



UNIVERSIDADE CATÓLICA PORTUGUESA

How Does European Regulation for Artificial Intelligence Affect Healthcare Businesses?

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by

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Abstract

This master's thesis addresses the critical issue of integrating Artificial Intelligence (AI) in healthcare within the European regulatory landscape, underscoring its significance for healthcare businesses facing ethical, legal, and practical challenges. Employing a comprehensive methodology that includes policy analysis, managerial strategy evaluation, and case study examination, the research seeks to uncover effective strategies for AI integration in healthcare settings. The objectives are to navigate the strategic, ethical, economic, and compliance hurdles of AI adoption in healthcare and to offer actionable recommendations for healthcare leaders and policymakers. The main findings highlight the essential role of a balanced approach that recognizes the potential benefits and challenges of AI in healthcare, stressing the imperative of ethical considerations and the intricacies of the European regulatory framework for successful AI integration in healthcare management and policy-making.

Keywords: Artificial Intelligence, Healthcare Integration, European Regulatory Landscape, AI in Healthcare Management, Policy-Making Challenges

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Chapter 1

Introduction

1.1 What is Artificial Intelligence

AI is defined as "the simulation of human intelligence in machines that are programmed to think like humans and mimic their actions" (Encyclopedia Britannica, n.d.). This encompasses a broad spectrum of capabilities, including problem-solving, pattern recognition, language understanding, and decision-making, aiming to replicate or surpass human cognitive functions in machines.

Artificial Intelligence has become a transformative force in various sectors, particularly in healthcare. Its evolution is characterized by enhancing diagnostic accuracy, personalizing treatment plans, and optimizing administrative workflows (Davenport & Kalakota, 2019). The integration of AI in healthcare, such as in radiology and personalized medicine, has revolutionized diagnostics and treatment, albeit with challenges like data quality and ethical considerations (Saravi et al., 2022).

Policy and Managerial Implications in AI Adoption

The adoption of AI in healthcare necessitates robust policy frameworks and strategic management. Policymakers are tasked with creating regulations that balance innovation with ethical considerations and data privacy (World Health Organization, 2023). Healthcare managers must navigate these regulations while effectively integrating AI into clinical and administrative processes, requiring strategic planning and investment in AI literacy (Cutler, 2023).

Ethical Dimensions and Health Equity

Ethical considerations and health equity are critical in AI deployment in healthcare. An ethical framework that emphasizes transparency, equity, and human-centric values is essential to address potential biases and ensure responsible AI use (Khoury et al., 2022). Policies must ensure that AI technologies do not exacerbate health disparities but rather contribute to equitable health outcomes (Istasy et al., 2022).

AI in Healthcare Management

AI technologies like ChatGPT are reshaping healthcare management. The managerial challenge involves integrating these technologies while addressing privacy and ethical concerns. Future advancements will require healthcare managers to adapt their strategies to evolving AI technologies (Azamfirei et al., 2023).

Challenges in AI Automation and Regulation

Effective data management and regulatory compliance are crucial for AI automation in healthcare. Healthcare managers must focus on data engineering strategies that ensure scalability and reliability in AI applications. This includes addressing challenges in data ingestion and real-time processing (Artificial Intelligence 2023 Legislation).

Policy-Making in AI and Healthcare

Policy-making in AI and healthcare involves creating regulations that foster innovation while ensuring patient safety and data security. Policymakers must consider the rapid pace of AI advancements and their implications for healthcare delivery (World Health Organization, 2023).

Managerial Strategies in AI Integration

Effective managerial strategies are essential for the successful integration of AI in healthcare. This involves understanding the implications of AI on healthcare delivery, workforce training, and patient engagement. Managers must also navigate the complexities of AI implementation, including infrastructure development and ethical considerations (Cutler, 2023).

In summary, the integration of AI in healthcare is a complex interplay of technological advancements, policy-making, and managerial strategies. The subsequent sections of this thesis will delve deeper into European regulations for AI, their impact on healthcare businesses, and the role of policy-making and management in this evolving landscape.

1.2 Problem Statement: Managerial and Policy-Making Aspects of AI in Healthcare

The integration of AI in healthcare represents a transformative shift, offering innovative solutions to enhance healthcare delivery. However, this integration presents unique challenges, particularly in regulatory compliance, ethical considerations, and managerial decision-making. The European Union (EU), with its comprehensive regulatory framework, leads in establishing guidelines and regulations to manage AI applications, ensuring they align with fundamental rights and foster technological innovation.

Managerial Challenges in AI Integration

Healthcare managers face a multifaceted set of challenges in integrating AI. These include aligning AI initiatives with strategic healthcare goals, ensuring interoperability with existing technologies, managing transformational change within organizations, and addressing workforce implications. Managers must also navigate

the complexities of AI technology, including understanding its capabilities and limitations, to effectively implement AI solutions (Davenport & Kalakota, 2019).

Policy-Making in AI Healthcare

Policy-makers are tasked with creating a regulatory environment that balances the rapid advancement of AI technologies with patient safety, privacy concerns, and ethical considerations. The EU's General Data Protection Regulation (GDPR) is a key legislative framework that impacts how AI is used in healthcare, particularly in handling patient data (European Parliament, 2016). Policies must also address ethical concerns, such as algorithmic bias, decision-making transparency in AI applications, and the equitable distribution of AI benefits across diverse patient populations.

Ethical Considerations and Compliance

Ethical considerations in AI applications in healthcare are paramount. Healthcare organizations must ensure that AI applications comply with ethical standards and legal requirements, including patient consent and data privacy laws. The ethical deployment of AI also involves addressing potential biases in AI algorithms and ensuring that AI decisions are explainable and transparent (Luxton, 2020).

Economic and Business Implications

The economic and business implications of AI in healthcare are profound. Healthcare organizations must invest in AI technologies and training, which can be a significant financial undertaking. Additionally, the adoption of AI can lead to changes in healthcare delivery models, impacting revenue streams and operational costs (Jiang et al., 2017).

Strategic Planning for AI Integration

Strategic planning is crucial for the successful integration of AI in healthcare. This involves assessing the healthcare organization's readiness for AI, identifying areas where AI can add the most value, and developing a roadmap for AI implementation. Strategic planning also includes considering the long-term implications of AI on healthcare delivery, workforce requirements, and patient care models (Davenport & Kalakota, 2019).

Research Focus

This thesis aims to explore the managerial and policy-making challenges in the integration of AI in healthcare. It will examine the strategic, ethical, economic, and compliance-related aspects of AI adoption in healthcare settings. Through an analysis of current policies, managerial strategies, and case studies, this research will provide insights into effective AI integration in healthcare, offering recommendations for healthcare leaders and policy-makers.

1.3 Research Question: Managerial and Policy-Making Perspectives in AI Healthcare Integration

Navigating the intricate landscape of AI in healthcare, particularly within the EU's regulatory framework, presents a myriad of challenges and opportunities for healthcare businesses. The integration of AI technologies in healthcare promises enhanced efficiency and innovative solutions but also brings forth significant ethical, legal, and practical considerations. This thesis, recognizing the transformative potential and complexities of AI applications in healthcare, is centered around the following research question:

"How can healthcare businesses effectively harness AI technologies while concurrently adhering to European regulations and ensuring patient safety through strategic measures?"

Expanded Exploration of the Research Question

This research question is designed to guide a comprehensive exploration and understanding of the multifaceted aspects of implementing AI technologies in healthcare, with a focus on the European regulatory context. It aims to navigate the complexities of regulatory compliance, ethical norms, patient safety, and managerial challenges while leveraging AI's innovative potential.

Leveraging AI Technologies: Investigate various AI technologies and their applications in healthcare, understanding their potential in enhancing healthcare delivery, patient outcomes, and operational efficiency. This includes exploring managerial strategies for AI integration and innovation management.

Ensuring Compliance with European Regulations: Delve into the European regulatory framework for AI in healthcare, focusing on the Artificial Intelligence Act (AIA) and the GDPR. Analyze the stipulations, requirements, and challenges in ensuring compliance from a managerial and policy-making perspective.

Ensuring Patient Safety: Examine the implications of AI technologies on patient safety, exploring the challenges and solutions in ensuring that AI applications enhance patient care and safety. This includes understanding the role of management in implementing safe AI practices.

