger responsibility upon the shoulders of those in the FDA to provide more equal and safe access to CIs.

Methods

When examining CIs through the lens of their role in society, it is necessary to understand the regulations that are put into place for both the approval of and access to these devices. The scope of this research is primarily on the biases within CI regulation, so differences within specific CI devices were not considered as this is both variable and non-generalizable, which does not allow for insight into changes which would reduce or prevent these biases on a large

scale. In particular, age and hearing condition criteria for CI candidates, Class III device regulations from the FDA database, 510k premarket approvals (PMAs), special controls, and limitations or exemption rules were investigated to highlight potential gaps within the regulations themselves. Additionally, research and literature surrounding impacts of these regulations on CI access and use were examined to understand the impact of these regulations on patients and the evolution of the CI field. In particular, insurance coverage and overall CI accessibility statistics were investigated.

Literature Review

Over time, the FDA approval process for device improvements has changed to allow for some acceleration as an incentive for more rapid technological advancement, yet fails to acknowledge the effects that subtle differences in CI technology may have on the diverse patient base it aims to treat (Humphries, 2020). When delving into the use of premarket approvals (PMAs), which are required for high-risk and novel devices, it was found in section 510k of the Food, Drug & Cosmetics (FD&C) Act that once medical devices are approved, clinical trials are not always required and can instead be fast-tracked via a 510k submission in order for a "less-burdensome process" to market their device ("Medical Devices"', 2023). In order to do this, the device must be proven to be substantially equivalent to an existing device, meaning it is "at least as safe and effective…[as] a legally marketed device that is not subject to premarket approval". Notably, many improvements on CIs have been approved through 510ks ("Center for Devices", 2023). In the case of potential software modifications or updates, different rules may apply. Manufacturers have the option of submitting either a more lenient special 510k submission, which only requires substantial equivalence to the manufacturers' own predicate device, or no submission at all if the changes do not impact safety or effectiveness of the device

(“Deciding When to Submit”, 2016). The FDA does clarify that in these cases, the determination of potential unintended safety consequences of such changes is up to the manufacturers themselves based on their own validation testing data, which makes the process of evaluating overall risk more subjective. For example, as a part of the special 510k submission, the manufacturers are allowed to submit a rationalization of device safety data (“Center for Devices”, 2023). In addition to this, reclassification of CI technology into a different category of medical devices has also been promoted. According to the Federal Register, the FDA has recently classified the powered insertion system for a CI electrode array as class II (special controls), stating that doing so “will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III,” (“Medical Devices”, 2023). The lack of regulation in clinical trials in the aforementioned acceleration processes also brings into question the efficacy of these devices in terms of early language acquisition, as well as whether these “improved” devices are even providing significant improvements in hearing for children as well as adults. This clarification is important, as CIs that have to undergo premarket trials are rarely tested on pediatric patients (Hwang et al, 2014). As such, it is possible that the effect of these accelerated approvals is that devices are not extensively tested on a range of demographics and hearing loss types, and consequently may not be entirely effective in treating deaf individuals holistically.

FDA regulations do not just impact CI availability through the approval process, but also affect the determination of CI candidacy and use. There is still a large discrepancy between the rate of device approval and the rate of expansion of CI candidacy criteria due to FDA labeling of CIs. The major criteria for candidacy include word recognition scoring and level of hearing loss, and as such candidates who do not meet FDA-approved indications for these scores often pursue

