Erasmus School of
Health Policy
& Management

Regulation of Artificial Intelligence in Medicine: Upholding Public Health

THESIS

Master of Science in Health Economics, Policy & Law

Atalay Demiray

657053

Thesis Supervisor	**:** Prof. Dr. Ernst Hulst
Reading Committee	**:** Dr. Jan-Willem Weenink
Course Code	**:** Master Thesis - GW4555M
Word Count	**:** 18734

Rotterdam, the Netherlands
20 June 2023

Erasmus University Rotterdam
Making Minds Matter

Scholar and Programme Information Form

Name/Surname	Atalay Demiray
Contract No.	TR2020/DG/03/A1-01/1321
Sector as of the Application Date (Public-University-Private)	University
Institution as of the Application Date	Koc University
Title as of the Application Date	Student
Field of Study (i.e. EU Acquis Chapter)	Consumer and Health Protection
Country of Host Institution	The Netherlands
City of Host Institution	Rotterdam
Language of the Programme	English
Host Institution	Erasmus University Rotterdam
Faculty (If Applicable)	Erasmus School of Health Policy & Management
Department (If Applicable)	
Name of the Programme	Master of Science in Health Economics, Policy & Law
Start/End Dates of the Programme (as in the PDS)	01/09/2022 – 31/08/2023
Duration of the Programme (months)	12 months
Title of the Dissertation/ Research Study	Regulation of Artificial Intelligence in Medicine: Upholding Public Health
Name of the Advisor	Prof. Dr. Ernst Hulst
E-mail/s of the Advisor (If Applicable)	hulst@eshpm.eur.nl

THESIS/RESEARCH REPORT APPROVAL

I have examined the thesis entitled

Regulation of Artificial Intelligence in Medicine: Upholding Public Health

presented by

Atalay Demiray

and hereby certify that it is fully adequate, in scope and in quality,

as a thesis for the degree of Master of Science in Health Economics, Policy & Law.

12/07/2023

Prof. Dr. Ernst Hulst

Erasmus University Rotterdam

The Netherlands

Table of Contents

Acknowledgments

I would like to express my heartfelt gratitude to the Jean Monnet Scholarship Programme for making this thesis possible. Their generous support and funding have been instrumental in enabling me to pursue my studies and complete this master's thesis.

I am indebted to the T.C. Dışişleri Bakanlığı (Ministry of Foreign Affairs), Avrupa Birliği Başkanlığı (Directorate for EU Affairs), Hazine ve Maliye Bakanlığı (Ministry of Treasury and Finance), Merkezi Finans ve İhale Birimi (Central Finance and Contracts Unit), and the Avrupa Birliği Türkiye Delegasyonu (Delegation of the European Union to Turkey) for their coordination and administration of the Jean Monnet Scholarship Program. Their dedication and commitment to fostering the EU-Turkiye relationship and promoting these opportunities have played an integral role in shaping my academic journey.

I would also like to express my sincere appreciation to the entire team involved in the programme's implementation, including administrators, and staff members who have worked tirelessly to ensure the smooth functioning of the scholarship program. Their professionalism and guidance have been invaluable throughout my endeavor.

Furthermore, I extend my gratitude to my advisors, professors, and mentors, whose unwavering support and expertise have been pivotal in shaping the outcome of this thesis. Their intellectual guidance, insightful feedback, and encouragement have profoundly influenced my academic growth and development.

The accomplishments reflected in this thesis would not have been possible without the Jean Monnet Scholarship Programme and the aforementioned stakeholders. I am truly honored to have been a beneficiary of their support, and I hope to contribute to the EU-Turkey relationship, and the chapter of Customer and Health Protection in ways that reflect the magnitude of their investment.

Thank you once again for the invaluable opportunity and support provided by the Jean Monnet Scholarship Programme and its coordinating institutions.

Özet

Giriş: Yapay zeka (YZ) ve makine öğrenmesi (MÖ) teknolojilerinin gelişmesi ve uygulamalarının yaygınlaşması ile dönüştürücü etkileri her alanda olduğu gibi sağlık alanında da daha belirgin hale geldi. COVID-19 salgınından bu yana, bu teknolojilerin tıp alanında da kullanılmasına yönelik uygulamalar hız kazandı. Tıbbın geliştirilmesi ve sağlık hizmetlerinin iyileştirilmesi için önemli bir potansiyele sahip olan bu teknolojilerin güvenli bir biçimde kullanılabilmesi için birçok endişenin ele alınması gerekiyor.

Çalışmanın Amacı: Tez; tıp alanında kullanılan YZ/MÖ teknolojilerinin halk sağlığı üzerindeki etkisini inceleyerek mevcut yasal düzenlemelerde halk sağlığının geliştirilmesine yönelik potansiyel politika önerileri geliştirmeyi amaçlamaktadır.

Yöntem: Tıpta YZ/MÖ uygulamalarının mevcut yasal düzenlemelerini incelemek için grounded teori temelli nitel bir araştırma yaklaşımı kullanmıştır. İki veri tabanının sistematik olarak incelenmesi ve uzmanlarla derinlemesine, yarı yapılandırılmış görüşmeler yoluyla veriler toplandı. Daha sonra toplanan verilerin tematik analizi yapıldı.

Bulgular: Sistematik literatür taraması yoluyla yirmi dokuz makale çıkarıldı. On iki uzmanla görüşüldü. Yapılan görüşmelerin analiz sonucunda ana kök kodları; yönetim, belirsizlikler ve potansiyeller olarak belirlendi. Verilerin tematik analizinden on tema ortaya çıktı. Tespit edilen temalar şu şekildedir: (i) AI yönetimi karmaşık, (ii) önce veri yönetimi çözülmeli, (iii) uluslararası iş birliği gerekli, (iv) amplifikatör: mevcut eşitsizliklere dikkat edilmeli, (v) kara kutu daha şeffaf olmalı, (vi) önyargı sorunu çözülmeli, (vii) etkileri değerlendirilmeli, (viii) herkes için sağlık hizmetleri erişimin geliştirilmesi, (ix) halk sağlığı için daha iyi gözetim olanakları, (x) kişiselleştirilmiş tıp uygulamaları ile daha iyi sağlık çıktıları.

Değerlendirme ve Sonuç: Tıpta YZ/MÖ uygulamalarının mevcut yasal düzenlemelerini iyileştirmek için beş önemli alana odaklanılmalıdır. Bunlar: (i) "herkes için yapay zeka" ön koşullarının yerine getirilmesi, (ii) küresel sağlık veri alanın oluşturulmasına yönelik çalışılması, (iii) üretici mükemmelliğinin sürekli değerlendirilmesini sağlamak için yasal mevzuatların uyarlanması, (iv) sağlıkta eşitlik kriterlerinin belirlenmesi, (v) insan odaklı bağımsız denetim mekanizmaları ve dinamik YZ/MÖ etiketleri oluşturmaktır.

Abstract

Background: The transformative impact of artificial intelligence (AI) and machine learning (ML) has become more noticeable as these technologies advance and proliferate in various fields, including healthcare. Since the COVID-19 pandemic, discussions for utilizing such technologies in medicine have accelerated. They have significant potential for advancing medicine, while many concerns still need to be addressed.

Aims and objectives: The thesis aims to explore potential policy improvements to promote public health in the current regulatory frameworks by exploring the impact of AI/ML in medicine on public health.

Design: Thematic analysis of in-depth interviews and systematic literature review.

Methods: The thesis employed a qualitative research approach, using grounded theory to explore the regulatory frameworks of AI/ML in medicine. Data was collected via a systematic review of two databases and in-depth, semi-structured interviews with experts. Then, the thematic analysis of the collected data was employed.

Results: Twenty-nine articles were extracted via systematic literature review. Twelve experts were interviewed. Ten themes emerged from the thematic analysis of the data collected through interviews with the main root codes of governance, uncertainties, and potentials. Identified themes were as follows: (i) AI governance is complex, (ii) Data governance should be solved first, (iii) International collaboration is required, (iv) Amplifier tool: Be careful about existing baseline, (v) The black box must be more transparent, (vi) Bias must be addressed, (vii) Impact must be assessed, (viii) Enhanced healthcare access for all, (ix) Better surveillance for public health, (x) Personalized medicine leading to better health outcomes.

Conclusion: To improve current regulatory frameworks governing AI/ML in medicine, policymakers should focus on five crucial areas. These include (i) fulfilling the pre-conditions of "AI for all", (ii) building toward global health data space, (iii) adapting regulations for continuous evaluation of manufacturer excellence, (iv) setting health equity benchmarks, (v) creating dynamic AI/ML labels with independent oversight.

Introduction

The term ‘artificial intelligence’ (AI) has been frequently defined as ‘the development of intelligent machines, particularly intelligent computer programs that display characteristics associated with intelligence in human behavior such as reasoning, learning, goal-seeking, problem-solving, and adaptability’ (Monostori, 2014). AI encompasses not only mimicking or simulating human behaviors but also any methods or abilities not found in humans, animals, or communities (e.g., the capacity to perform complex computations on a large scale). Machine learning (ML), a subset of AI, involves training and designing algorithms that can learn, recognize patterns, and make data-based decisions (Minssen et al., 2020). Depending on their design, ML algorithms can either be ‘locked’ or ‘allowed to continuously learn from data to adapt and improve their performance in real-time’ (Food and Drug Administration, 2019). ML serves as the basis for many current applications of AI in medicine and healthcare. As differences between different techniques of AI is not within the scope of this thesis research, they will be treated as a unified entity. Henceforth, the abbreviation of **‘AI/ML in medicine’** refers to all applications, algorithms, and technologies which incorporate AI and ML for medical purposes or are used in healthcare.

Ever since the ChatGPT, Generative Pretrained Transformer 4 (GPT-4) with a chat interface, became widely available, people have become more aware of the applications of AI/ML and their potential impacts (Lee et al., 2023). While AI/ML was once an unfamiliar term to many, it has become well-known now. AI/ML technologies have brought transformative impacts to every aspect of our world, and medicine is no exception (Haug & Drazen, 2023; Mosch et al., 2022). Discussions for the utilization of AI/ML in medicine, its impact, and regulations came into existence long before the popularity of ChatGPT (Ahuja, 2019; Pesapane et al., 2018). Since the COVID-19 pandemic, discussions regarding the use of AI/ML in medicine have been accelerated (Da Silva et al., 2022).

One of the biggest challenges of healthcare is managing, learning from, and acting on the vast amount of data generated by healthcare, and this became a pressing issue during the pandemic as the number of patients accumulated. During the pandemic, the need for fast

medical data analysis and recognizing patterns worldwide simultaneously was crucial to saving lives. This required a large-scale complex computational power that humans cannot provide adequately without the assistance of AI/ML technologies. As a result, individuals have increasingly relied on the assistance of these technologies to make decisions within a very short time, which has been a lifesaving measure during the pandemic (Loeza-Mejía et al., 2021). AI/ML's ability to learn from real-world data and improve their performance to act on data simultaneously is one of their crucial benefits in medicine, among many others (Haug & Drazen, 2023; Wen et al., 2022).

The utilization of AI/ML in medicine is not limited to pandemic-related areas, but it also has broad applications in almost all fields of medicine and healthcare, from clinical practice to biomedical research. According to all 24 experts surveyed, AI/ML will play a vital role in a steadily increasing number of areas in healthcare and will be embraced by physicians and patients in the future (Mosch et al., 2022). Some of the most prominent application areas of AI/ML in medicine are diagnosing and treating patients (Jansen et al., 2023; Tran et al., 2021), analyzing radiological images (Chervenkov et al., 2023), discovering new drugs (Vemula et al., 2023), enhancing the monitoring of patients' conditions (Van den Eynde et al., 2022), identifying risks (Bernert et al., 2020), and enabling personalized precision medicine focusing on prevention (Vadapalli et al., 2022). Several studies showed that AI/ML in medicine could perform as well as or even better than physicians in several different medical fields, such as radiology (Hosny et al., 2018), dermatology (Esteva et al., 2017), and pathology (Berbís et al., 2023). Accumulating evidence reinforced the undeniable potential of the utilization of AI/ML in medicine to enhance the quality and efficiency of healthcare services with improving patient safety (Haug & Drazen, 2023). AI/ML technologies have been remarkably affecting almost all dimensions of society, particularly public health, due to their transformative nature (Morgenstern et al., 2021).

Despite their countless benefits and tremendous potential, the use of AI/ML in medicine came with numerous ethical and societal concerns, including but not limited to data governance (data privacy, data sharing, and data ownership), safety, effectiveness, transparency, accountability, potential bias, and unjustified discrimination, especially concerning for public health (Vokinger & Gasser, 2021). Effective and trustworthy

regulatory frameworks can play a crucial role in maximizing the beneficial effects of AI/ML in medicine and addressing these concerns. Like their rapid dissemination worldwide, many regulatory bodies started working on new solutions and regulations for AI/ML in medicine. The first response of regulatory bodies such as the United States Food and Drug Administration (US FDA) and the European Medicines Agency (EMA) was proposing modifications in the existing regulatory frameworks of medical devices to address these concerns (Minssen et al., 2020; Sampson et al., 2019).

Effective governance for AI/ML in medicine is crucial to leveraging its full potential while minimizing public health risks. Experts are optimistic about AI's positive impact on public health; however, inadequate regulation was recognized as a significant barrier and risk (Morgenstern et al., 2021). A better understanding of the necessary regulatory frameworks of AI in medicine is required to balance the opportunities and risks of its utilization. In the current literature, the potential utilization of AI/ML in medicine and discussions regarding its regulations mainly consist of biomedical applications and neglect other social determinants of health and public health. There is clearly a lack of emphasis on AI's relevance to public health while considering its potentials, risks, and regulations. In this thesis, I focused on filling this knowledge gap in the literature by interviewing experts to gain insights into the regulatory frameworks of AI/ML in medicine to uphold public health.

This thesis will focus on three main pillars of the utilization of AI/ML in medicine: (i) its impact on public health, (ii) current regulatory frameworks governing the utilization of AI/ML in medicine, and (iii) policy improvements in its regulation to uphold public health while protecting its innovative potential. This thesis aims to shed light on these three pillars of the utilization of AI/ML in medicine from a public health point of view. Therefore, the findings of this thesis will help policymakers to improve current regulatory frameworks governing AI/ML in medicine to promote public health (see Figure 1).

The research question of this thesis is: *"How do policymakers improve the current regulatory frameworks governing the use of AI in medicine to uphold public health while protecting its innovative potential?"*

In order to answer the main research question, the following secondary research questions will be discussed:

- How does the current utilization of AI/ML in medicine impact public health?
- What are the current regulatory frameworks governing AI/ML in medicine?
- What are the potential risks and opportunities of AI/ML in medicine to public health, and how can regulatory frameworks address these issues?
- How can regulatory frameworks ensure that the use of AI/ML in medicine does not exacerbate existing health disparities but help to alleviate them (in other words, improve health equity)?

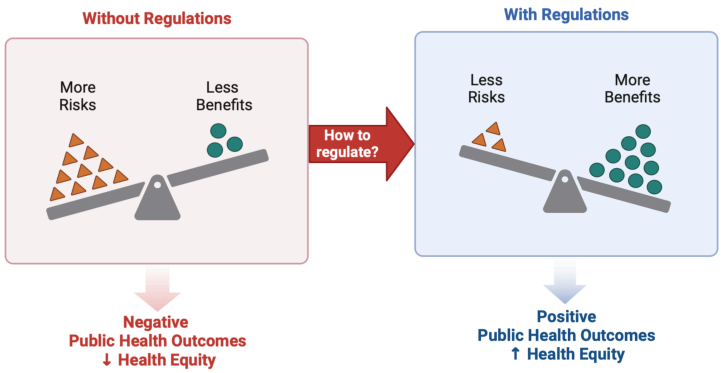

Figure 1. Illustration of the research question.

After giving current knowledge on the applications of AI/ML in medicine and their impact on public health, an overview of the regulatory issues and the EU's regulatory framework governing AI/ML in medicine are presented with evidence from the literature in the background. Then, a research strategy including a systematic literature review, semi-structured interviews, and thematic analysis is presented in the methodology. The result section presents the findings of the systematic literature review, including the summary of twenty-nine articles and the thematic analysis of twelve interviews, including ten themes. Finally, the discussion identifies and explains the improvement areas in current regulatory frameworks of AI/ML in medicine. After providing strengths, limitations, and future directions, the thesis concludes with five key policy improvements for regulatory frameworks.

Background

In this thesis, grounded theory is employed because it is an effective research method for exploring and comprehending complicated social phenomena. The grounded theory focuses on collecting and analyzing empirical data to generate theories contrary to traditional research methods that focus on previous theories or hypotheses (Charmaz, 2006). It involves a continuous cycle of data collection, analysis, and theory development, while each stage informs and influences the others (Noble & Mitchell, 2016).

The conceptual model of the thesis is illustrated in Figure 2. This thesis explores the relationship between AI/ML in medicine and its impacts on public health (illustrated in green) to provide policy recommendations for improving the regulatory frameworks (illustrated in light blue). To a certain extent, other regulations (illustrated in dark blue) that affect public health will be mentioned if they are relevant to the research question. While AI/ML impacts all sectors and aspects of healthcare, this thesis will mainly focus on their effects on public health. The primary goal of this thesis is to contribute to the development of effective governance for AI/ML in medicine that prioritizes public health while preserving its innovative potential in medicine (illustrated in red).

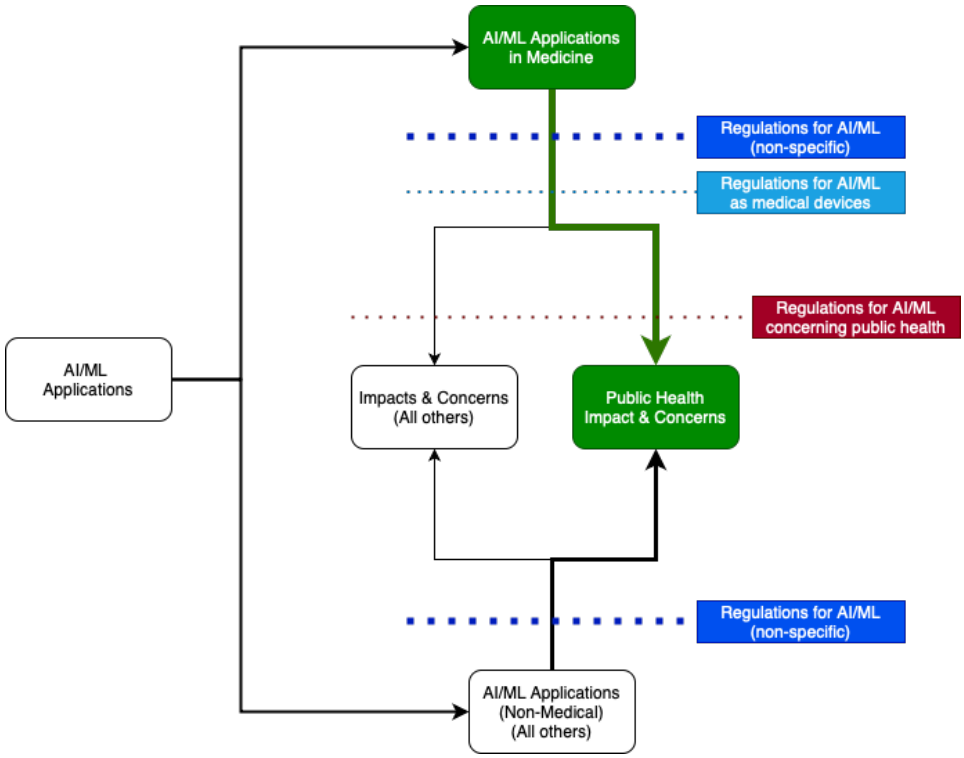

Figure 2. Conceptual model of the thesis.

