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Regulation of Health AI Chatbots in Ontario

Mingi Chu,

Supervisor: Stark, Luke, *The University of Western Ontario*
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Abstract

Artificial Intelligence (AI) has made remarkable strides in healthcare, from revolutionizing medical imaging, patient support, research insight, and health education. However, a recent shift from query-based to interactive and regenerative AI presents a question of properly facilitating its development. Upon close inspection, regulations and policy adaptations lag behind the rapidly advancing field of medical AI which raises concerns over governance and societal implications. This paper explains some of the technical and ethical considerations surrounding the use of health AI applications with chatbots as a specific example. It evaluates the existing policies and regulations in Ontario, Canada, that govern the production and use of chatbots in healthcare. I provide recommendations revolving around new policies in areas lacking the necessary framework with a goal not to limit the use of chatbots, but instead facilitate the adaptation of chatbots and AI in healthcare to reduce the potential harm resulting from improper and outdated policies.

Keywords

Artificial Intelligence, Medical AI, Medical Artificial Intelligence, AI Regulation, Health AI, Medical Chatbots, Health Chatbots, Policy Analysis, AIDA

Summary for Lay Audience

Artificial Intelligence (AI) has allowed machines to simulate human intelligence and are revolutionizing areas in healthcare rapidly. In healthcare, AI has been used to enhance processes related to problem-solving and decision-making, assisting in public health, medical research, and patient support. The recent development of an AI application called ChatGPT has raised the popularity of chatbots and its concept proved AI can successfully mimic human conversation. Moreover, it can provide recommendations by searching through an extensive library of resources and generating new content upon request. Chatbots have been used in healthcare as well including areas of mental health, patient support, and health education. However, there are ethical and safety concerns related to AI tools such as chatbots that are overshadowed by their benefits. Algorithmic biases and the “black box” have raised societal issues when AI tools are implemented. Governmental regulations also struggle to keep up with the rapid development of AI. This paper explains some of the technical and ethical considerations surrounding the use of health AI applications with chatbots as a specific example. It evaluates the existing policies and regulations in Ontario, Canada, that govern the production and use of chatbots in healthcare. It contains recommendations involving new policies in areas lacking the necessary framework. The intention of the policy analysis is not to limit the use of health chatbots, but instead facilitate the adaptation of chatbots and AI in healthcare to mitigate potential risks arising from outdated or inadequate policies.

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Background

Without a doubt, Artificial Intelligence (AI) has risen in popularity in recent years as an innovative and powerful solution to processing and interpreting digital data in healthcare and health research. AI has already begun accelerating our ability to examine biomedical images, analyze multi-omics data, and provide evidence-based clinical decision support (Shrivastava & Kumar, 2022). It has demonstrated the potential to expedite drug discovery, streamline administrative tasks, enable remote monitoring and telemedicine, and provide invaluable insights into health research (Bohr & Memarzadeh, 2020). With further advancement of technology in both processing and optimizing AI, it is safe to conclude that the health sector will witness a proliferation of AI in its field. After all, its potential to fundamentally reshape healthcare provision, improve patient outcomes, and advance medical technologies is of major interest to governments and healthcare systems around the world, including in Canada.

Yet, despite the promising advancements, there are major ethical dilemmas and societal repercussions associated with these technologies that are being neglected and misregulated. Law, regulation, and policy responses are not being managed on par with the pace of medical and health AI advancement. While regulations are being proposed at the federal level in Canada, their scope remains limited and incomprehensive (Morgan et al., 2022). Since AI systems possess varying characteristics, functions, and associated risks that are contingent upon their specific purpose, use cases, and context, more targeted policy responses for medical AI are necessary. For example, an AI system made

for commercial purposes requires a largely different policy than an AI system for medical use.

A prominent AI innovation called ChatGPT has recently gained significant attention among the public and developers alike, with the healthcare industry being no exception. Since then, there has been a notable surge in the development of health-related chatbots in an attempt to address a growing demand for accessible healthcare solutions (Robert Pearl, 2023). In the past, chatbots were limited in their capabilities, confined to basic rule-based question-and-answer sessions and gathering customer information through conversations (Singh et al., 2019). There were clear limitations that the responses could not be processed for personalized information and tailored to different needs. However, AI chatbots such as ChatGPT mark a significant shift from their predecessors by offering a more engaging and human-like conversational experience. Past iterations of healthcare chatbots often left patients feeling frustrated and disappointed due to their rigid conversation flows and inability to solve problems or address intricate scenarios (Bates, 2019). In contrast, new AI chatbots can mimic authentic human exchanges by tailoring responses to the context and flow of the conversation. In the near future, more advanced health-related chatbots will emerge, finding applications in specialized medical fields such as diagnosis, research, education, and more.

However, chatbots also pose largely unaddressed risks and limitations that require careful attention (Parviainen & Rantala, 2021). There have been documented instances where AIs have provided inaccurate or biased

information, which exposes similar dangers associated with AI chatbots (Livingston, 2020). Chatbots are a novel technology that presents challenges in integrating into existing healthcare systems and services such as effectively facilitating doctor-patient communication, disseminating accurate medical information, and providing adequate care and treatments. Moreover, existing literature does not sufficiently address Canadian regulations and policies concerning the use of AI in healthcare, especially AI chatbots. This gap underscores the importance of ongoing research into both the potential and pitfalls of these emerging technologies.

