ETHICAL CHALLENGES ARISING FROM THE UNDERREPRESENTATION OF THE ELDERLY IN THE DEVELOPMENT OF ARTIFICIAL INTELLIGENCE (AI) FOR MEDICAL APPLICATIONS: EXCLUSION, BIAS, AND THE LIMITS OF ACCESSIBILITY

ETHICAL CHALLENGES ARISING FROM THE UNDERREPRESENTATION OF THE ELDERLY IN THE DEVELOPMENT OF ARTIFICIAL INTELLIGENCE (AI) FOR MEDICAL APPLICATIONS: EXCLUSION, BIAS, AND THE LIMITS OF ACCESSIBILITY

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A Thesis Submitted to the School of Graduate Studies in Partial Fulfillment of the Requirements for the Degree Master of Arts

McMaster University MASTER OF ARTS (2023) Hamilton, Ontario (Philosophy)

TITLE: Ethical Challenges Arising from the Underrepresentation of the Elderly in the Development of AI for Medical Applications: Exclusion, Bias, and the Limits of Accessibility

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NUMBER OF PAGES: x, 80.

Lay Abstract

Artificial Intelligence (AI) is revolutionizing healthcare through its potential for improving diagnoses, treatments, and care. However, medical AI tools pose a critical challenge due to the lack of elderly experiences being considered in the development of these tools. This thesis explores the underrepresentation of elderly experiences in medical AI development, evaluating its implications and proposing solutions.

This thesis consists of five chapters. Chapter One outlines the potential of medical AI tools and their limitations. Chapters Two to Four examine how AI training data sources (i.e., clinical trials, electronic health records [EHRs], and self-reporting tools) inadequately capture elderly experiences. Clinical trials lack elderly participation, resulting in a lack of available data that reflects their medical needs. Age bias in EHRs further distorts AI training, as the data they contain do not accurately reflect patient's true conditions. Self-reporting tools neglect the unique abilities of older adults, leading to inadequate representation.

This paper concludes with proposed solutions, such as enhancing elderly participation in clinical trials, addressing physician bias in EHRs, and catering to the needs of older adults in the design of self-reporting tools.

Abstract

As artificial intelligence (AI) increasingly revolutionizes healthcare, the development of AI-powered medical tools holds promise for improving patient care by increasing the accuracy of diagnoses, providing precise treatments, and more. Despite the promise of AI tools, they suffer from a critical limitation due to a lack of representation of elderly experiences. In this paper, I examine the multilayered issue of the underrepresentation of the elderly in the data used in the development of medical AI tools, assessing its implications and proposing relevant solutions.

This thesis is divided into five chapters, with Chapter One providing an overview of the current state of AI, highlighting the potential of AI-powered tools for improving healthcare outcomes, and their relevant limitations. Chapters Two to Four assess how various sources of AI training data (i.e., clinical trials, electronic health records [EHRs] and self-reporting tools) fail to adequately represent elderly experiences.

Clinical trials have long suffered from a lack of elderly representation, originating from efforts to protect vulnerable populations from research-induced harm. While the attempt has been to protect, the result has been to arbitrarily exclude older adults from participation in clinical research. As such, there is a lack of diverse data that accurately reflects the complexities of their unique medical needs. Further, the presence of age-based bias towards the elderly presents an additional layer of concern. The manifestation of such biases in EHRs perpetuates inaccurate data that informs the development of medical AI tools, consequently maintaining disparities in healthcare. Additionally, self-reporting tools fail to account for the distinct cognitive and physical abilities of older adults, presenting useability challenges that result in the inadequate representation of elderly experiences in the data.

Finally, the paper culminates with a compilation of proposed solutions to address the underrepresentation of elderly experiences in medical AI development. These solutions propose efforts to improve elderly participation in clinical trials, efforts to mitigate physician bias in EHRs, and the design of self-reporting tools that are cognizant of the unique needs of older adults.

Acknowledgements

First, I would like to express my deepest gratitude to my supervisor, Dr. Claudia Emerson. Her patience, guidance, and thoughtful feedback were an integral part of my success, and I could not have completed this project without her unwavering support. Thank you for everything. I would also like to acknowledge my second reader, Dr. Sandra Lapointe, for both her contributions to this project and for her role as an academic mentor throughout my time at McMaster.

I also want to thank my friends and peers, both in the department and beyond, for their continuous support. I am very lucky to have found friendship in such a vibrant, and diverse group of academics. Your unique perspectives and expertise helped me develop the various dimensions of my work, and for that I am grateful. I must also acknowledge the brilliant team at the Institute on Ethics and Policy for Innovation (IEPI) for their kindness and willingness to extend a helping hand whenever I needed it. I have learned so much from each one of you.

To my parents and brother, thank you for always supporting me and for believing in me even when I did not believe in myself. I will never have the right words to express how grateful I am to you for all that you have done and continue to do to support my dreams. To my partner, thank you for your consistent support, and for always showing an interest in my work. You have supported me from the start, and I am thankful to be able to experience this achievement with you. Finally, a special thank you to my fur baby, Snow, who was by my side for all the long nights spent working on this project.

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List of Abbreviations and Symbols

ADS – Automated Decision Systems

AI – Artificial Intelligence

CIOMS – Council for International Organizations of Medical Sciences

CONSORT-AI – Consolidated Standards of Reporting Trials – AI Extension

CT – Computed Tomography

DL – Deep Learning

EHR – Electronic Health Record

EMR – Electronic Medical Record

ER – Emergency Room

FDA – U.S. Food and Drug Administration

IRB – Institutional Review Board

ML – Machine Learning

NLG – Natural Language Generation

NLP – Natural Language Processing

NLU – Natural Language Understanding

PI – Principal Investigator

RCT – Randomized Control Trial

RWD – Real-World Data

SPIRIT-AI – Standard Protocol Items: Recommendations for Interventional Trials – AI Extension

TCPS 2 – The Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

WHO – World Health Organization

Chapter 1 – The State of AI: Its Uses and Challenges

Introduction

In recent years, Artificial Intelligence (AI) has been gaining significant attention, leading to the term 'AI' gaining buzzword status. However, despite AI's rapid expansion and growth into various aspects of society, many people have a limited understanding of what AI is, how it affects their daily lives, and the potential challenges it may present. One area of recent AI research and development is the medical field. Medical applications of AI, such as the development of machine learning (ML) algorithms for illness detection and automated decision systems (ADS) for patient admission determinations are being increasingly utilized as tools in the administration of medical care.[1] The use of AI in medical care can improve patient outcomes, especially in the case of populations with more than one illness, such as the elderly. Timely diagnoses and precise treatment recommendations made possible by AI can greatly benefit the overall health outcomes of elderly patients, who often experience comorbidities and co-occurring illnesses. While AI can improve elderly medical care, it also poses considerable challenges resulting from elderly exclusion from clinical trials and the presence of ageist biases in healthcare settings. To understand these challenges in the context of elderly populations and their implications on AI development for the elderly, we must first have a comprehensive understanding of AI. This chapter will provide an overview of the history of AI, explain how it is currently used in society, as well as present an analysis of the benefits and challenges of its

[1] "Grand River Hospital to Partner with Signal 1 to Enhance Patient Care and Clinician Expertise Using Artificial Intelligence Technology | Grand River Hospital," accessed February 16, 2023, https://www.grhosp.on.ca/news/2023/grand-river-hospital-to-partner-with-signal-1-to-enhance-patient-care-and-clinician-expertise-using-artificial-intelligence-technology; Lydia X.Z. Brown et al., "Challenging the Use of Algorithm-Driven Decision-Making in Benefits Determinations Affecting People with Disabilities" (Center for Democracy and Technology, October 2020).

development and deployment, with a specific focus being placed on AI tools for medical and public health applications. This analysis will serve two purposes: (1) to explore the most significant challenges posed by the use of AI tools in medical care settings, namely, the need for vast data sets for algorithmic training and the subsequent concerns about the quality and inclusion of patients' experiences in the data; and (2) to serve as a primer for the forthcoming discussion regarding these specific challenges in the context of elderly populations.

What is Artificial Intelligence?

While many individuals have heard of the term 'AI', few have a precise understanding of what is being referenced by the term. The lack of a cohesive, singular definition shared by researchers across disciplines further inhibits the public's understanding of artificial intelligence. Abdulkareem and Petersen define artificial intelligence as "the concept of developing computer algorithms with human-like intelligence to solve specific tasks."[2] Choudhry, Renjilian and Asan define it as a computer program capable of making intelligent decisions through the use of machine learning.[3] Others have defined it as the attempt for machines to simulate intelligent human behaviour,[4] the foundation of enhanced machine cognitive ability,[5] as well as a system's ability to correctly interpret data.[6] These are just a few of the many distinct definitions found in

[2] Musa Abdulkareem and Steffen E. Petersen, "The Promise of AI in Detection, Diagnosis, and Epidemiology for Combating COVID-19: Beyond the Hype," *Frontiers in Artificial Intelligence* 4 (May 14, 2021): 652669, https://doi.org/10.3389/frai.2021.652669.
[3] Avishek Choudhury, Emily Renjilian, and Onur Asan, "Use of Machine Learning in Geriatric Clinical Care for Chronic Diseases: A Systematic Literature Review," *JAMIA Open* 3, no. 3 (October 1, 2020): 459–71, https://doi.org/10.1093/jamiaopen/ooaa034.
[4] Adam Kassam and Naila Kassam, "Artificial Intelligence in Healthcare: A Canadian Context," *Healthcare Management Forum* 33, no. 1 (January 2020): 5–9, https://doi.org/10.1177/0840470419874356.
[5] J.Mark Munoz and Alka Maurya, "Introduction," in *International Perspectives on Artificial Intelligence*, ed. Alka Maurya and J. Mark Munoz (Anthem Press, 2022), 1–4, https://www.cambridge.org/core/books/international-perspectives-on-artificial-intelligence/introduction/624346A5F4CE5FC3B17FD9565D547046.
[6] Michael Haenlein and Andreas Kaplan, "A Brief History of Artificial Intelligence: On the Past, Present, and Future of Artificial Intelligence," *California Management Review* 61, no. 4 (August 2019): 1–10, https://doi.org/10.1177/0008125619864925.

the literature on AI, indicating that there does not currently exist a singular, precise explanation of what it means for a system to be deemed artificially intelligent.

One reason for the varied definitions is that AI and machine learning (a subset of AI) are often assumed to mean the same thing.[7] However, AI is an all-encompassing field with various methods being used to achieve artificial intelligence[8]. Common methods used for producing an artificially intelligent system include machine learning (ML), deep learning (DL), expert systems, natural language processing (NLP), and many others. Due to its vast nature and numerous applications, artificial intelligence becomes difficult to define, and as a result, difficult to understand.

An additional challenge arises when considering the two types of AI: software and embodied AI. The average individual often thinks of the latter type when thinking of AI applications. While software applications are mainly composed of algorithms and follow ML and DL models, embodied AI includes a physical form interacting in the physical world. Some examples of embodied AI include robots, robotic arms, self-driving cars, and more. Although developments in embodied AI continue to increase at a significant rate, software applications of AI are much more common and widely used. Some examples of software AI applications include facial recognition systems, chatbots, image analysis, algorithmic decision systems, and many others.

While most individuals interact with some form of AI daily, many have limited awareness of AI's presence in their lives. The Pew Research Center recently published the results of a

[7] Sumeet Hindocha and Cosmin Badea, "Moral Exemplars for the Virtuous Machine: The Clinician's Role in Ethical Artificial Intelligence for Healthcare," *AI and Ethics* 2, no. 1 (February 2022): 167–75, https://doi.org/10.1007/s43681-021-00089-6.
[8] Hindocha and Badea.

survey that sought to determine Americans' awareness of AI. The survey included 11,004 U.S. adults and was conducted in December 2022. The results of the survey indicated that 27% of Americans reported they interact with AI at least several times a day, 28% believe they interact with AI between once a day and several times a week, and 44% do not think that they regularly interact with AI.[9] One of the questions participants were asked was designed to measure individual awareness of the specific uses of AI in daily life. While many performed well in identifying AI in wearable fitness trackers, service chatbots, and other similar applications, when it came to questions about email providers using AI to identify spam messages, 49% of participants answered incorrectly. All answers considered, the survey results showed that 30% of Americans have a high level of awareness of AI, 38% have a medium awareness, and 31% have a low awareness of AI applications in their daily lives. However, when considering public awareness of AI separated by level of education, there is an indication of a knowledge gap between those with postgraduate degrees and those who lack a post-secondary education. The survey found that 53% of Americans with postgraduate degrees identified applications of AI in daily life correctly in each question asked. However, in individuals with a high school diploma or lower, 51% answered no more than 2 of the 6 questions asked to them correctly.

Although there are some limitations to the general public's understanding of AI due to the limited accessibility of knowledge and the numerous definitions in existence, current definitions contain two common characteristics: (1) they reference systems that make decisions or perform tasks autonomously, and (2) they accomplish this by independently analyzing data to produce said independent task or outcome. Within these parameters, numerous applications of AI can be

[9] Reem Nadeem, "Public Awareness of Artificial Intelligence in Everyday Activities," *Pew Research Center Science & Society* (blog), February 15, 2023, https://www.pewresearch.org/science/2023/02/15/public-awareness-of-artificial-intelligence-in-everyday-activities/.

found containing various data models and intended uses. For this paper, we will adopt the following definition used by Choudhry, Renjilian and Asan:

> AI is defined as a computer program that operates with predefined rules and data-driven models that are capable of making intelligent decisions.[10]

Now that we have established what definition of AI we will be adopting for our analysis, we will provide a brief overview of the common data-driven models utilized in AI development. In so doing, we will be better suited to both understanding the workings of various AI methods and in turn, be able to recognize the potential challenges they present.

Data Models

AI applications currently use several data-driven models to produce a desired result (i.e., detect faces, detect spam emails, recognize the presence of malignancy on radiographic images, etc.). The two types of models most frequently used are Machine Learning (ML), and a subset of ML called Deep Learning (DL). Machine Learning includes several algorithms and data models for achieving AI, some of which include Reinforcement Learning, Supervised/Unsupervised Learning, Random Forests, Bayesian Models, Support Vector Machines, and others. Deep Learning (DL) often consists of sets of ML algorithms that are based on neural networks that mimic the neural networks found in the human brain. Deep Learning models contain multiple layers between their input and output layers, which is the reason that it is referred to as 'deep' learning.[11] While it is beyond the scope of this thesis to assess each of the models used individually, it is important to formulate a general understanding of the most common methods

[10] Abdulkareem and Petersen, "The Promise of AI in Detection, Diagnosis, and Epidemiology for Combating COVID-19"; Choudhury, Renjilian, and Asan, "Use of Machine Learning in Geriatric Clinical Care for Chronic Diseases."
[11] Abdulkareem and Petersen, "The Promise of AI in Detection, Diagnosis, and Epidemiology for Combating COVID-19."

employed in Machine Learning. Table 1 below provides a list and explanation of the most used models in the development of AI applications.

Table 1 – Learning Models used in AI Development and their Definitions

Terms and Definitions	
Term	**Definition**
Machine Learning (ML)	The ability of a computer program to learn from experience without being specifically programmed.
Deep Learning (DL)	A subset of ML that consists of ML algorithms that are based on the neural networks that replicate the neural networks found in the human brain.
Supervised Learning	ML algorithms used to develop mathematical models through the use of data, where the data includes both the input and target output (e.g., making classifications, house prices, etc.).
Unsupervised Learning	ML algorithms designed to find underlying patterns in each data set, using only the input data (e.g., detection of an illness, customer patterns, etc.).
Reinforcement Learning	ML algorithms that are based on interactions between an agent and its environment. In this case, the agent is seeking a reward for performing a particular action in its environment (e.g., robotic vacuums, autonomous cars learning to drive on their own, etc.).

