**Voice Restoration Device Using Machine Learning of Acoustic and Visual Output During Electrolarynx Use**
(Technical Paper)

**The Digital Age and the Insufficiency of HIPAA in Protecting Virtual Data**
(STS Paper)

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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**

Research guides the knowledge that society has, especially medicine and healthcare. Healthcare is an ever-evolving field with continuous collaboration and innovation. This innovation and progress primarily stem from the increase in data needed to understand new phenomena. With this increase in data, there has been so much computational innovation, coupled with exponential increases in computing power and processing capabilities; there is some computation or program involved in every aspect of design and problem-solving. However, even with such advancement and improvement, there are still many unresolved problems in medicine that could benefit from the application of computational methodologies. The technical project discussed in the prospectus focuses on one such area: speech therapy devices, such as an electrolarynx. With these current devices, the speech isn't intelligible and there are possibilities to improve the capabilities by using machine learning and incorporating training data from patients (Kohlberg et al., 2016).

Sadly, with such great innovation, certain barriers tend to hinder progress. With an increase in healthcare data, there was a need for standardized and controlled dissemination of patient information. Because of this need, the Health Insurance Portability and Accountability Act (HIPAA) of 1996 was established. The HITECH act of 2009 and the HIPAA omnibus rule of 2013 cemented these frameworks that were instated to control and reduce any possible breaches of confidentiality and integrity of electronic personal information (Patil & Chakrabarti, 2021). However, with such a strict definition of protection, there are broad areas of information dissemination not explicitly covered in the bylaws. In such cases, there are breaches in violation of patient privacy (Gostin & Nass, 2009). Furthermore, these regulations restrict access to patient data, leading to issues in research and patient care. The STS discussion of this prospectus will delve into analyzing the impact of HIPAA on research and advancement. With a deeper understanding of HIPAA, the pioneer of privacy in healthcare, HIPAA can be reformed to provide succinct security while also promoting controlled access to information that helps with innovation in medicine through research (Patil & Chakrabarti, 2021).

**Technical Description**

Each year, approximately 3,000 people undergo total laryngectomy for laryngeal cancer, a major source of speech dysfunction (Kohlberg et al., 2016). After the procedure, patients are unable to phonate, requiring alternate methods of communication such as the electrolarynx. The electrolarynx, first introduced in the late 1920s, relies on a single frequency vibration transmitted via an external device to the oral and pharyngeal mucosa, which results in monotonic robotic voices and limitations in tonal languages. Furthermore, the reliance of direct finger pressure on a pitch button adds unnecessary burden to the users and is not an intuitive way to modulate intonation. (Rameau, 2020).

Even with these devices, laryngectomees have limited phonotary capacity. Those who are not satisfied with these voice restoration capabilities report making fewer phone calls, being anxious about speaking to others, and having fewer friends. Overall, there is a decrease in quality of life due to difficulties with communications. Because of this, there is a need for a noninvasive, intelligible voice restoration therapy that will improve the laryngectomee's quality of life (Rameau, 2020).

Currently, to address this problem, there are speech devices known to produce synthesized speech. The data captured in these devices include electromagnetic data and surface electromyography data. Electromagnetic field data capture is done through magnets embedded within a patient's mouth to monitor the motion of the vocal apparatus. Though this technology can better identify words or phonemes, the technology is invasive and uncomfortable (*Development of a (Silent) Speech Recognition System for Patients Following Laryngectomy - ClinicalKey*, n.d.). Surface electromyography data are captured from sensors placed on the neck and face, which allow for automatic speech recognition. This method is noninvasive, but more conspicuous (Meltzner et al., 2017). Using machine learning, a speech recognition program known as the Xbox Kinetic Model 1414 was developed by Microsoft. The algorithm tracks lip movements of speaking subjects and has ~77% classification accuracy. Even though it is less accurate than other speech recognition methods, the implementation is more portable, noninvasive, and inexpensive in comparison (Kohlberg et al., 2016).

Using previous studies and conceptualizations, the goal of this technical project is to implement a trained Artificial Neural Net (ANN) that is a combination of a Convolutional Neural Network (CNN) and Long Short-Term Memory (LSTM). This ANN will be able to interpret visual and auditory data- from laryngectomees using electrolarynxes- to produce computer-generated, intelligible speech. Since both visual and auditory signals will be used in conjunction, two separate algorithms are required to process each component. At the end, both ANNs will be combined.