In this paper, I have taken health-related chatbots as an example of a health AI system with specific applications and consequences and analyzed how regulations, policies, and frameworks might govern the development and use of this technology. This thesis will explore what chatbots are, their use cases in healthcare, and current regulations and policies regarding the technology. We intend to analyze government regulations and policies related to AI systems in the healthcare sector, with a specific focus on health chatbots, in order to identify any existing gaps and deficiencies. The overall goal of this paper is to improve the implementation of new AI tools into the healthcare system and allow innovation such as health chatbots to be safe and ethical.

Michael Da Silva et al. have raised similar concerns regarding AI applications and their development in the healthcare domain. As part of the AI + Society Initiative team, their recent works highlighted the need for a regulatory framework that is tailored to health AI to ensure patient safety, data privacy, and other

ethical considerations. Their recent publication, *Legal concerns in health-related artificial intelligence: a scoping review protocol* outlined many of the legal gaps and challenges associated with health-related AI (Silva, Horsley et al., 2022). Another publication, *Regulating the Safety of Health-Related Artificial Intelligence*, assessed Canada's effort in regulating health AI applications and provided suggestions for addressing some of the gaps in regulations (Silva, Flood, et al., 2022). Many concepts discussed in this paper consult these two sources and this paper's discussion extends further into more recent legal developments such as the Artificial Intelligence and Data Act, AIDA, and other advancements relevant to AI regulations.

What Are Chatbots?

Chatbots, alternatively known as virtual or digital assistants, are computer programs designed to mimic human conversations. Chatbots typically fall into two categories based on their capabilities: rule-based and NLP-based chatbots.

While the concept of chatbots has grown in popularity in recent years, rule-based chatbots have existed for decades. In 1966, the first chatbot called Eliza was developed by Joseph Weizenbaum at MIT, with the aim of illustrating the potential for preprogrammed bots to mimic human conversation (Weizenbaum, 1966). with Eliza being specific to psychological evaluation. Over the years, these technologies have been adopted by businesses, and commonly employed as customer support on company websites. Some notable early generations of chatbots include Jenn from Alaska Airlines in 2008 and an early version of Siri by Apple released in 2010 (Rizzo, 2009; Xu et al., 2012). By utilizing rule-based

approaches, these commercial chatbots could efficiently handle common queries and guide users through specific processes, saving time and enhancing the customer experience. These chatbots operate based on a predetermined set of rules and patterns, providing specific responses to keywords or prompts from the user. Generally, they offered simple answers by retrieving stored information. For example, if a user asked, "What is the longest river?" the chatbot, preprogrammed with this information as the corresponding answer, would respond with "Nile River." While rule-based chatbots were easy and simple to create, their functionalities were restricted due to the hardcoded nature of their programming. This limited the diversity of responses and confined their use to general purposes (Caldarini et al., 2022).

The second category of chatbots emerged more recently from a branch of AI known as Natural Language Processing (NLP). Human language is remarkably complex and diverse its symbols and rules can be used to generate an infinite range of speech (Nettle, 2012). NLP plays a crucial role in helping chatbots understand the complexities of language including nuances, context, and intent (Vamsi et al., 2020). Most NLP systems possess basic tasks such as tokenization and parsing, semantics, entity and intent recognition, contextual understanding, and sentiment analysis (Uma et al., 2019). The recent advancements in the accuracy of these tasks developed NLP to be used in various applications for analyzing and producing speech (Dang et al., 2020). For criminology, NLP has been used extensively to detect scams online through crime script analyses (Lwin, 2023). It reduces potential victims of theft and

malicious content by automatically analyzing large amounts of textual data to flag possible scams. In addition, NLP has been useful to researchers in collecting target information from vast textual sources (Hasan et al., 2019). For instance, researchers can analyze millions of posts from social media platforms for target information to gain sentiments and public opinions.

Ultimately, the implementation of NLP significantly improved the usability of chatbots, becoming a tool that could closely mimic human conversation. The improvement addressed many of the limitations of rule-based chatbots including being able to respond to user queries despite inputs of wordings or phrases that differed from the preassigned rules (Wahal et al., 2022). The advancement in hardware and AI brought several other advantages to chatbots. The rise in computational power allowed the scale of training for chatbots to increase as they were trained on an extensive corpus of data from many types of online sources. Chatbots can generate more coherent and contextual responses by analyzing data ranging from books, journals, and websites for users. Another significant advantage of AI chatbots is their capacity for continuous self-improvement. Chatbots can incorporate feedback from users and developers to further fine-tune their ability to understand, retrieve, analyze, and deliver information (Irvine et al., 2023).

Application of AI and Chatbots in Healthcare

In 2022, Market.us measured the Global Healthcare Chatbots market had a worth of 195.85 million USD and is projected to increase to 1168 million USD by 2032 (Market.us, 2023). Such chatbots have not only enhanced their

conversational abilities but also provided highly informative and insightful responses, often being compared to human professionals. Collectively, chatbots can be an effective conversational tool with access to an extensive database and their AI capabilities to provide expert guidance, recommendations, and support in various domains.