Table 1. A list of learning models used in the creation of AI applications and their definitions.[12]

The History of Artificial Intelligence

The concept of artificial intelligence (AI) can be traced back to the 1940s when three separate occurrences were taking place. The first foundation for what would later develop into AI

[12] Abdulkareem and Petersen.

was found in the seminal paper written by doctors Warren McCulloch and Walter Pitts describing the architecture of neural arrangements, serving as the foundation for the concept of neural networks.[13] The second notable occurrence was the publication of Isaac Asimov's short story, *Runaround*.[14] The story follows a robot engineer's development of a robot, and the evolution of the three laws of robotics: (1) a robot may not injure a human, they may not allow a human to be injured through inaction, and they may not allow a human to come into harm; (2) a robot must obey the orders of human beings, except where doing so would violate the first law; and (3) a robot must protect its existence so long as it does not conflict with the first two laws.[15] Around the same time that Asimov's book was published, Alan Turing developed a machine to crack the Enigma code used by the German Army in World War II.[16] The machine was able to crack the code used by the Germans and in turn, allowed the British Army to decipher German communications. In the years that followed, Turing published his seminal paper titled *Computing Machinery and Intelligence,* where he explained how to both create intelligent machines and test their intelligence.[17] The combined developments by McCulloch, Pitts, and Turing, and the publication of Asimov's classic work led to the official coining of the term artificial intelligence by a cognitive scientist – and founder of the MIT AI research laboratory – Marvin Minsky and computer scientist John McCarthy in 1956.

In the years that followed the birth of AI, AI development experienced little growth. The types of AI that were developed at that time all followed the same form and are known as expert systems. Expert systems depend heavily on the formalization of rules consisting of 'if-then'

[13] Kassam and Kassam, "Artificial Intelligence in Healthcare."
[14] Haenlein and Kaplan, "A Brief History of Artificial Intelligence."
[15] Haenlein and Kaplan.
[16] Haenlein and Kaplan.
[17] Haenlein and Kaplan.

statements, however, as we know now, human intelligence is far more complex than a formal rule system consisting of basic prompts and subsequent responses. For a system to replicate human intelligence, it must be able to interpret data correctly, learn from it, and apply its knowledge to achieve a given task.[18] This led to the development of theories for achieving 'true' AI, the first of which was discussed as early as the 1940s by Donald Hebb – a Canadian psychologist.[19] Hebb developed a method of learning that replicates human learning, through the process of replicating the neurons in the human brain. While this formed the foundation of artificial neural networks, commonly found in current applications of AI, computers of that time did not have the computing abilities to be able to handle the work required by artificial neural networks.[20] As a result, AI development came to a standstill and the AI Winter ensued in the early 1970s.[21] During the AI Winter, interest in AI research remained stagnant for decades.[22]

Since the resurgence of AI research beginning in the early 1990s, AI developments increased exponentially.[23] The result of this has been various systems and methods for developing AI, each with its unique abilities. As such, various forms of AI have been – and continue to be – developed and deployed in many different industries for various purposes. While the presence of AI tools in healthcare contexts is becoming increasingly prevalent, the progression of AI did not anticipate its substantial involvement in healthcare and human subjects research. Further, the AI Winter was a recent event that coincided with crucial developments in ethical practices for research involving human subjects (i.e., the Nuremberg Code, The

[18] Haenlein and Kaplan.
[19] Haenlein and Kaplan.
[20] Haenlein and Kaplan.
[21] Haenlein and Kaplan.
[22] Haenlein and Kaplan.
[23] Philip L. Frana and Michael J. Klein, *Encyclopedia of Artificial Intelligence: The Past, Present, and Future of AI* (Santa Barbara, UNITED STATES: ABC-CLIO, LLC, 2021), http://ebookcentral.proquest.com/lib/mcmu/detail.action?docID=6526148.

Declaration of Helsinki, The Belmont Report, etc.).[24] Thus, one can posit that this disconnect in AI's development has contributed to its rigid algorithmic focus, which undermines the human dimension, despite the current expectations that AI and its applications should be closely connected with human interests.

AI in Society

General Landscape

As has been discussed, artificial intelligence (AI) is a broad concept containing numerous methods and models used for its creation and development. As a result, its applications in society are vast including digital security, autonomous vehicles, and agriculture. AI applications have additionally been deployed in public administration and justice systems. In the United States alone, there were over 88 applications of Automated Decision Systems (ADS) using AI algorithms to make benefit determinations.[25] In Canada, Veterans Affairs Canada deployed the use of an AI algorithm tasked with determining the eligibility of veterans for mental health benefits and implemented an ADS system to make said benefit determinations.[26] Further applications include the utilization of algorithms to assist with the sentencing of criminals, and the use of facial-recognition tools to identify potential suspects in criminal cases.[27]

Applications of AI that are being deployed in healthcare settings are increasing in incidence as well. Scheduling tools, triage systems, and ML algorithms used to detect the

[24] "Research Ethics Timeline - David B. Resnik, J.D., Ph.D., Bioethicist, NIEHS/NIH Florian W. Hofweber," National Institute of Environmental Health Sciences, accessed August 24, 2023, https://www.niehs.nih.gov/research/resources/bioethics/timeline/index.cfm.
[25] Brown et al., "Challenging the Use of Algorithm-Driven Decision-Making in Benefits Determinations Affecting People with Disabilities."
[26] Treasury Board of Canada Secretariat and Treasury Board Secretariat of Canada Open Government, "Access to Information: Completed Request Summaries," accessed February 16, 2023, http://open.canada.ca/en/access-to-information.
[27] Luke Stark and Zenon W. Plyshyn, "Artificial Intelligence (AI) in Canada | The Canadian Encyclopedia," The Canadian Encyclopedia, 2020, https://www.thecanadianencyclopedia.ca/en/article/artificial-intelligence.

presence of illnesses are a few of the many applications found in healthcare settings. In Canada, St. Michael's Hospital in Toronto, and Grand River Hospital in Kitchener have partnered with AI start-up Signal 1 to explore the use of clinical decision support systems powered by AI to assist with clinical recommendations for hospital patients.[28]

Healthcare AI Applications

One of the most important sectors involved in AI development and deployment is the healthcare sector. In 2022 alone, the U.S. Food and Drug Administration (FDA) database showed 91 submission decisions made regarding Artificial Intelligence and Machine Learning (AI/ML)-enabled medical devices.[29] As of October 2022, there were a total of 521 FDA-authorized AI-enabled devices. The submissions include applications ranging from diagnostic tools to automated image processing, and more. In Canada, several AI tools have been deployed in various hospitals. A leading body in the deployment of AI-powered tools in healthcare settings is Unity Health Toronto. A few programs they are currently using include CHARTWatch by Signal 1, CHARTWatch surgical, MuScRAT, and ED Volume Forecasting Tool.[30]

CHARTWatch and CHARTWatch surgical both operate by continuously gathering more than 100 variables of data on patients such as their lab results, vital signs, and demographic data.[31] The data is then put through a machine learning algorithm that predicts the risk of a patient entering intensive care or dying. CHARTWatch Surgical utilizes the same process to

[28] "Grand River Hospital to Partner with Signal 1 to Enhance Patient Care and Clinician Expertise Using Artificial Intelligence Technology | Grand River Hospital."
[29] Center for Devices and Radiological Health, "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices," *FDA*, May 10, 2022, https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices.
[30] Patty Winsa, "How Artificial Intelligence Is Helping Toronto Hospitals Predict Patient Outcomes and Save Lives," Gemini, September 30, 2022, https://www.geminimedicine.ca/post/how-artificial-intelligence-is-helping-toronto-hospitals-predict-patient-outcomes-and-save-lives.
[31] Winsa.

determine how much support a patient will need by using data found on the hospital's electronic medical records.[32] MuScRAT is a tool that was developed for the St. Michael's Hospital multiple sclerosis clinic.[33] The program is used by the clinic to synthesize a patient's medical record and summarize key points, symptoms and treatments into a one-page visual in seconds. Unity Health also currently utilizes ED Volume Forecasting, which is a patient forecasting tool developed specifically for the St. Michael's Hospital emergency department.[34] The tool uses historical data to determine necessary staffing levels and to predict hospital needs.

Additionally, Grand River Hospital in Kitchener recently partnered with Signal 1 (the developers of CHARTWatch and CHARTWatch Surgical) to "explore a clinical decision support system powered by artificial intelligence".[35] The initiative marks the first time a Canadian teaching community hospital has partnered with Signal 1 to inform clinical decisions using artificial intelligence. Signal 1 analyzes existing patient data and uses AI to predict patient care and identify potential patterns to inform future care decisions. See Table 2 below for a list of current healthcare AI applications in Canada.

Table 2 – Healthcare AI Applications in Canada

Application Name	Institution	Function

[32] "AI-Powered Tool on St. Michael's Surgical Unit to Improve Patient Care," Unity Health Toronto, February 7, 2023, https://unityhealth.to/2023/02/chartwatch-surgical/.
[33] Winsa, "How Artificial Intelligence Is Helping Toronto Hospitals Predict Patient Outcomes and Save Lives."
[34] Winsa.
[35] "Grand River Hospital to Partner with Signal 1 to Enhance Patient Care and Clinician Expertise Using Artificial Intelligence Technology | Grand River Hospital."

Grand River Hospital and Signal 1	Grand River Hospital	Explores a clinical decision support system powered by artificial intelligence to support clinician judgment by predicting changes in patient needs and conditions.
St. Michaels Hospital - Unity Health Toronto and Signal 1	St. Michaels Hospital	Builds on and commercializes AI systems already in use to reduce mortality among high-risk patients and improve patient care.
CHARTWatch Surgical by Signal 1	Unity Health Toronto	Predicts the level of support a patient will need by using data on the hospital's existing electronic medical record.
CHARTWatch	St. Michaels Hospital	Runs an ML algorithm that predicts the risk of the patient going to the intensive care unit or dying within the next 48 hours.
MuScRAT	St. Michaels Hospital	Synthesizes a patient's years-long medical record in seconds.
ED Volume Forecasting Tool	St. Michaels Hospital	Helps determine necessary staffing levels in the emergency department using historical data.

COBRA	St. Michaels Hospital	A three-day advanced warning system that predicts a bed shortage due to patient demand.
Scheduling Tool	St. Michaels Hospital	Produces an optimized schedule for nurses in the emergency department, using staffing rules.

Table 3. A Summary of AI Applications in Canadian Healthcare Systems[36]

Benefits of Healthcare AI Applications

Utilizing AI-powered tools for healthcare applications can be beneficial in several ways. One large potential benefit of using AI-powered tools is the ability to streamline healthcare services and improve the overall quality of medical care. As the team at Unity Health has illustrated, deploying AI tools for scheduling, and predicting hospital demands can be very effective for improving overall care quality. Additionally, using AI tools to monitor patient data and implement unique care plans can in theory increase the amount of time that nurses and physicians can spend with patients. Such tools have the potential to be particularly useful in groups that have comorbidities and require diverse treatment plans, such as the elderly.

Challenges of Healthcare AI Applications

Despite the potential benefits of AI for improving healthcare, it poses several challenges and raises issues of ethical concern. Namely, the ethical challenges of privacy, transparency, explainability, bias, fairness, and exclusion. Privacy, transparency and explainability are ethical

[36] "Grand River Hospital to Partner with Signal 1 to Enhance Patient Care and Clinician Expertise Using Artificial Intelligence Technology | Grand River Hospital"; Winsa, "How Artificial Intelligence Is Helping Toronto Hospitals Predict Patient Outcomes and Save Lives."

concerns that are raised by most AI applications. Due to the nature of medical AI tools and their demand for vast amounts of data, there are concerns regarding the nature of the data used, how it is acquired, whether informed consent was obtained, and what information it reveals about the individuals it is taken from.[37] Further, there is a hesitancy toward the acceptance of AI tools resulting from their lack of transparency and explainability. There is an ethical dilemma existing between the demand for transparency and explainability of AI tools, and the protection of sensitive data and the relevant issues of data ownership.[38] Making AI transparent and explainable requires that sensitive information regarding the processes undertaken by AI tools be shared with the public, making these tools vulnerable to malicious actors (i.e., hacking into medical systems, stealing sensitive patient information, etc.).

Furthermore, bias is of additional concern for medical AI tools, as the data used to develop and train these tools may perpetuate existing societal biases regarding race, age, sex and gender that can result in missed and incorrect diagnoses for the affected groups.[39] Fairness and exclusion are accompanying concerns to bias, as the presence of biased data may in turn lead to certain groups being excluded from reaping the potential benefits of medical AI tools as well as facing an unfair distribution of harms as a result. In addition to the ethical concerns presented, there are specific concerns that pertain to AI applications for discrete populations, such as the elderly.

[37] Humerick, Matthew, "Taking AI Personally: How the E.U. Must Learn to Balance the Interests of Personal Data Privacy & Artificial Intelligence," *Santa Clara High Technology Law Journal* 34, no. 4 (May 3, 2018): 393–418.
[38] Lorenzo Cobianchi et al., "Artificial Intelligence and Surgery: Ethical Dilemmas and Open Issues," *Journal of the American College of Surgeons* 235, no. 2 (August 2022): 268, https://doi.org/10.1097/XCS.0000000000000242.
[39] Natalia Norori et al., "Addressing Bias in Big Data and AI for Health Care: A Call for Open Science," *Patterns* 2, no. 10 (October 8, 2021): 100347, https://doi.org/10.1016/j.patter.2021.100347.

Challenges Posed by Healthcare AI Applications for the Elderly

By 2050, the global population of adults over 60 will double to 2.1 billion.[40] Older adults will comprise nearly one-quarter of the global population, and as such, it is necessary to ensure that AI tools are safe and effective for use in this population.[41] A significant characteristic of the elderly is the many ways in which they are vulnerable. The first way in which they are vulnerable is due to the natural processes of ageing, and the subsequent increase in the presence of cognitive and physical ailments in ageing populations. Studies have suggested that as much as 62% of adults over the age of 60 have multimorbidity, where multimorbidity is defined as the presence of two or more chronic conditions (e.g., heart disease, hypertension, diabetes, etc.).[42] In addition to physical illnesses, there is the additional presence of cognitive decline in many older adults. While the incidence of Alzheimer's disease is approximately 1 in 9 (10.7%) individuals over the age of 60, It has been reported that over 40% of older adults present with some form of cognitive impairment.[43] The increased presence of physical illness and cognitive impairment in elderly populations has created a subsequent desire to protect older adults as a vulnerable population, however, in an effort to protect this vulnerable group, there has been an exclusion of older adults from participation in research – particularly so in clinical trials – increasing ageist stereotyping and biases.

[40] "Ageing and Health," accessed March 23, 2023, https://www.who.int/news-room/fact-sheets/detail/ageing-and-health.
[41] "Ageing and Health."
[42] Marcel E. Salive, "Multimorbidity in Older Adults," *Epidemiologic Reviews* 35 (2013): 75–83, https://doi.org/10.1093/epirev/mxs009.
[43] "Alzheimer's Disease Facts and Figures," Alzheimer's Disease and Dementia, accessed May 29, 2023, https://www.alz.org/alzheimers-dementia/facts-figures; Robabeh Soleimani et al., "An Investigation into the Prevalence of Cognitive Impairment and the Performance of Older Adults in Guilan Province," *Journal of Medicine and Life* 11, no. 3 (2018): 247–53, https://doi.org/10.25122/jml-2018-0017.