The conceptual model of the thesis includes three main components:

1. The Impact of AI/ML in Medicine on Public Health
2. Regulatory Frameworks Governing AI/ML in Medicine
3. Policy Improvements for Public Health

Here, two main concepts from the existing literature are explored: (i) the public health impact of AI/ML in medicine and (ii) regulatory frameworks governing AI/ML in medicine. The thesis aims to explore the connection of these concepts to provide policy recommendations in the current regulatory frameworks to maximize their positive impact on public health while minimizing their risks. In order to achieve this, current applications of AI/ML in medicine and their public health implications will be elucidated. Then, the current regulatory framework in the EU will be presented in detail.

The Applications of AI/ML in Medicine

As AI/ML technologies advance rapidly, they are expected to bring significant innovations to medicine. The growth of digital health data, advancements in computing power fueled by hardware technologies, and developments in AI/ML in medicine, are all making an unprecedented impact in healthcare (Obermeyer & Emanuel, 2016). Many medical journals have already published studies showing the utility of AI/ML in medicine to diagnose and treat patients by analyzing vast amounts of health data. Moreover, many clinical trials are still ongoing for the evaluation of AI/ML in medicine (Chervenkov et al., 2023; Kim et al., 2018; Pesapane et al., 2018; Ryu et al., 2020; Tran et al., 2021).

The current utilization of AI/ML in medicine can be summarized as follows: **(i) Disease Surveillance,** *(public health)* such as identification of outbreaks, monitorization of local factors and progression of epidemics, contact tracing, and analysis of cases and outcomes (Jiao et al., 2023), etc.; **(ii) Image Analysis,** *(diagnostic)* such as analysis of electrocardiograms (Hannun et al., 2019), white-cell differential count from a blood sample (Haug & Drazen, 2023), analysis of retinal images (Ting et al., 2017), identification of malign pathologies from microscopic images (Berbís et al., 2023), identification of diseases by interpreting radiological imaging techniques, including

computed tomography (CT), magnetic resonance imaging, ultrasound (Currie et al., 2019; Kim et al., 2018; Park et al., 2019), identification of cutaneous lesions and the detection of skin cancer (Esteva et al., 2017), etc.; **(iii) Disease Management,** *(therapeutic)* such as prediction of the course of diseases, development of medical devices to support patients (Dankwa-Mullan et al., 2019; Rodriguez-León et al., 2021), development of tools to support decision-making for treatments and medications (Bertsimas et al., 2022), etc.; **(iv) Medical Research,** *(clinical trials)* such as patient identification and recruitment, decision support in clinical trial design, monitorization of outcomes and side effects, etc.; **(v) Retrieval of Medical Information,** *(data management)* such as the use of multiple medical sources to make decisions in healthcare, utilization and encryption of electronic medical records (EMRs) (Park et al., 2020; Patra et al., 2021), etc.; **(vi) Operational Organization,** such as patient follow-up, scheduling operating room, and billing (Haug & Drazen, 2023).

The Impact of AI/ML in Medicine on Public Health

In the current literature, limited evidence exists for evaluating the impact of AI/ML in medicine on public health. Although ongoing discussions still have disagreements on its impact, there is a broad consensus on emphasizing the role of their regulations (Pierson & Tsai, 2023).

In the literature, the positive impacts of AI/ML in medicine on public health can be summarized as follows: **(i) providing better surveillance systems** for diseases and pandemics by converting big health data into actionable medical and public health insights (Benke & Benke, 2018); **(ii) promoting preventive and personalized health** by utilization of precision medicine and targeted public health interventions for better and more effective healthcare; **(iii) improving medical and public health research** by enhancing predictive analytics, establishing causal inference, and helping to generate more hypothesis (Morgenstern et al., 2021); **(iv) increasing the access to healthcare** by making it more available and affordable for all, particularly people in limited-resource settings; **(v) improving diagnostic accuracy and efficiency** leading to better health outcomes, and **(vi) advancing treatments and therapies** by helping to develop novel drugs and promoting precision medicine (Haug & Drazen, 2023). Any of these impacts

can help to promote health equity while bridging the gap between different groups if they are effectively used for the purpose of *"health for all"*.

On the other hand, the negative impacts of AI/ML in medicine on public health can be summarized as follows: **(i) losing the human touch in healthcare** by overreliance on AI/ML technologies and devaluation of empathy, the doctor-patient relationship, and human judgments (Cordeiro, 2021); **(ii) increasing discriminatory health outcomes** against affecting marginalized or underrepresented populations due to their potential biases; **(iii) compromising patient safety and public health** due to their unpredictable nature of black-box issues with lack of transparency and accountability (Fisher & Rosella, 2022); **(iv) widening existing gaps within healthcare and exacerbate health disparities** due to their limitations (Thomasian et al., 2021); **(v) raising several ethical concerns** due to use of sensitive health data, patient privacy, data security, and the potential for unauthorized access or misuse (Morley et al., 2020). Therefore, some authors also argued that these technologies could harm public health and global health.

The main concern for public health is widely mentioned as potential bias issues, which can lead to unjustified discriminatory health outcomes (Haug & Drazen, 2023; Morgenstern et al., 2021). When we conduct medical research, inform medical decisions, and deliver medical care; we ensure that all patients receive equitable benefits, regardless of their individual characteristics. However, AI/ML technologies have potential bias issue because they make decisions according to the characteristics of the population used to train their algorithm. The question arises whether AI/ML in medicine should consider public health factors, like resource constraints. It is still unknown how these considerations can be incorporated into the decision-making algorithms of AI/ML in medicine.

Despite having vast literature on the impact of AI/ML in medicine, the relationship between this and regulatory frameworks is mostly overlooked. Even though there is broad consensus on the call for regulatory action on AI/ML in medicine for the sake of public health, there is very limited evidence on how to achieve this. Morgenstern et al. (2021) published an important qualitative study to explain the implications of AI for public health; however, the scope of regulatory discussions was limited without providing any concrete recommendations.

Regulatory Frameworks Governing AI/ML in Medicine

Regulating AI/ML in medicine has gained significant attention from various stakeholders. A growing literature on this topic mainly focuses on ethical concerns, such as transparency, safety, effectiveness, and reproducibility when utilizing AI/ML in medicine (Crossnohere et al., 2022b). However, there has been limited discussion for public health concerns. Schwalbe and Wahl (2020) pointed out that several public health concerns still need to be addressed, particularly in implementing and distributing these technologies in low and middle-income countries (LMICs).

Authorities and government entities have created regulatory frameworks to establish rules, guidelines, and standards for applications of AI/ML in medicine to promote the common good and minimize risks. Therefore, these frameworks are needed to balance the interest of all stakeholders and uphold societal and ethical values such as increasing public welfare and protecting consumers and the environment by providing governance, oversight, and accountability for AI/ML in medicine.

In the literature, two key areas for regulations of AI/ML in medicine appear as medical devices and data governance. Since The International Medical Device Regulators Forum (IMDRF) has designated AI/ML technologies developed for medical purposes as "Software as a Medical Device (SaMD)", regulatory authorities preferred to modify existing regulations of medical devices for the inclusion of AI/ML in medicine (Pelayo et al., 2013). In 2017, the United States Food and Drug Administration (US FDA), the central regulatory agency for medical devices in the US, approved the use of the first AI/ML in medicine and published the guidelines for SaMD (Park et al., 2020). Regulations for SaMD mainly focus on pre-market approval of AI/ML in medicine, so their implications have been mostly on accuracy, safety, and accountability concerns.

As AI/ML in medicine depends on real-world health data, regulations regarding data governance are also essential. These regulations for data governance mainly focus on cybersecurity, protecting the rights of individuals and their privacy. Wang et al. (2022) provided a comparative perspective for the regulatory frameworks governing the medical data protection of the EU, the US, and China. They discussed the similarities and differences between data governance schemes in these countries. Despite these regulatory

efforts, privacy issues regarding medical data protection have not been resolved systematically (Park et al., 2020).

Several professional organizations have also created frameworks for developing, reporting, and validating AI/ML in medicine. These frameworks provided guidance to the developers and aimed to increase transparency in design via better reporting. However, regulatory oversight of AI/ML in medicine is still limited, while authorities are working to improve the regulatory frameworks. For instance, the European Commission initiated a multidisciplinary approach to increase the trustworthiness of all AI/ML technologies. At the same time, the European Medicines Agency (EMA) has identified AI/ML regulations as a strategic priority. The US FDA is also working to improve current regulations governing AI/ML in medicine. Because this thesis will primarily examine the regulatory framework of the European Union (EU), regulations in other countries, such as the US, will be mentioned if they are deemed significant to the research question.

Regulatory Framework Governing AI/ML in Medicine in the EU

The EU has been reforming its regulatory frameworks governing AI/ML technologies with a series of changes in directives and introducing new legislation. The EU's relevant regulatory landscape for AI/ML in medicine can be grouped into four pieces: (i) regulations for data governance, (ii) regulations for medical devices, (iii) regulations for all applications of AI/ML, (iv) non-binding guidelines for the utilization of such technologies in healthcare. An overview of relevant EU regulations is presented in Table 1.

General Data Protection Regulation (GDPR) is a comprehensive data governance law that took effect in May 2018 with several important implications for AI/ML in medicine. Since its application, all personal data processing, including sensitive health data, has become opt-in and depends on explicit user consent in accordance with the six data protection principles defined by the GDPR. According to GDPR regulations, using any third-party, non-opt-in personal data for any purpose is prohibited. The GDPR has become a crucial instrument to influence and control AI/ML in medicine as these technologies strictly depend on vast amounts of personal health data to process, learn, and decide.

Table 1. Overview of relevant EU regulations governing AI/ML in Medicine

Data Protection	
Directive 95/46/EC	Directive on data protection Has been replaced by the GDPR
Regulation (EU) 2016/679 *GDPR*	Regulation on data protection Applies from 25 May 2018 Repeals Directive 95/46/EC
Regulation (EU) 2016/1148	Directive on cybersecurity Applies from 10 May 2018
Medical Devices	
Directive 93/42/EEC	Directive on medical devices Replaced by MDR on 26 May 2020
Regulation (EU) 2017/745 *MDR*	Regulation on medical devices Applies from 26 May 2021 Repeals Directive 93/42/EEC
Regulation (EU) 2017/746 *IVDR*	Regulation on in vitro diagnostic medical devices Applies from 26 May 2022
Artificial Intelligence	
AI Act (proposal)	In progress EU Parliament adopted the proposal on 14 June 2023
Non-binding Guidelines	
MEDDEVs MEDDEV 2.7/1 (rev. 4)	Not legally binding guidelines of medical devices Guidance on the clinical evaluation of medical devices
European Data Protection Board (EDPB) Guidelines	Recommendations on data governance including personal data protection

MDR, Medical Device Regulation; IVDR, In Vitro Diagnostic Medical Device Regulation; EEC, European Economic Community; EC, European Community; GDPR, General Data Protection Regulation; EU, European Union; MEDDEV, Medical Device Guidelines.

Regarding data protection, the EU has also implemented the Cybersecurity Directive, Directive (EU) 2016/1148, which took effect in May 2018. The EU established rules for member states to prevent cyberattacks and manage their consequences if they occur. Member states are enforced to ensure measures are in place to prevent cyberattacks, reduce the effects of incidents, maintain service continuity, and promptly notify supervisory authorities in case of such incidents (Pesapane et al., 2018).

Two cornerstones of the EU's regulatory framework governing AI/ML in medicine are Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR), which came into force in May 2017. MDR and IVDR set regulatory provisions regarding medical devices, including AI/ML in medicine. MDR, replacing Directive 93/42/EEC as of May 26, 2021, safeguards medical device accuracy, reliability, and

safety while holding manufacturers more accountable for faulty products by imposing stricter monitoring. Furthermore, these regulations promote public access to information about medical devices, which increases transparency and accountability by empowering users. An overview of the regulatory roadmap for medical devices is illustrated in Figure 3. Even though discussion regarding the impact of the EU medical device regulations from different perspectives is present in the literature, no literature discussed the implications of these regulations from a public health point of view (Beckers et al., 2021)

Artificial Intelligence Act (AI Act) proposal, the first comprehensive legislation governing AI/ML technologies in the world, was adopted by the European Parliament on June 14, 2023 (News: European Parliament, 2023b). It aims to ensure the development of AI/ML technologies that are human-centric, safe, traceable, and non-discriminatory via bringing new transparency and risk-based management rules. With the introduction of the AI Act, AI/ML technologies that can be a threat to EU citizens, such as certain facial recognition and social scoring, would be banned. AI/ML in medicine would be accepted as high-risk AI systems, which would be strictly regulated. Generative AI/ML systems like ChatGPT must comply with more transparency requirements (News: European Parliament, 2023a). Furthermore, the AI Act will complement the GDPR for data management and usage, which is especially important for big data analytics and medical research. These regulations can provide a strong foundation for the safe and innovative utilization of AI/ML in medicine (Meszaros et al., 2022).

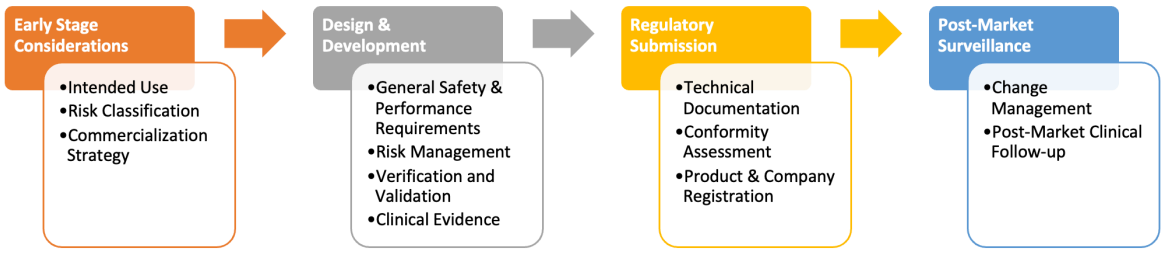

Figure 3. Overview of Regulatory Roadmap for Medical Devices

Methodology

This thesis employs a qualitative research design to explore how the regulations of AI/ML in medicine can be improved to uphold public health while protecting its innovative potential. The grounded theory approach is particularly preferred for this thesis as it allows for the discovery and development of theories to explore and understand this complex phenomenon based on the data collected. Charmaz's book, named "Constructing Grounded Theory" was utilized for the application of grounded theory methodology in this thesis (Noble & Mitchell, 2016).

The thesis primarily focuses on the regulatory framework for AI/ML in medicine. COREQ (COnsolidated criteria for REporting Qualitative research) checklist was employed to ensure the quality of reporting for the research design (see Appendix 1) (Tong et al., 2007). I conducted a systematic literature review and in-depth, semi-structured interviews with experts in public health and/or artificial intelligence. A thematic analysis of the data collected through interviews and literature review underlies the findings of this thesis through a systematic and inductive research approach.

Data Collection I: Systematic Literature Review

I reviewed the MEDLINE® and Web of Science for peer-reviewed research articles published in English between January 1, 2018, and May 1, 2023. The search strategy for the systematic literature review was created via a preliminary search of notable articles and analyzing their titles, abstracts, keywords, and Medical Subject Headings (MeSH) in MEDLINE®. The final search strategy for the literature review is presented in Appendix 2. Keywords were used in the search strategy as follows: "artificial intelligence", "machine learning", "deep learning", "neural networks", "computational intelligence"; "regulation", "regulatory frameworks", "legislation", "law", "legal", "medico-legal", "guidelines", "governance"; "public health", "population health", "community health", "health disparities", "health surveillance" "health equity", "epidemiology".

In order to facilitate a systematic literature review, search results were exported into Covidence, a proprietary review software program. Peer-reviewed publications satisfying the following two primary conditions were selected: (1) analyzing the public health

implications of AI/ML in medicine, and (2) discussing or reporting policy recommendations for regulating AI/ML in medicine. Any article that failed to satisfy both criteria was excluded. After reviewing all retrieved articles for eligibility by screening the titles and abstracts, duplications were removed. Then eligible articles were read in full text for the final selection. Articles without any results sections, such as editorials, study protocols, and meeting notes, were also excluded during the full-text review. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guideline was additionally followed to increase the reliability and validity of the systematic literature review (Page et al., 2021).

Data Collection II: Semi-structured Interviews

Significant articles from the literature review were identified according to their relevance to public health. All authors whose articles also included policy recommendations for regulating AI/ML in medicine were included in a pool of experts for this thesis. Experts from relevant non-governmental organizations, such as The World Medical Association (WMA), The Standing Committee of European Doctors (CPME); regulatory authorities, such as the European Commission and the European Medicine Agency (EMA); and industry representatives were also included in this pool of experts as agencies.

Among this pool of experts, 60 participants were selected via a combination of convenience and stratified purposeful sampling to ensure diversity in perspectives and experiences (Palinkas et al., 2015). During the expert selection, the first corresponding authors of each article were contacted. If a corresponding author was unavailable or did not reply to the interview invitation, other article authors were also contacted to invite to an interview. NGOs, regulatory authorities, and industries were also asked for representative experts, and they were free to choose whom to participate on behalf of their association.

All participants were contacted with a standard email invitation (see Appendix 3). If no response was provided, the second follow-up e-mail was sent after one week. No further efforts were made after the second e-mail to contact the unresponsive individuals. An interview guide was created for the semi-structured interview process (see Appendix 4). Interview questions were framed around the impact and regulation of AI in medicine,

concerning public health. Besides these interview questions, follow-up questions on statements made by interviewees were asked (Green & Thorogood, 2018). Different questions were also asked to each interviewee based on their publications and primary expertise areas.

All interviews were conducted on the Zoom platform, and meetings were planned to last between 30 to 60 minutes, accordingly to the availability of the expert. At the beginning of all interviews, consent was obtained for recording and data usage. All interviews were recorded via the Zoom platform. These recordings and interview transcripts were stored for analysis, with field notes taken during interviews. During the interview, only the interviewer and interviewee were present. No repeat interview was conducted.

All interviews were conducted by me, Atalay Demiray, MD. I am a male researcher with a background in medicine, had a medical degree, and trained in qualitative research methods during medical school. I also had two years of experience in public health research before studying for this thesis. Throughout this research, I was studying Master of Science in Health Economics, Policy, and Law. As a master's student, I have no conflict of interest regarding AI/ML in medicine. I had no prior relationships with any experts who participated in the interviews. Before conducting interviews, I reviewed the book named “Qualitative Methods for Health Research” (Green & Thorogood, 2018). No other researchers were involved in the research process.

Coding and Thematic Analysis

Interviews were transcribed verbatim using an automated transcription program (Descript, 2023). After the transcription of interviews, transcripts were imported to ATLAS.ti, a qualitative research data-processing program (ATLAS.ti, 2023). I utilized the article named “Thematic analysis of qualitative research data: Is it as easy as it sounds?” (Castleberry & Nolen, 2018) for the methodological soundness of the thesis.

Before starting the analysis, I read the transcripts thoroughly to gain familiarity with the data and to identify initial thoughts and impressions. Initial codes were generated via an open-coding approach with an iterative process to categorize components of each transcript using ATLAS.ti. After initial coding, an iterative process was employed for

thematic analysis, and themes were identified by combining the most-used codes iteratively. A world cloud of the study codes was formed, and the size of each code in the word cloud was determined by the number of utilizations of each code.

I systematically reviewed and refined the themes to ensure they accurately represented the patterns and meanings to answer the research question. The final themes were also validated by revisiting all transcripts to identify key quotations concerning each theme. Interviewees are contacted to confirm the accuracy of their quotations from the interviews for member checking. After identifying the final themes, the themes were also interpreted with existing literature. Different perspectives from participants and the current literature are compared to identify commonalities and divergences between different data sources for triangulation of data sources. Peer debriefing was conducted monthly to seek feedback from other master students to confirm the accuracy and completeness of the analysis. Member checking, triangulation, and peer debriefing were employed to increase the validity and reliability of the thesis (Raskind et al., 2019).