Balancing Innovation and Compliance: Explore how healthcare businesses can balance the need for innovation with the imperative of compliance. Investigate

strategies and approaches that facilitate ethical and compliant implementation of AI technologies in healthcare.

Managerial Challenges in AI Integration: Address the specific managerial challenges healthcare businesses face in integrating AI technologies. This includes managing organizational change, aligning AI initiatives with strategic goals, ensuring staff training and development, and effectively handling data governance and privacy concerns.

Case Studies and Practical Implications: Analyze case studies of healthcare businesses that have implemented AI technologies. Explore their journey in navigating the regulatory landscape, ensuring compliance, and leveraging AI technologies effectively, with a focus on managerial and policy-making insights.

Aim of the Research

Through this research question, the thesis aims to provide a comprehensive exploration of the measures that healthcare businesses can adopt to effectively leverage AI technologies while ensuring compliance with European regulations and safeguarding patient safety. The subsequent chapters will delve deeper into exploring this research question, navigating through the regulatory, ethical, practical, and managerial aspects, and providing insights and recommendations for healthcare businesses, policymakers, and other stakeholders in the domain.

1.4 Justification: Managerial and Policy-Making Perspectives in AI Healthcare Integration

The integration of AI into healthcare is a pivotal advancement, offering innovative solutions and enhancing healthcare delivery efficiency and effectiveness. However, implementing AI technologies in healthcare involves complexities, especially in regulatory compliance, ethical considerations, and patient safety. This thesis, centered

around the research question, "What measures can healthcare businesses adopt to leverage AI technologies effectively while maintaining compliance with European regulations and ensuring patient safety?", aims to explore the multifaceted dimensions of AI applications in healthcare within the European regulatory context. The justification for this research is anchored in several key considerations:

1.4.1 Navigating the Regulatory Landscape

The EU's robust regulatory framework for AI, including the AIA and GDPR, presents challenges for healthcare businesses in ensuring compliance. This research seeks to explore these challenges, focusing on managerial and policy-making strategies for effective navigation through the regulatory landscape.

1.4.2 Ensuring Ethical and Safe AI Applications in Healthcare

AI applications in healthcare raise significant ethical considerations, including data privacy, bias, transparency, and accountability. This research aims to explore these ethical implications from a managerial perspective, providing guidelines for ensuring ethical and safe AI applications in healthcare.

1.4.3 Balancing Innovation and Compliance

Healthcare businesses face the challenge of balancing innovation with regulatory compliance. This research explores how healthcare businesses can navigate this balance, providing insights into effective strategies for leveraging AI technologies while ensuring compliance.

1.4.4 Contributing to Policy Development and Implementation

By exploring the challenges and solutions in implementing AI technologies within the regulatory framework, this research aims to contribute to policy development and implementation, offering insights for policymakers in enhancing the regulatory framework for AI in healthcare.

1.4.5 Guiding Healthcare Businesses in AI Implementation

This research provides valuable insights and recommendations for healthcare businesses in implementing AI technologies. It aims to guide healthcare businesses in adopting measures to leverage AI effectively while ensuring regulatory compliance and patient safety.

In light of these considerations, this research is justified in its aim to provide a comprehensive exploration of the measures that healthcare businesses can adopt to leverage AI technologies effectively while ensuring compliance with European regulations and safeguarding patient safety. The insights and recommendations derived from this research could guide healthcare businesses, policymakers, and other stakeholders in navigating the complexities of AI applications in healthcare, ensuring a balanced approach that fosters innovation while safeguarding ethical and legal norms.

1.5 Methodology: Managerial and Policy-Making Perspectives in AI Healthcare Integration

This methodology section outlines the research design and methods employed to explore the central research question: "What measures can healthcare businesses adopt to leverage AI technologies effectively while maintaining compliance with European regulations and ensuring patient safety?" The research navigates through the complexities of the European regulatory landscape, ethical considerations, and practical challenges in implementing AI technologies in healthcare businesses, with a focus on managerial and policy-making aspects.

1.5.1 Research Design

The research will employ an exploratory design to understand the managerial and policy challenges of AI in healthcare within Europe's regulatory environment, using a qualitative approach to delve into the nuanced ethical and practical aspects from a managerial viewpoint.

1.5.2 Data Collection

A comprehensive literature review on AI in healthcare, focusing on European regulations and management perspectives, will be complemented by case studies to illustrate real-world applications, challenges, and successes of AI technology in the healthcare sector.

1.5.3 Data Analysis

Thematic analysis will be utilized to extract key themes from the literature and case studies, focusing on AI in healthcare management and policy-making, while a comparative analysis will elucidate diverse managerial approaches and policy strategies, spotlighting best practices and innovations.

1.5.4 Limitations

The study focuses on AI in healthcare within Europe, emphasizing managerial and policy aspects, with the acknowledgment that findings might not apply broadly to

other regions. Limited data availability, especially for case studies, could affect the depth of research, but efforts to include diverse sources aim to address this challenge.

Through this methodology, the research aims to provide a comprehensive exploration of the measures that healthcare businesses can adopt to leverage AI technologies effectively while ensuring compliance with European regulations and safeguarding patient safety, with a focus on managerial and policy-making aspects. The insights and recommendations derived from this research could guide healthcare businesses, policymakers, and other stakeholders in navigating the complexities of AI applications in healthcare.

1.6 Scope of the Study: Managerial and Policy-Making Perspectives in AI Healthcare Integration

The exploration of AI applications in healthcare within the European regulatory framework encompasses various facets, including technological, ethical, legal, and practical aspects, with a specific focus on managerial and policy-making challenges. This research, centered around the question, "What measures can healthcare businesses adopt to leverage AI technologies effectively while maintaining compliance with European regulations and ensuring patient safety?", aims to provide a comprehensive exploration and understanding of these multifaceted dimensions. The scope of this study is expanded as follows:

1.6.1 Geographical Scope

European Context: The research will focus on AI applications in healthcare within the EU, exploring the regulatory framework, including the AIA and the GDPR, and its implications on healthcare businesses in the EU. This includes a detailed examination of how these regulations impact managerial decisions and policy-making processes in healthcare businesses.

1.6.2 Sectoral Scope

Healthcare Sector: The research will be focused on the healthcare sector, exploring AI applications in various facets of healthcare, including patient care, healthcare management, and healthcare delivery. Special attention will be given to how AI technologies are integrated into healthcare management practices and policy frameworks.

1.6.3 Technological Scope

AI Technologies: The research will explore various AI technologies and their applications in healthcare, including machine learning, natural language processing, robotics, and other AI technologies. The focus will be on understanding the managerial implications and policy considerations of these technologies in healthcare.

1.6.4 Regulatory Scope

European AI Regulations: The research will explore the European regulatory framework for AI in healthcare, focusing on the existing and proposed regulations, including the AIA and GDPR, and their implications on healthcare businesses. The study will delve into how these regulations are shaping managerial strategies and policy-making in healthcare.

1.6.5 Ethical and Legal Scope

Ethical and Legal Considerations: The research will explore the ethical and legal considerations in implementing AI technologies in healthcare, including data privacy, bias, transparency, and accountability, within the European regulatory context. The emphasis will be on how these considerations are managed and addressed from a policy and managerial perspective.

1.6.6 Practical Scope

Implementation of AI in Healthcare Businesses: The research will explore the practical aspects of implementing AI technologies in healthcare businesses, including the challenges, solutions, and strategies for ensuring regulatory compliance and leveraging AI technologies effectively. This includes a focus on managerial practices and policy development for AI implementation.

1.6.7 Temporal Scope

Current and Future Implications: While the research will focus on the current regulatory framework and its implications, it will also explore the future implications of the evolving regulatory landscape on AI applications in healthcare. This includes predicting future trends in managerial and policy-making strategies in response to evolving AI technologies and regulations.

Through this expanded scope, the research aims to provide a comprehensive exploration of the measures that healthcare businesses can adopt to leverage AI technologies effectively while ensuring compliance with European regulations and safeguarding patient safety. The findings and recommendations derived from this research aim to guide healthcare businesses, policymakers, and other stakeholders in navigating the complexities of AI applications in healthcare, ensuring a balanced approach that fosters innovation while safeguarding ethical and legal norms.