The exclusion of older adults from participation in clinical trials presents challenges for the development of medical AI tools in several ways. Interventions such as automated radiology interventions for the detection of diseases and algorithmic-based interventions must be put through testing in the form of Randomized Control Trials (RCTs) before adoption in clinical settings.[44] Despite the importance of clinical trials for ensuring the safety and efficacy of novel medical interventions, elderly individuals remain underrepresented in said trials. Traditionally, most participants enrolled in clinical trial research are adults under the age of 65, with participant enrolment in RCTs reflecting a consistent underrepresentation of minority demographics.[45] Again, the exclusion of older adults in the assessment of medical-AI interventions prevents the safe and effective deployment of these tools in elderly populations.

The presence of ageist stereotyping, and biases presents additional challenges in the development of medical AI tools. In addition to the use of clinical trial results as sources of AI training and development data, there is the use of Electronic Health Records (EHRs) as an additional data source. As with clinical trial data, EHRs suffer from their own limitations. As much as 80% of physician-authored medical records contain recycled verbiage from the medical reports of previous patients.[46] There is a tendency to group elderly patients and engage in biased language when reporting on their conditions in EHRs.[47] The concerns of elderly patients are often dismissed as being a result of old age,[48] and in female patients, doctors often dismiss them as

[44] Deborah Plana et al., "Randomized Clinical Trials of Machine Learning Interventions in Health Care: A Systematic Review," *JAMA Network Open* 5, no. 9 (September 29, 2022): e2233946, https://doi.org/10.1001/jamanetworkopen.2022.33946.
[45] Plana et al.
[46] Eric J. Topol, *Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again*, First edition (New York: Basic Books, 2019).
[47] Jenny Park et al., "Physician Use of Stigmatizing Language in Patient Medical Records," *JAMA Network Open* 4, no. 7 (July 14, 2021): e2117052, https://doi.org/10.1001/jamanetworkopen.2021.17052; Michael Sun et al., "Negative Patient Descriptors: Documenting Racial Bias In The Electronic Health Record," *Health Affairs* 41, no. 2 (February 2022): 203–11, https://doi.org/10.1377/hlthaff.2021.01423.
[48] Donald Calne, "Parkinsonism and Ageing," 1989.

anxious or chronic complainers, resulting in delayed and missed diagnoses.[49] Taken together, EHRs as sources of data risk creating biased, inaccurate AI-powered healthcare tools that perpetuate longstanding societal stereotypes.

The numerous ways in which elderly populations are vulnerable present several challenges in the development of medical AI tools that are safe and effective for use in this population. The efforts to protect the elderly as a collective, vulnerable population have resulted in the perpetuation of ageist biases and stereotyping, that are reflected in EHRs and the exclusion of older adults from participation in clinical trials. To ensure that AI-powered healthcare tools are safe and effective for elderly populations, it is necessary to consider the aforementioned challenges in further detail. Chapter Two considers the routine exclusion of the elderly from participation in clinical trials due to efforts to protect vulnerable populations from research-induced harm. However, I will argue that vulnerability is contextual, and exclusion from participation in research must be empirically justified. Chapter Three considers how AI tools carry the risk of perpetuating healthcare disparities for the elderly when developed with EHR data that reflects the age-related biases found in healthcare settings. These biases impact diagnosis and treatment for elderly patients, creating unequal power dynamics between patients and care providers, leading to testimonial injustice and the perpetuation of inequitable access to healthcare. Chapter Four considers the potential for self-reporting tools to mitigate the challenges with quality and representation in AI training data. However, I will argue that self-reporting tools possess their unique limitations. Most notably, accessibility challenges for elderly individuals who are physically and cognitively impaired. Finally, there will be a discussion of proposed

[49] Rachel Thomas, "Medicine's Machine Learning Problem," *Boston Review*, 2021.

solutions to addressing these problems (i.e., trial sponsor accountability, storytelling, etc.) and their subsequent benefits and limitations.

Chapter 2 – Considering Elderly Exclusion in Clinical Trials and its Impact on Healthcare Algorithm Development

In recent years, the development of medical AI applications has experienced significant growth. In 2022 alone, the U.S. Food and Drug Administration (FDA) approved 91 AI/ML-enabled devices, accounting for approximately 17% of all FDA-approved AI/ML-enabled devices.[50] These tools are widely recognized for their many potential benefits, including their speed and efficiency in diagnosing illnesses, triaging patients, and providing medication dosing recommendations.[51] However, despite the potential for medical AI applications to improve health outcomes for elderly populations and provide an overall improvement to elderly care, the elderly are often excluded from developments in health algorithms involved in disease diagnostics and treatments. This exclusion is particularly concerning given the increasing global elderly population. In October 2022, the World Health Organization (WHO) reported that by the year 2050, the global population of people aged 60 and older will double to a total of 2.1 billion people.[52] While the elderly population is growing at a significant rate, little effort has been made to improve elderly representation in the development of AI tools and to ensure the safety and efficacy of such tools for use in elderly populations. One way in which this exclusion is occurring is through the omission of elderly individuals from clinical trials, which are an important aspect of the development of health algorithms. The critical role of clinical trials in medical AI development is twofold: (1) clinical trial data is used in the development and training

[50] Geeta Joshi et al., "FDA Approved Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices: An Updated 2022 Landscape," preprint (Health Informatics, December 12, 2022), https://doi.org/10.1101/2022.12.07.22283216.
[51] Thomas Davenport and Ravi Kalakota, "The Potential for Artificial Intelligence in Healthcare," *Future Healthcare Journal* 6, no. 2 (June 2019): 94–98, https://doi.org/10.7861/futurehosp.6-2-94.
[52] "Ageing and Health," accessed March 14, 2023, https://www.who.int/news-room/fact-sheets/detail/ageing-and-health.

of some medical AI tools, and (2) clinical trials test the safety and accuracy of medical AI tools before they are deployed in healthcare settings. Despite the important role of clinical trials in the translation pathway, many clinical trials continue to use poorly justified inclusion criteria to arbitrarily exclude elderly participants, as they often impose upper age limits or exclude individuals with comorbidities. While some have argued that this exclusion is necessary to ensure the safety of participants, particularly in populations deemed vulnerable as in the case of the elderly, I argue that the omission of elderly participants from clinical trials poses greater risks than those posed by their inclusion.

The Role of Clinical Trials in Medical AI Development

Medical AI tools often use data from multiple sources, depending on the task the tool is intended to perform. In the case of medical AI tools that detect the presence of illnesses, predict the likelihood of an individual developing an illness, or make treatment and medication recommendations, there is a need for numerous data points, each taken from different sources. Common sources of data include Electronic Medical Records (EMRs), wearable devices, clinical trials, publicly available datasets, and more.[53] The utilization of diverse restricted data sets gives rise to distinct ethical dilemmas in every instance of data application; however, one challenge remains consistent between all data sources – the risk of encoding bias as a result of imbalanced or inaccurate data.

The risk of encoding bias by using imbalanced training data is particularly relevant in the case of data taken from clinical trials. Currently, clinical trial data is not widely used to train medical AI tools as the data acquired through clinical trials cannot be easily shared outside of the

[53] "Ageism in Artificial Intelligence for Health," accessed March 11, 2023, https://www.who.int/publications-detail-redirect/9789240040793.

organization or domain it was conducted in.[54] Many clinical sites continue to use protocol binders, pen-and-paper data collection, and old software systems that present challenges with sharing trial data, even after obtaining consent from participants to allow the sharing of their data.[55] It is for these reasons that the use of clinical trial data has been limited, as this data can only be accessed within the organization sponsoring the trial unless the data has been included as part of a publicly available dataset.

While not all medical AI applications use clinical trial data for model training, there is evidence to suggest that trial data is being used for this purpose by AI developers. The two largest developers of medical AI tools – General Electric (GE) Healthcare and Siemens – have both sponsored clinical trials to gather data to develop and test their medical AI tools. In 2016, GE Healthcare sponsored a clinical trial that had the intended purpose of collecting clinical raw scan data using dual-energy CT (computed tomography).[56] They reported that the primary outcome measures for this study were the collection of raw CT scan data for future engineering and regulatory purposes.[57] Siemens conducted a similar study to compare the diagnostic accuracy of Siemens Image Processing (SIP) algorithms with Lorad's Image Processing Algorithm (LIP), declaring in the trial summary that the study was to help support new image processing software applications.[58]

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[54] Vivek Subbiah, "The Next Generation of Evidence-Based Medicine," *Nature Medicine* 29, no. 1 (January 2023): 49–58, https://doi.org/10.1038/s41591-022-02160-z.
[55] Subbiah.
[56] GE Healthcare, "Clinical Evaluation of a Dual Energy CT System," Clinical trial registration (clinicaltrials.gov, May 3, 2017), https://clinicaltrials.gov/ct2/show/study/NCT02731937.
[57] GE Healthcare.
[58] Siemens Medical Solutions USA - CSG, "A Multi-Center Feature Analysis Study to Compare the Diagnostic Accuracy of Siemens' Image Processing (SIP) Algorithms With Lorad's Image Processing (LIP) Algorithms in Detecting and Characterizing Breast Lesions," Clinical trial registration (clinicaltrials.gov, November 11, 2020), https://clinicaltrials.gov/ct2/show/study/NCT00756496.

In addition to clinical trial sponsors using clinical trial data to develop medical AI tools, independent researchers and AI developers working at other organizations have also been able to make use of data from clinical trials in the form of publicly available datasets. For example, a team from PathAI and the biopharmaceutical company Bristol Myers Squibb utilized a commercially available dataset containing samples from a melanoma clinical trial to develop a machine-learning model to detect CD8 positivity in lymphocytes.[59] In addition to this, numerous AI tools have been developed using an NIH Chest X-Ray dataset that was made publicly available containing more than 100,000 images from over 30,000 patients.[60]

The Limitations of Clinical Trial Data

Clinical trials are a useful source of information that helps to develop and test medical interventions before large-scale adoption. While they can be useful tools, clinical trials have historically suffered from a lack of representation of older adults and other vulnerable populations. In 2017, 46% of all cancer deaths were in patients aged 70 and over, yet only 25% of all cancer trials enrolled individuals over the age of 65.[61] Data from cancer clinical trials can then be shared with other researchers in data repositories that allow researchers to utilize this data and develop tools that will improve cancer treatments, care, and prevention.[62] While increased accessibility of data from clinical trials is important for developing effective tools, the

[59] Benjamin Glass et al., "821 Machine Learning Models Can Quantify CD8 Positivity in Lymphocytes in Melanoma Clinical Trial Samples," *Journal for Immuno Therapy of Cancer* 9, no. Suppl 2 (November 2021): A859–A859, https://doi.org/10.1136/jitc-2021-SITC2021.821.
[60] "NIH Clinical Center Provides One of the Largest Publicly Available Chest X-Ray Datasets to Scientific Community," National Institutes of Health (NIH), September 27, 2017, https://www.nih.gov/news-events/news-releases/nih-clinical-center-provides-one-largest-publicly-available-chest-x-ray-datasets-scientific-community.
[61] Ruth M. Parks, Holly M. Holmes, and Kwok-Leung Cheung, "Current Challenges Faced by Cancer Clinical Trials in Addressing the Problem of Under-Representation of Older Adults: A Narrative Review," *Oncology and Therapy* 9, no. 1 (June 1, 2021): 55–67, https://doi.org/10.1007/s40487-021-00140-w.
[62] Anu Maria Sebastian and David Peter, "Artificial Intelligence in Cancer Research: Trends, Challenges and Future Directions," *Life* 12, no. 12 (December 2022): 1991, https://doi.org/10.3390/life12121991.

lack of representation of older adults in these data sets may result in the development of tools that are not safe for use in elderly populations, or in any other population that is not well-represented in the data.

Additionally, the lack of elderly representation in clinical trials extends beyond just cancer trials. In the data collection trials conducted by GE Healthcare, a similar pattern was noticed. GE's clinical evaluation for the General Electric CT system enrolled a total of 49 participants with the intent to obtain clinical data to be used in product and technology development. [63] While the study aimed to enroll 150 participants, a total of 49 participants enrolled in the study and only one of them were over the age of 65. A search of the FDA's Clinical Trials database reveals many similar studies conducted by GE, Siemens, and others, however, despite the studies being complete, their results have not been posted. As a result, the demographic of the individuals enrolled in the trials remains unclear. This lack of transparency reflects an ongoing challenge with trial sponsors neglecting to share the results of their studies, in turn preventing doctors and patients from discovering the outcomes and limitations of novel treatments. Despite a 2007 law mandating that trial sponsors are required to disclose trial results, many trial sponsors continue to neglect their obligations.[64] This challenge is particularly relevant to ensuring the safety and efficacy of AI-powered health interventions. Many of these novel tools are being promoted as having capacities that exceed the quality of care being provided by traditional medical care, however, without access to trial results, these claims cannot be substantiated.[65]

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[63] "Clinical Evaluation for General Electric (GE) CT System - ClinicalTrials.Gov," accessed March 14, 2023, https://clinicaltrials.gov/ct2/show/NCT01909180.
[64] "FDA and NIH Let Clinical Trial Sponsors Keep Results Secret and Break the Law," accessed March 24, 2023, https://www.science.org/content/article/fda-and-nih-let-clinical-trial-sponsors-keep-results-secret-and-break-law.
[65] "AI Can Outperform Doctors. So Why Don't Patients Trust It?," accessed March 24, 2023, https://hbr.org/2019/10/ai-can-outperform-doctors-so-why-dont-patients-trust-it.

The Role of Clinical Trials in Medical AI Testing

Although randomized control trials (RCTs) are normally a pre-requisite for the clinical adoption of an intervention, the nature of many medical AI devices allows developers to bypass the important step of conducting RCTs.[66] Most AI tools are marketed as tools to assist with clinician decision-making and are to be used as tools as opposed to replacing clinician judgment. As a result, RCTs are often not required due to the perceived low overall risks imposed by the tools. While currently RCTs are not often required, there has been increased advocacy for conducting RCTs to assess all AI tools that will be deployed in medical settings.[67] The argument that most medical AI applications are designed to assist physicians and therefore pose low risks is misguided. While a tool may not be intended to replace clinician judgment, it does not mean that the risks imposed by the tool are low.

The most pertinent risk posed by bypassing clinical trials is the risk to patient safety. Physicians regularly use many tools to treat their patients, and the use of these tools has a scientific justification ensuring their safety and reliability. Consider the use of stethoscopes to listen to the hearts and lungs of patients. Physicians use this tool to listen to the patient's organs and gather information on their health. While this tool by no means replaces physicians, it must work to ensure doctors are making accurate judgments. We know that these tools work by transmitting vibrations through the mechanism and allowing the physician to hear an acoustic noise. In the case of AI-powered medical tools, we cannot know if they work without clinical trial testing. To neglect to test these tools before deploying them is to put the safety of patients into the hands of blind fate. The mechanisms by which medical algorithms handle data and

[66] Plana et al., "Randomized Clinical Trials of Machine Learning Interventions in Health Care."
[67] Thomas Y. T. Lam et al., "Randomized Controlled Trials of Artificial Intelligence in Clinical Practice: Systematic Review," *Journal of Medical Internet Research* 24, no. 8 (August 25, 2022): e37188, https://doi.org/10.2196/37188.

produce outputs cannot be explained by a simple mechanism, and as such, it is important to ensure their efficacy and reliability using clinical trials.

