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Abstract

To address the need for specialized treatment and optimize resource utilization, the healthcare industry must undergo a comprehensive digital transformation. Various healthcare departments are actively exploring alternative e-health services and technologies. However, progress in this area has been slow due to challenges related to a growing population, safety concerns, patient security, limited data availability, overworked medical staff, and a decentralized organizational structure. The future of AI is increasingly being labeled as the answer for tackling the challenges ahead and improving overall efficiency and quality of services in healthcare. However, the adoption rate has been slow compared to other countries. To uncover the underlying reasons for Norway's lagging position, we have formulated the following research question: *How can hospitals implement and adopt AI technologies to improve hospital care and provide a more efficient pathway for everyone in need of healthcare services?* We also included a sub-question: *What are the challenges to implementing AI into public healthcare?*

Our thesis aimed to unravel the possibilities of AI implementation in Norwegian hospitals, investigating only AI technologies classified as "medical devices." To answer the research question(s), we chose a qualitative method using two research projects developing machine learning algorithms for improving cancer diagnostics and treatment optimization as case studies. The empirical findings were collected through 14 semi-structured interviews and six unstructured interviews with people from the two projects, the MIM and DoMore!, as well as other key experts from related industries.

Based on our research, we hypothesized that successful AI implementation in healthcare depended on seven identified factors that were investigated: (a) AI algorithm/technology, (b) data access and structure, (c) interdisciplinary collaborations, (d) legal and regulatory frameworks, (e) AI validation and documentation, (f) procurement and economic considerations, and (g) competence and leadership. The study suggests that the hypothesis was indeed true but that each determinant differed in value depending on case-to-case differences. By outlining the drivers and barriers to successful implementation, we provide an alternative approach to help the healthcare sector implement AI.

Although the abovementioned variables all play a crucial role in successfully implementing AI in healthcare, we found that, based on the current healthcare setting, one approach for complete AI integration could depend on three steps:

- ➢ Building a standardized platform for data transparency and availability
- ➢ A collaborative approach for mapping regulatory frameworks for AI development
- ➢ Integrate a networked organizational structure with emphasis on AI leaders and interdisciplinary collaborations

While the reflections in this thesis collectively integrate several barriers and facilitators of successful AI implementation, the study found that to integrate AI medical devices and avoid risks associated with the technology/algorithm, there needs to be a common platform for sharing data between healthcare institutions, their partners and third parties. This also necessitates the need for anonymization and protection of patient privacy. Arguably, any uncertainties regarding the use of AI could be avoided by exposing the AI models to more data and training them in certified environments. The study further concludes that in terms of regulatory frameworks, there needs to be a complete overview of the necessary steps for an AI product development process to reach integration.

As indicated in the study, most developers and healthcare professionals find it difficult to navigate through all the regulations of developing medical devices. This requires extensive cross-industry collaborations and responsible agencies to take action to enable developers and healthcare professionals to move forward with suitable AI projects. Additionally, we found that integrating a networked organizational structure with an emphasis on supporting AI leaders and interdisciplinary collaborations fosters an innovative environment for AI adoption. In this strategic initiative, we found that several of the identified barriers would be mitigated by introducing a flexible approach to innovation that promotes creativity and knowledge-sharing between industries. Finally, we found that efforts to improve the AI adoption rate in healthcare are a collective undertaking. It required the state and decision-making authority of hospitals to initiate a detailed plan as well as assume a bigger role in leading the research projects through the entire development process to complete implementation.

Table of Contents

Abbreviations

1. *Algorithm:* a set of instructions programmed to solve a mathematical problem or perform a specific function (Raynor, 2020).

2. *Big Data*: high-volume, high-velocity, and/or high-variety information assets that demand cost-effective, innovative forms of information processing that enable enhanced insight, decision-making, and process automation (Gartner, 2023).

3. *CE Marking:* CE is a product marking that stands for Communauté Européenne. CE marking is a declaration from the manufacturer that the product complies with the requirements of the relevant directive and facilitates free market access throughout the EEA area (The Norwegian Directorate of Health, 2021).

4. *Saul Goodman*: is a character from the famous tv-shows "Breaking Bad" and "Better Call Saul." The character is a lawyer who deals with many challenges during the series. Saul Goodman is used as a reference in a quote from one of the informants in the interviews, indicating that AI research projects need a lawyer to help them during the product development process.