Chapter 2

Literature Review

2.1 Overview of the Literature Review

The integration of AI in healthcare, particularly within the European regulatory framework, has emerged as a pivotal area of research. The incorporation of AI technologies into healthcare practices, management, and delivery is recognized for its potential to enhance efficiency, improve patient outcomes, and innovate traditional healthcare models. However, it also introduces significant challenges and considerations, especially in terms of regulatory compliance, ethical implications, and practical implementation within the European context. This section introduces the literature review, outlining its purpose, approach, and structure, and sets the stage for an in-depth exploration of existing literature related to AI applications in healthcare within the European regulatory framework, with a specific focus on managerial and policy-making aspects.

Purpose

The literature review aims to explore, analyze, and synthesize existing research and studies related to AI applications in healthcare, with a specific focus on the European regulatory context. It seeks to understand the current state of research, identify gaps, and establish a foundation for exploring the research question: "What measures can healthcare businesses adopt to leverage AI technologies effectively while maintaining compliance with European regulations and ensuring patient safety?"

Approach

The approach to the literature review involves a meticulous exploration of various databases and platforms to identify relevant research studies, publications, and

articles related to AI applications in healthcare within the European regulatory context. The literature review focuses on research and studies published from 2021 onwards, ensuring the relevance and currency of the explored literature.

Structure

The literature review will navigate through various facets related to AI applications in healthcare within the European regulatory context, exploring the technological, ethical, legal, and practical aspects. It will delve into the European regulatory framework for AI in healthcare, ethical considerations, legal implications, practical challenges and solutions, and economic implications, providing a comprehensive exploration and understanding of the multifaceted dimensions of AI applications in healthcare.

Preliminary Insights from Recent Studies

The integration of AI in healthcare, particularly through AI-assisted smartphone apps and web-based services, necessitates a comprehensive understanding of the associated risks and implications. Sangers et al. (2023) highlight the need for transparency and a robust regulatory framework to mitigate risks like inaccuracy and misuse. Similarly, functional requirements outlined by Garc'ia-G'omez et al. (2023) emphasize the importance of continuous performance evaluation and bias checks to safeguard patient well-being. The ethical landscape, as discussed by Mohammad Amini et al. (2023), underscores the critical need for GDPR compliance and ethical norms in AI applications.

The anticipation and reception of Europe's AI Strategy, as explored by Polyviou & Zamani (2023), reveal stakeholder concerns around governance and data protection. This is echoed in the public's trust in data governance, particularly within the NHS, as examined by Kerasidou (2023), highlighting the delicate balance between

innovation and privacy. Wang et al. (2023) introduce an adaptive federated learning framework, AFEI, demonstrating the potential of privacy-preserving technologies in healthcare.

The principles of responsible AI, discussed by Sivarajah et al. (2023), call for ethical considerations in digital health. Noia et al. (2022) and Kiseleva et al. (2022) delve into the regulatory impacts on recommender systems and the necessity for a multilayered approach to AI transparency in healthcare. The evolving European regulations on AI and cybersecurity, as analyzed by Mueck et al. (2023), along with the potential for AI highlighted by Davenport & Kalakota (2019), set the stage for transformative healthcare delivery.

Meszaros et al. (2022) discuss the future regulation of AI systems in healthcare services, stressing the legal and ethical challenges. The importance of secure telemedicine options, as reviewed by Cubo et al. (2021), and the role of government interventions in stimulating innovation, as noted by Shneiderman (2022), underscore the multifaceted approach needed for AI integration in healthcare.

In conclusion, the literature presents a consensus on the transformative potential of AI in healthcare, tempered by the need for vigilant regulatory, ethical, and technical oversight to ensure safe, effective, and equitable healthcare delivery.

In conclusion, the literature review has provided a comprehensive overview of the current state of AI applications in healthcare within the European regulatory context. It has highlighted the multifaceted nature of AI integration in healthcare, encompassing technological advancements, ethical considerations, legal implications, and practical challenges. The insights gathered from the reviewed literature underscore the importance of balancing innovation with regulatory compliance, ethical norms, and patient safety. This exploration sets a solid foundation for further investigation into the research question and contributes significantly to understanding how healthcare businesses can effectively leverage AI technologies while adhering to European regulations.

2.2 Managerial and Policy Implications of AI in Healthcare: A Historical Perspective

2.2.1 Evolution of AI in Healthcare: Implications for Management and Policy

The evolution of AI in healthcare has been marked by significant advancements in machine learning, natural language processing, and robotics. These technologies have transformed healthcare delivery, management, and patient care. The journey from rudimentary applications to sophisticated, personalized healthcare solutions provides insights into the technological advancements and innovations in AI applications in healthcare. This evolution has necessitated a rethinking of healthcare delivery models, resource allocation, and strategic planning, significantly impacting healthcare management and policy-making.

2.2.2 Historical Challenges and Policy Responses in AI Healthcare Applications

The integration of AI in healthcare has historically faced numerous challenges, including ethical dilemmas, data privacy concerns, and regulatory hurdles. These challenges have necessitated significant policy responses, shaping the current regulatory landscape in healthcare AI.

Ethical challenges in AI healthcare revolve around transparency, bias, privacy, safety, responsibility, justice, and autonomy. The integration of AI into smart healthcare products, particularly medical electronic devices, has brought these issues to the forefront. Policymakers and healthcare managers must address these ethical challenges in the design, validation, clinical trials, deployment, monitoring, repair, and retirement of AI-based healthcare products. The differences between traditional ethics in the medical domain and emerging ethical challenges with AI-driven healthcare are particularly notable. As AI technologies become more integrated into healthcare, the need for ethical guidelines and frameworks becomes increasingly critical. These guidelines must address the unique challenges posed by AI, such as

algorithmic bias, which can perpetuate existing healthcare inequities, and the need for transparency in AI decision-making processes (Pasricha, S., 2022).

2.2.3 Comparative Analysis of AI Healthcare Regulations: Ethical and Economic Implications in China, the United States, and the EU

The regulatory frameworks governing AI in healthcare across China, the United States, and the EU are pivotal in shaping the trajectory of healthcare innovation and its ethical implications. This paper endeavors to compare and contrast these frameworks, highlighting the unique approaches adopted by each region and the underlying ethical and economic considerations that inform these policies.

In China, the government's approach to AI regulation is characterized by a strong emphasis on state control and economic ambition. The Chinese regulatory framework is designed to leverage AI as a strategic tool to achieve national economic and geopolitical objectives (Fischer et al., 2023). Recent legislation emphasizes the importance of aligning AI development with the values of socialism, underscoring the state's role in guiding AI innovation in alignment with national interests (Leadership, 2023). However, this centralized approach raises significant concerns regarding privacy and civil liberties, particularly in the context of healthcare, where sensitive patient data is at stake.

Contrastingly, the United States adopts a more decentralized, market-driven approach to AI regulation. The absence of a comprehensive federal AI policy has resulted in a fragmented landscape, where state-specific regulations address the ethical, privacy, and bias challenges of AI in healthcare (Sullivan, 2023). This regulatory environment fosters innovation but also poses challenges in ensuring consistent standards and protections across different jurisdictions.

The European Union offers a more holistic regulatory model, with a strong focus on ethics, fundamental rights, and data protection. The EU's proposed AI Act represents a significant effort to categorize AI applications based on risk levels, imposing stringent compliance requirements on high-risk domains such as healthcare (Fischer et al., 2023). This approach aims to balance the need for innovation with ethical considerations, striving to foster public trust in AI technologies.

The global AI race underscores the strategic importance of AI regulation, with nations vying for innovation leadership (Data Innovation, 2019). This competitive landscape highlights the need for regulatory frameworks that not only foster innovation but also address the ethical and legal challenges posed by AI in healthcare. These challenges include ensuring patient privacy, avoiding algorithmic bias, and maintaining transparency in AI-driven decision-making processes (Ethical and Legal Challenges, 2020).

In conclusion, the regulatory landscapes for AI in healthcare in China, the United States, and the EU reflect diverse approaches to balancing innovation with ethical governance. As AI continues to evolve, these frameworks must adapt to address emerging challenges, ensuring that AI advancements in healthcare are harnessed ethically and effectively to benefit society at large.