Results

Systematic Literature Review

In the literature search, a total of 1563 articles were identified from the database of Web of Science and MEDLINE®. After removing duplicates, 1140 articles were screened, of which 1022 were excluded after the title and abstract screening due to irrelevancy. Relevant articles were allowed for full-text evaluation with the assessment of the inclusion and exclusion criteria. 118 articles were carefully reviewed in full text, 89 of which were excluded for the following reasons: not discussing implications for public health (n=64), not discussing regulations (n=16), editorials (n=5), study protocols (n=2), meeting reports (n=2). Finally, twenty-nine articles were included as data sources for the thesis. The selection procedure, PRISMA, is illustrated in Figure 4.

The overview of the included articles is presented in Table 2. The abovementioned 29 articles were conducted in the following countries: The United States (n=7), The United Kingdom (n=4), China (n=3), France (n=2), Germany (n=2), Canada (n=2), Austria (n=1), Italy (n=1), Netherlands (n=1), Malaysia (n=1), Pakistan (n=1), Portugal (n=1), South Africa (n=1), Sweden (n=1) and Switzerland (n=1) thus covering different perspectives from different continents in North America, Asia, Africa, and Europe.

Although eighty articles, which were excluded during the full-text review due to not discussing implications for public health (n=64) or not discussing regulations (n=16), were also utilized if their contents were useful and relevant to explain concepts mentioned in the thesis.

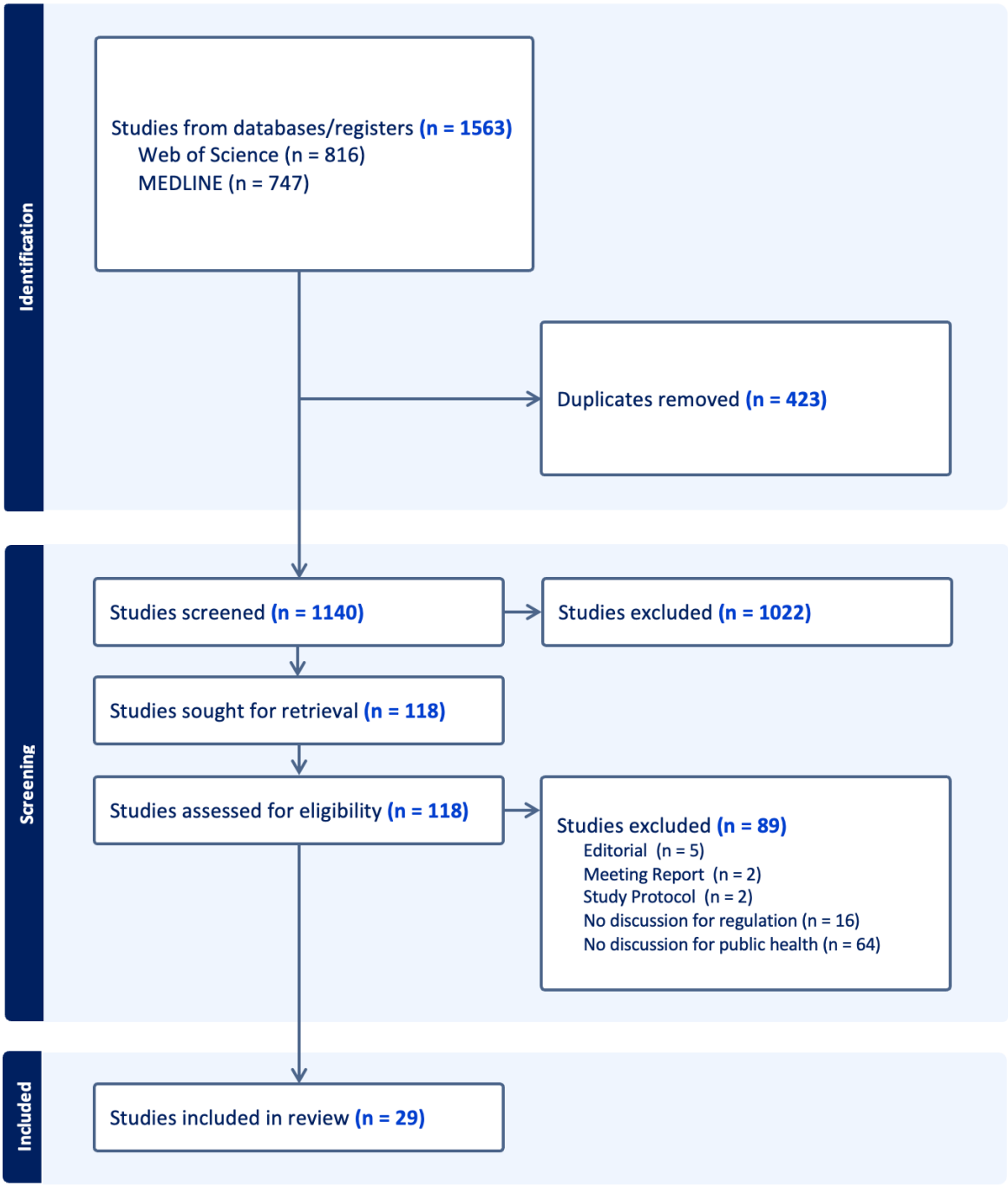

Figure 4. The PRISMA of the systematic literature review

Table 2. Overview of the articles found in the literature

Reference (Authors, Year)	**Country***	***Title***	**Category & Context**	**Main Findings**
(Aerts & Bogdan-Martin, 2021)	Switzerland	*Leveraging data and AI to deliver on the promise of digital health*	Data Governance & Digital Health	Institute regulatory frameworks to enable digital health solutions while protecting patients and driving innovation. Ensure access to digital communication infrastructure by making connectivity affordable for all. Ensure components of digital health systems are interoperable by setting regulatory standards for interoperability.
(Bak et al., 2022)	Netherlands	*You Can't Have AI Both Ways: Balancing Health Data Privacy and Access Fairly*	Data Governance & Ethics	The utilization of AI for healthcare involves trade-offs between all-embracing data privacy and realizing the full potential of AI and countries allocate resources reflecting the chosen balance between data privacy and access conditions to address distributive justice concerns in ethical debates on health-related AI.
(Brand et al., 2022)	South Africa	*Data sharing governance in sub-Saharan Africa during public health emergencies: Gaps and guidance*	Data Governance & Public Health Emergencies	A reliable and accessible data ecosystem in sub-Saharan Africa requires continental and international cooperation, development of standard data formats, harmonization of data sources, and integration into national health information systems to support evidence-based decision-making, while ensuring transparency, fairness, and accountability, and facilitating cross-border data transfers through the development of standard contractual provisions by data protection authorities in Africa.
(Carolan et al., 2022)	The United Kingdom	*Technology-Enabled, Evidence-Driven, and Patient-Centered: The Way Forward for Regulating Software as a Medical Device*	SaMD & Regulations	Global standards and regulatory requirements specific to SaMD should be set to ensure patient safety and promote the effectiveness of SaMD to improve healthcare. A continuous learning algorithm, and ongoing communication between regulators, developers, and users to maintain vigilance, understand the technology and ensure optimal clinical effectiveness are necessary.
(Cordeiro, 2021)	Portugal	*Digital Technologies and Data Science as Health Enablers: An Outline of Appealing Promises and Compelling Ethical, Legal, and Social Challenges*	Data Governance & Digital Health	The impact of digital health is significant with its ethical, legal, and social implications. All stakeholders, including ethicists, legal scholars, patients, scientists, health professionals, regulators, and decision-makers, work together to ensure that the use of digital technologies in healthcare is ethical and innovative.
(Crossnohere et al., 2022a)	The United States	*Guidelines for Artificial Intelligence in Medicine: Literature Review and Content Analysis of Frameworks*	AI Guidelines & Literature Review	The current literature and regulatory frameworks provide some guidance on overseeing AI in medicine, but there is a need for more comprehensive input on engaging stakeholders in AI development and providing recommendations for the translational stage of surveillance. Patients, clinicians, and other end users in the development, use, and evaluation of AI in medicine should be included to ensure efficiency and safety with better outcomes for all.

(Dankwa-Mullan et al., 2021)	The United States	*A Proposed Framework on Integrating Health Equity and Racial Justice into the Artificial Intelligence Development Lifecycle*	AI Development & Health Equity	AI in public health crises is a promising tool for decision-making and resource allocation, but challenges remain in avoiding unintended harm. Implementing health equity, racial justice principles, and an ethical framework throughout the AI lifecycle is crucial to mitigate risks of exacerbating health disparities. The creation of a systematic and comprehensive AI evaluation framework can ensure safe and effective adoption in healthcare settings.
(Federspiel et al., 2023)	Malaysia	*Threats by artificial intelligence to human health and human existence*	AI & Global Health	The rapid development of artificial intelligence in healthcare has the potential for both beneficial and negative impacts on human health, including social determinants, lethal autonomous weapons, employment, and the threat posed by self-improving artificial general intelligence, necessitating effective regulation and a moratorium on its development until appropriate safeguards are established.
(Ferryman, 2020)	The United States	*Addressing health disparities in the Food and Drug Administration's artificial intelligence and machine learning regulatory framework*	FDA & Health Disparities	A comprehensive ML policy promoting the health equity is needed. Regulations should not prioritize "agility" over the well-being of marginalized groups. Recognition of health disparities explicitly and implementation of proactive regulations to alleviate the anticipated risks are crucial while governing AI/ML in medicine for guidance to ML tools.
(Fisher & Rosella, 2022)	Canada	*Priorities for successful use of artificial intelligence by public health organizations: a literature review*	AI & Public Health	Six key priorities defined to fully utilize the advantages of AI in public health: Modernization of data governance and investing in data infrastructure, addressing skills gap in workforce, developing collaborative partnerships, best practice sharing for transparency and reproducibility, explicit consideration of bias and health equity. With delivering these six pillars, AI in public health can be used effectively, ethically, and for the benefit of all.
(Fletcher et al., 2021)	The United States	*Addressing Fairness, Bias, and Appropriate Use of Artificial Intelligence and Machine Learning in Global Health*	AI/ML & Global Health	In the context of global health, effective and safe use of AI/ML in medicine requires guidelines for controlling the appropriate use of these technologies, maintaining transparency for critical decisions, enforcing transparency in data and algorithms, addressing bias, and agreeing on a fairness metric through stakeholder participation, ensuring that the ultimate goals are met without causing harm to any involved parties.
(Gallifant et al., 2023)	The United Kingdom	*Equity should be fundamental to the emergence of innovation*	Innovation in healthcare & Health Equity	Innovations in healthcare without considering moral outcomes can result in inequitable outcomes. In order to everyone can benefits the applications of AI/ML in medicine, funding bodies should incentivize equity-focused AI and regulatory authorities should hold manufacturers accountable for the differential impact of these algorithms after deployment, ensuring fairness and equitable outcomes across all groups.

(Guckert et al., 2022)	Germany	*The Disruption of Trust in the Digital Transformation Leading to Health 4.0*	Trust & Health 4.0	Developing policies for Health 4.0 requires trust relationships between several stakeholders which may be disrupted or strengthened by information and communication technology. Nine actionable actions were recommended to foster trust such as incorporating a trust framework into the design methodology, building system of accountability, implementing compulsory review of datasets, improving trainings.
(Haneef et al., 2020)	France	*Innovative use of data sources: a cross-sectional study of data linkage and artificial intelligence practices across European countries*	Data Governance & Public Health	The current practices of health data sharing and AI use in European countries' national institutes of public health are reviewed. The need for sustainable health information systems, flexible data governance frameworks, and increased awareness are crucially needed to improve public health surveillance and support evidence-based practices.
(Hashiguchi et al., 2022)	France	*Fulfilling the Promise of Artificial Intelligence in the Health Sector: Let's Get Real*	Current AI & Healthcare	The transformative potential of AI in healthcare is significant but its current use still not routine with limited practical examples of its benefits. The need for caution, through evaluations, consistent data governance, regulatory frameworks, trust building, and equipping the workforce and patients with necessary skills for safe and effective deployment are necessary.
(Ho, 2022)	China	*Operationalizing "One Health" as "One Digital Health" Through a Global Framework That Emphasizes Fair and Equitable Sharing of Benefits From the Use of Artificial Intelligence and Related Digital Technologies*	One Digital Health & Health Equity	The digitalization of One Health through the concept of One Digital Health using AI and big data aims to enhance our capacity to address climate-related threats to human, animal, and plant health by promoting data-sharing, fairness, and equity through a global framework. Comprehensive and detailed information across different domains can enable better insights, predictions, monitoring, and implementation of preventive strategies to protect biodiversity and promote global justice.
(Jungwirth & Haluza, 2023)	Austria	*Artificial Intelligence and Public Health: An Exploratory Study*	AI & Public Health Research	The implementation of policies to ensure transparency and credibility of AI-generated texts is needed. It is important to adhere to good scientific practices and engage in a broad scientific discourse on AI contributions to research to ensure responsible and safe utilization of these technologies.
(Kyhlstedt, 2022)	Sweden	*The need for action by evaluators and decision makers in Europe to ensure safe use of medical software*	SaMD & the EU	The MDR addresses several issues by requiring independent evaluation prior to market approval, mitigating anticipated risks of AI/ML, and promoting collaborative efforts between stakeholders to ensure the safe and effective use of Digital Health Solutions. More discussions and policymakers' attention are needed to understand the risk of using devices approved under the MDD class I.

(Lopez et al., 2022)	Germany	*Challenges and solutions for transforming health ecosystems in low- and middle-income countries through artificial intelligence*	AI Applications & LMIC	This review of healthcare AI in LMICs found that clinical records and radiology images were the most common data types used to create public health interventions primarily targeting maternal and child health. The gaps and challenges for scaling AI in LMIC, are the need for improved data quality, contextual training and modeling, privacy and ethics considerations, and stakeholder involvement.
(Morgenstern et al., 2021)	Canada	*"AI's gonna have an impact on everything in society, so it has to have an impact on public health": a fundamental qualitative descriptive study of the implications of artificial intelligence for public health*	AI & Public Health	AI's impact to public health is undeniable, but barriers are existed for full potential. Experts emphasized the need for research on disease surveillance and health promotion interventions, increased AI expertise and funding, improved data standardization and availability, mitigation of bias, promotion of health equity, realistic training on AI limitations, and ongoing collaboration to regulate AI for the benefit of population health.
(Morley et al., 2022)	The United Kingdom	*Governing Data and Artificial Intelligence for Health Care: Developing an International Understanding*	Data Governance & International Organization	The role and collaboration of international organizations like WHO/ITU, GDHP, and GPAI are crucial to achieve the global AI governance in healthcare. More discussion and research for policymaking to bridge gaps between current policies and ideal standards are needed. The strategic implications of investing in data and AI policy in the context of global public health are emphasized.
(Morley et al., 2020)	The United States	*The ethics of AI in health care: A mapping review*	Ethics of AI & Literature Review	Ethical issues surrounding the use of AI in healthcare are explored. This study identifies three categories of ethical issues in the incorporation of AI in healthcare: epistemic, normative, and traceability, which manifest at individual, interpersonal, group, institutional, and societal levels. Addressing these ethical concerns to promote evidence-based and accountable AI integration in healthcare is needed.
(Pickering, 2021)	The United Kingdom	*Trust, but Verify: Informed Consent, AI Technologies, and Public Health Emergencies*	Informed Consent & Public Health Emergencies	A need for a different approach to negotiating ongoing consent is emphasized noting with the insufficiency of traditional process of informed consent. The focus should be on defining trust from the social psychology literature pertaining to person-to-person interactions. A more dynamic trust-based negotiation in response to situational changes over time is needed in AI technologies and public health emergencies.
(Schwalbe & Wahl, 2020)	The United States	*Artificial intelligence and the future of global health*	AI Applications & LMIC	The global health community should swiftly incorporate human-centred design of AI, ensure equitable access to datasets, establish global assessment systems, prioritize implementation research, and develop comprehensive standards and guidelines that protect the interests of LMICs to leverage the potential of AI for improving health in LMICs and achieve SDGs, universal health coverage.

(Shah & Khan, 2020)	Pakistan	*Secondary Use of Electronic Health Record: Opportunities and Challenges*	Data Governance & Regulations	An overview of electronic health records (EHR) was presented with analyzing their secondary uses and the associated privacy challenges. The effectiveness of GDPR and HIPAA regulations was assessed and areas of improvement to safeguard personal data and address evolving cyber threats and AI-assisted techniques in data analytics was proposed.
(Tacconelli et al., 2022)	Italy	*Challenges of data sharing in European Covid-19 projects: A learning opportunity for advancing pandemic preparedness and response*	Data Governance & the EU	It is important that GDPR is applied consistently across Member States to overcome challenges in data governance. Some recommendations for data collection and sharing are establishing common standards and interoperability for data use with agreeing on metadata standards, implementing standardized reporting procedures, providing training and education on digital literacy and data science skills. Building institutional capacity for IT infrastructure and inter-institutional collaboration, devising alternative collaborative formats, addressing barriers to sharing patient data, and promoting broad informed consent for data sharing are also critical.
(Thomasian et al., 2021)	The United States	*Advancing health equity with artificial intelligence*	AI Bias & Health Equity	The need for consensus on regulating bias in healthcare AI to ensure its ethical integration into the healthcare is clear. Regulatory strategies to address bias via three principles approach for bias mitigation throughout the algorithm life cycle including development, validation and implementation.
(Wang et al., 2022)	China	*Privacy Protection in Using Artificial Intelligence for Healthcare: Chinese Regulation in Comparative Perspective*	Data Governance & Chinese Regulations	Reasonable regulations to safeguards sensitive health data and prevents privacy infringements while still allowing for technological innovation and the development of AI tools are need to balance the potential benefits of AI in healthcare with the threats to patient privacy. Achieving this requires a legal framework which involves unifying concepts, classifying data types, enhancing informed consent, implementing strict accountability mechanisms, and adopting international standards for data governance in healthcare.
(Wen et al., 2022)	China	*Research on emergency management of global public health emergencies driven by digital technology: A bibliometric analysis*	Digital Technologies & Global Public Health	The management of public health emergencies is explored with the focus of digital technologies. Considering regional distribution of research power, the potential of digital technologies in improving public health management, the need for international cooperation is needed to address challenges and improve response capabilities by digital public health emergency management systems.

*If a study involves multi-national cooperation or authors from different countries, then the country of the corresponding author was indicated.

Semi-structured Interviews

Out of the 60 experts invited for an interview, 47% (28) did not respond, and 34% (20) declined to participate due to being overwhelmed with their other responsibilities and busy schedule. Interviews were conducted with 12 experts who accepted participation, and the median duration of 12 interviews was 55 minutes, while the shortest was 22 minutes and the longest was 68 minutes.

Table 3. The Characteristics of Participants

	Number of participants (%)
Female	5 (42)
Continent	
Europe	8 (67)
North America	3 (25)
Asia	1 (8)
Organization Type	
Academia	8 (67)
Non-governmental Organization	3 (25)
Industry	1 (8)
Primary Area of Expertise	
Public Health	4 (34)
Data Informatics	3 (25)
Law	2 (17)
Medicine	1 (8)
Ethics	1 (8)
Artificial Intelligence	1 (8)

The characteristics of experts who participated in an interview are presented in Table 3. All experts had significant experience or interest in AI/ML in medicine, although their primary expertise differs, such as public health, data informatics, law, medicine, and ethics. The characteristics of each participant's ID are presented in Appendix 5.