"off-label" use of a CI; in fact, a survey conducted by the members of the American Neurotology Society (ANS) found that 78% of doctors had performed cochlear implantation for both children and adult candidates who did not qualify according to FDA labeling indications (Carlson, 2018). It is also important to note that CIs are able to provide significant benefits to those who use them off-label, with pre- and postoperative speech recognition improving with a mean score of 91.9% after a year of implantation (Amoodi, 2012). Off-label use is also attributed to the difference in criteria for adults and children. For example, criteria for adult candidates has expanded significantly in accommodations since 1990, while the age and speech perception criteria for children who are CI candidates has only changed with a reduction in the minimum age from 24 to 9 months in the past 30 years (Park, 2021). Pediatric criteria set by the FDA expect children to access and learn spoken language with more significant levels of hearing loss, while a 2016 study comparing speech recognition of children found that children have a 75% greater chance of benefit with a CI relative to use of a hearing aid. The consequences of this are that only 50% of U.S. child candidates receive a CI, whereas 90% of child candidates in countries such as Australia, New Zealand, and European countries receive CIs (Sorkin, 2016). Resultantly, there has been an increase in off-label use over time as both researchers and medical professionals maintain that FDA criteria are too restrictive, with only (Zwolan, 2021; Moses, 2021). The most detrimental impact of this in terms of CI accessibility is on insurance coverage, as a study done on third-party payers for CIs found that "contemporary clinical practices and outcomes are advancing at a rapid pace and FDA criteria and private insurance coverage are not expanding quickly enough to keep up,". In fact, in some states it was found that reimbursement for a CI device from the Medicaid program covers less than 10% of the actual cost of the device due to variations in clinical and FDA recommendations (Sorkin, 2013).

To understand the extent of social factors intertwined with the implications of these regulations on CI use, I will be using a care ethics framework to allow for insight into how regulations overlook the diversity of deaf experiences when administering care. Care ethics emphasizes the significance of "care", or empathy and consideration, in decision-making processes. Most traditional and well-known ethical theories prioritize certain principles, rights, laws and rules to decide what is justifiable and accepted in modern society. However, care ethics brings into light the emphasis on understanding and considering the interconnectedness of human beings when making decisions involving different relationships, including those ranging from the individual level to larger scales such as familial and communal relationships. Care ethics gained recognition in part due to "In a Different Voice" by Carol Gilligan, whose work first introduced care ethics as a divergent viewpoint from the traditional ethical frameworks. Primarily, her work is founded upon the basis of ethical behavior being the ability to both comprehend and appropriately respond to the needs of others, pulling into light the dichotomy between emotion and reason in ethical behavior.

Analysis

The complexity within CI regulations lies within the fact that there are a variety of social factors which undoubtedly impact who CIs are accessible to, as well as how they are able to access them. A primary issue in the field of CIs is that of equal access, and care ethics directly pulls into question how regulatory frameworks prioritize a certain "standard" and allow for generalizations that devalue deafness. Current regulations may point to a "one size fits all" approach to deafness being the most drastic perspective of CI implementation (Held, 2006). Critics of this framework argue that there is not enough of a foundational basis for this theory, as basing ethics on emotion means basing it on something which is both highly nuanced and

subjective to individual perception when compared to more concrete principles and human rights. However, Gilligan rebuts this critique best, stating that “The blind willingness to sacrifice people to truth, however, has always been the danger of an ethics abstracted from life”; in essence pointing out that this argument fails to give weight to the specifics of the context of certain ethical dilemmas, which in many cases is more difficult to navigate with rigid guidelines (Gilligan, 1982). The implications of this ethical framework in the field of CIs–which is simultaneously highly technical and interpersonal–is vast, especially in terms of the ethics of the devices which are approved, as well as how doctors, patients, and regulatory bodies interact with them.

To delve further into the ethics of care in CI use specifically, it is necessary to examine first the push for technological advancement that may oppose accessibility. Failure to understand this allows for the narrative surrounding a specific technology to be engineered by those who create or profit from it. An important first step is to grasp the “technological imperative”, which states that “once technology is in place, there is a tendency for people to think that because technology makes it possible for us to do something, we therefore must do it” (Groehnhout, 2019). In the literature review, it is apparent that the FDA has made significant strides towards fast-tracking the device approval process, while at the same removing the requirement for stringent clinical trials and allowing manufacturers to rationalize device modifications. This takes away from the potential of more comprehensive evaluation regarding how these devices are able to impact different consumers; considering that racial diversity in clinical trials is not a requirement during original device testing, the consequently approved modifications to these devices likely abide by the original testing results and perpetuate the biases within the device (Grant, 2023; “Center for Devices”, 2023). As a result of both these regulations and the

technological imperative, manufacturers are more inclined to believe that these technological advancements are justified as they are intended to cure some kind of divergence from the preferred standard of health or normalcy.