2.2.4 AI and Healthcare Economics: Managerial Decision-Making

AI's role in healthcare economics is pivotal, especially in resource management and decision-making during outlier events like pandemics. Data-driven methods, such as reinforcement learning and genetic algorithms, provide healthcare managers with tools for optimum resource allocation. These methods help in navigating the

complexities of healthcare economics, ensuring efficient and equitable distribution of resources.

Algorithm fairness in AI for medicine and healthcare is a challenging problem in delivering equitable care. Inequities in diagnosis, treatments, and healthcare costs have been revealed when AI models are stratified across race sub-populations. Addressing these issues is crucial for healthcare managers to ensure fair and equitable healthcare delivery. The development and deployment of AI systems in healthcare must consider algorithm fairness to avoid exacerbating existing healthcare disparities. This involves evaluating AI models across diverse populations and ensuring that they do not introduce or perpetuate bias. Emerging technologies such as federated learning, disentanglement, and model explainability play a crucial role in mitigating bias and ensuring fairness in AI-SaMD (Software as a Medical Device) development. Chen et al., (2021)

2.2.5 Risk Management in AI Healthcare: A Regulatory Perspective

The proposed EU AI Act, as a comprehensive attempt to regulate AI, highlights the importance of risk management in AI healthcare. Understanding the regulatory concept behind risk management provisions is crucial for compliance and safe integration of AI in healthcare. Trust and medical AI are closely linked, and failures in medical AI could erode public trust in healthcare institutions. Education and accreditation of new expert groups specializing in the development, verification, and operation of medical AI technologies are proposed to maintain trust in healthcare institutions. These groups would be responsible for ensuring that AI technologies in healthcare are developed and operated safely and effectively. They would also play a key role in verifying that these technologies meet regulatory standards and ethical guidelines. This approach would help address the major conceptual, technical, and

humanistic challenges in medical AI, including issues related to data quality, algorithmic transparency, and the potential for unintended consequences in clinical outcomes (Quinn, et al. 2020).

2.2.6 Implementing AI in Healthcare: The Three Lines of Defense Model

The Three Lines of Defense (3LoD) model in risk management can be adapted for AI in healthcare. This model helps in assigning and coordinating risk management roles, identifying gaps in risk coverage, and increasing the effectiveness of risk management practices (Schuett, J. 2022).

2.3 Ethical Considerations in AI Applications in Healthcare

The integration of AI in healthcare has been transformative, offering innovative solutions and enhancing healthcare delivery. However, the implementation of AI technologies in healthcare also brings forth ethical considerations that need to be meticulously addressed to ensure the responsible and ethical use of AI.

2.3.1 Data Privacy and Protection

Ensuring data privacy and protection is paramount in AI applications in healthcare, particularly considering the sensitive nature of healthcare data. Ethical considerations related to data privacy encompass ensuring the confidentiality, integrity, and availability of data, safeguarding patient privacy, and ensuring compliance with data protection regulations, such as the GDPR.

2.3.2 Patient Autonomy and Consent

Respecting patient autonomy and ensuring informed consent in AI applications in healthcare is crucial. Ethical considerations related to patient autonomy and consent involve ensuring that patients are adequately informed, their autonomy is respected, and their consent is obtained in an informed and voluntary manner.

2.3.3 Addressing Bias and Policy Measures

Combatting bias and promoting equity in AI applications is a critical policy challenge. Policies must be developed to ensure AI systems are fair and equitable, avoiding discriminatory practices in healthcare delivery. Ethical and philosophical concerns such as bias, transparency, autonomy, responsibility, and accountability are paramount in integrating AI into healthcare. Key measures and techniques to address these ethical challenges include addressing data scarcity, racial bias, lack of transparency, and algorithmic bias. The democratization of AI tools in healthcare can potentially reduce the cost of care, optimize resource allocation, and improve the quality of care. However, this democratization must be accompanied by a comprehensive understanding of the ethical issues involved. AI can uncover complex relations in data from a large set of inputs and even lead to new evidence-based knowledge in medicine. However, this potential must be balanced with the need to ensure that AI systems are transparent, and unbiased, and respect patient autonomy. The integration of AI into healthcare raises several ethical and philosophical concerns that must be addressed through rigorous standards and best practices in clinical settings (Jha, et al., 2023).

2.3.4 AI and Healthcare Economics: Policy Implications

The role of AI in healthcare economics extends to policy implications, especially in resource management and decision-making during critical events. The COVID-19 pandemic has highlighted the challenges of deploying AI models in rapidly evolving situations. Policymakers need to focus on the moving clinical needs and the importance of translating models to reflect local healthcare environments. Both basic and applied research are essential to accelerate the potential of AI models, particularly during rapidly evolving pandemics. The limited impact AI has had to date in the management of COVID-19 underscores the need for more effective integration of AI

technologies in healthcare. This involves not only developing AI models that are capable of addressing the clinical needs at different stages of an epidemic but also ensuring that these models are adaptable to local healthcare environments. The global scientific community must react swiftly and effectively to combat future disease outbreaks, leveraging AI technologies in a way that is responsive to the evolving nature of such crises (Hu, Y., et al., 2020).

2.3.5 Accountability and Responsibility

Ensuring accountability and responsibility in AI applications in healthcare is essential to safeguard patient interests and promote ethical AI use. Ethical considerations related to accountability and responsibility involve establishing clear accountability and responsibility frameworks for AI applications in healthcare. These frameworks should delineate the roles and responsibilities of various stakeholders, including AI developers, healthcare providers, and regulatory bodies, to ensure that AI applications are used in a manner that is ethical, transparent, and beneficial to patients.

2.4 Legal Implications of AI Applications in Healthcare

The legal landscape of AI applications in healthcare is intricate and multifaceted, especially within the European context. The integration of AI technologies in healthcare not only brings forth innovative solutions and enhanced healthcare delivery but also introduces various legal implications that need to be navigated meticulously. This section explores the legal implications of AI applications in healthcare, focusing on regulatory compliance, data protection, patient rights, liability, and legal frameworks, particularly within the European regulatory context (Rob Procter, et al. 2022).

2.4.1 Regulatory Compliance

Ensuring regulatory compliance in AI applications in healthcare involves navigating a complex array of regulations and guidelines. This includes the GDPR and the proposed AIA, which are pivotal in shaping the development, implementation, and utilization of AI technologies within legal frameworks. The Italian National Health Service's adoption of AI underscores the need for special care in formalizing the knowledge domain, leveraging domain-specific data spaces, and addressing data governance issues from an interoperability perspective. The healthcare data governance and interoperability legal framework is characterized by the interplay of different pieces of legislation, including the GDPR, the Data Governance Act, and the Open Data Directive. Additionally, the Data Act and the European Health Data Space proposals will impact health data sharing and must be considered. The platform developed by the Italian NHL will have to be integrated in a harmonized manner with the systems already used in the healthcare system and with the digital assets (data and software) used by healthcare professionals (Reale, R. 2023).

2.4.2 Data Protection and Patient Rights

Data protection and safeguarding patient rights are paramount in AI applications in healthcare. Legal implications related to data protection and patient rights involve ensuring the confidentiality, integrity, and availability of data, safeguarding patient privacy, and ensuring that patient rights are upheld in AI applications in healthcare. The increasing use of AI in algorithmic decision-making raises questions about how bias can be excluded or mitigated. The shift from a process-oriented to a result-oriented discrimination assessment in AI decision-making necessitates the societal determination of the appropriate fairness measures for specific scenarios, especially in contexts like hiring decisions. This shift has significant legal implications based on EU law (Hauer, et al. 2022).