Thematic Analysis

I developed 102 codes, which were applied 803 times to 559 excerpts. As the interviews progressed, fewer new codes were generated, with interviews 10, 11, and 12 producing thirteen, seven, and two new codes, respectively. Although absolute saturation cannot be guaranteed given the extent of the topic, the emergence of fewer new codes in later

interviews indicates relative saturation of data collected from the interviews. My coding system includes three levels of nested codes, with the majority falling under the second level. The main root codes were Governance, Uncertainties, Potentials, and Innovation. Governance root code was used the most (379 uses when including sub-codes), followed by Uncertainty codes (232 times), and Potential codes (113 times).

Figure 5 illustrates a word cloud of the codes to visualize the analysis. The size of each word reflects the number of times the codes were applied in the analysis. The detailed coding information is presented in Appendix 6. Ten themes emerged from the thematic analysis of data collected from twelve in-depth expert interviews (See Table 4).

Figure 5. The Word Cloud of the Codes

Table 4. Identified Themes

Themes
Governance
AI Governance is Complex
Data Governance Should be Solved First
International Collaboration is Required
Uncertainties
Amplifier Tool: Be Careful about Existing Baseline
The Black Box Must be More Transparent
Bias Must be Addressed
Impact Must be Assessed
Potentials
Enhanced Healthcare Access for All
Better Surveillance for Public Health
Personalized Medicine Leading to Better Health Outcomes

A description of each theme is presented with key quotes as follows:

AI Governance is Complex

The regulatory framework governing AI, namely AI governance, was a primary focus of discussion during interviews. Many experts explicitly noted the need for a norm-based (principle-based), holistic regulatory approach for AI/ML in medicine.

> *The ethical implementation of AI requires a holistic approach to public health. And when I say holistic approach, I mean multidisciplinary approach. (Participant ID #7)*

Experts have also highlighted the need for a significant shift in how regulations approach the rapidly evolving field of AI/ML in medicine. This includes finding new methods for validation, certification, and testing of these technologies, such as frequent re-assessment, living approach to guidelines, and constant benchmarking.

> *AI, the algorithm is not static and constantly improving. So if a diagnostic algorithm gets a bunch more data points, its efficacy could actually shift in a way that you weren't expecting, which may actually no longer be clinically appropriate or maybe clinically better. So, it's a whole shift in thinking that this [using AI for diagnostics, for example] is a constantly evolving process. […] We have to build in constant benchmarking. […] A rethinking of the [process of] guidelines and guidance [development]. There's nothing static about it anymore. […] We have to have a living approach to guidelines and regulations and keep up with it [the data and evidence] […] And we always have to be assessing and reassessing and reassessing. (Participant ID #3)*

Furthermore, experts acknowledged that the rapid pace of technological advancement poses a significant challenge for policymakers. To address the constantly evolving nature of AI/ML in medicine, a principle-based regulatory approach has been recommended.

> *When things are moving very fast, a hundred percent control is not possible. Then you would start to look at these principle-based approaches where you just say: 'Okay, I won't set all the specific rules for you, but I want you to be really careful and to do your work with due diligence.' (Participant ID #9)*

Some experts also suggested moving from a product-based to a manufacturer-based regulatory approach to address this challenge. An expert provided an example of the Digital Health Software Precertification (Pre-Cert) Pilot Program of the US FDA as a new way of thinking for regulating AI/ML in medicine (U.S. Food and Drug Administration, 2022)

> *The Pre-Cert program was FDA's effort in the digital health space. It maybe doesn't make sense to regulate device by device as much. Instead, we should be saying: 'this is a manufacturer or a developer that demonstrates that they do things well, they have a culture of excellence, and they make safe and effective products.' So we're going to scrutinize the entity more and then look into each individual device less to make it easier to get new products on the market. (Participant ID #5)*

Many experts identified the liability issue as a crucial point of discussion for AI/ML in medicine while setting regulatory frameworks.

> *The supply chain for an AI product might be much more complex because you might have someone who's collected the data, and someone else who's labeled it. Someone else who's pre-processed it. […] All of those different actors play some roles. Then, how can the liability be attributed if something goes wrong? (Participant ID #4)*

Given the complexity of these technologies, most experts agreed on two main ideas for liability such that (i) It is complex to ensure, but all stakeholders should take responsibility, and

> *(Liability issue) It's not that different from everything else. […] You need to make sure that's your responsibility. […] If you are a carmaker, you cannot say that: 'Oh, you know, I think this car can't run safely, so the parliament needs to put some regulations for breaks.' You have to have the breaks. [..] For example, just like drugs, you should know about side effects, you should know about when not to use it […]. That's your responsibility. (Participant ID #8)*

(ii) human supervision at all levels and parts of the AI/ML ecosystem should be ensured transparently.

> *We always need to be careful that these technologies are always supervised by a human. (Participant ID #7)*

Experts provided several best-practice examples from other sectors to address similar concerns which AI/ML in medicine has brought to healthcare. The recommended sectors were *accountancy* for a principle-based regulation approach, *financial system (international banking sector)* for data interoperability and cybersecurity, *nuclear energy production* for ecosystem management and holistic approach of regulation, and *international treaties prohibiting weapons mass destruction* for the creation of international standards including the prohibition of automated weapon systems.

> *An example of nuclear energy: So people ask, "What makes it safe? And then lay people have a tendency to focus on simple details like temperatures of blue cooling liquids, the thickness of the concrete walls, etc., but is it all about that? It's about the system of nuclear safety, and the integrity of the supply chain. How nuclear material is transferred, the calibration of the Geiger counter, and even the salary of the security guards are important. […] It's the whole thing together that makes whether that is safe or not and healthcare is no different. (Participant ID #9)*

An expert also emphasized that the level of complexity of health data is much more than the data used in the banking sector for comparison; however, he still pointed out the ways of learning from them, especially for cybersecurity.

> *People often say, well, banking has solved so many problems. But banking […] is relatively simplistic and doesn't try to do the hard things. […] We could learn about cyber security, for example, from banking and from the military, so I don't mean that there's nothing to learn - but the hard problems that health care is facing have not been tackled, to my knowledge by any other sector. (Participant ID #10)*

Data Governance Should be Solved First

Most experts indicated that data governance should be prioritized to create effective regulatory frameworks for AI/ML in medicine. Because AI/ML in medicine relies on big data, a reliable regulatory framework for AI/ML in medicine cannot be constructed

without considering data governance for health data with special considerations for data ownership.

> *The technology (AI) really requires the application of data which raises questions about who owns that data and how that data will be governed, so that the data and the AI, are used for positive reasons and not used for malign reasons. So it's a big question here ... the ownership of data and the governance of data and technology. Presently the problem is that we have regulatory systems that are inadequate and incomplete. […] A lot of data that is being collected, managed, and governed by private entities without adequate democratic oversight and without adequate transparency. (Participant ID #1)*

Experts also pointed out the uncertainties around data sharing for public health purposes, emphasizing the prioritization of data governance for addressing these uncertainties.

> *There's a few things that I think need to be prioritized, and one of them is how we think about data governance, data contributions and data sharing. This has come up a lot during the [Pandemic Accord] negotiations at WHO: If you put data in, what do you get out of it? (Participant ID #3)*

Almost all experts marked health data interoperability unequivocally and identified as a vitally important issue to be solved for AI/ML in medicine to fulfill its potential in healthcare and public health.

> *Interoperability for connecting at the single patient level is increasingly important because their care is divided across multiple locations […] and because people move […] and because of the many opportunities to use data at scale for research including public health intelligence gathering. (Participant ID #10)*

Experts pointed out that the utilization of AI/ML in medicine for every country will differ as each country has its own electronic health record system with different data architectures and management from others.

> *The use of AI will be very different in different parts of the world […] as different regions have different ways when it comes to how we deal with data. In the US, almost all data is owned by, you know, some companies like Facebook, Google, hospitals, […] In China, on the opposite side, everything is owned by the government, and then we have some of Europe in between. […] So, I think you know, these things will be applied differently, depending on the way we look at data in the region or country. (Participant ID #8)*

As digital data keeps expanding and big data accumulates, the opportunities for healthcare and public health are getting more significant every day.

> *There's more data that's digital, so the opportunity is there. It's ridiculous that we might have lots and lots of silos of data that are not interoperable and so prevent us. So, the needs for interoperability are greater than ever before. (Participant ID #10)*

The GDPR was a frequently mentioned regulation regarding personal data protection during interviews. While all experts praise the achievement of GDPR in data protection regulations for individuals, some experts emphasize some improvements in the GDPR for enabling big-data analytics, secondary use of health data for research and public health, and AI/ML in medicine.

> *GDPR is actually good legislation […]it does a lot to protect people […] Its application encourages societal trust […] The difficulty comes […] in applying it to big data research and for AI development where you need large volumes of data. […] GDPR in this area is less precise. It allows a little bit more interpretation by Member States, for example, regarding pseudonymized data safeguards where you need to link data sets through a key. This is often needed to have longitudinal data for*

> *AI and other research purposes […] It's complicated to get big data access (under GDPR). (Participant ID #10)*

Some experts also suggested a need for significant regulatory and societal shifts to overcome the challenges regarding interoperability and data protection regulations.

> *GDPR sets specific protections for health data […] There are lots of challenges. It's not going to be very easy to combine this data in a way that is seamless and effective unless there's a significant regulatory and societal shift in how we think about these things. […] Analogy of open banking rules: […] Banks have to develop their systems in a way that interoperates, and that provides this flow of data between them. (Participant ID #4)*

European Health Data Space (EHDS) is acknowledged as a significant opportunity to serve as an ecosystem to solve health data issues in the EU regarding interoperability, data protection, and data sharing.

> *Now we have the opportunity through the European Health Data Space. The EHDS is imposing a set of standards […] It won't be detailed enough for really serious diseases like cancer, or even diabetes […] But it's at least as reasonable as a starting point. […] It is a practical starting point, and we have to have a roadmap for how we will enrich that with more relevant data, more detailed data for the common diseases and the rare diseases as we progress. (Participant ID #10)*

The potential of EHDS is highlighted especially for addressing regulatory challenges regarding the secondary use of health data for research, public health, big-data analytics, and AI/ML in medicine.

> *The European Health Data Space could have a valuable opportunity here, by offering a kind of data superhighway across Europe for health data flows, including secondary use data. (Participant ID #10)*

Another discussion point regarding the secondary use of health data was privacy issues surrounding AI/ML in medicine. Experts emphasized the importance of respecting data privacy while formulating regulatory solutions for AI/ML in medicine.

> *You have to design systems, procedures, and protocols in such a way that that you don't build in privacy violations. […] There is a huge industry that is looking at all kinds of sophisticated data techniques that could be utilized to do two things: One is to squeeze the knowledge that we need for treatment and for preventive medicine or epidemiology, whatever we want to do. Another is not to violate privacy. […] True innovations often have this structure: […] not willing to compromise and try to achieve both of them together. (Participant ID #9)*

International Collaboration is Required

Most experts emphasized the need for regulation both at the international level for setting common principles and at the national level for setting specific regulations.

> *Regulatory authorities have a lot of catch-up to do. But this really requires governance structures based at both the national and international levels. (Participant ID #1)*

All experts supported the international collaboration for the harmonization of governance structures. Most experts do not foresee that joint global health governance or global AI governance can be achieved soon. However, all experts stressed the importance of informal cooperation internationally for knowledge and expertise sharing.

> *Supranational regulatory regime […] is not going to happen any time in the reasonable future. […] On the other hand, there's something kind of in the middle, informal cooperation and collaboration between regulators at an international level to try to harmonize rules. And that absolutely does happen. […] The most obvious example is the International Medical Device Regulators Forum (IMDRF). (Participant ID #5)*

Some experts brought forward the role of the *World Health Organization (WHO)* in achieving international collaboration for the harmonization of regulatory frameworks.

> *If I had the power to do one thing, I would probably fund and empower WHO to lead a global regulatory working group. (Participant ID #3)*

Many experts praised the EU's ongoing efforts to improve regulatory frameworks, and some experts stated that *EU-level governance* is the right level for regulating AI/ML in medicine.

> *End users are really helpless to fight against big companies. How could we, as end users deal with large international companies (in case of liability issues)? I hope that governments, and especially the European Union, are, really, figuring out how to regulate the use of AI in that regard. (Participant ID #6)*

The *European Health Data Space (EHDS)* was defined as a role model for the rest of the world.

> *I hope that the European Health Data Space helps to develop a European Health Data Ecosystem that reflects really good practice without being too restrictive. So that it finds the right balance, and that other parts of the world migrate towards the same model. […] and that Europe learns from those who have already made some progress that we haven't yet made in Europe. I really want us to learn so that we actually grow together at the planet level. (Participant ID #10)*

Furthermore, the current knowledge and expertise of other international institutions were underlined, for instance, *International Telecommunication Union.*

> *The key institution that is leading the conversation on international standards is the International Telecommunications Union. […] They are the ones who define the standards of making phone calls and making the Internet available in the world. (Participant ID #7)*

Amplifier/Enhancer Tool: Be Careful about Existing Baseline

As health equity is one of the central topics of public health, experts were asked about their perspectives on the impact of AI/ML in medicine on health equity. Many experts drew attention to the existing inequalities and described them as the most significant issue to be resolved without delay. Experts pointed out that existing inequalities could be exacerbated by the inequitable utilization of AI/ML in medicine.

> *It wouldn't be incorrect to say that AI has the potential to amplify existing inequalities and existing abuses of power. […] AI has the potential to amplify these biases and therefore kind of amplify and accentuate any problems associated with them in medicine and healthcare (Participant ID #1)*

Ensuring data representativeness and biases are frequently defined as uncertainties surrounding AI/ML in medicine (Fisher & Rosella, 2022), and experts highlighted that these issues should be addressed effectively.

> *If we don't have equity of choice (for all segments of society including vulnerable and minority groups), we won't have equity of decision-making. We won't have representativeness in the data. And you know, for AI development issues, representativeness is one of the most important areas of concern. (Participant ID #10)*

Ensuring internet connectivity and technological infrastructure with improving digital literacy were defined as enabling factors for utilizing AI/ML in medicine globally.

> *The foundational issue here (health equity), is connectivity and literacy as new social determinants or enabling factors. […] The first thing we need to do in this digital world is to have connectivity, but also bandwidth everywhere. […] add the element of digital literacy. (Participant ID #7)*

Some experts also pointed out the danger of widening the health gap globally.

> *These technologies undoubtedly bring their innovative powers to healthcare, but will the distribution of AI technologies across the world be homogenous? Definitely not when some countries are still lacking the basic infrastructure to utilize these technologies. Then, it is hard to claim that AI will bring global health equity. On the opposite, it can widen the gap between those countries that can use them and those that are not. (Participant ID #12)*

Utilizations of AI/ML in medicine and their benefits may differ according to the resource available to healthcare. If necessary precautions are not taken, the inequitable expansion of AI/ML in medicine can widen the gap between well-resourced and under-resourced centers.

> *How will more poorly resourced centers get access to what is supposed to close the gap? If they don't have access to these technologies, then the gap will only get bigger and bigger […] I don't see another way than […] being willing to fund more poorly resourced centers to buy these technologies. (Participant ID #2)*

Another issue mentioned by most experts was the amplification of existing biases. If minority groups or disadvantaged groups are underrepresented in training data sets of AI/ML in medicine, these technologies can discriminate against these groups. Many experts underlined the importance of transparency for training data sets and ensuring diversity and inclusion of these data sets to prevent the amplification of existing biases.

> *Even though it has the opportunity to close down inequalities, it also has the potential risk of increasing these inequalities because of the way the tool is designed. […] These tools might have biases against minority groups. (Participant ID #2)*

The Black Box Must be More Transparent

Many experts stated that the black box issue is vital in the context of public health. Most experts emphasized the role of digital literacy and education in understanding the true

nature of these technologies rather than just scaring the public. The significance of transparency to overcome black box issues was frequently underlined.

> *Very complex neural network, which is a black box in which you don't even understand how it's coming to the conclusions. […] Those pose different challenges for regulation, if you can't necessarily predict what the output will be. […] In contrast to a medicine, a pill, an injection, or something where you are giving identical therapy to a large sample of people, you can predict their outcomes. However, the neural network will generate a result that is inappropriate in a number of cases, and you don't actually know that in advance. (Participant ID #4)*

Most experts emphasized the role of regulators in ensuring the safety of AI/ML in medicine. Reliability, transparency, and explainability are other emerging features commonly mentioned during interviews.

> *First and foremost is the reliability. […] the patient safety, reliability, transparency, and explainability. Do we know exactly what these things are doing? Why they're doing that? In medicine, it's greatly important that we are familiar with the causal mechanism. (Participant ID #9)*

Bias Must be Addressed

All experts underlined the fact that AI/ML is intrinsically prone to bias which should be resolved when these technologies are employed in medicine.

> *A lot of AI's applications and medicine will be dependent on the data that is fed into the AI systems. I think that's where we get some of the dangers in that any data that is fed into AI systems may be biased or incomplete. (Participant ID #1)*

> *There are a ton of biases that it's going to be challenging to address. (Participant ID #5)*

The risk of transferring historical biases into AI/ML in medicine and the amplification of these biases by the underrepresentation of health data from minority patients were

frequently recognized by many experts as a vital challenge to be addressed for AI/ML in medicine.

> *Black patients received fewer recommendations for referrals (from AI/ML in medicine) because historically, they had lower referral rates for various reasons. […] Like all AI or data-driven predictive systems. They're only as good as the data that goes in. And if you have historical under-representation, then you're likely to have those historical trends sort of mapped onto the future. (Participant ID #4)*

The active and explicit role of regulations in addressing bias issues was highlighted.

> *People of color or different ethnic backgrounds could be disadvantaged because they're not well represented in the data set. […] We have to actively organize ourselves in such a way that we prevent this from happening is hugely important. (Participant ID #9)*

AI/ML in medicine will produce efficient and reliable results for the group of people who are represented the most in the training data of AI/ML in medicine. Experts were very cautious about the utilization of AI/ML in medicine for people outside the training data as this can create serious safety and reliability issues given their black box nature.

> *If you intend to deploy your (AI) product on men who are between 30 and 40 who are in London hospitals, then it's okay for you to test your product in that context. As long as it's not deployed outside of that context. So, anyone using that product should read a label that says this product is licensed for use or approved for use on men 30 to 40 in London. The principle is that the training and testing data has to reflect the population that you're deploying into. (Participant ID #4)*

Many experts mentioned the context-dependence of AI/ML in medicine as a significant barrier to fulfilling their potential in the public health context, as transferring these technologies and their benefits from one region to another becomes difficult (Minssen et al., 2020). For example, deploying complex treatment algorithms produced in a well-equipped, state-of-art tertiary hospital to rural primary care centers could create

unexpected problems that may make them useless in different settings. This strict context dependence was defined as *'contextual bias'* by an expert.

> *Contextual bias. […] demonstrating localized performance. […] How well they work when you take them from place to place because of different populations or different data structures, or different care workflows? […] It's really hard to get at that sort of validation, that sort of evaluation from a centralized place like the FDA. You're not going to make sure that this works in hospitals A, B, C, and D. You're just going to be able to make sure that you know it works generally, and maybe that it works in the hospital like A but not B. And so that's, I think, a big challenge. (Participant ID #5)*

Regulatory frameworks are also needed to respond to contextual biases of AI/ML in medicine and figure out new ways of governance different from the existing regulatory frameworks for medical devices. The strict context-dependence of AI/ML in medicine makes medical device regulations inadequate for AI/ML in medicine because other (non-AI/ML) medical devices and their functions do not change from one context to another.