Regardless of the shortcomings within FDA regulations, the increase in off-label CI use during recent years demonstrates a critical oversight in the regulatory process: the failure to adapt swiftly to evolving clinical practices and patient needs. According to care ethics, this degree of oversight demonstrates a large disconnect between what FDA knowledge on CI capabilities and who the target users for CIs *actually* are. The lack of updates in candidate criteria for children in particular pose the biggest risk to equitable access, as most doctors point towards early implantation for best outcome, while FDA criteria suggest that in cases other than severe hearing loss, hearing aids are adequate treatment (Sorkin, 2013, 2016). As mentioned previously, hearing disabilities are able to heavily factor into child development, and the lack of access to off-label CIs that can drastically improve hearing may factor into low self-esteem scores of deaf children (Percy-Smith, 2008). The fact that healthcare providers are so willing to provide off-label options and go against FDA recommendations further proves the point that while healthcare providers are in a more personal position to provide holistic care, they also lack the ultimate authority to make changes (Moses, 2021). Moreover, the case of insurance coverage being severely limited due to the restrictiveness of candidate criteria points to the idea that the FDA regulations put into place do not place value upon the patient condition in terms of updates and modifications, but rather prioritize profit and advancement. This brings into light the need for revision amongst FDA regulations themselves as they ultimately create a socioeconomic barrier to access with CIs, as only those who can afford off-label use would be able to be treated outside of the FDA candidacy criteria. Furthermore, racial barriers are also perpetuated due to

intersection between the two human factors, as a majority of those receiving CIs, both children and adults, are white Americans (Stern, 2005).

Surprisingly, this increase in off-label use also points to the faith patients have in medical technology, despite being at the greatest potential risk to issues with it. Groenhout explains this faith in the technological imperative; "medical technology is seen as a powerful force, offering protection and cure for illness and death—two of humanity's deepest fears…because [it] has done amazing things, and because the medical field is one that is structured to benefit patients, faith in technology seems warranted in this context in a way it is not in other [technologies]" (Groehnhout, 2019). Considering this deep-rooted faith from the users of these technologies, deciphering potential issues with CIs through a framework of care ethics must be centered upon those who regulate, create, and profit from these technologies via the technological imperative.

Accounting for the inherent power and social structures built into the use and medical care surrounding CIs, care ethics ultimately places an obligation upon the shoulders of healthcare providers, regulators, and manufacturers to be aware of the dimensions of the emotional, cultural, and societal considerations that surround the individuality of patients using these technologies. Although, it should also be noted that care ethics makes the realistic assumption that much of this obligation is left unfulfilled, and that in the case of CIs, this causes discord between whether certain devices align with the true values and desires of those who they are assumed to assist. The reason for this lack of fulfillment is best summarized in "The Technological Imperative and Medicine" as follows: "To contribute to people's health through technology, medicine must view patients as organisms measurable by nomological patterns (that is, law-like patterns). Because their success as healthcare providers depends on the successful application of technology, the providers may acknowledge the patient's personal aspects, but

they cannot make them a primary focus of their treatments" (Samson, 2018). Considering the validity of scope of work for both healthcare providers and engineers to be limited to largely technical or "logical" aspects in order for effective results, who might bear the burden of truly being inclusive of the ethics of care? The answer to this lies in the fact that this obligation extends to those who regulate these devices as well, as regulations are the first–and only other–point where the technological imperative factors into the marketing and use of these technologies. Regulatory bodies as a whole must be cautious in how they may impose certain technological solutions that do not recognize diverse perspectives and backgrounds. Moreover, they must understand how these solutions propagate some societal marginalizations of those who do not adopt them.

Conclusion

This paper critically examines the complexities and societal implications of cochlear implant (CI) regulations, particularly as governed by the FDA in the United States. In particular, highlighting how the existing regulatory framework and candidacy criteria for CIs not only perpetuate biases but also inadvertently contribute to the marginalization of individuals with hearing impairments. As such, I argue that a reevaluation of CI regulation to include more diverse testing requirements, increased access that is not severely limited by age group is necessary, as well as increased transparency of regulations to patients is necessary. Furthermore, an effort on the part of regulators and manufacturers to integrate knowledge from healthcare providers surrounding real-life complications of and barriers to access would allow for regulations which were more lenient to patient conditions. In the future, this work may contribute to similar discourse on other medical device regulation and shed a light on its effect on those

with disabilities, serving as a call to embrace diversity and promote equity within healthcare access and technological development.

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