2.4.3 Liability and Legal Frameworks

Navigating liability and establishing clear legal frameworks for AI applications in healthcare is crucial to ensure accountability, responsibility, and legal clarity in the development, implementation, and use of AI technologies in healthcare. The use of AI in legal proceedings, driven by the economics of smaller budgets and larger case numbers, necessitates examining the concept of disparate impact and how biases in training data lead to the search for fairer AI. This discourse includes criticism of pre-processing methods in a legal context, outlining how pre-processing is used to correct biased data and examining the legal implications of effectively changing cases to achieve a fairer outcome. This includes the black box problem and the slow encroachment on legal precedent (Boswell, et al. 2021)

Insights from Recent Studies

For a detailed examination of the recent studies that informed the discussions on liability and legal frameworks within the context of AI applications in healthcare, please refer to the Appendix A-1. This section delves into the pivotal insights and findings from contemporary research, highlighting the ethical, practical, and legal challenges and considerations underpinning the deployment of AI in the healthcare sector.

2.5 Implementation Challenges of AI Applications in Healthcare: Managerial Focus

The implementation of AI in healthcare presents a range of managerial challenges that need to be navigated to ensure successful and effective AI applications in healthcare settings. This section explores these challenges, focusing on managerial aspects such as technical, organizational, ethical, and regulatory challenges, particularly within the European context.

2.5.1 Technical Challenges

From a managerial perspective, technical challenges in implementing AI applications in healthcare involve ensuring the accuracy, reliability, and robustness of AI technologies. This includes addressing data quality and management issues and ensuring the interoperability and integration of AI technologies within existing healthcare systems. Managers must navigate the complex nature of healthcare workflows, the intricacies in managing large and secure medical imaging data, and the absence of standardized frameworks for AI development. These barriers require a new paradigm to address them, emphasizing the role of interoperability in connecting disparate applications within healthcare workflows (Erdal, et al. 2023).

2.5.2 Organizational Challenges

Organizational challenges in implementing AI applications in healthcare involve navigating change management, ensuring alignment with organizational goals and strategies, and addressing issues related to culture, leadership, and workforce development. Managers must consider the ethical challenges of integrating AI into smart healthcare products, including medical electronic devices. Differences between traditional ethics in the medical domain and emerging ethical challenges with AI-driven healthcare are presented, particularly as they relate to transparency, bias, privacy, safety, responsibility, justice, and autonomy (Pasricha, S., 2022).

2.5.3 Ethical and Regulatory Challenges

Ethical and regulatory challenges in implementing AI applications in healthcare involve ensuring ethical use, navigating regulatory compliance, and addressing issues related to data privacy, patient rights, and ethical considerations in AI applications.

Managers must be aware of the technical and ethical challenges and implications of deploying AI in hospitals and public organizations. Key measures and techniques to address ethical challenges, data scarcity, racial bias, lack of transparency, and algorithmic bias are crucial (Jha, et al., 2023).

2.5.4 Scalability and Sustainability Challenges

Scalability and sustainability challenges involve ensuring that AI applications in healthcare are scalable and sustainable, addressing issues related to scalability, sustainability, and the long-term viability of AI applications in healthcare. Managers must consider the potential risks and ethical implications of imaging AI solutions, which are perceived as complex, opaque, and difficult to comprehend, utilize, and trust in critical clinical applications (Rosenfeld, et al. 2019).

Insights from Recent Studies

Further insights into the scalability and sustainability challenges associated with AI applications in healthcare, including the risks, ethical considerations, and strategies for effective implementation, can be found in the Appendix A-2. This additional information draws from recent studies that shed light on the complexities of ensuring that AI technologies not only meet current healthcare needs but are also viable in the long term.

Chapter 3

Objectives

3.1 Objectives

This section of the thesis sets forth the objectives aimed at dissecting the multifaceted relationship between AI in healthcare and the regulatory frameworks within the European Union. It begins by delving into the existing and proposed regulations, notably the AIA and the GDPR, to elucidate their impact on healthcare management and policy formulation. A critical examination of the AIA's risk-based approach is undertaken, evaluating its challenges and practicality in the healthcare sector from a managerial vantage point.

Furthermore, the thesis endeavors to unpack the ethical, legal, and social ramifications of AI in healthcare. This includes an in-depth analysis of ethical considerations such as data privacy, bias, transparency, and accountability, and their influence on healthcare management. The legal implications, particularly concerning data protection, patient rights, and regulatory adherence, are scrutinized from a managerial perspective. Additionally, the social repercussions of AI, including its effects on patient care, healthcare delivery, and societal perceptions, are explored to understand their implications for managerial decision-making.

The impact of AI regulations on healthcare businesses is also a focal point, with an investigation into how these entities navigate the regulatory landscape, emphasizing compliance, innovation management, and the practical challenges encountered. Through case studies, the thesis aims to provide real-world insights into the experiences of healthcare businesses with AI adoption, regulatory compliance, and the strategies employed to surmount obstacles.

Finally, the thesis proposes actionable recommendations for various stakeholders. For policymakers, it suggests enhancements to the regulatory framework that encourage innovation while maintaining ethical and legal standards. For healthcare businesses, it offers guidelines on implementing AI technologies effectively while ensuring compliance with regulations. The thesis also highlights areas where further research is needed, proposing future directions to deepen the understanding of the regulatory environment for AI in healthcare.

By achieving these objectives, the research aspires to furnish a thorough comprehension of the EU's regulatory landscape for AI in healthcare, presenting the intricacies of integrating AI technologies in healthcare businesses. It aims to provide valuable insights and recommendations for stakeholders, fostering an environment that balances innovation with ethical and legal considerations in the realm of AI in healthcare.

Chapter 4

Findings

1. Managerial and Policy-Making Strategies in Healthcare AI: The research identified diverse strategies healthcare businesses adopt in integrating AI. Key strategies include developing AI-specific policies, investing in employee training for AI readiness, and fostering partnerships with AI technology providers. These strategies are crucial in navigating the complex regulatory landscape and in harnessing the full potential of AI for improved patient care and operational efficiency.

2. Validation and Ethical Considerations in AI Implementation: The integrity of AI applications in healthcare hinges on stringent validation processes and ethical considerations. Data triangulation has confirmed the reliability of these findings. Ethical considerations extend beyond data confidentiality and privacy, encompassing issues like algorithmic bias and the ethical use of AI in decision-making. Transparency in AI operations and decision-making processes emerged as a pivotal factor in building trust among stakeholders.

3. Challenges in Data Availability and Application: A significant challenge in AI implementation is the limited availability and variability of quality data. This limitation affects AI algorithms' training and efficacy, potentially leading to biased or inaccurate outcomes. Additionally, the research highlighted the need for frameworks to ensure data is used ethically and responsibly in AI applications.

4. Legal Implications and Patient Rights in AI: Legal considerations, particularly regarding data protection and patient rights, are critical in AI applications in

healthcare. The research underscored the importance of aligning AI applications with existing legal frameworks like GDPR. Furthermore, safeguarding patient privacy and upholding patient rights in AI-driven processes are essential for ethical and legal compliance.

5. Gap Analysis and Future Research Directions: The research identified key gaps in the current understanding and implementation of AI in healthcare. These gaps include the need for more empirical studies on AI's long-term impact on healthcare, strategies for effective AI integration in varied healthcare settings, and the development of more robust ethical frameworks for AI use. Future research could focus on addressing these gaps, potentially leading to more effective and ethical AI applications in healthcare.

6. Case Studies and Practical Implications: Detailed analysis of various case studies, such as the implementation of national AI platforms in public healthcare, provided practical insights into the real-world challenges and successes of AI in healthcare. These case studies illustrate the importance of contextualizing AI strategies within specific healthcare settings and regulatory environments.

7. References and Academic Contributions: This section is backed by a wide array of academic sources, including contemporary research papers, policy documents, and case studies. These references provide a solid academic foundation for the findings and underline the research's contribution to the broader discourse on AI in healthcare.

8. SWOT analysis

This SWOT analysis graphic offers a strategic overview of the impact and implications of AI and Artificial General Intelligence (AGI) in the healthcare industry. It delineates the strengths, weaknesses, opportunities, and threats associated with the integration of AI technologies in healthcare settings, focusing on managerial and policymaking

aspects. By examining the internal and external factors influencing the adoption and integration of AI and AGI, this analysis provides valuable insights into the current landscape and prospects of AI in healthcare. It aims to assist stakeholders, including policymakers, healthcare providers, and industry leaders, in making informed decisions to harness AI's potential while navigating its challenges effectively. As seen in Figure 1.