> *How should we think about governance issues? Responding to this question of contextual bias in a world where centralized regulation has these limits with respect to localized performance. (Participant ID #5)*

Experts also pointed out that addressing biases requires significant social and political discussion as the problem is not a mere technological issue.

> *The biases are addressed in various ways by people trying to improve data sets and make them more representative, etc. But the extent to which data can be made more representative so that the kind of biases within data sets can be eliminated is really a social and political challenge rather than something that is technological. (Participant ID #1)*

Impact Must be Assessed

AI/ML technologies are not limited to medicine/healthcare, and the impact of AI/ML in medicine is not limited to health. So, other considerations should also be taken into account when discussing AI/ML in medicine. Their social, economic, and political impact must be assessed thoroughly for public health (Federspiel et al., 2023).

> *I think AI is a major threat to health […] The way it will be applied in the medical and healthcare sector also has a set of wider dangers to health and well-being through social, economic, and political pathways. (Participant ID #1)*

Throughout interviews, an emerging uncertainty, or potential threat, of AI/ML in medicine has been stated as the dehumanization of medicine/healthcare in case of utilization of these technologies without considering their real value for healthcare and impacts on humanity.

> *It is not only about treating better, diagnosing faster and faster, making it accessible to all, but also how we do these, and how these can be achieved using AI/ML in healthcare. I think healthcare will involve less and less human connection as these technologies advance in healthcare settings. Then the impact of dehumanization should be carefully considered for healthcare which is intrinsically linked to human-human interactions as a doctor-patient relationship. (Participant #11)*

Many experts also mentioned the impact of AI/ML technologies applied in other sectors (non-medical) on democracy, the economy, and social justice. At the same time, some experts also called for a fast regulatory response to prevent potential detrimental implications.

> *You can't start using it in a hospital without it having been validated. Whereas if you look at the potential impact that AI can have on democracy with let's say deep fakes […] create some random stuff […] extremely large scale risk. Where if we don't actually find a way to*

> *regulate them asap, […] it can mean the end of democracy in many ways. (Participant ID #2)*

An expert also pointed out the impact considerations for energy consumption of AI/ML in medicine.

> *The energy use of AI […] It takes a lot of energy. We think it as nothing because […] we count on all these things right here, but somewhere there is a data storage center that consumes a lot of energy. […] So, if you replace one doctor, but you use the energy for 10 people. That should also be part of the calculation. (Participant ID #8)*

Enhanced Healthcare Access for All

Experts explicitly highlighted their optimistic views regarding the 'democratization of medical care/healthcare' via the utilization of AI/ML in medicine. The transformative potential of these technologies can make healthcare accessible to more people and make it more affordable.

> *I am highly excited about the idea of AI coming and having the potential to really democratize care and bring access to lots more people. […] I lean more towards: "Let's get it working because there are lots of people that currently can't access care." (Participant ID #5)*

Despite all uncertainties and concerns discussed during the interviews, there was strong determination for the democratization of medicine from most experts.

> *Whatever you call it, the data technology, AI technology [...], We'll democratize medicine using it. (Participant ID #8)*

Many experts defined the value of AI/ML in medicine in saving valuable time for healthcare workers to increase their communications with patients, especially for addressing the concerns of dehumanization.

> *Because the algorithms can analyze big data like medical data, […] also giving them, the doctors and nurses, more actual time for*

> *communicating with the patients. Time. It's the most valuable resource in health care. I mean time for human-human interaction, the patient dialogue. (Participant ID #6)*

Enhanced healthcare services with shorter waiting times in clinics were also frequently mentioned by many experts.

> *There's a real opportunity there in terms of health equity and enabling many people to access top-level care. […] the obvious ones: improving diagnosis, improving care in general, perhaps saving time, meaning shorter care pathways for patients. […] ultimately leading to better health outcomes. (Participant ID #2)*

Furthermore, some experts argued that the impact of AI/ML in medicine on increasing access to healthcare was not only mediated via an enhancement of healthcare services but also mediated via patient empowerment. As patients' health literacy increase with easier access to health data, they will have more access and control over their own health.

> *I hope the most important effect is going to be more equal treatment with AI can empower people with less education. […] For example, ChatGPT. […] If you have no education, you can ask: 'Can you please write a letter' so that in a way that I will get this new job. It will help people. and so it's my hope that it will. (Participant ID #8)*

Better Surveillance for Public Health

Many experts identified the benefits and potential use of AI/ML in medicine within the context of public health. Emerging ideas from experts mostly clustered around better disease surveillance at a population level, better detection of outbreaks via prediction modeling, and better health policymaking for public health using these technologies.

> *The use of AI for simulation and modeling and prediction at the population level, […] AI capable of helping to anticipate outbreaks, spread of disease spread of high-risk situations. The effectiveness of*

> *public health measures that are trying to control risk. (Participant ID #10)*

All experts specifically identified extracting meaningful public health insights from big data as a significant potential benefit of AI/ML in medicine. These technologies can easily enhance and accelerate public health efforts in several areas, as public health has always relied on vast amounts of data. Many experts highlighted surveillance as the most applicable area for AI/ML.

> *It can also be applied to a variety of public health functions, including surveillance. You know, it could be deployed to conduct epidemiological analyses. It's the ability to generate […] research findings through the analysis of big data. (Participant ID #1)*

Many experts also mentioned exploratory analyses for identifying and improving public health interventions by extracting valuable insights from big unstructured data.

> *The possibility of analysis, the concept of big data analytics, the possibility of analyzing big data in real-time, […]to make a modeling forecasting to support the prevention activities for potential public health emergencies. (Participant ID #7)*

Furthermore, real-time insights generated from big data can facilitate the creation of more personalized preventive measures, including personalized health promotion, resulting in more efficient preventive public health measures rather than one size fits all approach.

> *When we're thinking about public health is very sort of government public health. You know. One size fits all. And with AI tools, […] you can be more specific. […] Sort of more personalized public health. (Participant ID #8)*

Personalized Medicine Leading to Better Health Outcomes

Several experts mentioned the potential benefit of AI in personalized health with improved diagnostic and therapeutic interventions targeting patients better by taking their individual characteristics and medical histories into account.

> *Personalized medicine is revolutionizing the way we approach healthcare, leading to better health outcomes for patients. We hope that utilization of such technologies will drastically improve the effectiveness of medical interventions. (Participant ID #11)*

Moreover, many experts underlined the significance of personalized approaches in healthcare, and some further elaborated for a more precision public health.

> *Personalized medicine is something that never happened in the history of humankind. We want to move the concept of precision medicine to a more precision public health. So, we can use AI for understanding the local context culture, languages, etc., in order to develop more customized policies for a particular population. (Participant ID #7)*

An expert also emphasized the distinction between precision medicine and personalized health concepts by emphasizing that the latter includes personal preferences in the decision-making processes of medicine.

> *We will also, you know, have more personalized health choices. […] I also include personal preferences so that you can say that I prefer this or that. For example, if you have a chronic disease, do I want to remove all pain, or do I want to be able to move around? I'm hoping that personalized medicine, as we go forward, will also take into account preferences. (Participant ID #8)*

Discussion

I combined my findings from the qualitative research with those from the literature review to answer the thesis question. These understandings and interpretations can serve as a preliminary roadmap for improving regulatory frameworks of AI/ML in medicine.

Pre-conditions of "AI for All" to Achieve "Health for All"

Although these concepts are not directly relevant to regulatory frameworks, technological infrastructure and digital literacy (education) are frequently mentioned by many experts to unlock the full potential of AI/ML in medicine for all. As health equity is one of the main concepts of public health, discussions regarding widening or closing gaps in healthcare become central to the thesis. AI/ML in medicine can be a valuable tool for achieving "health for all" which is a widely anticipated concept. However, the utilization of AI/ML in medicine will not be the same within different regions of the world, within different cities of a country, within different hospitals of a city, or for two patients treated by different doctors with different levels of digital literacy. Two crucial enabler factors for utilizing AI/ML in medicine are widely recognized: (i) technological infrastructure (connectivity, bandwidth, and hardware) and (ii) digital literacy of people.

Unfortunately, the full potential of utilizing AI/ML in medicine to close health gaps cannot be achieved unless all regions have reliable internet connectivity and adequate bandwidth for such technologies to operate seamlessly. Policymakers should work on improving technological infrastructure worldwide to close existing technological gaps between different regions of the world. Otherwise, AI/ML in medicine is expected to amplify the existing disparities and widen health gaps. In line with this recommendation, the EU Commission has introduced a connectivity package, including the Gigabit Infrastructure Act, which aims to provide affordable and timely deployment of high-capacity networks to meet the growing demand for connectivity within the European Union (DIGITALEUROPE, 2023). Given that the context of this thesis is limited to the regulatory frameworks of the EU, no analysis for other regions is provided. However, the EU's efforts to expand these infrastructures could be seen as guidance for the rest of the world.

The second important pre-condition to make AI/ML in medicine available to achieve the goal of "health for all" is educating all people to promote their digital literacy. Despite living in well-resourced areas, people may have challenges accessing these technologies if they or their doctors do not know how to use them effectively. Most experts emphasized the importance of education for digital literacy from elementary school to medical school. The future generations should know digital literacy thoroughly as opposed to current people who are learning day by day when there is a necessity. There is also a particular emphasis on the medical education of future doctors, as Sauerbrei et al. (2023) suggested that medical education should be adapted to ensure future doctors are prepared to work in an AI-assisted environment. In this way, the positive impact of AI/ML in medicine can be realized by improving patient-centered doctor-patient relationships.

Therefore, some recommendations for improvement in this area are:

- Leading as an example with the Gigabit Infrastructure Act to other regions of the world.

- Inclusion of relevant digital health topics (e.g., ethics, safety, privacy of AI, etc.) into the medical curriculum to train future doctors. Inclusion of digital literacy knowledge and skills, including data science curriculum, into all phases of education for everybody.

- Funding the resource-limited settings such as rural primary care centers more to close their technological infrastructure gap before implementing these technologies.

Building Towards Global Health Data Space/Framework

As AI/ML in medicine utilizes stockpiles of big data to fulfill their potentials for public health, the question of data governance becomes one of the central discussion points for the regulatory frameworks of these technologies. All experts and literature agreed that we could not utilize the full potential of AI/ML in medicine with respect to public health without having common health data spaces and frameworks that make health data interoperable across hospitals, countries, and regions (Morley et al., 2022). However, the complexity of health data makes data governance challenging. Health data can include but is not limited to *medical history data* generated by hospitals and laboratories;

prescription data from pharmacies; *well-being data* generated by individuals using wearable medical devices to track heart rate and step counts; and *medical expense claims data* generated by insurance companies. The fragmented nature of health data is presented as distributed among various organizations, such as hospitals, pharmacies, insurers, state, and private companies, etc., with different data architectures and data management systems (Winter & Davidson, 2019). Thus, the current reality of lack of data standardization and interoperability constitutes a significant barrier to health data sharing and utilization for advancing AI/ML in medicine for all world, especially for LMICs (Lopez et al., 2022; Schwalbe & Wahl, 2020).

The second challenge in health data governance, especially concerning the effective deployment of AI/ML in medicine, is posed by regulations such as GDPR in the EU, which makes the use of personally identifiable health data increasingly complex and costly for researchers (Aerts & Bogdan-Martin, 2021). Furthermore, some vague parts, or unfilled regulatory context, of the GDPR in big data utilization, which may lead to different interpretations and implementations by member states, is another barrier to fulfilling the public health potential of AI/ML in medicine. The GDPR is defined as 'the strongest data protection regime in the world' (Winter & Davidson, 2019). However, some argue that it is also inadequate to address the tradeoffs between individual privacy/autonomy and the anticipated individual, societal and economic benefits of healthcare applications utilizing big data analytics, including AI/ML in medicine (Bak et al., 2022). For instance, Article 22(1) of the GDPR specifies that data should only be gathered for 'specified, explicit, and legitimate purposes', and secondary use of data for other purposes is not permitted. However, training AI/ML in medicine requires secondary utilization of vast amounts of health data, which may have been collected for other purposes while providing healthcare services (Shah & Khan, 2020). Thus, more flexible data governance is required to enable the secondary use of health data for research and public health purposes, including developing AI/ML applications in medicine that can benefit society's greater good (Haneef et al., 2020).

The third challenge in health data governance is the health data generated by individuals via wearable devices and phone applications. Health privacy protection laws may not adequately address this data as it is created outside the healthcare setting and frequently

framed as well-being data by private companies. Most individuals unknowingly give these companies the right to govern their health data without being fully informed (Winter & Davidson, 2019).

Nevertheless, the recent initiative of the European Commission for European Health Data Space (EHDS) offers a promising framework for improving health data governance in the EU. It sets a best practice example for the world to address challenges. The EHDS can build the much-needed health data ecosystem, including standardization rules for health data, data sharing and management infrastructure, and solid governance to ensure data quality and interoperability (Tacconelli et al., 2022). The EHDS aims to empower individuals by increasing their access to and control over health data at the national and EU levels. At the same time, it aims to provide a consistent, trustworthy, and efficient set-up for the secondary use of health data under GDPR for various public health concepts, including research, innovation, policy making, and patient safety (Directorate-General for Health and Food Safety, 2022). AI/ML in medicine can reach its full potential with the realization of EHDS.

Therefore, some recommendations for improvement in this area are:

- Adaptive data governance frameworks to create common standards and rules for data interoperability, support secondary use of health data for public health, and harmonize the implementation of GDPR between member states with the realization of the EHDS.

- Increasing collaborations and informal technical knowledge/expertise sharing to harmonize data infrastructures and regulatory frameworks by encouraging best practices to disseminate worldwide.

- Working towards creating global health data space under the leadership of the WHO.

Continuous Ecosystem Evaluation of Manufacturer Excellence

Even though currently approved AI/ML in medicine are all locked algorithms, one of the important benefits of AI/ML technologies comes from their potential to continuously improve themselves, contrary to other (non-AI/ML) medical devices and

pharmaceuticals. Despite this distinguishing characteristic of AI/ML in medicine, there is no shift in thinking for regulatory approaches as regulatory authorities have continued evaluating and validating it like other medical devices (Carolan et al., 2022).

Firstly, many experts pointed out that even incremental changes in training data sets of AI/ML may result in significant differences in the outcomes of such technologies. The basic characteristics of the testing population could be adequate for the licensure of non-AI/ML devices and pharmaceuticals; however, full transparency, dynamic reporting, and explanation of training data are required for AI/ML in medicine (Thomasian et al., 2021). Even with complete transparency, the dynamic nature of their training data can make any static validation attempt futile. Furthermore, the capacity and resources required for regular re-testing of such technologies are estimated to be beyond a reasonable level for centralized regulatory agencies such as the FDA and the EMA.

Secondly, continuously improving AI/ML technologies will respond differently to the same input if they improve and change themselves on a day-to-day basis. For other medical devices, upgrading and re-licensing issues are clearly set because non-AI/ML medical devices change in longer durations, like once a year, and the outcome of such changes in these medical devices can be easily predicted (e.g., new calibration metrics included in an insulin pump). Thus, the continuity of licensure and re-testing standards for non-AI/ML medical devices are easier to set than AI/ML in medicine with their continuously and unpredictably changing nature.

Thirdly, the response of locked AI/ML in medicine may differ accordingly to the circumstances surrounding them, contrary to other medical devices and pharmaceuticals, which are sensibly assumed to work and produce similar, if not the same, outcome in different contexts. For instance, a drug discovered and proved safe and effective in Europe can easily be transferred to other parts of the world, and it is expected to act similarly in other regions. However, AI/ML in medicine produced and proved safe and effective in a European country cannot be easily transferred to other regions and even to other European countries because of the context-dependence. Among bias issues of AI/ML in medicine, contextual bias appears very important from the public health perspective as an important barrier to using these technologies and regulating them for the sake of the general population.

Because of the reasons mentioned earlier, a fundamental shift in the thinking of regulatory frameworks for AI/ML in medicine is needed, as current regulatory frameworks clearly have drawbacks to addressing AI-specific concerns of these technologies. One emerging idea from experts and literature was migrating towards *regulatory processes for manufacturer-based excellence recognition based on principles and norms to be checked continuously with pre-specified benchmarks on a regular basis* from regulatory processes for product-based approval. In this way, regulators can better evaluate the manufacturing ecosystem of these technologies holistically and focus more on ensuring manufacturers apply principles in the right way to their products.

A critical preliminary trial example of such change in regulatory thinking appeared in the US with a pilot program of the FDA, *Digital Health Software Precertification (Pre-Cert)* (U.S. Food and Drug Administration, 2022). Some other positive impacts of such change are also anticipated. For example, the products of manufacturers recognized for excellence can reach the market easier and faster than the current product-based regulatory approach. In this way, the innovative potential of these technologies can be better realized, and manufacturers may become more eager to follow principles and better focus on converting their whole production ecosystem to be fairer, more equity-caring, safe, and transparent, etc., rather than focusing on filling extensive regulatory checklist.

Responsibility and liability issues are other important discussion points for regulations. Most literature and experts agreed on strictly attaching the responsibility to manufacturers with principle-based regulatory approval and ensuring that centralized regulatory agencies can continuously test and re-test AI/ML in medicine to evaluate the compliance of manufacturers to pre-specified principles. In case of non-compliance with these principles in *any part of the manufacturer ecosystem*, not only limited to product safety and effectiveness, regulatory agencies can hold manufacturers liable with proportionate punishments accordingly to exposed risk to the population (e.g., all products of a manufacturer can be prohibited if it dangers a life). Thus, empowering centralized regulatory agencies to oversee all ecosystems of manufacturers carefully and continuously and giving them regulatory power and tools are needed to reveal principle-based, holistic ecosystem evaluation of manufacturer excellence for AI/ML in medicine.

Finally, human oversight and independent auditing are continuously required to safely implement AI/ML in medicine. As many experts defined the role of these technologies as an assistive tool for doctors to have better decision-making for their patients, experts unified in the understanding that human oversight is a must for AI/ML in medicine. Moreover, independent public health and patient organization audits can ensure better transparency. However, the main concern for human supervision is the challenge of finding people with the qualifications and expertise to provide meaningful contributions. An expert stated, "*Are our doctors equipped with the necessary expertise and knowledge to use these technologies and even supervise them effectively?"* In the literature, there are also discussions regarding the qualification of human oversight which *"must ensure that any oversight of the decision is meaningful, rather than just a token gesture"* and controllers should have the necessary authorities and competencies to change decisions when AI/ML in medicine does not work optimally (Meszaros et al., 2022).

Therefore, some recommendations for improvement in this area are:

- Shifting our thinking in regulatory approaches to address challenges specific to AI/ML in medicine.

- Migrating towards recognition of manufacturer-based excellence based on principles and learning from the pilot study experiences of pre-Cert as a preliminary example.

- Continuously holistic control of the whole ecosystem of AI/ML in medicine using pre-specified benchmarks, ensuring constant and qualified human supervision.

Health Equity Benchmarks

Among many uncertainties and concerns of AI/ML applications in medicine, the issue of bias appears as the primary problem to be solved in the context of health equity (Thomasian et al., 2021). Health equity is a crucial goal of public health which refers to 'the ability of everyone to achieve their full health potential, irrespective of social determinants' (Barton et al., 2023). Without the inclusion of health equity principles and the construction of regulations based on these equity principles, AI/ML in medicine can lead to discriminatory results due to no representation or misrepresentation of minority and marginalized groups (Ferryman, 2020).