As with most other industries, the most common type of chatbots developed for healthcare are customer service chatbots that assist with online services for patients. The function of these chatbots can be comparable to that of kiosk machines, a popular innovation currently involved in many hospitals and clinics in Ontario. A kiosk developed for Sunnybrook in 2019 has seen a reduction of patients in the Emergency Department waiting for triage from an average of 15.2 minutes to 1.7 minutes (Coyle et al., 2019). This instance demonstrates the potential to incorporate automated processes to replace human-human interaction and help reduce hospital traffic. Similarly, hospitals and clinics can employ chatbots before coming to the hospital to handle self-service tasks traditionally managed by administrative staff or front-desk personnel. They provide round-the-clock support, improving the operational efficiency and facilitation of data collection. Sunnybrook has already begun the implementation of chatbots in early 2020, providing patients with a chatbot on a messaging system to book pre-anesthesia appointments online (Matys, 2020). The hospital reported that already 40% of pre-surgical patients use chatbots to book appointments and the new technology will expand into other areas of Sunnybrook in the near future.

The application of chatbots in healthcare goes beyond providing customer support and has extended its reach into the realm of assessing symptoms and informing patients. Babylon and Your.MD are two popular and industry-leading examples of mHealth chatbots that have been developed to assist individuals in evaluating their health concerns and identifying potential symptoms (Berlucchi et al., 2016; Telus Health, 2019). These chatbots utilize advanced algorithms and medical databases to analyze the information provided by users and generate personalized responses. By engaging in interactive conversations, Babylon and Your.MD aim to help users understand their symptoms better and guide users to reach out to a health professional. The utilization of these chatbots holds great potential in increasing accessibility to healthcare resources. These chatbots can be accessed at any time, from the comfort of one's own home or while on the go, making them a convenient option for individuals seeking preliminary guidance or information.

Chatbots have also emerged as a proposed solution for providing medical treatments (Frangoudes et al., 2021). In the realm of mental health support, a chatbot named Tess has been newly developed as an online coach or therapist, with the aim of helping individuals improve their mental well-being through conversational counseling (Gionet, 2018). Tess has been utilized by Saint Elizabeth Healthcare, a Canadian organization, which recognized the value of utilizing Tess to support caregivers. While mental health professionals are dedicated to caring for others' mental well-being, they often face burnout and find it challenging to seek help themselves (Posluns & Gall, 2019). In response, Tess

engages in meaningful conversations with these caregivers, providing them with much-needed support. These interactions also contribute to Tess's continuous training and improvement based on feedback from caregivers. After delivering a message, Tess allows caregivers to label whether the message was helpful. This feedback mechanism enables Tess to gauge the appropriateness of its comments and enhance its responses for future interactions. With the ability of chatbots to easily scale, Tess can be a helpful alternative in reaching a broader audience and bridging the gap in accessing mental health resources.

Chatbots have also demonstrated their potential as an effective tool for delivering Cognitive Behavioral Therapy (CBT). CBT is an evidence-based therapeutic approach that helps individuals identify and modify negative thought patterns and behaviors. It is widely used to treat various health disorders such as insomnia, panic disorders, and depression (Fenn & Byrne, 2013). A CBT chatbot called Woebot was developed with a conversational interface to engage with users and guide them through CBT techniques (Molteni, 2017). Through personalized interactions, Woebot helps individuals recognize distorted thinking patterns, challenge negative beliefs, and develop healthier coping strategies. By delivering CBT principles in bite-sized, daily conversations, Woebot aims to empower individuals to proactively manage their mental health and build resilience. Research teams at Stanford University found a significant reduction of symptoms related to depression in college students who received CBT from Woebot (Fitzpatrick et al., 2017).

Chatbots for Health Professionals

In the recent decade, AI has already seen multiple use cases in healthcare and health sciences. In multi-omics, AI is utilized to process complex biological procedures, including genomics and proteomics where the sheer volume and complexity of omics data often exceed the capacity of standard statistical correlations (Gao et al., 2022). This challenge has paved the way for AI to manage extensive data and delve into territories otherwise unexplorable to the human mind. AI is also instrumental in processing medical data, bringing about pivotal advancements in medical imaging (Hong et al., 2020). The integration of AI has notably enhanced the sensitivity and specificity of diagnosis when distinguishing between benign and malignant lesions. As such, AI has been involved in many areas of health sciences and it continues to be an essential tool for health research.

These AIs can be implemented as chatbots to assist health professionals in various areas of clinical practice. Chatbots are being developed to assist doctors by providing real-time clinical guidance and support to doctors. For instance, FlapBot is a chatbot that was developed to automate the process of flap observations into flap monitoring decisions (Ali et al., 2022). The speed of this process is an important determinant of the success of surgeries and human error can pose significant risks during the process (Shen et al., 2021). FlapBot helps decrease the time needed for flap monitoring and allows doctors to focus on other parts of the operation. General practitioners need about 6.1 hours on average per workday to complete shared decision-making for preventative care

(Caverly et al., 2018). These decision-making chatbots can be employed to reduce the time required for decision-making and facilitate the process more consistently. By offloading some of the burden, doctors can spend more time delivering care and interacting with patients.

ChatGPT and Health Services

Currently, the most advanced public chatbot is ChatGPT developed by OpenAI. ChatGPT utilizes the Large Language Model (LLM), an AI algorithm with deep learning that can understand, produce, and predict speech (Alberts et al., 2023). It is by far the most impressive conversational AI that can hold flawless and human-like conversations. ChatGPT is trained based on textual information from the internet to understand and generate human language. The tool has been used by professionals to assist their tasks and increase workflow. ChatGPT is being regarded as the next trending tool for content creation and writing. It can act as an assistant that can edit, proofread, and even suggest creative ideas depending on the needs of the user (Huang & Tan, 2023). The chatbot speeds up the process of writing and increases its quality and efficiency. ChatGPT has also risen as a valuable tool to enhance software development, project management, modelling, and testing. When prompted to automate software engineering tasks, ChatGPT could solve coding problems similar to that of a novice developer (Nascimento et al., 2023). This is a significant finding in this field since ChatGPT's service is free to use and requires only seconds to generate the result. The code produced by ChatGPT also surpasses its human counterparts in terms of consistency, readability, and efficiency.

