Developing a Comprehensive Meal Detection Algorithm and Meal Content Analysis for Patients with Type I Diabetes Using Continuous Glucose Monitoring Data

(Technical Report)

Integration of Algorithms in Healthcare: How Artificial Intelligence and Machine Learning May Restructure the Patient-Physician Relationship (STS Topic)

A Thesis Prospectus in STS 4500 Presented to the Faculty of the School of Engineering and Applied Science University of Virginia • Charlottesville, Virginia In Partial Fulfillment of the Requirements of the Degree Bachelor of Science in Engineering

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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

Since the conception of the Turing machine, the field of artificial intelligence (AI) has expanded from simple checkers-playing computer programs to intricate systems capable of outperforming humans in various complex activities, such as image and object recognition, predictive models, and artistic imitations. Indeed, the assumption that machines may displace humans is a fear that has existed since the early days of industrialization. Currently, the medical field is seemingly susceptible to these technological pressures because the diagnosis and prevention of diseases are progressively reliant on AI and machine learning (ML) algorithms.

AI is already being implemented for numerous roles within healthcare as it is anticipated to replace major surgical procedures by 2053 (Grace et al., 2018). Medical specialties that rely on pattern-recognitions such as radiology and pathology are also liable of being replaced by developing AI methods. Fogel and Kvedar (2018) note that the data available in the form of clinical and pathological images are ideally suited to power computer algorithms that lead to AI-generated predictions. With access to hundreds of biomarker data, imaging results from millions of patients, as well as thousands of physicians' notes, AI similarly possesses significant advantages in quick and accurate patient diagnosis (Krittanawong, 2018).

In these regards, the infiltration of AI technology has already begun influencing the healthcare landscape. AI technology, therefore, will challenge the roles traditionally ascribed to hospitals and the long-standing relationships established between patients and physicians will be called into question. However, despite the rapid developments in this field, successful implementation of clinical AI technology is highly dependent upon the willingness of certain social groups to adopt these machineries. Various agents ranging from patients, clinicians, and health care administrators alongside governmental organizations will undoubtedly have some control in limiting AI's function within medicine. Governmental regulation will be forced to keep pace with

the advancements observed in healthcare-based AI technologies due to safety and privacy concerns. Many improved technologies observed in research and development may purposely be delayed as a result of rigorous testing and cumbersome governmental requirements. Through the lens of *soft technologic determinism*, this sociotechnical study will thus explore how AI's integration within healthcare can help drive positive clinical practices, altering patient-physician relationships, and potentially changing the way clinicians approach healing. The technical project will similarly explore applications of machine learning algorithms and computational approaches in an attempt to reconstruct meal records based on continuous glucose monitoring data. Parallel to clinical AI methods, computational models provide scientists an effective and novel way of predicting effects that occur within a biological system.

Technical Topic

Type I diabetes (T1D) is characterized by the degradation of pancreatic β -cells, which inhibits a person's ability to produce insulin, leading to chronic health implications (Allen & Gupta, 2019). T1D management is burdensome and currently achieved through multidisciplinary approaches that require continuous attention to insulin administration, blood glucose monitoring, and timely meal planning (Daneman, 2006). Patients are often required to manually interact with their insulin delivery system due to frequent blood glucose checks and numerous daily insulin injections (Allen & Gupta, 2019). Clinical analysis of diabetic patients also proves difficult because an accurate meal record is crucial in generating reliable scientific studies. In most cases, however, the meal record provided by patients is missing meals and thus incomplete, indicating a need for a system that retrospectively reconstructs a patient's meal record. Novel computational approaches and meal detecting algorithms (MDA) are being implemented in reconstructing a patients' meal occurrence based on acquired continuous glucose monitoring (CGM) data via wearable sensors on the patient (Dassau et al., 2008). Various factors such as meal quantity, frequency, and *especially* meal content (i.e. protein, fat, fiber, carbohydrate) are also being considered due to limitations in insulin dosing based on carbohydrate counting alone (Bell et al., 2015). Thus, the objectives of this study can be divided into two parts: identifying meal occurrence via meal record reconstruction algorithms as well as modeling the effects of meal type from archived CGM data of select T1D patients.

Although meal detection algorithms for artificial pancreas (AP) system have previously been proposed, detecting meals through CGM data is a fairly novel concept (Samadi et al., 2017). The algorithms employed in closed-loop AP systems can be classified into four generic forms: model predictive control algorithms, proportional integral derivative algorithms, fuzzy logic, and biopharma-inspired mathematical models (Trevitt et al., 2015). These models have varying degree of successes, but typically are capable of predicting a meal detection with about 90% level accuracy. The proposed meal detection methods for this project utilize certain algorithmic features described above in conjunction with newer methodologies. In particular, we consider a voting scheme algorithm that depends on monitoring the rate of change in glucose levels and utilizes first and second derivative curves to determine the occurrence of a meal (Dassau et al., 2008). Preliminary studies with these implementations seem promising with an initial meal detection accuracy of about 75 percent.