Experts were concerned about the amplification of existing inequalities with the utilization of AI/ML in medicine as they propagate societal biases and intensify selection biases due to the misrepresentation of data. For instance, a recent study pointed out racial bias in an AI/ML algorithm created to assist in healthcare referrals. The algorithm showed bias by predicting lower health needs for black patients due to the usage of healthcare costs as a measure of need (Obermeyer et al., 2019). If not addressed, this type of bias could result in inappropriate allocation of services and preventive interventions in public health. Moreover, selection bias must be carefully addressed while training AI/ML models in medicine, as failure to include all relevant groups in training data sets can result in suboptimal results or even adverse outcomes for some underrepresented groups in the training data set (Dankwa-Mullan et al., 2021). An important example of selection bias was cardiovascular prediction models, which were mainly trained on data from white individuals (Gijsberts et al., 2015).

Socioeconomic and racial data gaps must be incorporated into AI/ML training data set to ensure adequate representation and equitable outcomes. Otherwise, companies could determine their training data in the most profitable way without any consideration for health equity and overall public health. This can ultimately lead to the proliferation of AI/ML in medicine that specifically targets wealthy people's health. This misdirection of producing such technologies only for certain high-income groups must be prevented, as incorporating more representative data into their AI/ML applications should be the ultimate aim for benefiting everybody. Current regulatory frameworks do not enforce specific requirements for the inclusion of all relevant input data or do not evaluate specifically to ensure data representativeness but primarily focus on the accuracy and reliability of results given the input data and circumstances.

The AI/ML in medicine works best (safety and effectiveness) for people similar to their training data. Therefore, a lack of transparent reporting of the demographic characteristics of training data should be addressed to ensure equitable and reproducible deployment of AI/ML in medicine with clear demographic data representativeness in training data and model transparency (Bozkurt et al., 2020). Regulatory authorities should be empowered to force manufacturers to increase their data representativeness by adopting specific regulatory provisions and reporting guidelines.

One of the aims of the AI Act proposal is defined as follows: “minimize the risk of algorithmic discrimination, in particular concerning the design and the quality of data sets used for the development of AI systems complemented with obligations for testing, risk management, documentation, and human oversight throughout the AI systems’ lifecycle” (Meszaros et al., 2022). It is also vital to create new regulatory tools to fulfill the promises of the AI Act proposal. The health equity benchmarks can ensure data representativeness and the quality of data sets concerning public health and empower both manufacturers and regulators to come to a common understanding of these issues. Health equity benchmarks are also important to embody abstract principles of equity and fairness and make these principles more applicable to these technologies and understandable for all stakeholders.

Therefore, some recommendations for improvement in this area are:

- Setting certain equity benchmarks like the definition of specific minority patient groups and enforcing manufacturers to fulfill equity benchmarks for getting regulatory approval.

- Ensuring robust regulatory oversight on training data via an open-data approach and nudging manufacturers to be as inclusive as possible and diversify their products to benefit all segments of society, including vulnerable and disadvantaged groups.

- Additional independent oversight of public health organizations to check and report global public health benchmarks. For example, the WHO sets broader global health equity benchmarks for the international context, and national regulatory agencies set more narrow country-specific health equity benchmarks.

Dynamic AI/ML Labels

In public health, labeling is a frequently employed concept to nudge people or ensure their safety, such as food safety labels, warning texts on cigarettes, and drug facts labels. Like all other products we use for our health or well-being, AI/ML in medicine also has do’s and don’ts. Therefore, having labels for these technologies can help lay people understand their utilization better and prevent potential harm. Labeling is also crucial for creating legal clarity for manufacturers and promoting transparency, which can increase

public trust in these technologies. Some pieces of information that are suggested to be included in the labels of AI/ML in medicine are as follows: model identifiers, type, characteristics, indications for use, validation models, details of data sets, preparation before use, limitations, and warnings (Gerke, 2023). Gerke also suggested the creation of AI/ML in medicine labels similar to the design of "nutrition fact labels" as their familiar design can empower users by giving an overview of all key information at once. While Gerke provided a comprehensive overview of this issue in the context of the US and FDA, no literature from Europe regarding the label of AI/ML in medicine was found.

Some experts also recommended labeling as a way to embody principles of explainability and transparency of AI/ML in medicine. However, some considerations should be employed before implementing these labels. First is the adaptability of the labels to the evolutionary nature of AI/ML. As these technologies can easily change, their labels must be dynamic in opposition to static labels of nutrition fact labels. When the input data of these technologies and their context changes, how they behave changes too. Therefore, dynamic labels of AI/ML in medicine should be responsive to these incremental but essential changes that can create different outcomes. While labels can bring much-anticipated transparency for data representativeness, how to illustrate this is still debatable. An expert mentioned that *'even AIs to solve biases can be created with their supercomputing powers as a technological solution'*. However, the will to create such applications and enforce their utilization is still a political matter and should be addressed by the regulatory authorities.

Secondly, labeling should not bring extra burdens to users as it aims to empower them to make informed decisions while utilizing these technologies. An unpredictable effect of GDPR appeared as plenty of new boxes on every webpage to accept cookies as producers try to circumvent the regulations for third-party data use. Although it empowers people to decide on accepting or rejecting "cookies", almost no one reads very small and lengthy explanations, and people make uninformed decisions that contradict the aims of GDPR in the first place. This experience could be one reason the European context seemed to be distanced from the idea of labeling. Nevertheless, the AI Act proposal and GDPR strictly require transparency and explainability for safety, and labels could be a valuable tool to achieve these. Effective dynamic label creation for AI/ML in medicine should be included

in the agenda of policymakers. Figure 6 illustrates the idea of a dynamic AI/ML label, including some of the critical aspects from a public health perspective. Please note that this is only a simplistic illustration of the concepts discussed and not a comprehensive realization of the idea.

Therefore, some recommendations for improvement in this area are:

- Create compelling and dynamic labels to prevent harm to consumers, empower users to know how to properly use these technologies, and assess their benefits, risks, and limitations.

- Enforce a standardized way of effectively illustrating the data representativeness of AI/ML in medicine to increase transparency and reproducibility.

- Harmonize the reporting of information regarding AI/ML in medicine and create global standards for labels to create a shared global understanding of these technologies.

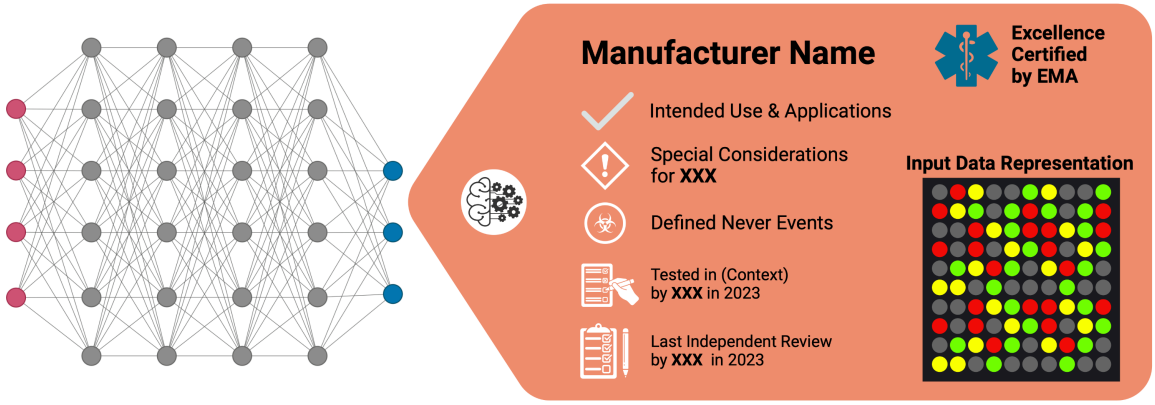

Figure 6. An illustration for Dynamic AI/ML Label

Strengths & Limitations

To my knowledge, this thesis is the first comprehensive research systematically and broadly exploring the regulatory frameworks of AI/ML in medicine from a public health perspective in the literature. I used a reliable qualitative research design that revealed diverse perspectives. One of the crucial strengths of this thesis is the data triangulation of the literature data with data collected from in-depth expert interviews. Employing the grounded theory approach allowed me to explore and understand the complex nature of regulatory frameworks governing AI/ML in medicine utilizing different data sources simultaneously. Applying the COREQ guideline for reporting qualitative research and the PRISMA guideline for reporting the systematic literature review is another strength of this thesis.

Because of the time constraint of the thesis, the search protocol for the systematic literature review only included articles from two databases published after 2018. However, more articles relevant to this topic were also published before 2018 or found in other databases. Given the rapid advancement of AI/ML technologies, any articles not included as a result of being published before 2018 might be unlikely to be representative of today. Also, the systematic literature review included only English-language articles, so this thesis does not include any articles published in other languages. This might limit the generalizability of findings to non-English speaking countries. As with all reviews, publication bias is another potential limitation. Developers may not prioritize publishing their perspectives in the academic literature because private companies develop many AI interventions for commercial purposes.

For interviews, a limited number of interviewees selected via the non-probability sampling approach is another significant limitation of this thesis. While there was a diverse selection of experts from academia with different expertise, the number of interviewees from NGOs and industry was very limited. More data collection from industry representatives, manufacturers of these technologies, NGOs, and patients is needed to broaden the perspectives on the subject. Furthermore, there was no pilot test to evaluate the interview guide due to the limited timeframe for completing the thesis. Similar to findings from the systematic literature review, the interview discussions mostly

focus on the regulatory frameworks of the EU and European context. Therefore, more research should also focus on other countries' regulatory frameworks. Nevertheless, the findings of this thesis can serve as a foundation for future research exploring regulatory frameworks of AI/ML in more detail.

Future Directions

For Research:

More research for exploring regulatory frameworks of AI/ML from different perspectives can be performed. As the implications of AI/ML are not limited to any sector or field, all perspectives must be considered while discussing their regulatory frameworks. The thesis findings can be triangulated with further research, including in-depth interviews with manufacturers, tech companies, policymakers, patients, etc. The same research strategy can be employed to explore other regulatory contexts, such as the US and China. Future research with different focuses can help us understand the generalizability of thesis findings.

Moreover, future research for monitoring the improvement of regulatory frameworks is needed to assess how regulation keeps up with the advancement of these technologies. As some of these regulations are currently in the modification and adoption phases, follow-up studies are needed to monitor their implementations and evaluate their impact.

For Policymaking:

- Ensure the internet connectivity and bandwidth for all, invest in data infrastructure to equalize the capacity of all regions, and educate everyone to promote digital literacy.
- Build toward a global health data space where health data of everyone can keep as interoperable and ensure the utilization of this data to benefit everyone back.
- Check, re-check, and re-check the ecosystem of manufacturers of AI/ML in medicine and ensure they are constantly applying the principles in their products. Rather than focusing on a narrow regulatory perspective on the evaluation and validation of

products, change the regulatory focus to a broader regulatory perspective on the evaluation and validation of manufacturers' excellence.

- Set benchmarks to protect health equity and prevent the amplification of biases by these technologies. These benchmarks should ensure equitable data representativeness in AI/ML in medicine so the benefits of these technologies leave no one behind.

- Create dynamic labels to explain important aspects of these technologies simplistically, so users such as doctors and patients can be empowered to use AI/ML in medicine safely.

Conclusion

The findings of the thesis underline that AI/ML in medicine has an enormous potential to improve healthcare and public health practices via several pathways, most significantly by democratizing access to healthcare, enhancing surveillance with big data analytics, and enabling personalized medicine and personalized public health. However, many uncertainties surround the realization of these potential benefits. Thus, current regulatory frameworks must be improved to address these uncertainties of AI/ML in medicine to bring the true potential of these technologies into healthcare and public health. The main uncertainties of AI/ML in medicine, especially concerning public health, are identified as being an amplifier tool for existing inequalities; having black box nature making transparency challenging; bias concerns, especially for disadvantaged and minority groups; unmeasured impacts such as the risk of dehumanization of healthcare, energy usage, the broader implications on society. Many experts during interviews prescribed different regulatory solutions to disentangle these uncertainties surrounding AI/ML in medicine. Accumulating evidence from the literature was combined with a thematic analysis of experts' input to provide five key improvement areas for current regulatory frameworks governing AI/ML in medicine with regard to public health.

These recommendations for policy improvement include (i) fulfilling enabler factors of AI via investing in internet connectivity and data infrastructure and educating everyone for digital literacy; (ii) building towards unified, interoperable health data management systems which enable secondary use of health data for research and public health while protecting the privacy of the individuals; (iii) shifting regulatory approach to continuous, holistic, ecosystem evaluation of manufacturer excellence based on principles from product-based evaluation; (iv) setting health equity benchmarks to mitigate risks of harm due to biases and to promote transparency of these technologies; (v) creation of proper product labels for AI/ML in medicine as like nutrition safety labels to empower users, increase societal trust, prevent harms, and harmonize standards of reporting for AI/ML in medicine. Finally, AI/ML in medicine will eventually deliver their potential to healthcare and public health. However, the realization of their beneficial potentials and harmful risks will mostly depend on how we regulate them. Policymakers can ensure equitable distribution of these benefits to all people while alleviating risks by utilizing the above

five key solutions to improve current regulatory frameworks of AI/ML in medicine. As regulations are constantly evolving, it is up to the policymakers to decide whether the utilization of these technologies will benefit all people equitably or not.

References

Aerts, A., & Bogdan-Martin, D. (2021). Leveraging data and AI to deliver on the promise of digital health. *International Journal of Medical Informatics (Shannon, Ireland), 150*, 104456. 10.1016/j.ijmedinf.2021.104456

Ahuja, A. S. (2019). The impact of artificial intelligence in medicine on the future role of the physician. *PeerJ, 7*, e7702. 10.7717/peerj.7702

ATLAS.ti, S. S. D. G. (2023). ATLAS.ti [computer software]

Bak, M., Madai, V. I., Fritzsche, M., Mayrhofer, M. T., & McLennan, S. (2022). You Can't Have AI Both Ways: Balancing Health Data Privacy and Access Fairly. *Frontiers in Genetics, 13*, 929453. 10.3389/fgene.2022.929453

Barton, M., Hamza, M., & Guevel, B. (2023). Racial Equity in Healthcare Machine Learning: Illustrating Bias in Models With Minimal Bias Mitigation. *Curēus (Palo Alto, CA), 15*(2), e35037. 10.7759/cureus.35037

Beckers, R., Kwade, Z., & Zanca, F. (2021). The EU medical device regulation: Implications for artificial intelligence-based medical device software in medical physics. *Physica Medica, 83*, 1-8. 10.1016/j.ejmp.2021.02.011

Benke, K., & Benke, G. (2018). Artificial Intelligence and Big Data in Public Health. *International Journal of Environmental Research and Public Health, 15*(12), 2796. 10.3390/ijerph15122796

Berbís, M. A., McClintock, D. S., Bychkov, A., Van der Laak, J., Pantanowitz, L., Lennerz, J. K., Cheng, J. Y., Delahunt, B., Egevad, L., Eloy, C., Farris, A. B., Fraggetta, F., García del Moral, R., Hartman, D. J., Herrmann, M. D., Hollemans, E., Iczkowski, K. A., Karsan, A., Kriegsmann, M., . . . Shen, J. (2023). Computational pathology in 2030: a Delphi study forecasting the role of AI in pathology within the next decade. *EBioMedicine, 88*, 104427. 10.1016/j.ebiom.2022.104427

Bernert, R. A., Hilberg, A. M., Melia, R., Kim, J. P., Shah, N. H., & Abnousi, F. (2020). Artificial Intelligence and Suicide Prevention: A Systematic Review of Machine Learning Investigations. *International Journal of Environmental Research and Public Health, 17*(16), 5929. 10.3390/ijerph17165929

Bertsimas, D., Borenstein, A. R. A., Dauvin, A., & Orfanoudaki, A. (2022). Ensemble machine learning for personalized antihypertensive treatment. *Naval Research Logistics, 69*(5), 669-688. 10.1002/nav.22040

Bozkurt, S., Cahan, E. M., Seneviratne, M. G., Sun, R., Lossio-Ventura, J. A., Ioannidis, J. P. A., & Hernandez-Boussard, T. (2020). Reporting of demographic data and representativeness in machine learning models using electronic health records. *Journal of the American Medical Informatics Association : JAMIA, 27*(12), 1878-1884. 10.1093/jamia/ocaa164

Brand, D., Singh, J. A., McKay, A., Cengiz, N., & Moodley, K. (2022). Data sharing governance in sub-Saharan Africa during public health emergencies: Gaps and

guidance. *South African Journal of Science, 118*(11-12)10.17159/sajs.2022/13892

Carolan, J. E., McGonigle, J., Dennis, A., Lorgelly, P., & Banerjee, A. (2022). Technology-Enabled, Evidence-Driven, and Patient-Centered: The Way Forward for Regulating Software as a Medical Device. *JMIR Medical Informatics, 10*(1), e34038. 10.2196/34038

Castleberry, A., & Nolen, A. (2018). Thematic analysis of qualitative research data: Is it as easy as it sounds? *Currents in Pharmacy Teaching and Learning, 10*(6), 807-815. 10.1016/j.cptl.2018.03.019

Charmaz, K. (2006). *Constructing Grounded Theory*. SAGE Publications.

Chervenkov, L., Sirakov, N., Kostov, G., Velikova, T., & Hadjidekov, G. (2023). Future of prostate imaging: Artificial intelligence in assessing prostatic magnetic resonance imaging. *World Journal of Radiology, 15*(5), 136-145. 10.4329/wjr.v15.i5.136

Cordeiro, J. V. (2021). Digital Technologies and Data Science as Health Enablers: An Outline of Appealing Promises and Compelling Ethical, Legal, and Social Challenges. *Frontiers in Medicine, 8*, 647897. 10.3389/fmed.2021.647897

Crossnohere, N. L., Elsaid, M., Paskett, J., Bose-Brill, S., & Bridges, J. F. P. (2022a). Guidelines for Artificial Intelligence in Medicine: Literature Review and Content Analysis of Frameworks. *Journal of Medical Internet Research, 24*(8), e36823. 10.2196/36823

Crossnohere, N. L., Elsaid, M., Paskett, J., Bose-Brill, S., & Bridges, J. F. P. (2022b). Guidelines for Artificial Intelligence in Medicine: Literature Review and Content Analysis of Frameworks. *Journal of Medical Internet Research, 24*(8), e36823. 10.2196/36823

Currie, G., Hawk, K. E., Rohren, E., Vial, A., & Klein, R. (2019). Machine Learning and Deep Learning in Medical Imaging: Intelligent Imaging. *Journal of Medical Imaging and Radiation Sciences, 50*(4), 477-487. 10.1016/j.jmir.2019.09.005

Da Silva, M., Horsley, T., Singh, D., Da Silva, E., Ly, V., Thomas, B., Daniel, R. C., Chagal-Feferkorn, K. A., Iantomasi, S., White, K., Kent, A., & Flood, C. M. (2022). Legal concerns in health-related artificial intelligence: a scoping review protocol. *Systematic Reviews, 11*(1), 1-123. 10.1186/s13643-022-01939-y

Dankwa-Mullan, I., Scheufele, E. L., Matheny, M. E., Quintana, Y., Chapman, W. W., Jackson, G., & South, B. R. (2021). A Proposed Framework on Integrating Health Equity and Racial Justice into the Artificial Intelligence Development Lifecycle. *Journal of Health Care for the Poor and Underserved, 32*(2), 300-317. 10.1353/hpu.2021.0065

Dankwa-Mullan, I., Rivo, M., Sepulveda, M., Park, Y., Snowdon, J., & Rhee, K. (2019). Transforming Diabetes Care Through Artificial Intelligence: The Future Is Here. *Population Health Management, 22*(3), 229-242. 10.1089/pop.2018.0129

Descript, I. (2023). Descript [computer software]

DIGITALEUROPE. (2023). *The Gigabit Infrastructure Act: Towards Europe's connectivity goals.* Retrieved June 5, 2023, from https://www.digitaleurope.org/resources/the-gigabit-infrastructure-act-towards-europes-connectivity-goals/

Directorate-General for Health and Food Safety. (2022). *Proposal for a regulation - The European Health Data Space.* Retrieved May 5, 2023, from https://health.ec.europa.eu/publications/proposal-regulation-european-health-data-space_en

Esteva, A., Kuprel, B., Novoa, R. A., Ko, J., Swetter, S. M., Blau, H. M., & Thrun, S. (2017). Dermatologist-level classification of skin cancer with deep neural networks. *Nature, 542*(7639), 115-118. 10.1038/nature21056

Federspiel, F., Mitchell, R., Asokan, A., Umana, C., & McCoy, D. (2023). Threats by artificial intelligence to human health and human existence. *BMJ Global Health, 8*(5)10.1136/bmjgh-2022-010435

Ferryman, K. (2020). Addressing health disparities in the Food and Drug Administration's artificial intelligence and machine learning regulatory framework. *Journal of the American Medical Informatics Association : JAMIA, 27*(12), 2016-2019. 10.1093/jamia/ocaa133

Fisher, S., & Rosella, L. C. (2022). Priorities for successful use of artificial intelligence by public health organizations: a literature review. *BMC Public Health, 22*(1), 2146. 10.1186/s12889-022-14422-z

Fletcher, R. R., Nakeshimana, A., & Olubeko, O. (2021). Addressing Fairness, Bias, and Appropriate Use of Artificial Intelligence and Machine Learning in Global Health. *Frontiers in Artificial Intelligence, 3*10.3389/frai.2020.561802

Food and Drug Administration. (2019). *Proposed regulatory framework for modifications to Artificial Intelligence/Machine Learning (AI/ML)-based Software as a Medical Device (SaMD).* ().Department of Health and Human Services (United States). Retrieved from Informit Analysis and Policy Observatory (APO) https://search.informit.org/documentSummary;res=APO;dn=228371

Gallifant, J., Nakayama, L. F., Gichoya, J. W., Pierce, R., & Celi, L. A. (2023). Equity should be fundamental to the emergence of innovation. *PLOS Digital Health, 2*(4), e0000224. 10.1371/journal.pdig.0000224

Gerke, S. (2023). "Nutrition Facts Labels" for Artificial Intelligence/Machine Learning-Based Medical Devices - The Urgent Need for Labeling Standards. *The George Washington Law Review, 91*(1), 79.