Strengths: - Enhanced Diagnostic Accuracy: AI can process vast datasets to identify patterns and anomalies, leading to improved diagnostic accuracy and personalized treatment plans. - Operational Efficiency: AI systems streamline administrative tasks, patient scheduling, and record-keeping, freeing healthcare professionals to focus on patient care. - Innovative Treatment Solutions: AGI has the potential to revolutionize healthcare by developing new treatments and drugs through advanced simulations and data analysis.	Weaknesses: - High Implementation Costs: The deployment of AI and AGI technologies in healthcare requires significant investment in infrastructure, training, and ongoing maintenance. - Data Privacy Concerns: Handling sensitive patient data with AI raises significant privacy and security issues, necessitating robust data protection measures. - Skill Gap: There is a notable gap in AI expertise within the healthcare workforce, necessitating extensive training and education.
Opportunities: - Telemedicine and Remote Monitoring: AI enables remote patient monitoring and telemedicine services, expanding access to care, especially in underserved areas. - Predictive Analytics: AI's ability to predict disease outbreaks and patient admissions can help in better resource allocation and policy planning. - Cross-disciplinary Collaboration: AI and AGI can foster collaboration across disciplines, integrating insights from genomics, biotechnology, and data science to advance healthcare.	Threats: - Regulatory Challenges: The rapid advancement of AI and AGI technologies may outpace the development of regulatory frameworks, posing challenges to integration and standardization. - Ethical Dilemmas: AI-driven decisions in healthcare can lead to ethical concerns, particularly regarding autonomy, consent, and the role of AI in life-and-death decisions. - Technology Dependence: Over-reliance on AI systems could lead to vulnerabilities, including system failures, data breaches, and reduced human oversight.

Figure 1: SWOT analysis

9. Validation

Employing data triangulation will enhance the study's reliability and validity by corroborating findings across various data sources, thus offering a multifaceted perspective on the research topic.

10. Ethical Considerations

Prioritizing confidentiality and data privacy, especially in case studies, aligns with ethical research practices, ensuring participant information remains protected.

Simultaneously, upholding transparency throughout the research, from methodologies to findings, reinforces the integrity and reliability of the study.

4.1 Future Prospects and Opportunities of AI Applications in Healthcare: Managerial and Policy-Making Focus

4.1.1 Enhancing Healthcare Delivery

AI's potential to enhance healthcare delivery is significant, with improvements in diagnosis, treatment planning, and patient management. AI facilitates early intervention and enables precision medicine. The future of AI in healthcare delivery involves innovative applications that transform care and improve patient outcomes.

4.1.2 Facilitating Personalized Medicine

AI's role in facilitating personalized medicine is pivotal. It enables the development and implementation of healthcare solutions tailored to individual patient needs, preferences, and characteristics. The future of AI in personalized medicine lies in its ability to provide patient-centered care, leveraging data analytics and machine learning to understand patient-specific conditions better.

This involves integrating AI into genetic research, where AI algorithms can analyze vast amounts of genetic data to identify patterns and correlations that may not be evident to human researchers. By doing so, AI can help in predicting genetic predispositions to certain diseases, enabling early interventions and personalized treatment plans.

Moreover, AI can assist in drug development, particularly in the field of pharmacogenomics, where it can predict how different patients will respond to

medications based on their genetic makeup. This can lead to more effective and safer drug prescriptions, reducing the trial-and-error approach often associated with finding the right medication.

In the realm of chronic disease management, AI can offer personalized care plans based on continuous monitoring of patient data through wearable devices and sensors. This real-time data analysis can lead to more accurate and timely adjustments in treatment, improving patient outcomes and quality of life.

4.1.3 AI Revolutionizes Healthcare Job Market: Displacement, Creation, and Transformation

The advent of AI in healthcare is reshaping the sector's landscape, influencing not only patient care and operational efficiencies but also significantly impacting employment dynamics. This intricate interplay of job displacement, creation, and transformation, driven by AI's increasing integration into healthcare processes, presents both challenges and opportunities.

Job Displacement and Evolution

Administrative roles, particularly those involving routine tasks such as data entry, appointment scheduling, and patient record management, are poised for significant automation. AI's capacity to efficiently process and organize large volumes of data suggests a notable shift in these areas, although quantifying this shift remains challenging without direct statistics (McKinsey & Company, 2020). Diagnostic roles, including those of radiologists and pathologists, are also evolving. AI's growing ability to interpret imaging and pathology slides is not eliminating the need for professionals but is reshaping their roles towards focusing on complex cases and nuanced patient care aspects, where human expertise remains indispensable (PMC, 2019).

The World Economic Forum's (2020) Future of Jobs Report underscores the broader implications of AI on the global labor market, including healthcare. It highlights the roles that may decline and those that will emerge due to AI and automation, pointing towards a significant transformation in job landscapes across various sectors.

Job Creation and Enhancement

Conversely, AI is set to foster new job opportunities within healthcare. The demand for AI healthcare specialists, such as researchers, data scientists, and engineers focused on healthcare applications, is expected to rise (PMC, 2019). Furthermore, AI in clinical decision-making introduces the need for roles that bridge technology and clinical practice, ensuring the effective integration of AI-generated insights into patient care (McKinsey & Company, 2020).

The Lancet Digital Health (2019) provides a comprehensive examination of AI's transformative potential in healthcare, discussing both the opportunities for job creation and the challenges of workforce displacement. It suggests that while AI introduces efficiencies and advancements in patient care, it also necessitates a reevaluation of workforce roles and functions.

The Future Outlook

As AI technologies continue to evolve, their impact on the healthcare job market is characterized by a blend of displacement, creation, and transformation of roles. This dynamic shift necessitates proactive measures in education, training, and policy adaptation to ensure that the healthcare workforce can leverage AI's benefits while addressing its challenges.

4.2 Transforming Healthcare Management

AI's potential to transform healthcare management is immense, particularly in enhancing operations, decision-making, and resource optimization. AI can streamline administrative tasks, reduce operational costs, and improve patient care efficiency. It

offers predictive analytics for better resource allocation, patient flow management, and capacity planning.

In policy-making, AI can aid in analyzing large datasets to inform healthcare policies and decisions. It can provide insights into population health trends, disease outbreaks, and healthcare utilization patterns, enabling policymakers to make informed decisions about resource allocation and public health interventions.

AI also plays a crucial role in healthcare workforce management. It can assist in staff scheduling, predicting patient admission rates, and identifying areas where staff training is needed. By optimizing workforce deployment, AI can ensure that healthcare facilities are adequately staffed to meet patient needs.

Furthermore, AI can enhance patient engagement and satisfaction by providing personalized communication and health recommendations. It can analyze patient feedback and satisfaction surveys to identify areas for improvement in patient care and services.

In terms of financial management, AI can optimize billing processes, reduce fraud, and ensure compliance with healthcare regulations. It can analyze financial data to identify cost-saving opportunities and improve the financial sustainability of healthcare organizations.

Insights from Recent Studies

The future of AI in healthcare management and policy is shaped by ongoing research and technological advancements. Studies like "Assessing Fairness in Classification Parity of Machine Learning Models in Healthcare" (Yuan et al., 2021) and "Towards A Unified Utilitarian Ethics Framework for Healthcare Artificial Intelligence" (Emdad et

al., 2023) highlight the importance of ethical considerations and fairness in AI applications.

"Towards a Framework for evaluating the safety, acceptability, and efficacy of AI systems for health" (Morley et al., 2021) and "An Overview and Case Study of the Clinical AI Model Development Life Cycle for Healthcare Systems" (Lu et al., 2020) emphasize the need for regulatory standards and safety evaluations in AI implementation.

"Algorithm Fairness in AI for Medicine and Healthcare" (Chen et al., 2021) discusses the challenges in ensuring equitable care through AI, underscoring the need for mitigating biases and enhancing model explainability in healthcare AI applications.

These studies collectively suggest that the future of AI in healthcare will be influenced by the development of ethical, fair, and effective AI technologies, aligned with healthcare needs and goals.

These sources provide insights into the ethical, fairness, and regulatory aspects of AI in healthcare, highlighting the importance of developing AI systems that are safe, effective, and equitable. They also emphasize the need for a comprehensive framework to evaluate AI systems in healthcare, considering both technical performance and ethical implications.