SPIRIT-AI and CONSORT-AI

In October 2019, CONSORT (Consolidated Standards of Reporting Trials) and SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) collaborated to form the CONSORT-AI and SPIRIT-AI Steering Group, issuing a joint statement on the need for reporting guidelines for clinical trials evaluating AI interventions.[68] The statement outlines the importance of optimal reporting for evaluating the clinical utility of algorithms and for informing evidence-based recommendations.[69] They note that most AI interventions are only being evaluated in the context of diagnostic accuracy, however, diagnostic accuracy alone does not translate to improved patient outcomes.[70] AI interventions present unique challenges not adequately addressed by existing CONSORT and SPIRIT guidelines, warranting the AI-specific extension initiated by the group.

The SPIRIT-AI checklist included an additional 15 items to be addressed by trial protocols for AI interventions.[71] The first item includes the requirement to indicate that the intervention involves AI/ML and to specify the type of model used in the title of the trial. Additionally, the title must also include the intended use of the intervention. Further, the checklist includes a requirement to explain the intended use of the intervention in the clinical context, including both its purpose and its intended users. The checklist also requires that in

[68] Xiaoxuan Liu et al., "Reporting Guidelines for Clinical Trial Reports for Interventions Involving Artificial Intelligence: The CONSORT-AI Extension," *Nature Medicine* 26, no. 9 (September 2020): 1364–74, https://doi.org/10.1038/s41591-020-1034-x.
[69] Liu et al.
[70] Liu et al.
[71] Samantha Cruz Rivera et al., "Guidelines for Clinical Trial Protocols for Interventions Involving Artificial Intelligence: The SPIRIT-AI Extension," *Nature Medicine* 26, no. 9 (September 2020): 1351–63, https://doi.org/10.1038/s41591-020-1037-7.

addition to declaring the inclusion/exclusion criteria of participants, there also be a stated inclusion/exclusion criteria at the level of input data.[72] The importance of this is that it requires AI developers to declare the type of data used to train their tools, in addition to identifying who the tools will be tested on. Additionally, the checklist also requires that there is a statement made regarding the procedure for assessing and handling poor quality and unavailable input data. The CONSORT-AI checklist added 14 items as well, all of which were the same as those included in the updated SPIRIT-AI checklist.

Despite efforts being made to standardize the testing of AI tools and ensure their safety, strict compliance with the proposed guidelines has been low. In 2021, Plana and colleagues conducted a systematic review of the literature to identify a total of 19,737 articles discussing AI interventions for healthcare.[73] Only 41 RCTs were identified, 16 of which were published in 2021. An analysis of the literature identified that no trials adhered to all CONSORT-AI standards, with a common reason for non-adherence resulting from not assessing poor quality and unavailable input data. 93% of trials did not assess poor quality data, 93% did not assess performance errors, and 90% did not include a statement on the availability of the algorithm.[74] A review of the literature also found only 11 of the 41 RCTs reported race and ethnicity, and in those that did, the median proportion of participants from minority groups was just 21%.[75] The findings of this literature review indicate that the risk of bias present in these interventions is high and that many AI developers are failing to address and correct these challenges before deploying their tools in their intended settings.

[72] Cruz Rivera et al.
[73] Plana et al., "Randomized Clinical Trials of Machine Learning Interventions in Health Care."
[74] Plana et al.
[75] Plana et al.

Ensuring the Safety of AI Tools with Clinical Trials

Although there is recognition of the importance of ensuring the safety of AI tools, guidelines for improving safety often fail to consider elderly populations. While RCTs are important for evaluating the safety of medical AI interventions, if the challenge of improving elderly inclusion in RCTs is not addressed, medical AI tools cannot safely be deployed in elderly populations. AI/ML tools are data-driven tools, and we cannot safely infer that a tool is safe for all if it has only been tested with a limited dataset. FDA, CONSORT-AI and SPIRIT-AI guidelines each encourage the importance of transparency and fair participant inclusion, however, there is no requirement to ensure an age-diverse population. Regulations often discuss the importance of including racial and ethnic minorities, however, outside the domain of cancer research, there is little advocacy for increasing the representation of older adults in clinical trials. With current measures being put into place to encourage RCT testing for all AI/ML interventions in healthcare settings, the current challenge of limited elderly inclusion in clinical trials must be addressed.

Improving the Representation of Older Adults in Clinical Trials

AI has much promise for improving the quality of care for elderly individuals, as it can handle multiple variables with greater ease and accuracy than a clinician or care provider can. The ability to handle multiple variables is especially relevant to elderly populations, as elderly individuals often have comorbidities.[76] Consider common practices for prescribing medications and suggesting interventions for patients with more than one illness. Current approaches involve providing a linear combination of therapies for each component disease.[77] Unfortunately, this

[76] Salive, "Multimorbidity in Older Adults."
[77] Cynthia M. Boyd and David M. Kent, "Evidence-Based Medicine and the Hard Problem of Multimorbidity," *Journal of General Internal Medicine* 29, no. 4 (April 2014): 552–53, https://doi.org/10.1007/s11606-013-2658-z.

approach is not always effective, and at times harmful, as current guidelines focus on singular diseases with specialized physicians for various groups of illnesses. Utilizing AI tools may help to address this challenge and improve care, resulting in improved health of patients and a reduced burden on medical systems. However, this can only be achieved if AI tools are trained and tested with data from diverse populations that reflect the demographic in which they will be deployed. Failure to do so may result in elderly populations being excluded from interventions that can at best, improve their health and quality of life, and at worst, expose them to significant harm.

Vulnerability and Participation in Research

The Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Health-related Research Involving Humans presents a series of guidelines on the fair selection of research subjects. In recognition of the effects of previous frameworks, the guidelines expressly advise against adopting traditional approaches of vulnerability wherein entire classes of individuals are deemed vulnerable by belonging to said class.[78] They argue that vulnerability is context-dependent and that empirical evidence is required to document the need for special protections.[79] Despite express international guidelines requiring empirical justification for research exclusion based on vulnerability, elderly persons remain underrepresented in clinical trials. As we have established, clinical trials can play a fundamental role in contributing to robust data sets used to develop medical AI tools, however, clinical trials suffer from a lack of elderly participation due to clinical trials maintaining exclusion criteria such

[78] Council for International Organizations of Medical Sciences (CIOMS), "International Ethical Guidelines for Health-Related Research Involving Humans" (Council for International Organizations of Medical Sciences (CIOMS), 2016), https://doi.org/10.56759/rgxl7405.
[79] Council for International Organizations of Medical Sciences (CIOMS).

as multimorbidity, upper age limits, and other factors that are put in place to protect the elderly as a vulnerable group. However, with the potentially vital role clinical trials will come to play in the development of safe and effective medical AI interventions, excluding elderly participants is unjust and poses great harm. Considering this, I argue that the risks associated with excluding elderly participants from clinical trials contribute to the increased susceptibility of elderly individuals to harm from medical AI developments, and it is, therefore, necessary to improve their representation in trials.

Reasons for Elderly Exclusion from Clinical Trials

The justifications for limiting elderly participation in trials often include the belief that (1) elderly populations are vulnerable and that there is a duty to protect vulnerable populations from harms in human subject's research, (2) that the burdens of research must be borne by those in the greatest position to bare them, and (3) that there are upper limits to risks that research subjects can be subjected to. Research with human subjects must aim to strike a balance between advancing research and producing generalizable knowledge, while also ensuring the protection of participants engaging in research.

The historical exploitation of vulnerable research subjects in the Willowbrook State School experiments and the Tuskegee syphilis studies resulted in the development of much-needed regulations for the ethical conduct of research with human subjects. In 1979, the United States National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research released the Belmont Report. The report provides guidelines and guiding ethical principles for conducting human subject research. The report is guided by the principles of

respect for persons, beneficence, and justice.[80] While the Belmont Report is often criticized for its conception of autonomy, and the implications of its emphasis on the protection of vulnerable populations, its guiding principles continue to be adopted by modern frameworks for ethical research with human subjects.[81] The Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) outlines similar principles guiding research with human subjects. Namely (1) respect for persons, (2) concern for welfare, and (3) justice.[82] Respect for persons requires that individuals be treated as autonomous agents and that those with diminished autonomy (through the result of illness, disability, or other considerations) be entitled to protection. Concern for welfare includes concerns for participants' mental and physical health, their economic and social circumstances, family life, employment and more. This principle requires that research conduct protect the various aspects of human welfare. Justice addresses concerns for the fair distribution of benefits and burdens of research. This principle requires that individuals be treated equitably, and with equal respect and concern.

While frameworks for ethical research conduct have been put in place to strike a fair balance between burdens and benefits while also protecting participants from undue harm, the principles they uphold produce competing obligations that have been used to justify excluding participants from valuable research. The principle of justice on its own has been interpreted in several ways. While the principle is intended to ensure fair subject selection, this can mean any number of things. Fair subject selection can include fair burden sharing, fair opportunity, fair

[80] Office for Human Research Protections (OHRP), "The Belmont Report," Text, HHS.gov, January 28, 2010, https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.
[81] Phoebe Friesen et al., "Rethinking the Belmont Report?," *The American Journal of Bioethics* 17, no. 7 (July 3, 2017): 15–21, https://doi.org/10.1080/15265161.2017.1329482.
[82] Interagency Advisory Panel on Research Ethics Government of Canada, "Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022)," January 11, 2023, https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html.

inclusion, and fair distribution of risks, and it is not possible to uphold each component at the same time[83]. Should the fair distribution of burden be prioritized over the enrolment of a diverse group of research participants? Does minimizing harm take precedence over producing generalizable knowledge? Many such questions arise in human subject research, and unfortunately, there is no single formula that can be used across studies to determine what principles are to take precedence. This results in many of these decisions being made by trial sponsors and Institutional Review Boards (IRBs), and often, these decisions involve the exclusion of participants deemed otherwise undesirable. For example, pregnant women are frequently excluded from research because of risk to the fetus, even if other conditions such as informed consent and the minimization of undue risks for harm are accounted for.[84] This is also the case in research with older adults. While most clinical trials have stopped including upper age limits for research conducted on adult populations, they continue to maintain exclusionary criteria that arbitrarily exclude elderly participants from participating in research. For example, many trials specifically include comorbidity as a reason for exclusions from clinical trial participation, however, as we have addressed, it is not uncommon for elderly individuals to have comorbidities. This results in the recruitment of populations that are in otherwise good health, and do not accurately reflect the populations in which the tested intervention will be deployed.[85]

While the ethical principles of beneficence, autonomy, and justice have been prioritized to protect research participants, the competing imperatives they generate have resulted in groups

[83] E.M. Smith et al., "Reviewing Fair Subject Selection Considerations for the Unique Case of Post Sequelae COVID-19 Translational Studies," *Journal of Clinical and Translational Science* 6, no. 1 (n.d.): e91, https://doi.org/10.1017/cts.2022.425.
[84] Rieke van der Graaf et al., "Fair Inclusion of Pregnant Women in Clinical Trials: An Integrated Scientific and Ethical Approach," *Trials* 19, no. 1 (January 29, 2018): 78, https://doi.org/10.1186/s13063-017-2402-9.
[85] Kaisu H Pitkala and Timo E Strandberg, "Clinical Trials in Older People," *Age and Ageing* 51, no. 5 (May 1, 2022): afab282, https://doi.org/10.1093/ageing/afab282.

being identified as susceptible to exploitation and harm being restricted from research participation, regardless of the magnitude of possible risks. While the intent has been to protect, the result has been to unduly exclude, and cause subsequent harm. In the U.S. Department of Health and Human Services regulations for the protection of human subjects, there is a focus on protecting vulnerable participants from research harm.[86] The concept of vulnerability defined in the guidance included minors, fetuses, prisoners and subjects likely to be vulnerable to coercion and undue influence (i.e., those with impaired decision-making, the elderly, the economically or educationally disadvantaged, racial and ethnic groups, those from rural areas, etc.).[87] This guidance has resulted in anyone who is not white, middle-aged, in good health, and from middle income or higher being excluded from clinical research. However, imposing such conditions with the intent to protect vulnerable participants has resulted in their underrepresentation in translational research, in turn leading to poorer health outcomes than those that are well-represented in clinical research.[88] When an entire population is labelled as disadvantaged or susceptible to harm, they are arbitrarily excluded from obtaining the benefits of research, resulting in tangible harm in the form of poor health outcomes. Thus, generalizing entire groups as vulnerable and excluding them from research does the reverse of what it intends to do – it perpetuates harm in vulnerable populations as opposed to preventing it.

Fair Subject Selection in Clinical Research

Due to the unintended consequences of protecting vulnerable groups against research-induced risks, there is a pressing need to accurately evaluate vulnerability, validate the rationale

[86] Smith et al., "Reviewing Fair Subject Selection Considerations for the Unique Case of Post Sequelae COVID-19 Translational Studies."
[87] Smith et al.
[88] Smith et al.

for exclusion, and guarantee equitable participant selection for historically marginalized groups. While not all medical AI tools utilize clinical trial data, several major AI developers have sponsored trials with the express intent of using their findings to build medical AI tools. Further, the increased pressure to conduct RCTs for all medical AI tools suggests that trials will play a vital role in the safe and effective development of medical AI tools. As these tools are becoming increasingly common in healthcare settings, we must ensure that they are safe and effective for all. It is therefore necessary that elderly representation in clinical trials be improved.[89]

MacKay and Saylor's 'Four Faces of Fair Subject Selection'

The principles and guidelines for ethical research conduct have resulted in competing imperatives, and this is especially prevalent in the case of fair subject selection. As the fair selection of subjects is best understood as a group of sub-principles – fair inclusion, fair burden sharing, fair opportunity, and fair distribution of risks – the task of fairly selecting subjects produces competing imperatives. MacKay and Saylor have proposed a method for resolving conflicts stemming from competing imperatives. They argue that fair inclusion should be prioritized over fair opportunity and burden sharing, except when enrolling a prospective participant who would face unacceptably high risks. Fair distribution of risks should be prioritized over fair inclusion, fair opportunity, and fair burden sharing, except when a prospective participant faces unacceptably high risks.[90] This produces the following decision procedure:[91]

[89] I recognize that the nature and design of clinical trials is not the only factor inhibiting elderly participation in trials. There is an additional component regarding willingness to participate, proximity to trial locations, willingness of caretakers to transport participants to and from trials, and other considerations. While these challenges are beyond the scope of this paper, they too require further exploration.

[90] Douglas MacKay and Katherine Witte Saylor, "Four Faces of Fair Subject Selection," *The American Journal of Bioethics* 20, no. 2 (2020): 5–19, https://doi.org/10.1080/15265161.2019.1701731.

[91] MacKay and Saylor.

1. Fair Inclusion: Design trial inclusion criteria to answer the scientific question in a way that fairly benefits members of society,
2. Fair Burden Sharing: Design exclusion criteria to exclude participants whose inclusion would produce unacceptably high risks,
3. Fair Distribution of Third-Party Risks: Design exclusion criteria to exclude participants whose inclusion would result in unacceptably high risks to third parties,
4. Fair Inclusion: Among potential participants meeting inclusion criteria and not meeting exclusion criteria, set goals for enrollment of potential participants to ensure research fairly benefits members of society, and
5. Fair Burden Sharing and Fair Opportunity: Fairly extend the offer of participation to all prospective participants satisfying inclusion and exclusion criteria.