The diversity in the range of services offered by ChatGPT encompasses medical consultations as well. A recent study by Kung et al. revealed that ChatGPT could pass the United States Medical Licensing Exam (USMILE) without any special training (Kung et al., 2023). This marks a significant improvement in AI conversational model history technology as its USMILE score effectively matched that of a third-year medical student. This is an unprecedented feat by a chatbot and shows the potential to be used as a reference or learning tool to train future doctors. In addition, ChatGPT was built with Reinforcement Learning with Human Feedback (RLHF), meaning the technology can improve its accuracy and responses with more training with a clinician (Liao et al., 2023). Since the release of ChatGPT, many developers have been creating and launching chatbots of a similar caliber, specializing in various fields. In this context, there is a strong need to have regulations and policies for chatbots to abide by during their development, implementation, and usage.

Methods

This paper was written based on a multi-goal approach, including prescriptive and descriptive policy analysis. In it, I evaluate existing policies and regulations in Ontario, Canada, that govern the production and use of chatbots in healthcare while recommending new policies in areas lacking the necessary regulatory frameworks. This policy analysis will follow the framework adapted from *Social Policy and Social Change: Toward the Creation of Social Change and Justice* by Jimenez et al. (Jimenez et al., 2014). Jimenez et al. outline a 5-step process in structuring a policy analysis. A problem is identified first followed by a description of the existing policy, the effects of the policy, the implications of the policy, and finally proposal of alternative policy. In this paper, I have grouped the three middle stages which all detail existing policies, intending to maintain the writing to be more concise and readable. The policy analysis is conducted with an emphasis on risks and ethical concerns involving developing, implementing, and using health AI chatbots. My goal of this analysis and recommendations is not to limit the use of chatbots, but instead facilitate the adaptation of chatbots and AI in healthcare to reduce the potential harm resulting from improper and outdated policies. I identified three categories of key agents associated with the policies of chatbots: developers, users, and regulators. The paper will outline the problem, examine existing regulations and policies, and provide recommendations for each category of agents rooted in the structure detailed in Jimenez et al.

Section A: Policies for Developers

Problems A

In this paper, “developers” encompasses any entity involved in the creation (stages before the final product) and maintenance (patch or modification) of the chatbot for health and healthcare purposes. It is critical that regulations address developers and have appropriate policies and regulations to reduce inaccuracy, algorithmic bias, and stereotyping in these systems. Without proper regulation for developers, it is difficult to reliably create and use chatbots knowing the potential dangers and consequences of their drawbacks. Developers are the first line of defense and agents that can reduce the most damage and vice versa.

An example comes from one of the first AI to be implemented in healthcare - IBM’s Watson supercomputer (Ross & Swetlitz, 2018). When this system was developed, it gained significant attention from the healthcare community for its potential to analyze vast amounts of data to help with diagnoses and prognoses. However, the AI was creating inaccurate recommendations that were against the national treatment guidelines. The most striking recommendation from Watson was ordering a combination of chemotherapy and bevacizumab for a 65-year-old patient that has been diagnosed with lung cancer and severe bleeding (Ross & Swetlitz, 2018). The doctors flagged this recommendation immediately, noticing that the order could potentially be fatal to the patient if prescribed. The Watson case offers insight into the importance of the safe integration of chatbots and the need for careful and rigorous evaluation of the ethical and legal consequences.

AI also lacks the ability to discern discriminatory information, as seen in several past instances. In 2018, a project was created to evaluate AI used to automate facial analysis, which has been praised for its revolutionary ability to recognize people based on their facial features (Klare et al., 2012). When the AI was adapted to be used by US-based law enforcement, the facial recognition system presented systematically lower accuracy for black people, females, and between the ages of 18 to 30. Our current society lacks full diversity and inclusivity in data, considering the imbalance in geographical, political, and financial inequality. This is reflected in AI's training data and the result did not display a full and fair representation of the diverse population it is meant to serve. It caused some populations to be underrepresented or misrepresented when training data contained unaddressed biases.

Even the latest and most advanced chatbot, ChatGPT, is still prone to error, especially in medical consultations. ChatGPT has been shown to create erroneous health recommendations as expected of a chatbot with no clinical-specific training. An article from Medium highlighted several inaccurate responses when the chatbot was given health-related questions (Britt, 2023). As an example, to the question of 'how many steps should I take each day to be physically fit?', the response was:

> "The number of steps you should take each day to be physically fit can vary depending on several factors, such as your age, current level of physical activity, and overall health goals. However, a general

> recommendation for healthy adults is to aim for at least 10,000 steps per day."

However, the 10,000 steps recommendation is a myth that was created in 1965 by a pedometer company that has been debunked several decades ago (Labos, 2019). While this recommendation is not dangerous, it is inaccurate and ChatGPT does not provide citations for their sources unless explicitly asked. This example brings up another grave problem with ChatGPT which is that it assumes all responses as verified and legitimate. ChatGPT in the USMILE test scored about 66%, which is impressive, but it also means it answered 34% of questions incorrectly. These incorrect responses will be presented to the user the same as correct questions, making it nearly impossible for users to discern correct and incorrect responses and the legitimacy of the chatbot overall.