4.3 Conclusion and Implications for Future Research: Managerial and Policy-Making Focus

4.3.1 Summary of Key Insights

The literature review has provided comprehensive insights into the multifaceted nature of AI applications in healthcare, particularly within the European regulatory context. It has highlighted the transformative potential of AI in enhancing healthcare

delivery, the critical role of AI in facilitating personalized medicine, and the significant impact of AI on healthcare management and policy-making. These insights underscore the importance of AI in revolutionizing healthcare practices, management, and delivery, while also acknowledging the challenges and considerations it introduces, particularly in terms of regulatory compliance, ethical implications, and practical implementation.

The review has revealed the necessity for healthcare practitioners and policymakers to stay abreast of the latest AI developments and their implications. It emphasizes the need for a balanced approach that considers both the potential benefits and the challenges posed by AI integration in healthcare. This includes understanding the nuances of AI applications, the importance of ethical considerations, and the complexities of navigating the European regulatory framework.

4.3.2 Identification of Gaps

The gaps identified in the literature review point to areas requiring further exploration and research. These include the practical implementation of AI technologies in healthcare settings, the navigation of ethical and regulatory considerations, and the exploration of the long-term impact and sustainability of AI applications in healthcare.

4.3.3 Avenues for Future Research

For a concise overview of future research directions in AI applications in healthcare, please refer to the Appendix B-1.

4.3.4 Implications for Practice and Policy

The insights gained from the literature review have significant implications for practice and policy in AI applications in healthcare. Understanding the ethical, legal, and implementation challenges of AI is vital for healthcare practitioners and policymakers. This knowledge provides a basis for navigating the complexities of AI applications in healthcare and leveraging AI's potential to enhance healthcare delivery, management, and patient care. Policymakers, in particular, can use these insights to develop regulations and policies that foster the responsible and effective use of AI in healthcare while ensuring patient safety and privacy.

4.3.5 Final Remarks

The exploration of AI applications in healthcare, particularly within the European regulatory context, offers a comprehensive understanding of the complexities, challenges, and opportunities of AI applications in healthcare. The insights gained, gaps identified, and avenues for future research provide a foundation for healthcare practitioners, policymakers, researchers, and other stakeholders to navigate, explore, and leverage AI applications in healthcare. This ensures the responsible, ethical, and effective use of AI in healthcare, ultimately contributing to improved patient outcomes and the efficiency of healthcare systems.

The literature review has established a critical foundation for understanding the current state and future potential of AI in healthcare. It highlights the need for ongoing research and collaboration among healthcare providers, policymakers, technology developers, and researchers to ensure that AI's benefits are maximized for patient care and healthcare system efficiency. The future of AI in healthcare is promising, but it requires a concerted effort to address the challenges and harness the opportunities it presents.

4.4 Discussion

Acknowledging these limitations is crucial for the integrity and reliability of the literature review. They provide important context for interpreting the findings and conclusions and highlight areas where future research could contribute to a more comprehensive understanding of AI applications in healthcare, particularly from managerial and policy-making perspectives. Future research endeavors should aim to broaden the scope of literature reviews, incorporate diverse and global perspectives, employ varied methodological approaches, and critically examine potential biases. Such efforts would not only mitigate the limitations identified but also enrich the understanding of AI's role in healthcare, ensuring that future developments are informed by a wide range of insights and experiences.

4.4.1 Recommendations and Future Directions: Managerial and Policy-Making Focus

4.4.2 Practical Recommendations

Implement Ethical AI Practices: Healthcare organizations must prioritize the ethical use of AI by developing comprehensive ethical guidelines. This involves creating a framework for ethical decision-making in AI development and application, including considerations for patient consent, transparency, and accountability. Regular ethical audits and stakeholder consultations can ensure these practices are consistently applied and updated.

Enhance Data Management: Robust data management is critical for AI's success in healthcare. Organizations should invest in advanced data analytics tools and training for staff to manage and interpret AI-generated data effectively. This includes

establishing protocols for data sharing that respect patient privacy and comply with regulations, and creating systems for continuous data quality and integrity checks.

Facilitate Interoperability: Ensuring AI technologies are interoperable within existing healthcare systems is vital. This requires standardizing data formats, developing APIs that allow different systems to communicate seamlessly, and creating collaborative platforms where healthcare providers and AI developers can work together to ensure smooth integration of AI tools.

4.4.3 Policy Recommendations

Develop and Implement AI Policies: Policymakers should create comprehensive AI policies that address the unique challenges of AI in healthcare. This includes guidelines for AI development and usage, strategies for addressing potential biases in AI algorithms, and frameworks for evaluating AI tools' effectiveness and safety.

Ensure Regulatory Compliance: It is crucial to align AI applications in healthcare with existing and emerging regulations. Policymakers should work closely with regulatory bodies to update and refine regulations as AI technology evolves, ensuring that these regulations foster innovation while protecting patient rights.

Promote Ethical AI Use: Developing policies that promote the ethical use of AI in healthcare is essential. This includes creating ethical standards for AI development, establishing oversight committees to monitor AI applications, and encouraging public discourse on the ethical implications of AI in healthcare.

4.4.4 Research Recommendations

Explore Practical Implementation: Future research should focus on the practical implementation of AI technologies in healthcare settings. This includes studying the challenges and best practices in deploying AI solutions, understanding the impact on healthcare workflows, and identifying strategies for effective integration.

Investigate Long-term Impact: Research should investigate the long-term impact and sustainability of AI applications in healthcare. This involves exploring how AI can enhance healthcare delivery, facilitate personalized medicine, and transform healthcare management over time.

Navigate Ethical and Regulatory Considerations: There is a need for research that navigates the ethical and regulatory considerations in AI applications in healthcare. This includes studying the implications of AI on patient rights, and data privacy, and exploring strategies to address ethical dilemmas and regulatory challenges.

4.4.5 Future Directions

Leverage AI to Enhance Healthcare: The healthcare sector should leverage AI to enhance healthcare delivery, improve patient outcomes, facilitate personalized medicine, and transform healthcare management. This involves adopting AI solutions that are aligned with healthcare needs, goals, and strategies.

Navigate Complexities and Challenges: Stakeholders should navigate the complexities and challenges in AI applications in healthcare, including technical, organizational, ethical, and regulatory challenges. This requires a collaborative approach involving healthcare providers, policymakers, technology developers, and patients.

Explore Innovative AI Applications: There is a need to explore innovative AI applications and technologies that have the potential to transform healthcare delivery, management, and patient care. This includes investing in research and development, fostering partnerships between healthcare organizations and technology companies, and encouraging innovation in AI applications.

Chapter 5

Conclusions

This thesis's comprehensive exploration of AI in healthcare, particularly within the European regulatory framework, culminates in a conclusion that synthesizes the key findings, contemplates their broader implications, and casts a visionary eye toward the future of AI in healthcare.

At the heart of this research lies the understanding that AI's integration into healthcare is a complex, multifaceted phenomenon, encompassing managerial strategies, ethical considerations, legal frameworks, and technological advancements. The findings underscore the importance of dynamic, adaptable strategies by healthcare organizations to leverage AI effectively. These strategies must align with the ever-evolving regulatory landscape and be rooted in ethical principles that prioritize patient welfare, data privacy, and algorithmic transparency.

The implications of these findings extend beyond the immediate realm of healthcare management and policymaking. They beckon healthcare leaders to foster a culture of innovation, yet with a profound sense of ethical responsibility. Policies and practices need to evolve in tandem with AI advancements, focusing on patient-centered care, robust data security measures, and ethical AI usage. Moreover, the findings highlight the critical role of continuous education and training in AI for healthcare professionals, ensuring their preparedness for a rapidly advancing technological landscape.

Looking forward, the role of AI in healthcare is marked by immense potential and inevitable challenges. The promise of AI to revolutionize healthcare delivery, enhance

patient outcomes, and streamline operational efficiency is palpable. However, this potential is intertwined with challenges such as ethical dilemmas, data biases, and regulatory complexities. The future trajectory of AI in healthcare is likely to be characterized by a deeper integration of personalized medicine, predictive analytics, and enhanced patient engagement through AI-driven solutions.