Fair-subject Selection and Risk-thresholds

MacKay and Saylor's procedure for addressing conflicts enables the selection of a diverse group of research subjects while at the same time ensuring the protection of subjects that may be at an unreasonably high risk of harm. While MacKay and Saylor do not specify a threshold for risk, the concept of permissible risk in human subject's research has been widely discussed. David Resnik argues that human subjects should not be exposed to greater than a 1% chance of serious harm, such as death, disability, and illness.[92] Others, like Eyal Nir, argue that there are no ethical upper limits to risk in research when all other conditions (i.e., informed consent, independent review, minimization of foreseeable risks, etc.) are met.[93] Both conceptions of

[92] David B. Resnik, "Limits on Risks for Healthy Volunteers in Biomedical Research," *Theoretical Medicine and Bioethics* 33, no. 2 (April 2012): 137–49, https://doi.org/10.1007/s11017-011-9201-1.
[93] Nir Eyal, "Is There an Ethical Upper Limit on Risks to Study Participants?," *Public Health Ethics* 13, no. 2 (July 1, 2020): 143–56, https://doi.org/10.1093/phe/phaa028.

acceptable risk to participants present challenges. On the one hand, Resnik's 1% limit suggests that risks can be quantified, however, this is not always feasible. On the other hand, Nir proposes virtually no limitations to risk, enabling the potential for research subjects to be used as mere means to an end (i.e., producing generalizable knowledge). The quantification of risk is often a difficult, arbitrary task, suggesting a need to focus on applying measures for the reduction of participant harm as opposed to attempting to quantify acceptable risk limits.

Similar to MacKay and Saylor, Ezekiel Emanuel has presented an ethical framework for biomedical research wherein he outlines seven ethical requirements for clinical research including value, scientific validity, fair subject selection, favourable risk-benefit ratio, independent review, informed consent, and respect for enrolled subjects.[94] This framework presents a less stringent limitation to risk, as it requires that several conditions are upheld while simultaneously advocating for a favourable risk-benefit ratio. In this account, benefits must outweigh risks, but trials must at the same time protect participants, obtain informed consent, undergo independent review, and be scientifically justified.[95] In upholding the other ethical requirements, the risks to participants will be minimized (e.g., protecting the well-being of participants will require preventing mental and physical harm).

Applying MacKay and Saylor's Framework to RCTs for Healthcare Algorithms

The methodology proposed by MacKay and Saylor can help to review the design of trials and verify if the inclusion criteria they propose are appropriately justified. When applying this

[94] Ezekiel J. Emanuel et al., *The Oxford Textbook of Clinical Research Ethics* (Cary, UNITED STATES: Oxford University Press, Incorporated, 2008), http://ebookcentral.proquest.com/lib/mcmu/detail.action?docID=665420; Ezekiel J. Emanuel, David Wendler, and Christine Grady, "What Makes Clinical Research Ethical?," *JAMA* 283, no. 20 (May 24, 2000): 2701–11, https://doi.org/10.1001/jama.283.20.2701.
[95] Emanuel et al., *The Oxford Textbook of Clinical Research Ethics*.

approach in the context of trials for the development of healthcare algorithms, we discover that many such trials arbitrarily exclude elderly participants.

A common type of trial conducted for gathering data for AI development involves computed tomography (CT) imaging studies. One such example is the GE CT system study referenced in earlier sections. Using MacKay and Saylor's methodology to assess the study, we discover that the trial was designed to arbitrarily exclude undesirable participants. At least two conditions of exclusion were not adequately justified – the exclusion of diabetic patients on metformin, even for the branch of the study that did not involve IV-contrast, and individuals with any conditions the principal investigator (PI) or designee determined would interfere with the evaluation or results of the trial.[96] Concerning the inclusion of diabetics on metformin, there is no in principal reason to exclude them from a trial on CT imaging if they are participating in the leg of the trial that does not involve IV contrast. It is estimated that 33% of people over 65 have diabetes,[97] and metformin is the most commonly prescribed medication for patients diagnosed with Type 2 diabetes. Excluding diabetics on metformin is eliminating the opportunity for many elderly individuals to participate in potentially beneficial research. The second condition to exclude those with any conditions the PI feels will interfere with the evaluation of the results or will pose harm to patients is equally detrimental to ensuring adequate elderly representation in the trial. This condition gives the PI the ability to exclude any individual with comorbidity that may pose a challenge to the trial sponsor and the results of the study. Trials should not impose broad, unjustified exclusions and limit trial participation without legitimate cause for doing so. As MacKay and Saylor argue, exclusion criteria should be designed to protect participants from

[96] GE Healthcare, "Clinical Evaluation of a Dual Energy CT System."
[97] "Diabetes and Older Adults," January 24, 2022, https://www.endocrine.org/patient-engagement/endocrine-library/diabetes-and-older-adults.

unreasonably high risks of harm and should not be used as a means of arbitrarily excluding any participant deemed non-ideal. Many older adults over the age of 65 are what PIs might deem to be non-deal participants. One study reported that 67% of seniors over 65 have multimorbidity and suffer from multiple – yet often manageable – illnesses such as hypertension, diabetes, and osteoporosis. There are degrees of severity with all illnesses, and simply having diabetes, hypertension or some other illness is not a reason to determine that an individual is at high risk of research harm. It is therefore necessary to make assessments on a case-by-case basis and determine what competing imperatives are most pervasive for a particular case and to act accordingly.

Conclusion

The rapid growth of the medical AI industry has produced significant improvements in the ability to detect, treat, and diagnose illnesses. The ability of these tools to handle vast amounts of data and numerous variables with ease makes them especially useful for improving the care of older adults who frequently have co-occurring illnesses. Despite their promise, these tools are only as effective as the data that is used to train them. Clinical trials play an important role in ensuring the efficacy of medical AI tools, as clinical trial data are both used to train certain models and to test tools against current standards of care. Unfortunately, older adults have been historically underrepresented in clinical trials, despite there being no in-principal reason for this exclusion. The guiding ethical principles of autonomy, beneficence, and justice have produced competing ethical imperatives that have in turn excluded any group that may be deemed vulnerable from participating in research to prevent them from harm and undue burdens. Unfortunately, this practice has resulted in harm to individuals belonging to these populations and has resulted in preventing vulnerable populations like the elderly from obtaining the benefits

of clinical research. MacKay and Saylor have developed a methodology for ensuring fair subject selection and reconciling the importance of protecting potential subjects that are susceptible to harm from research engagement while also ensuring they do not experience longstanding harm from a lack of participation. It is important to ensure no individual is arbitrarily excluded from participating in research, and this can be achieved by ensuring adequate inclusion/exclusion criteria that are well-justified. Maintaining the practice of fair subject selection is crucial for ensuring the improved representation of older adults in the trial data used in the development and testing of medical AI tools. In so doing, advancements in medical technologies will contribute to effectively improving elderly care and overall health outcomes.

Chapter 3 – Bias in Physician-Authored Reports and Epistemic Injustice in Healthcare

Background

One area in which AI tools have proven to be valuable in healthcare applications is through the use of Natural Language Processing (NLP) to assist with transcribing electronic health records (EHRs) and converting the contents of these reports into real-world data (RWD) at a very quick rate.[98] Despite their capabilities, the utilization of NLP tools amplifies the concern of potential harm when simplifying individuals' medical histories into data points, especially among vulnerable groups like the elderly. Much like various data sources, there exists a risk of inaccuracies, incompleteness, or biases in the data. As such, employing flawed data to build tools with direct implications on the health of individuals presents the added risk of exposing those whose experiences are not authentically captured in medical data to potential harm.

NLP Explained

NLP works by enabling a computer to understand the words and statements written in human language by teaching it the defined set of rules or symbols used to convey information in a given language.[99] NLP consists of two parts – natural language understanding (NLU) and natural language generation (NLG). Where the former involves understanding a text, the latter involves the generation of text that follows the specific rules of a given language. Some of the many tasks that NLP can perform include machine translation (the automatic translation of text

[98] Rachel Knevel and Katherine P. Liao, "From Real-World Electronic Health Record Data to Real-World Results Using Artificial Intelligence," *Annals of the Rheumatic Diseases* 82, no. 3 (March 2023): 306–11, https://doi.org/10.1136/ard-2022-222626; Diksha Khurana et al., "Natural Language Processing: State of the Art, Current Trends and Challenges," *Multimedia Tools and Applications* 82, no. 3 (January 1, 2023): 3713–44, https://doi.org/10.1007/s11042-022-13428-4.
[99] Khurana et al., "Natural Language Processing."

from one language to another) and named entity recognition (the extraction of information of recognized name entities and subsequent classification into classes) amongst many others.[100]

The many abilities of NLP to handle natural language at a large scale make it an effective tool for accurately abstracting data from EHRs.[101] EHRs are valuable sources of Real-World Data (RWD) as they can contain millions of data points for a single patient and provide a comprehensive overview of the progression of an individual's health over an extended period. Further, the large volume of data contained within EHRs makes them a useful tool in the development and training of other medical AI tools. The information contained within EHRs can be easily abstracted and categorized, providing comprehensive health data that can be used in the development and training of AI for the diagnosis of illnesses, clinician-assisted decision-making, and the design of clinical trials.[102]

Though the use of NLP tools for medical data extraction boasts many benefits (i.e., improved data extraction accuracy, cost savings, etc.), it is important to consider the content of EHRs, especially when the data they contain will be used to develop and train future medical AI tools. As noted, there is a particular risk of harm in reducing the medical history of individuals to mere data points when the data being used may be biased, flawed, or incomplete, particularly in vulnerable populations like the elderly. This risk is especially prevalent in elderly populations for three reasons – first, elderly persons are vulnerable when in receipt of medical care; second, physicians/clinicians have implicit biases regarding elderly patients that are reflected in the

[100] Khurana et al.
[101] Robert Y. Lee et al., "Assessment of Natural Language Processing of Electronic Health Records to Measure Goals-of-Care Discussions as a Clinical Trial Outcome," *JAMA Network Open* 6, no. 3 (March 2, 2023): e231204, https://doi.org/10.1001/jamanetworkopen.2023.1204.
[102] The data extracted from EHRs can be used for numerous applications that cannot all be named here. Some uses include tracking the trajectory of specific diseases, informing health insurance claims, forecasting hospital capacities, etc.

language physicians use to describe them and how their illnesses are treated; and third, the perceived cognitive and emotional unreliability of elderly patients as epistemic agents makes them vulnerable to testimonial injustice in healthcare settings.[103] As such, the presence of bias and epistemic injustice – wrongs done to individuals in their capacity as knowers – reflected in physician-authored reports used to train and develop AI tools poses significant ethical concerns and has detrimental effects on vulnerable elderly populations, perpetuating systemic inequalities and hindering equitable healthcare outcomes.

Vulnerability

Vulnerability is an overarching feature in healthcare settings. Arguably, the presence of illness or being in a position to receive medical care entails vulnerability. For Rogers, Mackenzie and Dodds, vulnerability describes "individuals, groups, or populations who suffer deprivation related to the social determinants of health," as well as "those who already have some form of ill health".[104] While Rogers and colleagues have developed an account of vulnerability that acknowledges that some sources of vulnerability are inherent (i.e., being ill), other accounts of vulnerability suggest that vulnerability is contextual. Most notably, Florencia Luna presents a contextual notion of vulnerability suggesting there are layers to vulnerability that are present in specific contexts. Luna and Vanderpoel argue that when we label an entire population as vulnerable we include individuals in this umbrella of vulnerability that are not vulnerable, and at the same time, exclude those that are vulnerable but do not fit into our classification of

[103] Havi Carel and Ian James Kidd, "Epistemic Injustice in Healthcare: A Philosophical Analysis," *Medicine, Health Care, and Philosophy* 17, no. 4 (November 2014): 529–40, https://doi.org/10.1007/s11019-014-9560-2.
[104] Wendy Rogers, Catriona Mackenzie, and Susan Dodds, "Why Bioethics Needs a Concept of Vulnerability," *International Journal of Feminist Approaches to Bioethics* 5, no. 2 (2012): 11–38, https://doi.org/10.2979/intjfemappbio.5.2.11.

vulnerability.[105] Thus, under Luna's account of vulnerability, it is necessary to assess the specific factors of a given situation and address the layers in which specific individuals may find themselves vulnerable.

Luna argues that using the label metaphor of classifying entire populations as vulnerable is "tantamount to using the vulnerability concept as a mere slogan, categorizing and stereotyping persons".[106] When classifying an entire population as vulnerable, one fails to consider what specific circumstances in a relevant case are contributing to vulnerability. In the case of ill patients, classifying every ill individual as vulnerable to worsening health and poor social and economic outcomes would be inaccurate. Individuals' experiences and circumstances contribute to mitigating and aggravating factors affecting degrees of vulnerability. For example, two patients with identical illnesses cannot be said to be equally vulnerable if one patient can afford high-quality treatments, and another cannot. Additional layers of vulnerability include one's support network, housing circumstances, whether their illness has caused them physical or mental decline, their ability to communicate, their domestic responsibilities, etc.

As Luna has illustrated, the generalization of entire populations as vulnerable has contributed to stereotyping and ignorance of variations between members of a group.[107] Unfortunately, in the case of elderly populations, this has contributed to ageism in healthcare with healthcare professionals disbelieving elderly experiences and dismissing elderly patients as

[105] Florencia Luna and Sheryl Vanderpoel, "Not the Usual Suspects: Addressing Layers of Vulnerability: Not the Usual Suspects: Addressing Layers of Vulnerability," *Bioethics* 27, no. 6 (July 2013): 325–32, https://doi.org/10.1111/bioe.12035.
[106] Florencia Luna, "Identifying and Evaluating Layers of Vulnerability – a Way Forward," *Developing World Bioethics* 19, no. 2 (June 2019): 86–95, https://doi.org/10.1111/dewb.12206.
[107] Florencia Luna, "'Vulnerability', an Interesting Concept for Public Health: The Case of Older Persons," *Public Health Ethics* 7, no. 2 (July 1, 2014): 180–94, https://doi.org/10.1093/phe/phu012.

complainers and attention-seekers.[108] This presents a dilemma – on the one hand, the classification of entire elderly populations as vulnerable has led to elderly patients being generalized and stereotyped, and on the other hand, this stereotyping has made elderly patients vulnerable in healthcare settings as they are frequently dismissed by healthcare providers. This challenge is exacerbated further when we consider subpopulations such as women, people of colour, and individuals of low socioeconomic status. In such contexts, there exists the presence of both inherent and contextual vulnerabilities that may amplify the degree to which an individual is vulnerable. While labelling the elderly as a vulnerable group has contributed to increased funding being allocated toward their unique needs (i.e., Alzheimer's research, funding to enable elderly independence, etc.), these effects do not outweigh the harms caused by ageism in healthcare.[109] Langmann takes this argument a step further to argue that "[l]abelling older adults as vulnerable [is] only helpful when it is used to raise awareness of the widespread ageism in society… especially in the setting of healthcare".[110]

Though Luna argues against labelling entire populations as vulnerable, there are cases in which a layered account yields similar results to that of a labelled approach. Applying Luna's layered account of vulnerability, most elderly patients receiving medical care, advice, or treatment are vulnerable in healthcare contexts. Luna acknowledges that a way in which elderly