1.0 Introduction

1.1 Background and Motivation

Healthcare stands as a vital institution in every society, demanding continual progress and investments in technologies to ensure the provision of high-quality patient care, particularly with the challenges posed by a growing population, the need for specialized treatments and rising expenses (Halamka & Cerrato, 2020). Nevertheless, according to the OECD, the healthcare industry falls behind other sectors in utilizing the potential of data and digital technology (2019, p. 11). Norway is recognized by the World Health Organization (2022) as having one of the world's best healthcare systems. Nonetheless, the country allocates more resources per capita to healthcare services than most other nations. Statistics Norway (2022) confirmed that the total expenditure on health-related services in 2019 was NOK 372 billion. In order to meet the ever-growing demand for specialized treatment and maximize resource utilization, the healthcare industry must undergo a complete digital transformation. While many departments are actively pursuing the adoption of digital e-health services and technologies, progress in this area has been slow. This can be attributed to several other pressing challenges inherent in healthcare, such as patient safety concerns, securing patient data, overworked medical staff, and limited capacity and flexibility to modify established procedures (Saunes et al., 2020). Given that alterations to the industry have proven to be highly challenging within the current framework of how the industry is currently organized, the Norwegian government is pursuing a new strategy to introduce innovative technologies. The National Health and Hospital Plan for 2020-2023 states: "We [have to] take advantage of the opportunities technology provides (...) and solve tasks as efficiently as possible." (The Ministry of Health and Welfare, 2019, p. 10). As part of the digital transformation strategy, one of the most prominent areas for evolving the healthcare industry and improving healthcare services is to utilize AI.

According to governing institutions, artificial intelligence (AI) can be defined as "computer systems that perform physical or digital tasks based on the analysis and processing of structured or unstructured data with the objective of achieving a specific goal" (The Norwegian Ministry of Local Government and Modernisation, 2020). AI uses data to imitate a human intellectual process capable of reasoning,

making suggestions, generalizing, and predicting new alternatives based on data. In recent years, the healthcare industry has seen a growing interest regarding the development of AI applications. There is a notable sense of optimism surrounding the potential benefits of AI in healthcare for patients, medical professionals, and stakeholders. Particularly within healthcare, AI technologies are already developed and continue to be modified in order to support clinician decision-making, diagnostic purposes, or other data purposes. The Ministry of Health and Welfare claims that AI could potentially revolutionize healthcare by improving efficiency, fairness, and safety (2019). Despite the hundreds of AI-based medical devices currently available, only a limited number have been successfully integrated into clinical practice due to various barriers and challenges (DNV, 2023).

Based on data from Statistics Norway, it is projected that by the year 2060, one out of every three Norwegians will have to work in the healthcare sector to maintain the current level of healthcare quality and meet the needs of the patients (Hjemås et al., 2019, p. 2). This highlights the significance of the healthcare sector adopting more innovative solutions like AI to optimize its resources. The National Health and Hospital Plan highlights that "artificial intelligence makes it possible to utilize our collective health data to offer faster and more precise diagnosis, better treatment, and more efficient use of resources" (2019, p. 26). The government's commitment to addressing challenges in the healthcare industry by harnessing the potential of AI technologies is evident, even though they acknowledge the inherent difficulties involved in this process.

Artificial intelligence (AI) has come a long way in the last two decades and is now prevalent and compliant with several industries adopting technologies such as customer service chatbots, targeted algorithms to optimize digital customer marketing, and better finance equipment (Chomutare et al., 2022). However, as stated, the healthcare industry has been slow to adopt AI technologies, even with the availability of advanced tools such as virtual health assistants, machines for better cancer treatment accuracy, automation of redundant healthcare tasks, and management of medical records (Feng et al., 2022). Despite Norway's substantial investments in research and development of AI with the objective to improve healthcare, the factors contributing to or hindering AI adoption, and the precise

process by which these medical devices are integrated into the healthcare system remain unclear (The Norwegian Directorate of Health, 2021).