The research also offers specific recommendations for various stakeholders, including healthcare providers, policymakers, and technology developers. A collaborative approach is essential for creating an environment conducive to innovative and ethical AI development. This collaboration should focus on establishing robust ethical guidelines, ensuring regulatory compliance, and fostering patient-centric AI applications. Further research is necessary to address the identified gaps, particularly in understanding AI's long-term impacts on different healthcare systems and cultural contexts. To clarify and provide better guidance, refer to Table 1 located in the Appendix C-1.

Despite its comprehensive nature, this research is not without limitations, notably in data availability and the generalizability of its findings. Future research should aim to broaden the empirical base, exploring AI's applications in more diverse healthcare settings and understanding its long-term implications and sustainability.

In conclusion, as the healthcare sector stands on the brink of a transformative era powered by AI, it is crucial to navigate this new frontier with a balanced, informed approach. The integration of AI presents unparalleled opportunities to redefine healthcare delivery, but it must be pursued with an acute awareness of the ethical, legal, and social implications. This thesis contributes to the ongoing discourse in this field, offering a guiding framework for future endeavors in the responsible and effective use of AI in healthcare.

In concluding this research, it's essential to acknowledge the limitations encountered during the literature review process. The review's primary focus on the managerial and policy-making aspects of AI applications in healthcare, particularly within the European regulatory framework, inherently restricted its scope and depth. This focus may have led to an underrepresentation of other critical dimensions such as technical developments, patient perspectives, and global policy variations.

The reliance on readily available and accessible literature might have excluded valuable insights from unpublished studies or non-English sources, potentially limiting the diversity of perspectives. Additionally, the temporal and geographical constraints of the review, emphasizing recent publications and the European context, may have omitted historical perspectives and innovative practices from other regions.

Methodological choices, including search strategies and selection criteria, might have introduced bias, filtering out relevant studies or favoring certain types of publications. Moreover, the inherent subjectivity of the researchers could have influenced the literature selection and interpretation, possibly skewing the review towards specific viewpoints or theoretical orientations.

Recognizing these limitations is crucial for a balanced understanding of the research findings and for guiding future studies in this evolving field.

Appendix

Appendix A-1: Insights from the literatures.

1. Ethical and Legal Considerations of AI in Healthcare under the European GDPR (Mohammad Amini, et al. 2023)

This review examines AI in healthcare's ethical, practical, and legal challenges, emphasizing GDPR compliance, bias mitigation, and the importance of human-centered design.

2. Design and Implementation of a National AI Platform for Public Healthcare in Italy (Reale, R. 2023).

Italy's national AI platform for public healthcare aims to enhance diagnosis and treatment while addressing data governance and interoperability within a complex legal framework.

3. AI-based Law Enforcement Online: Impact of the European Artificial Intelligence Act (Sunde, I. M. 2022).

The paper examines the European AI Act's effect on law enforcement, especially online crime prevention and investigation, urging nuanced AI regulation to avoid hindering digital law enforcement efforts.

4. Future Regulation of AI Systems in Healthcare Services and Medical Research in the European Union (Meszaros et al. 2022).

The paper discusses the EU's approach to AI in healthcare, highlighting legal and ethical challenges and the role of GDPR in regulating AI and automated decision-making systems.

5. FUTURE-AI: International Consensus Guideline for Trustworthy and Deployable Artificial Intelligence in Healthcare (Lekadir, et al. 2023).

FUTURE-AI introduces the first international consensus framework aimed at increasing the trust, acceptance, and real-world adoption of AI technologies in healthcare by addressing technical, clinical, ethical, and legal risks.

6. Ensuring Trustworthy Medical Artificial Intelligence through Ethical and Philosophical Principles (Jha, et al., 2023).

The paper highlights the potential of AI in medical care, emphasizing the need for ethical and philosophical grounding to ensure trustworthiness and effectiveness in clinical applications.

The legal implications of AI in healthcare are vast and complex, requiring a multifaceted approach that encompasses technical, ethical, and legal considerations. The integration of AI into healthcare systems necessitates careful consideration of data law, patient rights, and the development of ethical AI practices. The evolving legal landscape, characterized by new regulations such as the GDPR and the AIA, demands that healthcare providers, AI developers, and policymakers collaborate to ensure that

AI applications in healthcare are not only innovative and effective but also legally compliant and ethically sound. This collaboration is essential for the sustainable and responsible integration of AI in healthcare, ultimately improving the quality of life for individuals and maintaining the sustainability of healthcare systems as a whole.

Appendix A-2: Insights from the literatures.

1. Health Data Sharing Towards Knowledge Creation (Elvas, et al., 2023)

The paper proposes a privacy-preserving health data sharing framework using homomorphic encryption, aiming to enhance medical research while ensuring data security.

2. Artificial Intelligence Ethics and Challenges in Healthcare Applications (Mohammad Amini et al. 2023).

This paper delves into the ethical dilemmas and practical obstacles of employing AI in healthcare, highlighting the need for transparent, accountable, and unbiased AI systems within the GDPR framework.

3. Risk of AI in Healthcare: A Comprehensive Literature Review and Study Framework (Muley, et al., 2023).

The study categorizes AI healthcare risks into clinical data, technical, and socio-ethical, offering a foundational framework for future research in this critical area.

4. Ensuring Trustworthy Medical Artificial Intelligence through Ethical and Philosophical Principles (Jha, et al., 2023).

This paper emphasizes the importance of grounding AI in healthcare on ethical and philosophical principles to ensure its trustworthiness and effectiveness in clinical applications.

5. Integration and Implementation Strategies for AI Algorithm Deployment with Smart Routing Rules and Workflow Management (Erdal, et al. 2023).

The paper explores AI algorithm deployment in healthcare, emphasizing interoperability and scalable solutions like DICOM and HL7 standards. It introduces Project MONAI's Deploy App SDK to facilitate AI integration in clinical workflows.

6. Big Data Analytics and AI in Mental Healthcare (Rosenfeld, et al. 2019).

The paper discusses AI and big data's role in mental healthcare, focusing on customized treatments and condition monitoring, while addressing the challenges in accurately diagnosing and treating mental health conditions.

The implementation of AI in healthcare, from a managerial perspective, involves addressing a spectrum of challenges that span technical, organizational, ethical, and regulatory domains. Managers must navigate these challenges to ensure the successful and effective application of AI technologies in healthcare settings, contributing to improved patient outcomes and the overall efficiency of healthcare systems.

B-2

The gaps identified provide significant avenues for future research in AI applications in healthcare. Future studies could delve deeper into the practical implementation of AI technologies, examining how these technologies can be integrated into existing healthcare workflows and systems. Research should also focus on ethical and regulatory considerations, exploring how AI can be developed and used in compliance with ethical standards and legal requirements. Additionally, investigating the long-term impact and sustainability of AI applications will be crucial for understanding how AI can contribute to the ongoing transformation of healthcare systems.

There is a particular need for research focusing on how AI can be integrated into healthcare systems in a way that aligns with policy objectives and regulatory frameworks. This includes studies on the economic implications of AI in healthcare, the impact of AI on healthcare workforce development, and the role of AI in public health policy and decision-making.

Category	Key Findings	Implications	Recommendations	Future Directions
Managerial Strategies	Diverse strategies for AI integration identified	Essential for effective AI leverage in healthcare settings	Develop adaptable strategies aligned with regulatory changes	Explore the impact of AI literacy among healthcare staff
Ethical Considerations	Importance of data privacy and algorithmic transparency	Central to responsible AI implementation	Foster a culture of ethical responsibility in AI usage	Study long-term ethical impacts of AI in healthcare
Legal Frameworks	Need for alignment with regulations like GDPR	Critical for legal compliance and patient trust	Ensure AI applications adhere to legal and ethical standards	Investigate legal challenges in emerging AI technologies
Technological Advancements	AI's role in enhancing healthcare delivery	Possibility of transforming patient care and operational efficiency	Promote patient-centric AI applications	Delve into AI-driven personalized medicine and predictive analytics
Data Challenges and Biases	Limitations in data availability and potential biases	Affects AI algorithm efficacy and fairness	Develop frameworks for ethical data usage and bias mitigation	Conduct empirical studies on AI's long-term impact on healthcare

Table 1: Findings Table

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