The meal content analysis of this project relies on the double triangular minimal model (dTMM), consisting of nine equations to model subcutaneous insulin infusion in compartmentalized plasma and liver. Seven unique processes can be observed through this model: glucose kinetics, insulin kinetics, glucose rate of appearance, endogenous glucose production, utilization, secretion, and renal excretion (Dalla Man et al., 2007). When the fit of the dTMM is

optimized for a specific meal, the resulting parameters unique to each meal can be compared with the meal content. These classifications are crucial because meal content studies are only now beginning to relate glycemic index (GI), fat, and protein to glucose and insulin appearance for each meal type (Bell et al., 2015). If the dTMM model is properly integrated, the identification of a meal type based solely on glucose, time, and insulin data would be made possible—a monumental feat in metabolic studies.

The project is under the guidance of Dr. Chiara Fabris in Center for Diabetes Technology (CDT) at University of Virginia. The CDT has previously amassed a collection of CGM data with precise meal records over a 48-hour period for 15 total subjects—10 of which serve as usable datasets. Splitting this data for training and testing purposes, the prediction of both meal occurrence and meal content can be tested for accuracy based on the known meal profile of each patient. If successful, our work can be used to provide physicians with an accurate record of meals for patients affected with T1D, which can accordingly be utilized to provide enhanced and individualized care. Additionally, implementation of our algorithms into an AP system can minimize patient input, improving patient quality of life and the overall management of this disease. If the findings of this project are implemented with future systems, it is not inconceivable to imagine a novel product that allows TD1 patients to eat throughout the day without having to count carbohydrates, inject expensive doses of insulin, or fear the possibility of hypo/hyper-glycemic shock.

Science, Technology, and Society: Exploring AI's Impact on Patient-Physician Relationships

Although previously scoffed at as a science-fiction novelty, existing only in the realms of Hollywood and techno-dystopian novels, the integration of AI and predictive analysis is quickly becoming a lived reality. AI is perhaps making the greatest impact within medicine with applications ranging from diagnostic capabilities such as image detection to predictive capabilities in assessing surgical outcomes and prognosis. AI tools, therefore, offer great potential in developing healthcare and its implementation will inevitably exert some degree of influence on the social structures and relationships observed within the hospital milieu. Accordingly, as AI technology and computer-aided software become a staple within doctors' offices, it may profoundly impact not only the role of the physician, but also the relationships shared between patients and doctors. The major aim of this sociotechnical study lies in understanding how this shared patient-physician interaction might be re-defined in an AI driven world. AI's potential role in providing positive outcomes and promoting patient well-being will also be considered by exploring factors of care, including: access, quality, and cost. The study will similarly examine if AI technology holds the capabilities of replacing physicians altogether or if these tools will be integrated within the current patient-centered model to enhance the patient-physician interaction.

Historically, the physician's role is prescribed under the Hippocratic oath and has been continually upheld by practitioners in medicine. Although the oath has taken different meanings over time, its core tenets remain the same: respect for autonomy, beneficence, non-maleficence, and justice (Gillon, 1994). Indeed, many physicians view their role as transcending the protocols laid out in their job descriptions, instead focusing on redefining the very essence of what it means to heal patients. Dr. Paul Kalanithi (2016), a former surgeon, makes special note of the doctor's role by stating: "The physician's duty is not to... return patients to their old lives, but to take [them] into our arms... and work until they can stand back up...and make sense of their own existence." Along with these ideals, themes of compassion as well as a sense of "wholeness, narrative, and spirituality" also emerge as factors that underlie a holistic form of treatment (Egnew, 2005). However, there are equally those critical of the institutionalization of medicine and its detrimental

effects on the relationship between a patient and a doctor. Primary among these critics is Foucault (1973), who criticizes the very establishment of the "professional doctor." To Foucault and his contemporaries, the medical field and its many agents have dehumanized patients viewing them with the so called "medical gaze," where the patient is merely seen as a malfunctioning set of organs rather than a living entity. It is my goal to understand how the introduction of AI will act to address these differing social views on the patient-physician relationship.

Understanding AI's direct and covert impacts on patient-physician relationship can be best understood through *technological determinism*, a prevailing theory that suggests a society's technology is the most influential factor in driving human action (Smith & Marx, 1994). Harari (2017) argues that AI technology has already demonstrated some deterministic capabilities in the healthcare setting, suggesting that this grip will only strengthen over time. Although AI systems are currently incapable of displacing doctors and their roles entirely, Harari contends that the current obstacles within AI machines only need to be solved once. If *and* when this quandary is resolved, an infinite number of doctors would theoretically be available in a matter of seconds.