[108] Aya Ben-Harush et al., "Ageism among Physicians, Nurses, and Social Workers: Findings from a Qualitative Study," *European Journal of Ageing* 14, no. 1 (June 28, 2016): 39–48, https://doi.org/10.1007/s10433-016-0389-9.
[109] "Alzheimer's Disease Facts and Figures," Alzheimer's Disease and Dementia, accessed May 29, 2023, https://www.alz.org/alzheimers-dementia/facts-figures; Employment and Social Development Canada, "Government of Canada Funds Three Projects in Alberta to Empower Seniors to Age in Their Homes," news releases, July 17, 2023, https://www.canada.ca/en/employment-social-development/news/2023/07/government-of-canada-funds-three-projects-in-alberta-to-empower-seniors-to-age-in-their-homes.html.
[110] Elisabeth Langmann, "Vulnerability, Ageism, and Health: Is It Helpful to Label Older Adults as a Vulnerable Group in Health Care?," *Medicine, Health Care and Philosophy* 26, no. 1 (March 1, 2023): 133–42, https://doi.org/10.1007/s11019-022-10129-5.

persons may be vulnerable is due to disability and sickness.[111] The presence of illness is a common feature of elderly populations. The National Council on Aging reports that nearly 95 percent of older adults have at least one chronic condition, with approximately 80 percent having two or more.[112] Another study of Medicaid beneficiaries found similar findings, reporting that 62 percent of individuals aged 65-74 had multimorbidity, while the same was true for 81.5 percent of people over the age of 85.[113]

In addition to illness, there are the added layers of cognitive vulnerability and decline in physical ability that are present for some elderly persons. Despite Alzheimer's disease affecting 10.7 percent of elderly persons, the Illness is often considered a disease of old age, contributing to the stereotyping and dismissal of elderly persons as cognitively inadequate.[114] Studies have found that invoking the ageist stereotypes of old age and subsequent cognitive decline in turn results in the impairment of older adults' memory performance.[115] Additionally, the progressive decline in physical ability with age contributes to many elderly persons' complaints being dismissed by their physicians. Reports of pain and decreased physical abilities often go unanswered, and physicians default to attributing the patients' symptoms to the result of the aging process.[116]

Further, there is an additional added layer of vulnerability in the form of emotional vulnerability. As has been demonstrated, elderly patients are often stereotyped and dismissed,

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[111] Luna, "'Vulnerability', an Interesting Concept for Public Health."
[112] "Get the Facts on Healthy Aging," @NCOAging, accessed May 29, 2023, https://ncoa.org/article/get-the-facts-on-healthy-aging.
[113] Salive, "Multimorbidity in Older Adults."
[114] "Alzheimer's Disease Facts and Figures."
[115] Kim Gauthier et al., "Ageing Stereotypes and Prodromal Alzheimer's Disease (AGING): Study Protocol for an Ongoing Randomised Clinical Study," *BMJ Open* 9, no. 10 (October 7, 2019): e032265, https://doi.org/10.1136/bmjopen-2019-032265.
[116] Calne, "Parkinsonism and Ageing."

and the same trend follows when we consider the emotional states of elderly patients. Despite Alzheimer's being the hallmark of age-related illnesses, behavioural health disorders affect far more elderly persons than Alzheimer's disease. One in four older adults suffers from anxiety, depression, or substance abuse.[117] In 2020, approximately 14,500 older adults over the age of 60 died by suicide in the United States.[118] In the US, studies found that older persons who are women, Hispanics, and Blacks, have low income, and live alone had higher rates of depression and anxiety than those who did not fall into these categories.[119]

Though labelling an entire population as vulnerable can contribute to perpetuating stereotypes, in the case of elderly persons receiving health care services, there is a baseline level at which elderly persons are vulnerable. In such settings, elderly persons are not vulnerable by virtue of their age but rather, by virtue of being receivers of care in a system that is plagued with age bias and stereotyping.

Bias in EHRs

Evidence has shown that elderly persons are frequently stereotyped in healthcare settings and that many healthcare providers contain implicit biases about elderly persons. The result of this is physician/clinician biases manifesting in patient health records in several ways. First, implicit physician biases manifest themselves in physician reports, and second, when patients receive inadequate care as a result of said biases, their true condition is not reflected in EHRs. When biased health records are then used in the development of medical AI tools, there exists an

[117] Wyatt Koma et al., "One in Four Older Adults Report Anxiety or Depression Amid the COVID-19 Pandemic," *KFF* (blog), October 9, 2020, https://www.kff.org/medicare/issue-brief/one-in-four-older-adults-report-anxiety-or-depression-amid-the-covid-19-pandemic/.
[118] "Alzheimer's Disease Facts and Figures."
[119] Koma et al., "One in Four Older Adults Report Anxiety or Depression Amid the COVID-19 Pandemic."

increased risk of reinforcing existing biases, producing inaccurate outputs, and ultimately increasing the risk of harm to elderly persons.

Though medical care is objective in its intent, in practice, it is influenced by the implicit biases of care providers. This is demonstrated by both the language used in EHR reports and the differences in care provided to individuals suffering from identical illnesses. A qualitative study on ageism among care providers uncovered a common theme of doctors, nurses, and social workers using discriminatory communication patterns when communicating with and speaking about older adults.[120] Many of the care providers described elderly persons as difficult, demanding, and thankless. Further, elderly patients were often excluded from communication and contributing to discussions on their medical care. The patients were often not asked questions about their medical conditions, or medical history, and were not told about their prognoses and treatment plans.[121]

Several studies have been conducted on the use of stigmatizing language in patient medical records, with the results illustrating that physicians use language that stereotypes patients based on their age, health literacy, credibility, race, and social class.[122] Physicians used words such as "Mr. [Patient] is charming", "I provided much deserved praise", and "He does not want to add medication, so I will increase the dose," when they had positive attitudes toward the patient.[123] However, when they acted on their implicit biases, they utilized language such as "Chief complaint – 'I stay tired'," "Reports that the bandage got "a li'l wet," and "Counseled that there

[120] Ben-Harush et al., "Ageism among Physicians, Nurses, and Social Workers."
[121] Ben-Harush et al.
[122] Park et al., "Physician Use of Stigmatizing Language in Patient Medical Records"; Sun et al., "Negative Patient Descriptors."
[123] Park et al., "Physician Use of Stigmatizing Language in Patient Medical Records."

is no evidence for this, but the patient has strong beliefs".[124] The first set of quotes illustrates approval, compliments, and collective decision-making, while the second displays disapproval, stereotyping, condescending language, and questioning patient credibility.

Implicit biases held by physicians and care providers extend beyond using negative descriptors in EHRs, they also affect how illnesses are treated in elderly patients. A systematic review of 149 studies investigating how ageism affects the health of older adults found that in 85 percent of the studies on healthcare access, physicians were less likely to offer treatments to older patients than to younger patients, even when they were equally likely to benefit from the treatment.[125] A separate study also found disparities in the treatment of lung cancer in older adults than in those who are young. Despite reports that postoperative recovery is not dependent on the age of the patient, the likelihood of older adults being referred for surgical treatment is much lower than in young patients.[126] The same trend is witnessed for the treatment of breast cancer and the diagnosis and treatment of mental health disorders like depression and anxiety.[127]

While it is apparent that physicians possess biases that are manifested in the language they use and the treatments they provide, it is important to consider why this is the case. The relationship between care provider and care receiver is one of disproportionate power imbalance that is further exacerbated when considering how elderly patients in positions of receiving care are vulnerable. When harmful language and patterns of subpar care are entrenched into EHRs that may be later used to develop AI tools that will assist with developing future treatments,

[124] Park et al.
[125] Becca R. Levy, "The Role of Structural Ageism in Age Beliefs and Health of Older Persons," *JAMA Network Open* 5, no. 2 (February 9, 2022): e2147802, https://doi.org/10.1001/jamanetworkopen.2021.47802.
[126] Ben-Harush et al., "Ageism among Physicians, Nurses, and Social Workers."
[127] Ben-Harush et al.; Koma et al., "One in Four Older Adults Report Anxiety or Depression Amid the COVID-19 Pandemic."

guidelines and practices, it creates the risk of further entrenching stereotypes and poor quality of care for the elderly.

Epistemic Privilege

In addition to the risks imposed by EHRs containing personal physician biases, there are additional challenges posed by the exclusion and marginalization of knowledge, experiences, and perspectives. In medical care settings, all patient testimonies are filtered through the lens of the care provider. Through this process, care providers acquire the role of determining the veracity of patient testimonies and ultimately deciding which testimonies to act upon.[128] This role places care providers in an epistemically privileged role, while simultaneously increasing the degree to which ill patients are vulnerable. The degree of patient vulnerability is further amplified when considering how elderly patients are deemed to be cognitively and emotionally unreliable epistemic agents, and how their testimonies are disbelieved and ignored as a result.[129]

In Miranda Fricker's seminal book *Epistemic Injustice: Power and the Ethics of Knowing*, she presents the concept of epistemic injustice and broadly defines it as a wrong that is done to an individual in their capacity as a knower.[130] Fricker outlines two such wrongs – testimonial injustice and hermeneutical injustice.[131] Hermeneutical injustice occurs when a speaker is unable to articulate their experiences due to a gap in resources and exclusionary participation in practices of knowledge exchange.[132] Testimonial injustice occurs when a hearer attributes a deficit of credibility to a speaker, owing to prejudice held by the hearer.[133] For Fricker, a

[128] Carel and Kidd, "Epistemic Injustice in Healthcare."
[129] Carel and Kidd; Ben-Harush et al., "Ageism among Physicians, Nurses, and Social Workers."
[130] Miranda Fricker, *Epistemic Injustice: Power and the Ethics of Knowing* (Clarendon Press, 2007).
[131] Fricker; Carel and Kidd, "Epistemic Injustice in Healthcare."
[132] Carel and Kidd, "Epistemic Injustice in Healthcare."
[133] Fricker, *Epistemic Injustice*.

prejudice is a judgment (positive or negative) that displays resistance to counterevidence, due in some part to the resistance of the subject.[134] This conception entails that for a judgment to be prejudicial, there must be an availability of evidence to the contrary that the subject is resistant to. In cases where there is a genuine lack of knowledge or some form of epistemic bad luck, there is no sense of epistemic culpability.

Though both forms of epistemic injustice are present in healthcare settings, testimonial injustice is particularly relevant to the experiences of elderly patients receiving care. Despite the role of patients as first-hand knowers, their testimonies are not deemed to be credible, and they struggle to prove their testimonies to care providers.[135] The way in which elderly patients are excluded from discussions of their medical care is evidence of this. Elderly patients report not being asked questions about their medical conditions, and when they do provide their testimonies to attest to their conditions, care providers exclaim that "They want attention," diminishing the veracity of their claims.[136] Despite evidence suggesting that most doctors do not have the training required to effectively work with family members in the care of patients, they consistently engage family members in the care of elderly patients while excluding the patients from participating in their care.[137] There are cases where care providers must work together with the families of elderly patients, particularly when the patient has been diagnosed with an illness that affects their cognitive abilities and where engaging exclusively with the patient would result in the inability to gather knowledge of the patient's condition. Notably, cases of this kind would

[134] Fricker.
[135] Kristin Margrethe Heggen and Henrik Berg, "Epistemic Injustice in the Age of Evidence-Based Practice: The Case of Fibromyalgia," *Humanities and Social Sciences Communications* 8, no. 1 (October 15, 2021): 1–6, https://doi.org/10.1057/s41599-021-00918-3.
[136] Ben-Harush et al., "Ageism among Physicians, Nurses, and Social Workers."
[137] Ben-Harush et al.

normally be reserved for interactions with patients who have been diagnosed with neurodegenerative disorders affecting memory and cognition (i.e., Alzheimer's, dementia, etc.). However, as we have addressed, such illnesses affect less than one-fifth of elderly patients, and it should not be common practice to exclude elderly patients from participating in their care.

As has been discussed, while most elderly persons have a baseline level of vulnerability in medical care settings, there are additional layers of vulnerability that may increase the likelihood of certain elderly patients being susceptible to testimonial injustice – particularly women and racial minorities – indicating a risk of compound harms for the elderly. Numerous studies have illustrated the differential medical treatment of women and racial minorities. Studies have shown that women and people of colour receive less pain medication, delayed treatment, and lower quality of care than other patients.[138] It is reported that Black patients are 22 percent less likely to receive pain medication than Whites, and 29 percent less likely to be treated with opioids.[139] One reason for this is a result of the prejudicial beliefs of care providers that in turn result in the diminished testimonies of Black patients. This is evidenced by the language used to describe Black patients, including words such as difficult, combative, non-compliant, defensive, hysterical, and exaggerated.[140] Additionally, Black patients have 2.54 times the odds of having at least one negative descriptor in their medical history and notes compared to White patients.[141] The content of physicians' notes reflects a belief in the decreased credibility of Black patient testimonies that is reflected in the ways their pain is treated, the length of time it takes for them to receive diagnoses, and their overall experiences in healthcare settings.

[138] Thomas, "Medicine's Machine Learning Problem."
[139] Thomas.
[140] Sun et al., "Negative Patient Descriptors."
[141] Sun et al.

The experiences of women in medical care settings are equally troublesome. Women are often denied pain medication, at times having their pain attributed to psychological conditions they have not reported having the symptoms for.[142] The prejudicial stereotype of labelling elderly patients as cognitively and emotionally unreliable is magnified in the case of female patients. Elyn Saks recounts her experience as a psychiatric patient with a physical disorder.[143] Saks had symptoms such as a bad headache, impaired vision, weakness, numbness, and confusion. Her symptoms resulted in her taking a trip to the ER, at which point she was administered further testing. That is until her medical records revealed a history of psychiatric illness. It was at that point that no further testing was administered, and despite Saks pleading with doctors that her symptoms were not the result of a psychiatric episode, she was discharged from the ER. It was later discovered that she was not having a psychiatric episode, she had a brain hemorrhage.

Unfortunately, Elyn Saks' experience is not unique. Many women report having their credibility questioned and their testimonies disbelieved by care providers. Computer scientist and data ethicist Rachel Thomas reports a similar experience in her article *Medicine's Machine Learning Problem*. Like Saks, Thomas went to the ER with excruciating pain only to be discharged and told there was no medical problem to treat. After visiting another ER, she was admitted to the ICU and had brain surgery days later. Many more cases of the credibility of women being called into question exist, and this is illustrated by the discrepancies in diagnosis times between women and men. On average, it takes twelve months for men to be diagnosed with Crohn's disease and twenty months for women. The diagnosis of Ehlers-Danlos represents an even greater discrepancy, with men being diagnosed in four years, and diagnoses for women

[142] Thomas, "Medicine's Machine Learning Problem."
[143] Carel and Kidd, "Epistemic Injustice in Healthcare."

taking an average of sixteen years.[144] When we consider female-predominant illnesses such as multiple sclerosis and fibromyalgia, the gap continues to widen, with patients frequently being disbelieved and labelled as chronic complainers in the early stages of their illnesses.[145] This challenge is compounded further when considering elderly women. Illnesses such as heart disease and other cardiovascular disorders are frequently missed in elderly female patients due to the nature of their presentation. A study conducted in 2021 found that 85% of the women studied had atypical presentations for myocardial infarction, reporting symptoms such as dizziness, back pain and vomiting.[146] Despite the incidence of cardiovascular illnesses being 1% higher in women over 60 than in men (78.2% of women and 77.2% of men), the signs of cardiovascular diseases in women are often missed.[147] Hence, the existence of epistemic injustice poses harmful impacts on elderly communities, further entrenching systemic disparities and impeding the acquisition of fair healthcare outcomes.