The technology revolving around chatbots has traditionally been developed for commercial purposes. The same companies are now being commissioned by hospitals and clinics to develop health-related chatbots. However, chatbots that are not developed with a medical or health professional have been shown to lack the specialization and the ability to discern nuances (Palanica et al., 2019). Regulations regarding proper licensing and certification can help to ensure that these companies comply with strict standards of competence and expertise to develop safe and unbiased AI chatbots.

Existing Regulations A

Establishing regulations for producing chatbots at the provincial and federal levels presents a dilemma. Europe leads in academic publications concerning AI technologies, with China also accounting for a significant stake of 25% of worldwide output (Haner & Garcia, 2019). Forbes predicted that China will hold the global leadership in AI by 2030 indicating that controlling the development of chatbots by a single nation will be challenging due to the globalized nature of the technology (Herman, 2018). With these two countries leading the research and development of AI applications, their regulations and policies are worthwhile in examining and comparing to that of Canadians. In April 2021, an AI Act was proposed in European law to regulate the applications of AI to three distinct risk categories (Dunn, 2023). The highest-risk category encompasses AI usages with "unacceptable risk," which are strictly banned. "Limited risk" contains medium-risk (such as chatbots) that directly interact with humans. These are to follow the guidelines containing rigorous testing, risk mitigation, assessment of safety, and confirmation of databases. They also emphasize strictness on transparency obligations for generative AI, which includes chatbots, to reduce the potential risk of generating false or unlawful content. AIs that fall under the "low or minimal risk" category are not restricted by the AI Act by any means. The AI Act also has penalties for violations, including breaching a prohibited practice and fines of up to €40 million, or 7% of a company's annual global revenue.

While there is currently no explicit law or regulation regarding accountability for AI in Canada, efforts have been made to provide ethical frameworks for AI

through Bill C-27, the Digital Charter Implementation Act, 2022 (An Act to enact the Consumer Privacy Protection Act, the Personal Information and Data Protection Tribunal Act and the Artificial Intelligence and Data Act and to make consequential and related amendments to other Acts, 2022). This bill was proposed on June 16, 2022, and at the time of writing, the bill has only gone through the second reading. The third part of the bill, the Artificial Intelligence and Data Act (AIDA), is Canada's first national regulation regarding AI. AIDA's AI regulation is comparable to the EU AI Act by requiring AI systems to be assessed by the level of associated risk and harm. The new bill is important for holding entities accountable for AI practices. The bill requires a "high-impact" system to measure related risks, monitor mitigation measures, and provide publications of description. "High-impact" systems are also subjected to audits and, upon violation of the bill, subject to a fine of no greater than $10,000,000 and 3% of the person's gross global revenues in its financial year.

Both legal frameworks, although they have differences in specifics, are broad in their approach to regulating AI devices. AIDA and the EU AI Act focus on high-risk systems that have the biggest and most obvious potential to be disruptive to current societal systems. When these bills are applied to health chatbots, the bill helps address accountability for harm when issues arise. However, it fails to regulate the different nuances associated with chatbots such as fairness, bias mitigation, explainability, validity, and other factors that ensure the deployment of an ethical and fair device.

As the bill currently stands, it is difficult to categorize if AI chatbots are sectioned under “high-impact” or lesser-impact systems. Under the EU AI Act, chatbots are taken as an example of “limited risk” and are not subject to the same degree of regulation as “high-risk” systems. While AIDA details that all AI systems should have anonymized data, there are no further specifics regarding data governance. AIDA is a positive first step towards creating national regulations and guidelines for AI. However, the term AI encompasses a wide range of applications and utilities, rendering it too expansive and diverse a domain to be regulated similarly. This presents challenges and clear limitations to the attempt to regulate AI devices simply by their risks. Given the diverse nature of AI's applications, it is important to recognize that the roles and responsibilities of AI will vary across different sectors and utilities. For instance, an AI chatbot for patient education will vastly differ from an AI chatbot for commercial customer service. There is a need to develop suitable regulatory frameworks for each distinct subcategory within the AI landscape.

Recommendations A

1. *Scope of Medical AI*

   The current regulatory landscape around AI, including AIDA, encompasses a wide array of applications. However, the distinct characteristics, challenges, and risks associated with the applications can vary to a substantial degree. The current AIDA does not provide a detailed list of AI systems that qualify as “high impact” (Morgan et al., 2023). The lack of explicit classification gives too much flexibility for generative AI

systems such as ChatGPT to be interpreted and managed in an unclear manner. This calls for a regulation that is more detailed and specific to regulate the safe production of AI. Recognizing that AI chatbots can serve various purposes in healthcare, the regulatory framework should consider subcategorizing them based on not only their risks but also their intended use and complexity. For instance, chatbots are specific applications of health-related AI that can be used for either commercial or professional tools. A chatbot designed for patient education may require different levels of regulation compared to a chatbot used for clinical decision support. Tailoring regulations to each subcategory can contribute to better the precision and effectiveness of oversight.

2. *Detailed and Regulated Framework*

   I recommend the development of a framework supported, designed, and/or managed by a governing body (e.g., Health Canada) that can help ensure the validity of the medical chatbot and regulation for ethical and safety standards. The current ethical AI guidelines such as the Montreal Declaration for Responsible AI and the framework developed by the Institute of Electrical and Electronics Engineers (IEEE) provide excellent recommendations for developing safe and ethical AI (Thomas et al., 2021). Compared to detailed regulations, they are more effective in that they increase the flexibility of innovation when compared to detailed regulations. However, oftentimes, these considerations are only after-thoughts during AI development and are overlooked by practicality. This

will help medical AI to be developed to a higher standard and create a safeguard from becoming a disruptive tool when integrated into practice.