Within technological determinism, however, there are two trains of thoughts classified as either "soft" or "hard" determinism. Proponents of hard determinism argue that the force exerted by technology is inflexible, while those that argue for soft determinism assert that various social, economic, and political factors also impart some influence against technologies (Smith & Marx, 1994). It is difficult to suggest hard determinism as the sole driving factor in influencing physician's role in the advent of AI revolution given government's domineering involvement in regulating medical advancements. Cutcliffe's (2001) exploration of scientific accountability demonstrates how governmental agencies can establish regulations that mandate scientific compliance. With the passing of the Government Performance and Results Act (GPRA) in 1993, governmental agencies have begun inquiring about both scientific and medical institutions "what kind of results are being achieved?" From Cutcliffe's viewpoint, governmental regulations will not be eradicated anytime soon, and thus the implementation of AI within healthcare will be substantially controlled. Agencies such as Centers for Medicare and Medicaid Services (CMS) and Food and Drug Administration (FDA) would play a heavy role in ensuring that any form of AIpowered medical devices is both reliable and rigorously tested before they are placed anywhere near a hospital. Due to stringent political regulations within healthcare, the extent to which technology can impact patient-physician relation may purposely be curtailed, thus favoring a sociotechnical framework of soft technological determinism.

Research Question and Methods

The hidden roles of technological artifacts in shaping and driving the ways through which we interact often goes ignored by scholars that omit nonhuman elements from their analyses. This is especially true within the realms of healthcare, where novel technologies are rarely contextualized from a social perspective. Therefore, this sociotechnical study will be seeking to understand: How will new technological advancements such as machine learning and artificial intelligence algorithms play a role in reshaping patient-physician relationships?

Preliminary research indicated diverse positions regarding this inquiry exist, and thus discourse analysis seems to be the most appropriate method to gather and organize the collected data. I will conduct a comprehenisve review of newspaper articles, magazines, books, and peer-review journals. I will also be investigating any literature on current medical devices powered by AI. This enables me to gain perspective on how the actors most impacted by this technology—patients, doctors, governmental agencies, biomedical and data engineers—view the advent of AI. Further, I will explore how they anticipate the patient-physician relationship to be altered if and

when AI is implemented within health care. As part of the discourse, I would also like to reach out to patient advocacy groups including, Cancer Action Network, American Diabetes Association, Juvenile Diabetes Research Foundation, among others, as well as local physicians to understand their views regarding the interactions that patients and doctors currently share.

The various responses and positions provided by scholars, scientists, physicians, the media, and the public across different forms of platforms can ultimately be aggregated together, and separated based on the key arguments and themes each source provides. In the case of clinical AI technology, I would anticipate both positive and negative remarks from diverse groups depending upon their area of expertise and biasness. Claims that range from AI irrevocably replacing physicians to those that are highly wary of the AI technology must carefully be weighed before coming to a significant conclusion. Regardless, the goal of the data collected should be geared towards analyzing each of these differing opinions in ultimately providing evidence to support my STS framework of soft determinism.

Conclusion

The technical project aims to develop a computational model with some elements of machine learning techniques in an attempt to reconstruct missing meals as well as identify the meal contents from type 1 diabetes patients' CGM data. Combining these components together, the ultimate goal is to further develop this algorithm into a real-time tool with predictive capabilities that can be used in an artificial pancreas system, see Figure 1.

The utilization of such systems in practice, however, largely depends on both governmental allowance and societal acceptance of such a product. Therefore, the STS aspect of this study focuses on clinical application of computational products including machine learning and artificial intelligence algorithms. The ultimate goal of the sociotechnical study will be to utilize soft deterministic views in recognizing health-based technologies' ability to significantly influence doctor-patient relationships. Although significant consequence of such technologies remains to be seen, the paper hopefully highlights the responsibilities that all agents— both the human and non-human— share in delivering meaningful patient-centered care. Figure 2 below demonstrates the expected timeline for the STS research.

		SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY
Aim 1	Initial Algorithm Development									
	Analysis and Comparison of Existing Algorithms									
	Implementation of Refined Peak Identification Algorithm									
	Algorithm Testing/Validation									
	Reiteraton									
	Minimal Model Analysis and Literature Review									
	Initial Minimal Model Implementation									
41-1-2	Addition of supplemental model equations to identify Insulin Action									
Aim 2	Meal Isolation from Launchpad Data									
	Total Model Optimization for all Meals									
	Parameter Value analysis with meal content									
	Isolation of Data for Total Meal Detection and Meal Content Analysis									
	Combination of Peak Identification and Minimal Model Algorithms									
41	Testing and Validation/ Error Analysis									
Aim 3	Literature review of anti-causal CGM analysis systems									
	Implementation of anti-causal total meal analysis tool									
	Testing, Validation, and Reiteration									
	Specific Aims									
	Writing - Significance and Innovation									
Writing	Capstone NIH Proposal									
	Capstone Fall Progress Update									
	Thesis									

Figure 1. Timetable of Technical Project (Image Source: Pallavi Swarup)

		Spring Semester						
Tasks	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
Topic Selection for STS Thesis								
Statement of Topic								
Annotate Bibliography								
Prospectus Literature Analysis								
Prospectus								
Thesis Literature Analysis								
Develop Research Questions								
Interview Patient Advocacy Groups								
Interview Physicians and Patients								
Gathering and Analyzing Findings								
Writing Thesis								

Figure 2. Timetable of STS Research and Thesis (Image Source: Saurav Pandey).

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