Effects of Bias and Epistemic Injustice on the Development of Medical AI Tools

Most work in AI development has been through the use of highly organized, structured data containing labels and annotations that are then used to train AI tools through supervised learning by establishing "ground truths" to aid in training.[148] However, this is not the case for most medical AI tools. AI tools require vast amounts of data to be able to learn and make accurate predictions, requiring millions of data points – many of which are unstructured.[149] The use of

[144] Thomas, "Medicine's Machine Learning Problem."
[145] Thomas; Heggen and Berg, "Epistemic Injustice in the Age of Evidence-Based Practice."
[146] Neethu Maria Joseph, Lakshmi Ramamoorthy, and Santhosh Satheesh, "Atypical Manifestations of Women Presenting with Myocardial Infarction at Tertiary Health Care Center: An Analytical Study," *Journal of Mid-Life Health* 12, no. 3 (2021): 219–24, https://doi.org/10.4103/jmh.JMH_20_20.
[147] Jennifer L. Rodgers et al., "Cardiovascular Risks Associated with Gender and Aging," *Journal of Cardiovascular Development and Disease* 6, no. 2 (April 27, 2019): 19, https://doi.org/10.3390/jcdd6020019.
[148] Topol, *Deep Medicine*.
[149] Topol.

EHRs as sources of training data presents unique challenges in that the data contained within the reports are in the form of unstructured free text.[150] It is not always possible to "clean" such sources of data, and as a result, it becomes difficult to develop ground truths from which the AI can be trained. Further, the complexity of the data makes it difficult to assess in which ways the content of the EHRs is reflected in the outputs of the AI. Therefore, the data used to train medical AI tools must be accurate, unbiased, and complete.

Systemic Inequality and Healthcare Inequity

The effects of ageist and other prejudicial beliefs pose a challenge to developing safe and accurate AI tools that do not perpetuate further systemic inequalities and healthcare inequities. As we have noted, age-related biases are reflected in EHRs through the language used to report on the condition of elderly patients receiving medical care, reinforcing prejudices that are then reflected in the credibility awarded to the testimonies of elderly patients and the subsequent care that they receive. When healthcare providers disbelieve the testimonies of elderly patients, the result is the exclusion of valuable first-person perspectives, and this is reflected in the content of EHRs. Care providers may fail to accurately document the reported symptoms and concerns of patients, leading to an inaccurate and incomplete medical history being reflected in EHRs. If the content of these reports is then used in the development of medical AI tools, the outputs it will produce may be inaccurate.

Lack of Diversity

Further, when the testimonies of elderly patients are dismissed, the result is a pool of data that lacks diversity and is an inaccurate representation of the pool of patients the tool will likely be deployed in. If a medical AI tool is developed to detect the presence of an illness in patients of

[150] Topol.

all ages, ethnicities, sexes, etc., it must be trained with sufficient data representing the diverse demographic of people it will be utilized for. Failure to include sufficient data can lead to biased models that exhibit poor performance when used on elderly patients.

Healthcare Disparities

Finally, there is the pressing challenge of increasing healthcare disparities for elderly patients. When physicians exercise ageist biases and the testimonies of elderly patients are silenced, elderly patients may suffer from missed or delayed diagnoses, delays in treatment, and subpar standards of care. The risks of healthcare disparities increase when we consider how additional layers of vulnerability may contribute to the silencing of elderly persons not only based on their age but as a result of their sex and race as well. When AI tools are developed using data that is flawed, biased, and incomplete it risks reinforcing existing disparities and preventing vulnerable populations from receiving the same quality of care as those whose experiences are adequately reflected in AI training data.

Conclusion

The use of artificial intelligence to aid in improving the diagnosis, treatment and management of illnesses presents many promises for improving the quality of care patients receive. While these tools boast many benefits, they present a risk of reinforcing pre-existing systemic inequalities and inequitable healthcare practices if developed with incomplete or inaccurate data. These risks are most pertinent in elderly populations, as the medical care of elderly patients is plagued with the presence of age-related biases that impact how physicians communicate with, diagnose, and treat elderly patients. The age bias present in medical care enforces a power imbalance between care providers and elderly patients, making elderly patients vulnerable to testimonial injustice. The combined effects of these practices are the production of

patient EHRs that do not reflect the true medical history of patients, and the silencing of lived patient experiences. When such reports are used in the development of medical AI tools, they continue to reinforce age-related prejudices and continue to hinder equitable access to quality healthcare for all.

Chapter 4 – Limitations of Self-Reporting Tools in the Development of AI-Powered Healthcare Solutions

Developments in medical artificial intelligence (AI) contain great potential for transforming healthcare delivery, disease diagnosis, and overall patient outcomes. However, when considering the development of medical AI tools in the context of elderly populations, it becomes evident that there are fundamental limitations in the quality, accuracy, and completeness of data on elderly persons. As has been discussed in earlier chapters, data from elderly populations is frequently limited both in scope and breadth and is additionally plagued with ageist biases. In response to these limitations, the use of self-reporting tools has been proposed as a means of improving the representation of all individual experiences that would not otherwise be captured by traditional methods (i.e., clinical notes, EHRs, medical imaging, etc.).[151] Despite the promises of self-reporting, self-reporting measures contain significant limitations. First, there are concerns regarding the quality of the data acquired from first-person reporting tools, as first-person data is inherently biased. Second, the nature of self-reporting tools makes them inaccessible to individuals who have limited cognitive and/or physical abilities, as many self-reporting tools require the use of smartphone devices and require participants to engage in several steps to document their accounts. This chapter will explore these challenges and their implications for the development of medical AI tools in the context of elderly populations. Further, we will utilize Amartya Sen's capabilities approach to illustrate the challenges of converting access to capability for this vulnerable demographic, highlighting the importance of addressing these limitations to ensure equitable and inclusive healthcare developments.

[151] Youmin Cho et al., "Acceptance and Use of Home-Based Electronic Symptom Self-Reporting Systems in Patients With Cancer: Systematic Review," *Journal of Medical Internet Research* 23, no. 3 (March 12, 2021): e24638, https://doi.org/10.2196/24638.

Self-Reporting Tools and Cognitive Bias

There is a growing recognition of the importance of acquiring information on patients' views of their illness, as a means of providing a complete picture of a patient's condition and subsequently producing an improvement in symptoms and prognosis for ill patients. [152]The inclusion of first-person data is particularly promising for the development of medical AI tools, as data sources commonly used in AI development (i.e., EHRs, clinical notes, etc.) have exhibited ageist bias and neglect of elderly experiences. If the experiences of groups are not adequately reflected in the data used to train medical AI tools, the tools will produce inaccurate, and potentially harmful results for populations belonging to under-sampled groups. As such, it is necessary to supplement such gaps in data, with one approach to achieving this being the inclusion of first-person data. Though several studies have assessed the efficacy of self-reporting tools, patient attitudes toward such tools, and their role in improving patient outcomes, few have assessed how cognitive biases may contribute to the decreased validity of the information acquired through such reports.[153] While first-person accounts may present a view of the patient's beliefs on their conditions, this view may contain several cognitive biases impacting the accuracy of the account and subsequently impacting the accuracy of future medical AI tools based on the information contained within them.

[152] Stephen P. McKenna, "Measuring Patient-Reported Outcomes: Moving beyond Misplaced Common Sense to Hard Science," *BMC Medicine* 9, no. 1 (July 14, 2011): 86, https://doi.org/10.1186/1741-7015-9-86; Cho et al., "Acceptance and Use of Home-Based Electronic Symptom Self-Reporting Systems in Patients With Cancer."
[153] Cho et al., "Acceptance and Use of Home-Based Electronic Symptom Self-Reporting Systems in Patients With Cancer"; Elin Børøsund et al., "How User Characteristics Affect Use Patterns in Web-Based Illness Management Support for Patients with Breast and Prostate Cancer," *Journal of Medical Internet Research* 15, no. 3 (March 1, 2013): e2285, https://doi.org/10.2196/jmir.2285; Mette Terp Høybye et al., "Social and Psychological Determinants of Participation in Internet-Based Cancer Support Groups," *Supportive Care in Cancer* 18, no. 5 (May 1, 2010): 553–60, https://doi.org/10.1007/s00520-009-0683-6.

Hammond et. al. define cognitive biases as "systematic errors in human thinking due to human processing limitations or inappropriate mental models."[154] Cognitive biases frequently occur when the individual relies on intuitive, quick thinking in place of analytic thinking. As such, cognitive bias arises when the thinker fails to utilize logic, and sound reasoning when making a particular judgment. Because, analytical thinking requires conscious effort, making it a lengthy mental process, it is not frequently used in day-to-day decision-making.[155] Further, even when analytical thinking is used to make judgements, the process by which we critically analyze information is riddled with biases acquired through our intuitive thinking processes. Mitchell describes this problem of human processing by outlining two systems responsible for human thinking –System 1 and System 2.[156] System 1 works by subconsciously absorbing information about the world from the time of birth, resulting in the creation of several "shortcuts" containing our beliefs about the world. System 2 is where active, critical thinking is performed, however, System 2 is filtered by any biases that may have been acquired in System 1. As such, both systems of thinking – intuitive and analytical contain cognitive biases that the individual has acquired throughout their life.

The presence of inherent cognitive biases in our mental processes is further complicated when we consider the presence of illness. Patients suffering from illnesses often find themselves in states of uncertainty, tasked with making life-altering decisions in emotionally charged situations, in turn resulting in the presence of cognitive biases that impact their perceptions of their experiences. Savioni and Triberti outline three cognitive biases commonly occurring in the

[154] M. Elizabeth H. Hammond et al., "Bias in Medicine," *JACC: Basic to Translational Science* 6, no. 1 (January 25, 2021): 78–85, https://doi.org/10.1016/j.jacbts.2020.07.012.
[155] Hammond et al.
[156] Renée J. Mitchell, *Twenty-One Mental Models That Can Change Policing: A Framework for Using Data and Research for Overcoming Cognitive Bias* (New York: Routledge, 2021), https://doi.org/10.4324/9780367481520.

presence of illness: attentional, interpretation, and recall biases.[157] Schoth et. al. (2012) have defined attentional bias as selective attention to particular information, with a subsequent lack of consideration of alternatives resulting from prior.[158] For example, individuals suffering from a chronic illness that causes them pain will tend to focus on that pain and pain-related terminology.[159] The presence of attentional bias poses a challenge when considering elderly populations and the many elderly individuals living with chronic diseases. Approximately 54% of elderly Canadians over the age of 85 suffer from osteoarthritis, a condition characterized by joint pain and stiffness.[160] Having a chronic illness characterized by pain may result in elderly individuals reporting symptoms of pain on self-reporting tools used to gather information on another illness, potentially leading to incorrect conclusions (i.e., a patient with osteoarthritis-induced joint pain reporting pre-existing pain in a self-reporting tool used to measure new onset Covid-19 symptoms).

Further, the presence of interpretation bias may lead to internalized pessimism about a disease that one has been diagnosed with. This is especially prevalent in individuals previously diagnosed with cancer, and it manifests itself as a fear of reoccurrence. It is predicted that by 2040, 74% of cancer survivors in the USA will be aged 65 or older, suggesting that a fear of

[157] Lucrezia Savioni and Stefano Triberti, "Cognitive Biases in Chronic Illness and Their Impact on Patients' Commitment," *Frontiers in Psychology* 11 (October 28, 2020): 579455, https://doi.org/10.3389/fpsyg.2020.579455.
[158] Daniel E. Schoth, Vanessa Delgado Nunes, and Christina Liossi, "Attentional Bias towards Pain-Related Information in Chronic Pain; a Meta-Analysis of Visual-Probe Investigations," *Clinical Psychology Review* 32, no. 1 (February 2012): 13–25, https://doi.org/10.1016/j.cpr.2011.09.004; Savioni and Triberti, "Cognitive Biases in Chronic Illness and Their Impact on Patients' Commitment."
[159] Savioni and Triberti, "Cognitive Biases in Chronic Illness and Their Impact on Patients' Commitment."
[160] Public Health Agency of Canada, "Aging and Chronic Diseases: A Profile of Canadian Seniors," education and awareness, July 14, 2021, https://www.canada.ca/en/public-health/services/publications/diseases-conditions/aging-chronic-diseases-profile-canadian-seniors-report.html.

cancer reoccurrence may become a prominent concern for many older adults.[161] Individuals with a fear of reoccurrence often focus on the negative components of a physician's explanation of their disease or condition, limiting their ability to take into account all aspects of information regarding their condition.[162] This fear can then manifest itself through the patient taking ambiguous information about their condition and catastrophizing by assuming the worst-case scenario.[163] This is then represented in their perceptions of their health and may result in inaccurate symptoms and severity of symptoms being reported on self-reporting tools. The dominant presence of recall bias can also contribute to the discrepancy between actual symptoms and severity versus what is reported by patients – as recall bias occurs when individuals with prior experiences with illness-induced pain suffer from distorted memories of their prior suffering, resulting in an overestimation of the severity of present symptoms.[164]

Accessibility Limitations of Self-Reporting Tools for Older Adults with Cognitive and/or Physical Disabilities

Despite the threat of biased, inaccurate and clinically insignificant information being shared through self-reporting tools, these tools have the potential to effectively share first-person patient accounts when they are designed thoughtfully and with care. To achieve this, it is necessary to design questionnaires that as for specific information that is relevant to the condition that the research is being conducted. That is to say that if a reporting tool is being developed to assess the experiences relevant to a particular disease, the questionnaire must make this explicit and include

[161] Lisa Gallicchio et al., "Estimation of the Number of Individuals Living With Metastatic Cancer in the United States," *JNCI: Journal of the National Cancer Institute* 114, no. 11 (November 14, 2022): 1476–83, https://doi.org/10.1093/jnci/djac158.
[162] Savioni and Triberti, "Cognitive Biases in Chronic Illness and Their Impact on Patients' Commitment."
[163] Savioni and Triberti.
[164] Joan E. Broderick et al., "The Accuracy of Pain and Fatigue Items across Different Reporting Periods," *Pain* 139, no. 1 (September 30, 2008): 146–57, https://doi.org/10.1016/j.pain.2008.03.024.

reporting parameters (i.e., ask patients to declare pre-existing symptoms before the onset of the specific disease). Further, the questionnaires must include explanations behind units used to measure symptom severity and make expectations clear where possible. However, it is important to recognize that while such measures may help to mitigate bias, they will not eliminate it.

An additional concern with self-reporting tools is the mobile application-based nature of such tools. Traditionally Information on the patient's perceptions of their condition was acquired through the administration of questionnaires in clinical settings, however, there has been a recent shift toward the use of mobile applications for the administration of patient-reported outcome measures (PROMs).[165] Though PROMs provide a potentially valuable solution to understanding the unique experiences of patients, critics have outlined several challenges posed by this approach. In addition to the challenges we have already discussed, an additional criticism of self-reporting tools includes their lack of suitability for all patients.[166]

The design of mobile application-based self-reporting tools results in the development of tools that can only be accessed by populations that (1) have access to mobile devices with internet capabilities; and (2) have the cognitive and physical ability to (a) use the device, and (b) use the mobile application to self-report their experiences. While each dimension of this problem requires careful and thoughtful analysis, considerations regarding access and affordability of mobile devices are beyond the scope of this discussion. As such, the remainder of this paper will address how mobile self-reporting tools present accessibility challenges for older adults with

[165] Broderick et al.
[166] Rachel Campbell et al., "Perceived Benefits and Limitations of Using Patient-Reported Outcome Measures in Clinical Practice with Individual Patients: A Systematic Review of Qualitative Studies," *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation* 31, no. 6 (June 2022): 1597–1620, https://doi.org/10.1007/s11136-021-03003-z.

cognitive and/or physical disabilities, in turn, limiting their capabilities to use such tools and further inhibiting their representation in the development of AI-powered healthcare solutions.