Gijsberts, C. M., Groenewegen, K. A., Hoefer, I. E., Eijkemans, M. J., Asselbergs, F. W., Anderson, T. J., Britton, A. R., Dekker, J. M., Engstrom, G., Evans, G. W., Graaf, J. d., Grobbee, D. E., Hedblad, B., Holewijn, S., Ikeda, A., Kitagawa, K., Kitamura, A., Kleijn, D. P. d., Lonn, E. M., . . . Ruijter, H. M. D. (2015). Race/Ethnic Differences in the Associations of the Framingham Risk Factors with Carotid IMT and Cardiovascular Events. *PLoS ONE, 10*(7), e0132321. 10.1371/journal.pone.0132321

Green, J., & Thorogood, N. (2018). *Qualitative methods for health research* (4th edition ed.). SAGE.

Guckert, M., Milanovic, K., Hannig, J., Simon, D., Wettengl, T., Evers, D., Kleyer, A., Keller, T., & Pitt, J. (2022). The Disruption of Trust in the Digital Transformation Leading to Health 4.0. *Frontiers in Digital Health, 4*, 815573. 10.3389/fdgth.2022.815573

Haneef, R., Delnord, M., Vernay, M., Bauchet, E., Gaidelyte, R., Van Oyen, H., Or, Z., Perez-Gomez, B., Palmieri, L., Achterberg, P., Tijhuis, M., Zaletel, M., Mathis-Edenhofer, S., Majek, O., Haaheim, H., Tolonen, H., & Gallay, A. (2020). Innovative use of data sources: a cross-sectional study of data linkage and artificial intelligence practices across European countries. *Archives of Public Health = Archives Belges De Sante Publique, 78*, 55. 10.1186/s13690-020-00436-9

Hannun, A. Y., Rajpurkar, P., Haghpanahi, M., Tison, G. H., Bourn, C., Turakhia, M. P., & Ng, A. Y. (2019). Cardiologist-level arrhythmia detection and classification in ambulatory electrocardiograms using a deep neural network. *Nature Medicine, 25*(1), 65-69. 10.1038/s41591-018-0268-3

Hashiguchi, T. C. O., Oderkirk, J., & Slawomirski, L. (2022). Fulfilling the Promise of Artificial Intelligence in the Health Sector: Let's Get Real. *Value in Health : The Journal of the International Society for Pharmacoeconomics and Outcomes Research, 25*(3), 368-373. 10.1016/j.jval.2021.11.1369

Haug, C. J., & Drazen, J. M. (2023). Artificial Intelligence and Machine Learning in Clinical Medicine, 2023. *N Engl J Med, 388*(13), 1201-1208. 10.1056/NEJMra2302038

Ho, C. (2022). Operationalizing "One Health" as "One Digital Health" Through a Global Framework That Emphasizes Fair and Equitable Sharing of Benefits From the Use of Artificial Intelligence and Related Digital Technologies. *Frontiers in Public Health, 10*10.3389/fpubh.2022.768977

Hosny, A., Parmar, C., Quackenbush, J., Schwartz, L. H., & Aerts, H. J. W. L. (2018). Artificial intelligence in radiology. *Nature Reviews Cancer, 18*(8), 500-510. 10.1038/s41568-018-0016-5

Jansen, P., Baguer, D. O., Duschner, N., Arrastia, J. L., Schmidt, M., Landsberg, J., Wenzel, J., Schadendorf, D., Hadaschik, E., Maass, P., Schaller, J., & Griewank, K. G. (2023). Deep learning detection of melanoma metastases in lymph nodes. *European Journal of Cancer (1990), 188*, 161-170. 10.1016/j.ejca.2023.04.023

Jiao, Z., Ji, H., Yan, J., & Qi, X. (2023). Application of big data and artificial intelligence in epidemic surveillance and containment. *Intelligent Medicine, 3*(1), 36-43. 10.1016/j.imed.2022.10.003

Jungwirth, D., & Haluza, D. (2023). Artificial Intelligence and Public Health: An Exploratory Study. *International Journal of Environmental Research and Public Health, 20*(5)10.3390/ijerph20054541

Kim, J. K., Choi, M. J., Lee, J. S., Hong, J. H., Kim, C., Seo, S. I., Jeong, C. W., Byun, S., Koo, K. C., Chung, B. H., Park, Y. H., Lee, J. Y., & Choi, I. Y. (2018). A Deep Belief Network and Dempster-Shafer-Based Multiclassifier for the Pathology Stage of Prostate Cancer. *Journal of Healthcare Engineering, 2018*, 4651582-8. 10.1155/2018/4651582

Kim, K., Kim, S., Lee, Y. H., Lee, S. H., Lee, H. S., & Kim, S. (2018). Performance of the deep convolutional neural network based magnetic resonance image scoring algorithm for differentiating between tuberculous and pyogenic spondylitis. *Scientific Reports, 8*(1), 13124-10. 10.1038/s41598-018-31486-3

Kyhlstedt, M. (2022). The need for action by evaluators and decision makers in Europe to ensure safe use of medical software. *Frontiers in Medical Technology, 4*, 1063622. 10.3389/fmedt.2022.1063622

Lee, P., Bubeck, S., & Petro, J. (2023). Benefits, Limits, and Risks of GPT-4 as an AI Chatbot for Medicine. *The New England Journal of Medicine, 388*(13), 1233-1239. 10.1056/NEJMsr2214184

Loeza-Mejía, C., Sánchez-DelaCruz, E., Pozos-Parra, P., & Landero-Hernández, L. (2021). The potential and challenges of Health 4.0 to face COVID-19 pandemic: a rapid review. *Health and Technology, 11*(6), 1321-1330. 10.1007/s12553-021-00598-8

Lopez, D. M., Rico-Olarte, C., Blobel, B., & Hullin, C. (2022). Challenges and solutions for transforming health ecosystems in low- and middle-income countries

through artificial intelligence. *Frontiers in Medicine, 9*, 958097. 10.3389/fmed.2022.958097

Meszaros, J., Minari, J., & Huys, I. (2022). The future regulation of artificial intelligence systems in healthcare services and medical research in the European Union. *Frontiers in Genetics, 13*, 927721. 10.3389/fgene.2022.927721

Minssen, T., Gerke, S., Aboy, M., Price, N., & Cohen, G. (2020). Regulatory responses to medical machine learning. *Journal of Law and the Biosciences, 7*(1), D1-lsaa002. 10.1093/jlb/lsaa002

Monostori, L. (2014). Artificial Intelligence. In L. Laperrière, & G. Reinhart (Eds.), *CIRP Encyclopedia of Production Engineering* (pp. 47-50). Springer Berlin Heidelberg. 10.1007/978-3-642-20617-7_16703

Morgenstern, J. D., Rosella, L. C., Daley, M. J., Goel, V., Schunemann, H. J., & Piggott, T. (2021). "AI's gonna have an impact on everything in society, so it has to have an impact on public health": a fundamental qualitative descriptive study of the implications of artificial intelligence for public health. *BMC Public Health, 21*(1), 40. 10.1186/s12889-020-10030-x

Morley, J., Machado, C., Burr, C., Cowls, J., Joshi, I., Taddeo, M., & Floridi, L. (2020). The ethics of AI in health care: A mapping review. *Social Science & Medicine, 260*10.1016/j.socscimed.2020.113172

Morley, J., Murphy, L., Mishra, A., Joshi, I., & Karpathakis, K. (2022). Governing Data and Artificial Intelligence for Health Care: Developing an International Understanding. *JMIR Formative Research, 6*(1), e31623. 10.2196/31623

Mosch, L., Fürstenau, D., Brandt, J., Wagnitz, J., Klopfenstein, S. A., Poncette, A., & Balzer, F. (2022). The medical profession transformed by artificial intelligence: Qualitative study. *Digital Health, 8*, 20552076221143903. 10.1177/20552076221143903

News: European Parliament. (2023a). *AI Act: a step closer to the first rules on Artificial Intelligence.* Retrieved May 22, 2023, from https://www.europarl.europa.eu/news/en/press-room/20230505IPR84904/ai-act-a-step-closer-to-the-first-rules-on-artificial-intelligence

News: European Parliament. (2023b). *EU AI Act: first regulation on artificial intelligence.* Retrieved June 16, 2023, from https://www.europarl.europa.eu/news/en/headlines/society/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence

Noble, H., & Mitchell, G. (2016). What is grounded theory? *Evidence-Based Nursing, 19*(2), 34-35. 10.1136/eb-2016-102306

Obermeyer, Z., & Emanuel, E. J. (2016). Predicting the Future — Big Data, Machine Learning, and Clinical Medicine. *The New England Journal of Medicine, 375*(13), 1216-1219. 10.1056/NEJMp1606181

Obermeyer, Z., Powers, B., Vogeli, C., & Mullainathan, S. (2019). Dissecting racial bias in an algorithm used to manage the health of populations. *Science (American Association for the Advancement of Science), 366*(6464), 447-453. 10.1126/science.aax2342

Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D., Shamseer, L., Tetzlaff, J. M., Akl, E. A., Brennan, S. E., Chou, R., Glanville, J., Grimshaw, J. M., Hróbjartsson, A., Lalu, M. M., Li, T., Loder, E. W., Mayo-Wilson, E., McDonald, S., . . . Moher, D. (2021). The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ (Online), 372*, n71. 10.1136/bmj.n71

Palinkas, L. A., Horwitz, S. M., Green, C. A., Wisdom, J. P., Duan, N., & Hoagwood, K. (2015). Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research. *Administration and Policy in Mental Health and Mental Health Services Research, 42*(5), 533-544. 10.1007/s10488-013-0528-y

Park, C. W., Seo, S. W., Kang, N., Ko, B., Choi, B. W., Park, C. M., Chang, D. K., Kim, H., Kim, H., Lee, H., Jang, J., Ye, J. C., Jeon, J. H., Seo, J. B., Kim, K. J., Jung, K. H., Kim, N., Paek, S., Shin, S. Y., . . . Yoon, H. J. (2020). Artificial Intelligence in Health Care: Current Applications and Issues. *Journal of Korean Medical Science, 35*(42), e379. 10.3346/jkms.2020.35.e379

Park, H. J., Kim, S. M., La Yun, B., Jang, M., Kim, B., Jang, J. Y., Lee, J. Y., & Lee, S. H. (2019). A computer-aided diagnosis system using artificial intelligence for the

diagnosis and characterization of breast masses on ultrasound: Added value for the inexperienced breast radiologist. *Medicine (Baltimore), 98*(3), e14146. 10.1097/MD.0000000000014146

Patra, B. G., Sharma, M. M., Vekaria, V., Adekkanattu, P., Patterson, O. V., Glicksberg, B., Lepow, L. A., Ryu, E., Biernacka, J. M., Furmanchuk, A., George, T. J., Hogan, W., Wu, Y., Yang, X., Bian, J., Weissman, M., Wickramaratne, P., Mann, J. J., Olfson, M., . . . Pathak, J. (2021). Extracting social determinants of health from electronic health records using natural language processing: a systematic review. *Journal of the American Medical Informatics Association : JAMIA, 28*(12), 2716-2727. 10.1093/jamia/ocab170

Pelayo, S., Bras Da Costa, S., Leroy, N., Loiseau, S., & Beuscart-Zephir, M. (2013). Software as a medical device: regulatory critical issues. *Studies in Health Technology and Informatics, 183*(183), 337-342. 10.3233/978-1-61499-203-5-337

Pesapane, F., Codari, M., & Sardanelli, F. (2018). Artificial intelligence in medical imaging: threat or opportunity? Radiologists again at the forefront of innovation in medicine. *European Radiology Experimental, 2*(1), 35. 10.1186/s41747-018-0061-6

Pesapane, F., Volonté, C., Codari, M., & Sardanelli, F. (2018). Artificial intelligence as a medical device in radiology: ethical and regulatory issues in Europe and the United States. *Insights into Imaging, 9*(5), 745-753. 10.1007/s13244-018-0645-y

Pickering, B. (2021). Trust, but Verify: Informed Consent, AI Technologies, and Public Health Emergencies. *Future Internet, 13*(5)10.3390/fi13050132

Pierson, L., & Tsai, B. (2023). Misaligned AI constitutes a growing public health threat. *BMJ (Online), 381*, p1340. 10.1136/bmj.p1340

Raskind, I. G., Shelton, R. C., Comeau, D. L., Cooper, H. L. F., Griffith, D. M., & Kegler, M. C. (2019). A Review of Qualitative Data Analysis Practices in Health Education and Health Behavior Research. *Health Education & Behavior, 46*(1), 32-39. https://doi.org/10.1177/1090198118795019

Rodriguez-León, C., Villalonga, C., Munoz-Torres, M., Ruiz, J. R., & Banos, O. (2021). Mobile and Wearable Technology for the Monitoring of Diabetes-Related Parameters: Systematic Review. *JMIR mHealth and uHealth, 9*(6), e25138. 10.2196/25138

Ryu, S. M., Seo, S. W., & Lee, S. (2020). Novel prognostication of patients with spinal and pelvic chondrosarcoma using deep survival neural networks. *BMC Medical Informatics and Decision Making, 20*(1), 3. 10.1186/s12911-019-1008-4

Sampson, D., Dwyer, L., Tseng, E., Lorell, B., & Kavi, K. (2019). FDA Proposes Regulatory Framework for Artificial Intelligence/Machine Learning Software as a Medical Device. *Intellectual Property & Technology Law Journal, 31*(7), 12-16. https://search.proquest.com/docview/2255356660

Sauerbrei, A., Kerasidou, A., Lucivero, F., & Hallowell, N. (2023). The impact of artificial intelligence on the person-centred, doctor-patient relationship: some

problems and solutions. *BMC Medical Informatics and Decision Making, 23*(1), 73. 10.1186/s12911-023-02162-y

Schwalbe, N., & Wahl, B. (2020). Artificial intelligence and the future of global health. *The Lancet (British Edition), 395*(10236), 1579-1586. 10.1016/S0140-6736(20)30226-9

Shah, S. M., & Khan, R. A. (2020). Secondary Use of Electronic Health Record: Opportunities and Challenges. *Ieee Access, 8*, 136947-136965. 10.1109/ACCESS.2020.3011099

Tacconelli, E., Gorska, A., Carrara, E., Davis, R. J., Bonten, M., Friedrich, A. W., Glasner, C., Goossens, H., Hasenauer, J., Abad, J. M. H., Penalvo, J. L., Sanchez-Niubo, A., Sialm, A., Scipione, G., Soriano, G., Yazdanpanah, Y., Vorstenbosch, E., & Jaenisch, T. (2022). Challenges of data sharing in European Covid-19 projects: A learning opportunity for advancing pandemic preparedness and response. *The Lancet Regional Health.Europe, 21*, 100467. 10.1016/j.lanepe.2022.100467

Thomasian, N. M., Eickhoff, C., & Adashi, E. Y. (2021). Advancing health equity with artificial intelligence. *Journal of Public Health Policy, 42*(4), 602-611. 10.1057/s41271-021-00319-5

Ting, D. S. W., Cheung, C. Y., Lim, G., Tan, G. S. W., Quang, N. D., Gan, A., Hamzah, H., Garcia-Franco, R., San Yeo, I. Y., Lee, S. Y., Wong, E. Y. M., Sabanayagam, C., Baskaran, M., Ibrahim, F., Tan, N. C., Finkelstein, E. A., Lamoureux, E. L., Wong,

I. Y., Bressler, N. M., . . . Wong, T. Y. (2017). Development and Validation of a Deep Learning System for Diabetic Retinopathy and Related Eye Diseases Using Retinal Images From Multiethnic Populations With Diabetes. *JAMA : The Journal of the American Medical Association, 318*(22), 2211-2223. 10.1001/jama.2017.18152

Tong, A., Sainsbury, P., & Craig, J. (2007). Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care, 19*(6), 349-357. 10.1093/intqhc/mzm042

Tran, N. K., Albahra, S., May, L., Waldman, S., Crabtree, S., Bainbridge, S., & Rashidi, H. (2021). Evolving Applications of Artificial Intelligence and Machine Learning in Infectious Diseases Testing. https://escholarship.org/uc/item/348931dd

U.S. Food and Drug Administration. (2022). *Digital Health Software Precertification (Pre-Cert) Pilot Program.* https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-software-precertification-pre-cert-pilot-program

Vadapalli, S., Abdelhalim, H., Zeeshan, S., & Ahmed, Z. (2022). Artificial intelligence and machine learning approaches using gene expression and variant data for personalized medicine. *Briefings in Bioinformatics, 23*(5)10.1093/bib/bbac191

Van den Eynde, J., Lachmann, M., Laugwitz, K., Manlhiot, C., & Kutty, S. (2022). Successfully implemented artificial intelligence and machine learning applications in cardiology: State-of-the-art review. *Trends in Cardiovascular Medicine,* 10.1016/j.tcm.2022.01.010

Vemula, D., Jayasurya, P., Sushmitha, V., Kumar, Y. N., & Bhandari, V. (2023). CADD, AI and ML in drug discovery: A comprehensive review. *European Journal of Pharmaceutical Sciences, 181*, 106324. 10.1016/j.ejps.2022.106324

Vokinger, K. N., & Gasser, U. (2021). Regulating AI in medicine in the United States and Europe. *Nature Machine Intelligence, 3*(9), 738-739. https://doi.org/10.1038/s42256-021-00386-z

Wang, C., Zhang, J., Lassi, N., & Zhang, X. (2022). Privacy Protection in Using Artificial Intelligence for Healthcare: Chinese Regulation in Comparative Perspective. *Healthcare (Basel, Switzerland), 10*(10)10.3390/healthcare10101878

Wen, C., Liu, W., He, Z., & Liu, C. (2022). Research on emergency management of global public health emergencies driven by digital technology: A bibliometric analysis. *Frontiers in Public Health, 10*, 1100401. 10.3389/fpubh.2022.1100401

Winter, J. S., & Davidson, E. (2019). Governance of artificial intelligence and personal health information. *Digital Policy, Regulation and Governance, 21*(3), 280-290. 10.1108/DPRG-08-2018-0048

Appendices

Appendix - 1: Consolidated Criteria for Reporting Qualitative Studies (COREQ)

Developed from:
Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357.