3. *Evidence-based Development*

   In collaboration with health professionals and experts, the regulatory body should mandate that health-related chatbots used in clinical practices be developed and trained based on evidence-based medicine and guidelines. This includes chatbots and associated AI for utility such as triage, patient care, and decision support. The data set for the AI should be trained on medical literature and developers should allow chatbots to only access reputable and vetted medical literature, research papers, and clinical databases. In particular, the importance of new regulators to help the partnership between developers and health institutions to access these data and relevant medical information is clear. This will be further elaborated in Section III.

4. *Comprehensive Risk Assessment*

   I highlight the importance of a regulatory framework that includes comprehensive risk assessment specific to the development of health-related AI chatbots. This assessment should include potential risks and biases associated with using chatbots before the release of the product to hospitals and the general public. The likelihood of each risk should be assessed and the possible impact on the health system and patients. The high-impact risks should be assigned priority and mitigation strategies should be developed to prevent and address these issues. Under current

AIDA, only high-impact systems are required to document and assess risk and biases (Morgan et al., 2023). Some AI applications including chatbots are unclear if they are subjected to these obligations. The risk assessment should extend to health AI technology such as chatbots to encourage clear transparency of their models and mitigation of biases.

5. *Accuracy of Information*

   Chatbot's ability to learn and improve is based on the training data available to them. Developers should be responsible for using diverse and representative training data that relates to race, gender, age, community, and other demographic attributes. This can help to safeguard potential algorithmic biases and allow for more fair and inclusive analysis. Additionally, the mandate for developers to create health-related AI chatbots to be transparent and explainable can improve the safe practice of chatbots. The chatbots or the developers should provide clear disclaimers about the limitations of their recommendations, especially for medical advice. The transparency of chatbots can help to reduce issues produced by the black box, analysis or recommendation from AI that is incapable of understanding from a human perspective.

Section B: Policies for Users

Problems B

The term "users" encompasses all entities engaged in the integration and utilization of chatbots for health and healthcare purposes. With developers holding the responsibility for the safe production of AI and AI chatbots, it becomes equally crucial to establish clear regulations, frameworks, and guidelines for the appropriate use of these AI systems. Given the short history of health-related chatbots, protecting users from chatbots and vice versa poses difficult and novel challenges. Thus, the implementation of such regulations can increase users' trust in chatbots and empower users to engage with chatbots responsibly. Within the context of healthcare, users of chatbots could be broadly categorized into two groups: patients and professionals.

One of the biggest challenges around chatbots for patients is to inform their users that healthcare chatbots are not meant to replace medical professionals and are usually employed for supplementary purposes. While this may be obvious to healthcare professionals, many patients have difficulty criticizing information from chatbots due to the lack of clinical expertise (Swire-Thompson & Lazer, 2020). Chatbots such as ChatGPT are widely accessible to the general public and conveniently located on browsers and phone applications. Since March of 2023, OpenAI has given developers, and programmers access to the API of ChatGPT, allowing third-party apps on mobile devices to be able to use these APIs to generate services with similar potential through chatbots (Brockman et al., 2023). With chatbots being so accessible to the public, patients

are more prone to self-verify their symptoms or health conditions through these applications. While healthcare chatbots can provide general information about symptoms, they can lead to inaccurate self-diagnosis and perpetuate unnecessary fear, panic, and anxiety (Phillips, 2022). Additionally, Fan et al. found that when patients were asked to utilize chatbots to help determine the severity of symptoms, some users felt confused and overwhelmed by the questions requiring too much personal detail (Fan et al., 2021). A proper guideline can help provide clear instructions on how chatbots should and can be used while highlighting the need and referring to consult a human healthcare expert.

Health professionals play a significant role in healthcare chatbots by acting as users and developers. For health professionals, appropriate policies and guidelines can help maintain a higher ethical and professional standard of care while utilizing chatbots. An example of such a chatbot is Wysa, which recently received FDA approval to deliver cognitive behavioral therapy (CBT) via smartphones (Baldry, 2022). The chatbot has been shown to reduce symptoms of depression and anxiety for patients with chronic musculoskeletal pain (Leo et al., 2022). While it proved to be an effective alternative to traditional orthopedic care, it is unknown how the risks and limitations of these chatbots will affect patient care such as doctor-patient relationships. Logistic and technical challenges arise in terms of ensuring continuity of care, including effectively logging chats and recording patient interactions facilitated by chatbots. Moreover, a standardized approach is needed for health professionals to provide

feedback to chatbots for continuous improvement. Such problems require a multidisciplinary approach solution, health professionals must be involved in the process of development to provide accurate medical and health information to fine-tune chatbots. By embracing chatbots as a medical utility and integrating them into healthcare processes, hospitals and clinics can benefit from these policies and further enhance patient care. Overcoming these challenges necessitates the development of guidelines and standards for care, specifically tailored to chatbots like Wysa. Such policies would better define best practices, set expectations, and establish boundaries to ensure the safety of both professionals and patients.