The Capability Approach and Understanding the Impact of Physical and Cognitive Disabilities on the Capabilities of Older Adults

The Capability Approach, originally developed by Amartya Sen, is an approach to human welfare that emphasizes the actual capabilities of individuals to achieve a life that they value and argues for the necessity to investigate the distinction between function and capability.[167] For Sen, a function is that which pertains to a state of being (i.e., fear, happiness, etc.), whereas a capability is understood as a tangible possibility.[168] That is to say that for a possibility to be considered a capability, it must be achievable given the present circumstances. For example, it cannot be said that a homeless individual can simply find a job and purchase a home if, for example, the individual does not have clean clothing, a means of transportation, or the physical ability to work. Crocker has summarized Sen's capability approach as (a) having the actual possibility for X which (b) depends on my powers, and (c) there are no circumstances outside of my control preventing me from X.[169]

In the context of elderly mobile application users, several factors restrict their capability to engage with such technology. Although there is an upward trend in the elderly adoption of digital technologies, they remain the least likely demographic to have access to mobile devices and the Internet.[170] Several reports have been completed with the intent to identify barriers limiting

[167] Ingrid Robeyns, "The Capability Approach," in *The Stanford Encyclopedia of Philosophy*, ed. Edward N. Zalta and Uri Nodelman, Winter 2016 (Metaphysics Research Lab, Stanford University, 2016), https://plato.stanford.edu/archives/win2016/entries/capability-approach/.
[168] Amartya Sen, *Commodities and Capabilities* (Oxford, New York: Oxford University Press, 1985).
[169] David A. Crocker, "Ethics of Global Development: Agency, Capability, and Deliberative Democracy," Cambridge Core (Cambridge University Press, July 2008), https://doi.org/10.1017/CBO9780511492594.
[170] Charlene H Chu et al., "Digital Ageism: Challenges and Opportunities in Artificial Intelligence for Older Adults," *The Gerontologist* 62, no. 7 (September 1, 2022): 947–55, https://doi.org/10.1093/geront/gnab167.

elderly adoption of mobile technology[171] with limitations including the absence of technological infrastructure, reluctance to adopt novel technologies, and the high cost of devices.[172] While these are pertinent barriers to access, there is an incomplete explanation for the limited elderly adoption of technological tools in the presence of physical access to Information and Communication Technology. There are accompanying barriers that further limit the capability of elderly persons to utilize mobile-based applications, namely, barriers stemming from physical abilities (e.g., cognitive delays, physical disability), and psychosocial factors (e.g., lack of confidence, loneliness, skillset) that prevent the conversion of resources to capabilities.

A study assessing the experiences of older adults using technology for socialization during the COVID-19 pandemic found that 55.9% of respondents reported adopting new technology since the beginning of the pandemic.[173] However, despite this increase in elderly technology users, there continues to be a significantly low number of elderly mobile technology users. One reason for this is due to the nature of mobile devices, as most mobile devices are designed to be compact and handheld. While this is desirable for many on-the-go adults, it, unfortunately, presents challenges for the visually impaired. Unfortunately, many older adults suffer from visual impairment, with one study reporting that 27.8% of US adults over the age of 71 had visual impairment, with common impairments including distance and near visual acuity, as well as

[171] G. A. Wildenbos, Linda Peute, and Monique Jaspers, "Aging Barriers Influencing Mobile Health Usability for Older Adults: A Literature Based Framework (MOLD-US)," *International Journal of Medical Informatics* 114 (June 2018): 66–75, https://doi.org/10.1016/j.ijmedinf.2018.03.012; Aurora Saibene, Michela Assale, and Marta Giltri, "Addressing Digital Divide and Elderly Acceptance of Medical Expert Systems for Healthy Ageing," 2020.
[172] Saibene, Assale, and Giltri, "Addressing Digital Divide and Elderly Acceptance of Medical Expert Systems for Healthy Ageing."
[173] Kristen R. Haase et al., "Older Adults' Experiences With Using Technology for Socialization During the COVID-19 Pandemic: Cross-Sectional Survey Study," *JMIR Aging* 4, no. 2 (April 23, 2021): e28010, https://doi.org/10.2196/28010.

contrast sensitivity.[174] The Georgetown University Health Policy Institute reports that visual impairments are one of the leading causes of loss of independence in adults aged 65 and over.[175] As a result, older adults with vision loss require increased assistance from care providers to perform their day-to-day tasks, and it may not be possible for them to use mobile applications readily without the assistance of a care provider. The need to depend on a care provider to assist with the use of mobile technologies contributes to the hesitancy of mobile technology adoption by older adults.[176]

Further, the prevalence of cognitive impairment in older adults presents an additional challenge preventing the capability of older adults to engage with mobile technology. Mobile self-reporting tools such as symptom-tracking applications and other healthcare technologies often adopt multi-step processes for symptom reporting, presenting a tedious and difficult process that may be challenging for older adults suffering from cognitive impairment. It has been reported that cognitive impairment is present in over 40% of elderly individuals, and though some cognitive impairment is to be expected with aging, it is believed that mild cognitive impairment in half of elderly individuals will progress to dementia within five years.[177] The additional layer regarding the lack of relevant digital skills and literacy further impedes the capacity of older adults to interact with mobile interfaces effectively.[178]

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[174] Olivia J. Killeen et al., "Population Prevalence of Vision Impairment in US Adults 71 Years and Older: The National Health and Aging Trends Study," *JAMA Ophthalmology* 141, no. 2 (February 1, 2023): 197–204, https://doi.org/10.1001/jamaophthalmol.2022.5840.
[175] "Visual Impairments," *Health Policy Institute* (blog), accessed July 15, 2023, https://hpi.georgetown.edu/visual/.
[176] Haase et al., "Older Adults' Experiences With Using Technology for Socialization During the COVID-19 Pandemic."
[177] Soleimani et al., "An Investigation into the Prevalence of Cognitive Impairment and the Performance of Older Adults in Guilan Province."
[178] Irene Kitsara, "Artificial Intelligence and the Digital Divide: From an Innovation Perspective," in *Platforms and Artificial Intelligence : The Next Generation of Competences*, ed. Ahmed Bounfour, Progress in IS (Cham: Springer International Publishing, 2022), 245–65, https://doi.org/10.1007/978-3-030-90192-9_12.

Applying Sen's Capability Approach and the Implications of Impaired Capability for Medical AI Development

Applying the Capability Approach

As noted, under Sen's capability approach, a person can be said to possess a capability for X if (a) they have the *actual* possibility for X which (b) depends on their powers, and (c) there are no circumstances outside of their control preventing them from X.[179] In applying Sen's approach to elderly use of mobile self-reporting tools, we uncover several limitations preventing elderly persons from having the actual possibility for X – where X in this case is utilizing mobile self-reporting tools to share their first-person narratives. The actual possibility for X is dependent upon individual powers and external circumstances outside of the agents control preventing them from X. In the case of older adults with cognitive and physical impairments, we have identified several ways in which their powers are limited and circumstances outside of their control preventing them from X. When considering their powers, there are limitations arising from cognitive impairment, visual disturbances, physical disability, etc. Further, there is the additional limitation arising from a lack of digital literacy skills. Some of these limitations to their powers are outside of their control (i.e., cognitive and physical impairments), and other considerations such as mobile user interfaces that are not cognizant to their unique abilities is an additional consideration outside of their control that prevents them from possessing the capability to use mobile self-reporting tools.

Implications of Impaired Capability for Medical AI Development

The compromised capability of older adults with cognitive and physical disabilities to utilize mobile technologies presents several implications for both medical AI development and the

[179] Crocker, "Ethics of Global Development."

overall well-being of older adults. As we have discussed, while first-person reporting tools are not optimal sources of data, when they are designed effectively, they can be a valuable source of information illustrating how different individuals experience illnesses. Despite this potential, the impaired ability of older adults with physical and cognitive impairments to utilize mobile technologies results in the inability of self-reporting tools to adequately reflect elderly experiences. As a result, data acquired through mobile application self-reporting tools suffer from the same limitations as data sourced from clinical trials and electronic health records – the lack of representation of elderly experiences. As demonstrated by the King's College symptom tracking app, when the experiences of older adults are not represented, we risk drawing inaccurate conclusions about the health of this underrepresented population. Though self-reporting tools have been proposed as a measure to counteract the issues relevant to other sources of data used in the training of medical AI tools – namely, the under-sampling of older adults and the implicit biases contained within health records – the solution has failed to consider how the impairments held by many older adults have contributed to a diminished capability of utilizing self-reporting tools, thus demanding an alternative solution.

Conclusion

The developments in medical artificial intelligence (AI) offer immense potential for revolutionizing healthcare and improving patient outcomes. However, the application of medical AI tools to elderly populations illustrates significant challenges relating to data quality and representation. While self-reporting tools have been proposed to overcome these limitations, they too have their limitations, such as the inherent biases of first-person accounts and the limited accessibility of mobile self-reporting tools for those with cognitive and physical impairments. Addressing these challenges is crucial for ensuring equitable and inclusive healthcare

advancements for the elderly. Drawing on Amartya Sen's capabilities approach, we demonstrate the importance of acknowledging these limitations and striving to enhance access to capability for this vulnerable demographic.

Chapter 5 – A Way Forward

Medical AI tools present much promise for improving the care of older adults, as these tools are designed to handle multiple variables with ease. As older adults frequently have multimorbidity, AI-powered healthcare solutions can revolutionize the quality of care that they receive. Unfortunately, despite its promise, there currently exist several limitations. We have identified several ways in which the development of AI tools for healthcare applications excludes the accurate representation of elderly experiences and the subsequent implications of this. Medical AI tools require vast data sets to be able to perform the functions they set out to do – namely, to identify the presence of abnormalities in radiographic images, diagnose illnesses, make treatment and medication dosing recommendations, etc. The data used to develop and train these tools is taken from various sources, including clinical trials and electronic health records (EHRs). However, these sources of data contain several limitations. First, data taken from clinical trials is limited as clinical trials frequently exclude elderly participants. Many trials include upper age limits, and exclusion criteria that prevent many older adults from participating in studies. Attempts to protect vulnerable populations from research-induced harms have resulted in the exclusion of entire classes of individuals from reaping the full benefits of clinical research and exposing them to potential harms. In the context of AI tools, the arbitrary exclusion of the elderly has resulted in tools that are ill-fitted for application to elderly populations, potentially exposing elderly persons to harm. Additionally, the use of EHRs as sources of data for training and development presents further limitations. Bias is endemic in medicine. Physicians and other providers of medical care possess inherent biases that are reflected in the way they speak of patients, their belief in patient testimonies, and ultimately, the type of care they provide their patients. The presence of ageist biases is common in medical care settings, with elderly patient

narratives being filtered through the perceptions of care provider biases. Fairness requires that individuals are treated equitably and that healthcare decisions are impartial and unbiased. In utilizing data from biased EHRs in the development of healthcare AI tools, there is a risk of perpetuating existing healthcare disparities and preventing equitable access to high-quality healthcare. Methods to address the lack of elderly data that is suitable for use in the development of medical AI tools have been proposed, with suggestions made to include first-person reporting. First-person reporting tools present their own challenges, as these tools are frequently mobile-application-based, and do not always reflect the true nature of one's experiences. The mobile user interface of such tools prevents them from being accessible to elderly individuals with cognitive and physical impairments, creating inequality of access. Despite these limitations, they can prove to be a valuable tool for including first-person accounts, in conjunction with high-quality, complete, objective data.

Prospective Solutions

Clinical Trials

As we have discussed, clinical trials suffer from a lack of adequate representation of diverse pools of individuals. Much of this arises as a result of traditional conceptions of vulnerability, and the tendency to place classes of individuals into a single vulnerable class. In doing so, older adults, women, children, and racial minorities are all excluded from participating in clinical trials. While there are international guidelines in place to encourage a deviation from this norm, this alone has not been sufficient for improving representation. Future solutions should include ensuring trials only include empirically justified exclusion criteria. Enforcing upper age limits does not have an empirical basis, as there does not exist a limitation making it unsafe for each adult over a certain age to participate in a given trial. Utilizing upper age limits

continues to enforce the perception that the elderly – as a class – are vulnerable in research settings.

Additionally, there must be measures put in place to hold trial sponsors accountable for the criteria they implement, and the decisions they make when conducting research. Despite legal mandates requiring that trial sponsors report the findings of their trials, few do so.[180] And those that do not, are seldom held accountable. Further, trial sponsors should provide empirical justification when they neglect to enrol diverse pools of candidates. Sponsors must not enrol subjects for the sake of convenience and should actively recruit diverse pools of individuals unless there are safety or health-related reasons not to.

Electronic Health Records (EHRs)

Awareness of the ageist biases and stereotypes present in medical care interactions is an important step for developing possible solutions. Medical care is not objective, and doctors, like other humans, make mistakes and have their own cognitive biases that affect the care they provide. One cannot rely on the incomplete information held within EHRs, and they must not be accepted as concrete data sources. They are simply one part of a larger picture that paints the complete experiences of older adults. One method to improve the quality of EHR data is to ensure physicians utilize objective language when reporting on a patient's condition. As we have shown, physicians may use offensive, discriminatory language when reporting on the conditions of patients by mocking the language they use, openly disbelieving their testimonies, and imposing judgment.[181] In the event a doctor disbelieves a patient's testimony, they can utilize objective language to report this information. The relationship between patients and care

[180] "FDA and NIH Let Clinical Trial Sponsors Keep Results Secret and Break the Law."
[181] Park et al., "Physician Use of Stigmatizing Language in Patient Medical Records."

providers is an intimate relationship that requires mutual trust, and this can only be accomplished through shared respect for patient's experiences and physician judgment.

Self-Reporting

Perhaps an obvious solution to the problem of inaccessible self-reporting tools is to collaborate with older adults to identify their unique needs, and what they require to be able to share their first-person narratives regarding their conditions, symptoms, experiences, etc. As discussed, many such tools are platformed on mobile applications, requiring that those interested in sharing their narratives have access to, and be able to use mobile devices. The tendency to rely on mobile technologies for accomplishing such tasks assumes universal access to mobile technologies, however, as we have discussed, many older adults either lack access to such tools or lack the skills required to use them.

One way of capturing elderly narratives is to engage in recorded storytelling. Studies suggest that storytelling may help older adults feel empowered and recognized, improving well-being and quality of life.[182] Storytelling can be facilitated by having healthcare professionals or family members engage in a structured dialogue with the elderly patient to ask them questions about their unique experiences. This dialogue can then be recorded, and natural language processing tools can be deployed to extract the first-person experiences held within the dialogues.

Further Research

Many of the solutions we have presented are not limited to medical AI tools alone; they apply to the diverse array of data sources employed for AI tool development and training,

[182] Jennifer Stargatt et al., "Digital Storytelling for Health-Related Outcomes in Older Adults: Systematic Review," *Journal of Medical Internet Research* 24, no. 1 (January 12, 2022): e28113, https://doi.org/10.2196/28113.

including clinical trials, electronic health records (EHRs), and self-reporting instruments. While AI has the potential to exacerbate existing disparities, it also has the ability to rectify them if given the appropriate inputs. To ensure the creation of AI tools that are safe, efficient, and inclusive, it is imperative to confront the current systems and processes that contribute to the marginalization of the elderly population's voices. Consequently, any strategy aimed at mitigating the limitations of medical-AI tools must not only address the tools' inherent shortcomings but also acknowledge and tackle the constraints present within each data source (i.e., bias, exclusion, injustice, access, etc.).

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