The project is projected to span two semesters as part of BME 4064, with the team split into an auditory and visual group. As of this semester, Mp4 files of non-laryngectomees speaking the *Rainbow Passage* with an electrolarynx will be used as training for the algorithms to provide a baseline for how they would perform. *The Rainbow Passage* is a short passage that is phonetically balanced and a speech pathologist has trained each participant to recite the passage. The goal is to develop these algorithms on these training data. As of right now, the audio team is using Mel frequency cepstral coefficients (MFCC), an algorithm designed for speech extraction, for audio classification. With CNN, it has been seen that using MFCC improves accuracy by 6-10% (Padmini, 2017). The video portion utilizes DeepLabCut, a deep learning algorithm originally used for animal tracking to track lips moving in the video frame (Nath et al., 2019). The ANN's will be refined by providing data containing conversational speech spoken by non-laryngectomees. Once the performance of the refined algorithms is quantified, laryngectomees reading *The Caterpillar Passage,* a passage similar to *The Rainbow Passage,* and having conversational speech will be inputted as the test to see how each algorithm truly performs. Ultimately, past this Capstone, this algorithm will be incorporated into a device known as a "smart" electrolarynx, which will have the old functionalities of an electrolarynx supplemented by this continual learning algorithm. With this device, laryngectomees will be able to communicate easier with less hassle, reducing the limitations that come with an inability to speak. Ultimately, laryngectomy patients will be able to maintain contact with their loved ones and retain the quality of life they had before the laryngectomy.

**STS Description**

For the STS discussion of this prospectus, the impact of HIPAA regulations and privacy on the capability to provide patients with full-care and to conduct research for advancement will be evaluated. The technical project that I have undertaken involves data that require clearance through the Institutional Review Board (IRB), which includes a portion about HIPAA and its privacy rule. Though this protects patients' rights and ensures confidentiality and proper handling in any medical cases, the strictness of HIPAA seems to deter the advancement of research and encourages the spread of patient data through corrupt methods.

The privacy rule was established to help create a balance between protecting the privacy of identifiable patient health information and preserving the proper usage and dissemination of these data. However, such laws inevitably prevent the progress of research. For example, if researchers must use protected health information from patients, solely for research purposes, the investigators would need written authorization from the patients and/or a waiver of authorization requirement from an IRB. Often, these barriers hinder any potential progress in research and tend to dissuade those conducting/participating in it (Ness & Joint Policy Committee, 2007). Furthermore, there seem to be significant coverage gaps, leading to privacy breaches of many patients. Non-covered entities such as data warehouse companies, are not subject to the same restrictions under HIPAA, which means that personal data held by such entities are unregulated and can be shared without consideration (Gostin & Nass, 2009).

In fact, a study was designed to survey epidemiologists about their experiences with the HIPAA Privacy Rule. The questions were anonymously distributed. Responses indicated major research delays and added costs with studies that had the Privacy Rule Implementation. 67.8% of the respondents indicated that the HIPAA Privacy rule made research more difficult at a level of 4 to 5 on the Likert scale, where a score of 5 indicates a great deal of added cost and difficulty in study completion. Furthermore, respondents indicated that IRB applications had significantly more negative influence on human subjects than a positive influence. Out of all of those that were surveyed, only a quarter of respondents believed that HIPAA enhanced patient confidentiality and privacy. The majority perceived substantial, negative influence (Ness & Joint Policy Committee, 2007).

HIPAA clearly needs amendments that would help make data less susceptible to privacy breach risks, while also providing sufficient leeway for research studies (Patil & Chakrabarti, 2021). To determine the potential changes that need to be implemented for HIPAA, this STS research will first delve deeper into the historical component and evolution of the law. Understanding the changes made due to time and evolving societies will provide sufficient background to analyze other quantitative studies done to evaluate the influence of HIPAA on research and healthcare. Furthermore, it is important to understand how HIPAA affects industrial healthcare, hospital healthcare, and research to compare and contrast across the three different areas of applicability. This feedback in addition to quantitative data will determine the true impact of HIPAA and what components are unnecessary. Identifying areas that need changing is the first step to advocate for change and then eventual policy addition through legislation. Reform to HIPAA is essential for future advancements in medicine, while ensuring that there is controlled adaptability to the evolving technological world.

**Conclusion**

In a world with everything relying on technology and the transmission of data, a duality arises. This ease in information dissemination helps with fast research advancements due to collaboration and easy accessibility. However, the rapid growth in this data-driven world reduces controllability, which leads to the creation of policies that help to regulate and standardize the flow of information. With the technical project discussed in this prospectus, machine learning with ANN's will be used to improve the electrolarynx, a speech therapy device, by using patient data. However, due to this increased control over the dissemination of information, specifically patient information regulated by HIPAA, the ability to conduct research gets unnecessarily hindered. For this reason, it is essential to evaluate the true impact of HIPAA on research, as well industry and hospital healthcare, to propose potential reforms that establish the true balance between protection and feasibility for research advancement.

Word Count:1728

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