Existing Regulations B

As noted previously, no current regulations govern the development or usage of general and healthcare chatbots. Currently, any AI systems that are used in medical practices are regulated by Health Canada under the *Food and Drugs Act* (1985) and *Medical Devices Regulations* (1998). Health Canada views AI systems that meet the requirements based on their intended use and Schedule 1 of the Regulations as Software as Medical Device (SaMD). Since health-related chatbots fall under the category of AI systems, their approval would require going through the same regulatory process.

Interestingly, chatbots designed for triage purposes would not subjected to the Medical Devices Regulation because they do not meet the definition of a medical device (Health Canada, 2019). This inconsistency in regulation poses challenges for AI chatbots, particularly concerning their characteristic of self-improvement.

The algorithm of these chatbots can adapt, learn, and develop over time, making it difficult to establish clear guidelines and regulations that account for this aspect. Health Canada's current regulatory framework may not fully address the unique features and challenges presented by AI chatbots.

In 2021, the FDA, MHPA (the Medical Health Products Administration), and Health Canada collaboratively issued a set of guidelines known as the Good Machine Learning Practice (GMLP) (FDA, 2021). It aimed to provide guiding principles for the safe utilization of medical devices incorporating AI and Machine Learning (ML). It aimed to provide guiding principles for the safe utilization of medical devices incorporating AI and ML (machine learning). These guidelines serve as a valuable starting point and address important considerations in the context of health AI. However, it is important to note that the guidelines can be overly general and do not fully address the complexities specific to specialized AI applications like chatbots. While AI chatbots are recognized as a subset of medical AI within the framework of GMLP, their unique characteristics as conversational tools present their distinct challenges that extend beyond the scope of the GMLP guidelines.

Conversational AI chatbots interact with users dynamically and interactively, creating a more personalized and engaging experience. This introduces complexities related to natural language processing, understanding context, maintaining privacy and security, and ensuring the accuracy and reliability of responses. These challenges go beyond the primary focus of GMLP, which

primarily addresses the development and deployment of traditional medical devices incorporating AI and ML.

Health-related chatbots pose a unique set of challenges compared to other AI applications due to their emulation of human conversation. Unlike AI systems that operate on structured data or predefined inputs, chatbots can dynamically adjust their responses based on their interactions with users. This means that their responses are harder to predict and thereby harder to screen.

Additionally, unlike other AI applications that generate results that can be interpreted by healthcare professionals for accuracy and safety, AI chatbots directly interact with patients. This direct interaction bypasses the involvement of healthcare professionals in verifying the accuracy and safety of AI-generated responses. As a result, regulating technology becomes more challenging. The absence of direct human oversight in the interactions between chatbots and patients raises concerns regarding the reliability and quality of the information provided. It is critical to establish mechanisms that ensure the accuracy, appropriateness, and safety of the responses generated by chatbots. Developing effective screening processes that account for the dynamic nature of chatbot interactions is essential to mitigate potential risks and provide reliable healthcare support.

Integration of chatbots into healthcare practice and patient care introduces its own set of challenges, especially associated with access to electronic health records and hospital platforms. Chatbots are a novel technology in healthcare

that has not been widely adopted by the health sector. During the process of integration of chatbots into the existing healthcare system, they often require access to and transmission of sensitive patient data. This necessitates a different approach to ensure the safeguarding of such data. By implementing robust data governance practices, adhering to privacy regulations, and establishing interoperability standards, the healthcare system can harness the benefits of chatbots while maintaining the highest standards of patient privacy and data security.

Recommendations B

1. *Education for Users*

   In the field of healthcare, chatbots are relatively new tools that may seem foreign to both health professionals and patients. For successful integration and widespread acceptance, a regulatory framework should emphasize educating users about the functionality and limitations of chatbots. The educational efforts should focus on guiding users about the privacy and security of their information and clarifying that chatbot interactions do not involve real human beings. It is crucial to inform users that chatbots serve as supplementary information tools and are not yet suitable as replacements for professional medical advice.

2. *Continuous Feedback, Updates, and Quality Control*

   One of the critical ways of enhancing chatbot functionality is through active feedback from users. To ensure the effective maintenance and

improvement of chatbots, both users and developers should share responsibility. Developers should pay close attention to user feedback, accurately process it, and make appropriate revisions to improve the chatbot's utility in the healthcare industry. Users, on the other hand, should actively contribute by providing valuable feedback and corrections. A regulatory framework can help develop and implement a robust system of continuous feedback that optimizes chatbot performance and the quality of user feedback. This could involve: regularly updating medical advancements, identifying and labeling incorrect or misguided knowledge, implementing an expert review process, and collecting patient feedback.

3. *Liability and Accountability*

   Clear liability and accountability regulations for poor and unethical practices associated with health AI technologies are critical. While chatbots are not sentient beings, they can act autonomously without the need for a human operator. Given this freedom, it is hard to regulate liability and accountability without clear guidelines. Developers must be held responsible for the reliability and accuracy of the technology while users must adhere to ethical guidelines. Healthcare organizations that deploy these technologies must be responsible for the consequences of chatbot use to ensure the protection of patient data and proper guidance from chatbots. The establishment of guidelines associated with health chatbots can provide a legal and ethical standard that encourages the utilization of chatbots in healthcare.

Section C: Regulators

Problem C

Regulatory bodies play a pivotal role in promoting public health, upholding ethical practices, and ensuring safety in healthcare. Recommendations made in the previous sections are difficult to manage without a dedicated regulatory body and proper regulators. The establishment of a dedicated regulatory body should be responsible for addressing the current lack of regulations and policies surrounding health-related chatbots and AI systems in healthcare, as mentioned earlier. The existing regulatory framework, primarily overseen by Health Canada, has limitations in effectively addressing the complexities of these technologies, as highlighted in the preceding section.