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research Team and Reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the inter view or focus group?	**16**
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	**16**
3. Occupation	What was their occupation at the time of the study?	**16**
4. Gender	Was the researcher male or female?	**16**
5. Experience and training	What experience or training did the researcher have?	**16**
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	**16**
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	**75** Appendix - 3
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator?	**16**
Domain 2: Study Design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	**14**
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	**15**
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	**15**
12. Sample size	How many participants were in the study?	**24**
13. Non-participation	How many people refused to participate or dropped out? Reasons?	**24**

Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	**16**
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	**16**
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	**24 and 80 Appendix - 5**
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	**15 and 53**
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	**16**
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	**16**
20. Field notes	Were field notes made during and/or after the inter view or focus group?	**16**
21. Duration	What was the duration of the interviews or focus group?	**16 and 80 Appendix - 5**
22. Data saturation	Was data saturation discussed?	**24**
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	**17**
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	**One (The author)**
25. Description of the coding tree	Did authors provide a description of the coding tree?	**81 Appendix - 6**
26. Derivation of themes	Were themes identified in advance or derived from the data?	**25**
27. Software	What software, if applicable, was used to manage the data?	**16**
28. Participant checking	Did participants provide feedback on the findings?	**17**
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	**26-42**
30. Data and findings consistent	Was there consistency between the data presented and the findings?	**26-42**
31. Clarity of major themes	Were major themes clearly presented in the findings?	**26-42**
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	**26-42**

Appendix - 2: The Search Strategy for the Literature Review

Search Query		Results	
#	TS=Topic, TI=Title, AB=Abstract, AK=Author's Keywords with Timespan: 2018-01-01 to 2023-05-01	Web of Science	MEDLINE
1	(((TS=(artificial intelligence)) OR TI=(artificial intelligence)) OR AB=(artificial intelligence)) OR AK=(artificial intelligence)	96.393	33.692
2	(((TS=(machine learning)) OR TI=(machine learning)) OR AB=(machine learning)) OR AK=(machine learning)	266.776	81.550
3	(((TS=(deep learning)) OR TI=(deep learning)) OR AB=(deep learning)) OR AK=(deep learning)	226.340	53.975
4	(((TS=(neural networks)) OR TI=(neural networks)) OR AB=(neural networks)) OR AK=(neural networks)	201.192	52.090
5	(((TS=(computational intelligence)) OR TI=(computational intelligence)) OR AB=(computational intelligence)) OR AK=(computational intelligence)	10.872	2.845
6	**#1 OR #2 OR #3 OR #4 OR #5**	**596.329**	**163.322**
7	(((TS=(regulation)) OR TI=(regulation)) OR AB=(regulation)) OR AK=(regulation)	406.089	403.930
8	(((TS=(regulatory frameworks)) OR TI=(regulatory frameworks)) OR AB=(regulatory frameworks)) OR AK=(regulatory frameworks)	2.896	1.162
9	(((TS=(legislation)) OR TI=(legislation)) OR AB=(legislation)) OR AK=(legislation)	35.871	27.960
10	(((TS=(law)) OR TI=(law)) OR AB=(law)) OR AK=(law)	214.983	28.341
11	(((TS=(legal)) OR TI=(legal)) OR AB=(legal)) OR AK=(legal)	102.990	24.033
12	(((TS=(medico-legal)) OR TI=(medico-legal)) OR AB=(medico-legal)) OR AK=(medico-legal)	1.374	1.207
13	(((TS=(guidelines)) OR TI=(guidelines)) OR AB=(guidelines)) OR AK=(guidelines)	292.701	185.121
14	(((TS=(governance)) OR TI=(governance)) OR AB=(governance)) OR AK=(governance)	95.231	10.522
15	**#7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14**	**1.055.263**	**656.616**
16	(((TS=(public health)) OR TI=(public health)) OR AB=(public health)) OR AK=(public health)	237.212	201.798
17	(((TS=(population health)) OR TI=(population health)) OR AB=(population health)) OR AK=(population health)	232.291	202.759
18	(((TS=(community health)) OR TI=(community health)) OR AB=(community health)) OR AK=(community health)	140.755	113.073
19	(((TS=(health disparities)) OR TI=(health disparities)) OR AB=(health disparities)) OR AK=(health disparities)	41.413	36.297
20	(((TS=(health surveillance)) OR TI=(health surveillance)) OR AB=(health surveillance)) OR AK=(health surveillance)	35.136	35.506
21	(((TS=(health equity)) OR TI=(health equity)) OR AB=(health equity)) OR AB=(health equity)	17.021	14.804
22	(((TS=(epidemiology)) OR TI=(epidemiology)) OR AB=(epidemiology)) OR AK=(epidemiology)	162.607	640.713
23	**#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22**	**673.311**	**954.114**
24	**#6 AND #15 AND #23**	**835**	**759**
25	**#6 AND #15 AND #23 and English (Languages)**	**816**	**747**

Appendix - 3: Email Invitation Template

Subject: Expert invitation for an interview on regulating AI in medicine

Dear [Recipient],

My name is Atalay Demiray, and I am a master's student in Health Policy at Erasmus University Rotterdam. I am currently working on my thesis about regulating AI in medicine to uphold public health. As an expert in this field, I would like to invite you to participate in a semi-structured interview to gather your valuable input.

Experts are chosen based on a literature review with a search period of 2018-2023. Your publications and ideas are already included in the first part of my thesis as a literature review. The semi-structured interview aims to have an in-depth conversation to answer the following research question: "How do policymakers improve the current regulatory frameworks governing the use of AI in medicine to uphold public health while protecting its innovative potential?" Your input would be invaluable, given your expertise in this area.

The interview will last 30-60 minutes and will be conducted on Zoom. It will be recorded, and the script will be used for further analysis. I would be grateful for your response, whether it is positive or negative. If you agree to participate, please suggest a date and time according to your availability. Furthermore, if you have any sources you would like to mention during the interview, please share them with me beforehand. In case of a negative response, I would appreciate it if you could specify the reason to prevent selection bias.

If you have any questions, please do not hesitate to ask.
Thank you for your time and consideration.

Best regards,
Atalay Demiray, MD
Master Student
Health Economics, Policy & Law
Erasmus University Rotterdam

Appendix - 4: Interview Guide

A. Participant Information

Participant No.:	#
Participant name & contact information:	
Participant Background & Education:	
Participant Institution & *Expertise Area:*	
Meeting Platform:	Zoom
Date:	
Interviewer/Note-taker:	Atalay Demiray

B. Interviewer Checklist

- Confirm the date and time and send a reminder to the participant before the meeting.
- Make sure you send the link for the Zoom meeting to the participant.
- Ascertain the allotted interview time acceptable to the participant.
- Print a copy of the Interview Guide to take notes during interviews.

C. Introduction and Consent Statement

Say: Thank you very much for agreeing to participate in this interview. I am asking artificial intelligence (AI) experts about the impacts of AI and its regulations, especially focusing on the public health perspective. I will use your input to understand the potential regulation improvements in emerging AI technologies.

Let me first introduce myself. I am Atalay, and I am from Turkey. I am currently living in Rotterdam, where I am studying for my master's in health economics, Policy, and Law at Erasmus University. After finishing my master's thesis here, I will start my PhD in Health Policy at Yale University. I am a medical graduate, but I dedicated myself to Health Policy and Global Health. Due to my interest in AI applications in medicine, I chose my thesis topic on the regulation of AI in medicine.

Participant Consent Statement:

Say: Your input during this interview will be used in my master thesis at Erasmus University Rotterdam. With your permission, the session will be recorded on Zoom and will be analyzed and coded into themes. You may also withdraw your responses from the interview at any time.
Ask: Do you agree for the data collected in the study to be used in the thesis?

☐ Yes ☐ No Notes:

Ask: Do you also agree to have the interview recorded?
☐ Yes ☐ No Notes:

Ask: Do you have any conflict of interest regarding this topic?
☐ Yes ☐ No Notes:

Ask: Do you have any questions before we proceed?

D. Interview Structure

Say: Our interview will consist of three parts. We will first begin by getting you and your research areas know better, then we will talk about the impact of AI in medicine and public health. Then we will continue our talk with policies regarding its regulation. Discussion regarding the regulations of AI constitutes the main aim of my thesis research.

E. Questions

The interview will be semi-structured, and therefore, follow-up questions to probe further into interesting issues and to clarify statements will be posed at the discretion of the interviewer. If a question in the sequence has been addressed by earlier dialogue, then these can be skipped at the discretion of the interviewer.

Part 1 – Expert Identification

1. Could you please briefly introduce yourself and provide an overview of your professional background and experience, especially in the field of AI?
2. What motivated you to specialize in this area and contribute to the field of AI?

Possible Follow-ups:

- Have you been involved in any policy development or advisory roles related to the regulation of AI in the healthcare sector? If so, could you describe your involvement and the outcomes of those initiatives?
- What professional networks or associations do you actively engage with to stay up to date with the latest developments and discussions in AI and healthcare policy?
- Are there any specific areas within the field of AI in medicine where you have conducted extensive research or possess specialized knowledge? What are your primary areas of interest or expertise within the broader scope of AI in medicine and regulatory frameworks?

Part 2 – Impact of AI in Medicine

3. From your perspective, what will be the most significant impact of AI on medicine and/or public health?

Possible Follow-ups:

- In your experience, what are the primary benefits or advantages that AI brings to the field of medicine and public health?
- The proliferation of wearable biometric devices, social media, and connected smart home applications have raised hope for new approaches to disease surveillance, prediction, and prevention. What opportunities and risks do you foresee in the applications of AI to personalized, preventative medicine?
- In your opinion, what role does AI play in enhancing disease surveillance, early detection, and prevention efforts in public health?
- Can you provide any estimation for the impact of AI in medicine right now compared to its full potential, and when do you think it will reach its full potential?
- What are the potential future directions and opportunities for AI in medicine and public health, and how do you envision its impact in the coming years?

4. Are there any challenges or limitations associated with the implementation of AI in healthcare? If so, what are they?

Possible Follow-ups:

- Are there any ethical or privacy concerns that arise from the use of AI in medicine, and how are these concerns being addressed?
- As we attempt to leverage various data sources for the prevention and identification of disease, what privacy issues do you anticipate, and how, if at all, might these be overcome? What other risks do you foresee in both the short and long term, including issues of safety, human agency, and identity?
- What role do data quality, data privacy, and data security play in ensuring the successful and responsible implementation of AI in healthcare?

5. In your opinion, how the current application of AI in medicine affects health equity and disparities?

Possible Follow-ups:

- Can you share any insights or evidence regarding the impact of AI on health equity and disparities? Has it helped to bridge any gaps or created new challenges?
- In your opinion, what are the key considerations or strategies that policymakers and stakeholders should prioritize to maximize the positive impact of AI in medicine and public health?
- With advances involving low-cost sensors, the internet of things, and AI, how much of healthcare might be transferred into the home with no necessary involvement of human professionals? Could these advances be accessible to all? Should they be publicly funded?

Part 3 – Regulation of AI in Medicine

I would like to have a short answer for the following question by thinking broadly about regulating AI.

6. In your opinion,

- What to do? Shut it all down, regulate harshly, regulate lightly, no regulation at all.
- Who should be doing it? Government, corporations, politicians, academics, etc.
- Where (or at which level) should it be done? National, regional, and international level.
- When should it be done? Are we late, or early, still have time?
- How should it be done?

7. How do you perceive the balance between protecting public health and promoting innovation in the context of AI use in medicine?

Possible Follow-ups:

- How do you perceive the effectiveness of current AI regulations in upholding public health and fostering innovation?

8. In your opinion, what are the key challenges or gaps in the existing regulatory frameworks related to AI in medicine?

Possible Follow-ups:

- Are there any specific ethical considerations or principles that policymakers should prioritize while shaping regulatory frameworks for AI in medicine? If so, what are they?
- What specific measures or improvements would you recommend to current regulatory frameworks governing AI in medicine?
- How can policymakers ensure that the regulatory frameworks keep pace with the rapid advancements in AI technology, while also addressing emerging ethical and safety concerns?

9. What role do you think stakeholders, such as healthcare providers, researchers, technology companies, and patient advocacy groups, should play in shaping and improving the regulatory frameworks for AI in medicine?

Possible Follow-ups:

- Which stakeholder do you think has the biggest responsibility in this discussion?

10. How do you think international collaboration and harmonization of regulatory frameworks can contribute to addressing the challenges associated with AI in medicine? Possible Follow-ups: Are national regulations enough? Or is an international agreement a must? Which extent do we need international collaboration?

11. Are there any best practices or lessons learned from other domains or countries that policymakers could draw upon while improving the regulatory frameworks for AI in medicine?

Possible Follow-ups:

- What potential risks or unintended consequences do you foresee if regulatory frameworks become too restrictive or too lenient in governing the use of AI in medicine?

12. Final comments/additions

F. End of Interview

Say: Thank you very much for your participation.

Appendix - 5: Specific Characteristics of Interview Participants

Participant ID	Gender	Continent	Organization Type	Primary Area of Expertise	Interview Duration (hh:mm:ss)
#1	Male	Asia	Academia	Public Health	00:34:19
#2	Female	Europe	Academia	Public Health	01:08:50
#3	Female	North America	Academia	Public Health	00:22:43
#4	Male	Europe	Industry	Data Informatics	01:08:02
#5	Male	North America	Academia	Health Law	00:28:04
#6	Female	Europe	Academia	Public Health	00:58:56
#7	Male	North America	NGO	Data Informatics	00:54:03
#8	Female	Europe	Academia	Medicine	01:00:05
#9	Male	Europe	Academia	Ethics	00:43:37
#10	Male	Europe	NGO	Data Informatics	00:56:07
#11	Female	Europe	NGO	Health Law	00:54:33
#12	Male	Europe	Academia	Artificial Intelligence	01:04:09

NGO, Non-governmental organization.

Appendix - 6: Detailed Coding Information

Codes	Number of Times Coded (including all sub-codes)
Governance/Regulations	**379**
AI Governance	**157**
Principle-based/Norm-based	17
Medical Devices Regulation	16
AI/Technology Ethics	14
Complexity	13
Risk Assessment/Risk-based Approach	12
Liability/Accountability	10
Accelerated Speed	9
Holistic Approach	8
Finance/Banking System	7
Dynamic Evaluation/Re-testing	6
Human Oversight	6
Qualification/Certification	6
Trust	6
Pharmaceuticals/Pharmacy	4
Ecosystem Approach	3
New ways of validation	3
Nuclear Energy	3
AI Labelling	2
Data Governance	**128**
Data Privacy	24
Data Sharing/Access/Usage	21
Data Security/Protection	18
Data Management	8
Data Interoperability	8
Healthcare Data/Electronic Health Records/Patient Data	7
GDPR	6

Concern on Data Quality	5
Cybersecurity	4
Data Ownership	3
Wellbeing Data	2
Global/International Collaboration/Cooperation	**73**
Global Health Governance	12
Global Politics/Policymaking/Public Policy	11
International Organizations: UN, WHO, ITU	9
Global/International Agreement/Standards/Regulations	8
European Union (EU)	7
Global Health	7
Leadership	4
Globalization	4
Low and Middle-Income Countries (LMICs)	2
Top-down Approach	2
Uncertainties	**232**
Amplifier/Enhancer	**69**
Amplifier of Existing Inequalities	16
Amplifier of Biases	9
Lack of Expertise/Knowledge	9
Lack of Infrastructure	7
Amplifier of Social (in)Justice	6
Accessibility & Connectivity (Internet & Bandwith)	4
Insufficiencies of Healthcare	4
Lack of Digital Literacy	3
Black-box Issues	**66**
Safety Concerns & Reliability	18
Lack of Transparency	12
Inappropriate Use/Misuse	9
Poor Generalizability/Reproducibility	8
Limited Explainability	6

Distrust of algorithms	5
Bias	**53**
Diversity & Inclusion	15
Underrepresentation	8
Discrimination	8
Contextual Bias	6
Gender Bias	5
Data Representation	4
Impact	**27**
Power and Politics	7
Societal Issues	5
Dehumanization	4
Job Security/Displacement	3
Human-centric AI	2
Human-Human Interaction	2
Potentials	**113**
Enhanced Healthcare Access	**41**
Democratizing Medicine/healthcare	7
Empowering Patients	6
Closing the gaps/Information Asymmetry	5
Equal Treatment/Care	4
Improved Quality of Care/Healthcare	4
Health Equity	3
Universal Coverage/Access	2
Affordable Healthcare	2
Better Surveillance	**33**
Big Data Analysis	15
Disease Management/Prevention	5
Realtime Analysis	3
Epidemiology	2
Personalized Health/Medicine	**28**

Improved Medical Research	7
Precision Medicine	6
Improved Personal Health	5
Incentives and Nudges	4
Transforming Healthcare	2
Innovation	31
COVID-19	18
Government Politics	11
Education	7
Corporate Interest	5
Funding	4
Private Sector	3


Closing the gaps/Information asymmetry
Disease Management/Prevention
Improved Quality of Care/Healthcare
Accelerated Speed
Ecosystem Approach
Amplifier/Enhancer
Dynamic Evaluation
Lack of Infrastructure
Impact
Global
Distrust of algorithms
Insufficiencies of Healthcare
Inappropriate Use/Misuse
Personalized
AI
European Union (EU)
Data Interoperability
Health
Human-centric AI
Empowering Patients
Amplifier of Social (in)Justice
Concern on Data Quality
Enhanced
Health
Job Security/Displacement
Pharmaceuticals
AI Ethics
Data
Improved Personal Health
Healthcare
International Cooperation
Risk-based Approach
Access
Universal Coverage/Access
Education
Corporate Interest
Big Data Analysis
Underrepresentation
Data Protection
Access
Governance
Incentives and Nudges
Governance
Private Sector
Global Standards
Power and Politics
Global Politics
Global Health
Electronic Health Records
Funding
Trust
Low and Middle-Income Countries (LMICs)
Diversity & Inclusion
Governance/Regulations
New ways of validation
Safety Concerns & Reliability
Principle-based/Norm-based
Complexity
COVID-19
Equal Treatment/Care
GDPR
Improved Medical Research
Lack of Digital Literacy
Uncertainties
AI Labelling
Finance System
Medical Devices Regulation
Societal Issues
Realtime Analysis
Lack of Transparency
Leadership
Democratizing Medicine/Healthcare
Government Politics
Liability/Accountability
Affordable Healthcare
Black-box
Data
Health Equity
UN, WHO, ITU
Amplifier of Biases
Better
Holistic Approach
Data Representation
Precision Medicine
Poor Generalizability/Reproducibility
Surveillance
Issues
Amplifier of Existing Inequalities
Limited Explainability
Discrimination
Data Privacy
Innovation
Bias
Accessibility & Connectivity
Human-Human Interaction
Contextual Bias
Qualification
Cybersecurity
Dehumanization
Data Management
Gender Bias
Governance
Nuclear Energy
Wellbeing Data
Lack of Expertise/Knowledge
Human Oversight
Transforming Healthcare
Top-down Approach
Globalization
Potentials
Data Ownership
Epidemiology