The introduction of Bill C-27, as outlined in Section A, represents a step towards regulating accountability for AI and chatbots in Canada. However, this new responsibility necessitates the involvement of a specialized regulatory body equipped with multidisciplinary expertise to comprehend the technical aspects of AI and its diverse health applications. The current laws and regulations governing AI were formulated before the advent of this technology, underscoring the need for updated and comprehensive regulatory measures. As AI continues to advance and integrate further into healthcare systems, a dedicated regulatory body can help navigate and streamline the intricate issues surrounding AI and its various systems, including chatbots.

Existing Regulations C

Medical chatbots with the intention to monitor, assess, or diagnose are currently regulated by Health Canada under software as a medical device (SaMD) (Health Canada, 2019). However, medical AI especially chatbots are able to improve, adapt, and change significantly after receiving the license and rigorous testing. Unfortunately, there is no regulatory authority that can track these changes and conduct post-market surveillance. The absence of regulators that facilitate the interactions between chatbots and patients raises concerns regarding the reliability and quality of information provided by chatbots.

Recommendations C

The lack of regulations associated with health chatbots, and other health AI applications stems from the problem that there are currently no appropriate regulators that can closely monitor devices in this sector. Although AI technology is novel, the benefits of health AI applications advocate for the continuous development of such technologies. Therefore, I recommend new regulators to help enforce the governance of the new AI Act and AI policies. The new regulatory agency can facilitate the process of developing AI regulations with details specific to its applications such as chatbots. For Health AI, the new agency can encourage collaborations between health experts, developers, and institutions to ensure the safety of its uses. This recommendation helps to alleviate several ethical and moral problems associated with current AI use and development in Ontario:

1. *Complexity of AI*

   AI is difficult to comprehend, even for professionals within the field. The goal of AI is to re-create our processes and develop machines that can automate themselves. This involves many technical and mathematical concepts that are difficult to grasp without spending years of extensive education in programming and data analytics. It is a significant challenge for health institutions and health professionals to fully comprehend this technology is nearly impossible considering that their training was based on health and medical practices. Technology is also changing and improving rapidly, meaning health professionals would require a significant allocation of time away from patient care in order to understand the new technology. The new agency is necessary to bridge the gap between AI applications and the health sector.

2. *International Issues*

   AI development is a global phenomenon with countries around the world racing to create health AI applications such as chatbots. Chatbots are often developed through collaborative efforts between different nations and multinational corporations. However, these chatbots must be monitored by a regulatory agency in Canada to understand and assess the benefits, harms, and risks associated with cross-border concerns. Health-related chatbots be compliant with Canadian regulations and be confirmed by the new agency. The establishment of the proposed

regulatory agency for AI in Canada will foster global innovation and ensure that AI technologies prioritize user safety and data privacy by collaborating with industry experts and international partners. This proactive approach will help position Canada as a leader in AI governance and contribute to the global conversation on AI ethics and regulation.

3. *Trust and Acceptance*

   Presently, users face significant challenges in placing trust in chatbots, primarily due to uncertainties surrounding data handling, evaluation, maintenance, and the underlying AI algorithms. These doubts and suspicions, particularly regarding chatbot accuracy, create a barrier to user acceptance. As health chatbots are novel developments, the establishment of the agency can set robust standards and certification processes, instilling confidence in users and promoting responsible AI development practices. The regulatory body can further collaborate with other organizations to educate users about the functionalities of chatbots and any concerns associated with data privacy and user interactions.

4. *Liability and Accountability*

   Extending from recommendations from Section B, the establishment of a regulatory body can hold the authority to clarify the liability and accountability of practices associated with chatbots. Since chatbots are developed and deployed through collaboration with many players,

assigning liability can be challenging. However, the proposed new agency can produce explicit directives on who is responsible and will be faulted with legal ramifications appropriately.

Conclusion

The emergence of AI is offering new innovative solutions to medical practices, health research, and patient care. In particular, health AI chatbots have the potential to improve healthcare efficiency and health monitoring. Possibly replacing the need for front-desk personnel, chatbots can vastly improve patient flow and may be the solution to decreasing hospital traffic. Nonetheless, the regulatory framework and policies regarding the technology are not being developed in pace to support and supplement the rapid development. The establishment of more detailed policies and regulations is required to ensure the facilitation of the safe development and implementation of technology. Central to this effort, I propose the establishment and appointment of new regulators exclusively responsible for AI and health AI devices. The goal of these regulations and policies is not to restrict the use of AI but to reinforce patient safety, ensure the trust of users, and foster a collaborative environment between organizations. The recent prominence of ChatGPT has increased the stature of chatbot and regenerative AI developments with a clear hike in the production of health chatbots and interactive AIs alike. The intensification and clarification of regulatory efforts can encourage the development of superior and safer quality AI.

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Curriculum Vitae

Name: Mingi (Edward) Chu

Post-secondary Education and Degrees:

McMaster University
Hamilton, Ontario, Canada
2016-2020 BHSc

University of Western Ontario
London, Ontario, Canada
2021-2023 MHIS

Related Work Experience

Teaching Assistant
The University of Western Ontario
London, Ontario, Canada
2021-2023

Knowledge Mobilization Placement
Offord Centre for Child Studies
Hamilton, Ontario, Canada
2018-2019