Thanks to machine learning, AI has demonstrated great potential in various fields, including radiology and pathology, especially in cancer detection and treatment. Machine learning (ML) is a subset of artificial intelligence (AI) that provides a robust framework to tackle various tasks by analyzing extensive datasets and generating precise outcomes (The National Center for E-health Science, 2021). The rising availability of healthcare data and the rapid development of analytics techniques are driving the radical shift toward AI in healthcare (Jiang et al., 2017). The digitization of healthcare records and patient data has resulted in a substantial influx of data, which can be organized and effectively harnessed through machine learning techniques. The most distinguished feature of using ML is that the system improves over time using self-learning algorithms. Through models of data, the ML system learns through training and is a widely used form of AI. Most commonly detecting cancer by interpreting medical images, precisely diagnosing a patient, and procuring an optimized treatment plan once cancer has been discovered (The National Cancer Institute, 2022). Most of these machine-learning applications require labeled training datasets with known outcomes, also known as supervised learning. Today, machine learning is assisting radiologists and pathologists in spotting malignant tumors and providing oncologists with better patient treatment plans based on various sets of parameters.

Reports from the Research Council of Norway (2023) state that there are approximately 150 ongoing projects at various stages that are developing e-health and AI-based solutions to address the challenges in the healthcare sector in Norway. Among these projects, two initiatives called MIM and DoMore Diagnostics are specifically working towards improving cancer diagnostics and treatment services within the public healthcare sector (DoMore, 2022; The Norwegian Cancer Registry, 2023). To address the factors that influence the process of implementing AI, we have reviewed literature and recently published studies on AI adoption in healthcare settings (Davenport & Kalakota, 2019). The literature review is sectioned into three parts, AI in hospitals, Public healthcare industry dynamics, and Technology adoption. Each of them includes relevant research on the topic of AI and AI implementation in healthcare and incorporates

the key determinants we are investigating. In each of these sections, the thesis uses literature to identify key factors needed for an AI implementation process to be successful. We will include the following variables to investigate our hypothesis that employing AI is determined by these underlying factors: (a) AI algorithm/technology, (b) data access and structure, (c) interdisciplinary collaborations, (d) legal and regulatory frameworks, (e) AI validation and documentation, (f) procurement and economic considerations, and (g) competence and leadership. The purpose of this thesis is to utilize the MIM and DoMore Diagnostics projects as case studies to gain a comprehensive understanding of the implementation process of AI technologies in cancer diagnostics and treatment. The thesis will evaluate the abovementioned factors influencing the potential of these technologies to be utilized in clinical settings within Norwegian hospitals.

To provide further context for the thesis, it is essential to introduce the MIM and DoMore Diagnostics projects and their respective partners.

1.2 Case Studies

1.2.1 Machine Learning in the Mammography Program in Norway (MIM)

- *a research project aimed at streamlining and improving the quality of the Mammography Program in Norway by combining automatic image analysis with radiological expertise.*

Every year, the number of cancer patients steadily increases in Norway, with breast cancer being the predominant form of cancer affecting women in Norway and worldwide (The Norwegian Cancer Society, 2023). Even with advanced methods of predicting diagnoses based on risk factors such as family history and genetic testing, it is highly difficult to prevent the disease on an individual level (The Norwegian Computing Center, 2021). One of the most effective ways to detect breast cancer today is through screening of breasts, also called the Norwegian mammography program. This program automatically invites all women aged 50-69 for X-ray examinations. The interpretation of these screenings, called mammograms, is performed independently by two radiologists with specialized breast radiology training. Based on annual numbers, cancer is detected in 0.5% of those who undergo screening (The Norwegian Cancer Society, 2022, 2023). This means that radiologists spend an enormous amount of time

interpreting images of healthy breast tissue. As the number of radiologists in the country is already low, there are limited resources to evaluate these scans (The Norwegian Directorate of E-health, 2019). In terms of AI and machine learning advancements, several research projects are developing algorithms to assist radiologists in distinguishing between healthy breast tissue and cancer. The benefits of using machine learning to evaluate medical images are numerous, including better quality, more precise and efficient diagnosis, and optimized use of resources.

Led by the Cancer Registry (Kreftsenteret) in Norway in collaboration with the Norwegian Computing Center, they developed a model for AI-based analysis and machine learning to detect healthy and cancerous breast tissues tailored to the Norwegian mammography program. The main objective is to develop a method that could free up radiologists' resources so that they can spend more time focusing on patients suspected of having breast cancer. The research project began in 2018 and was funded by the Norwegian Research Council as part of their good and efficient health, care, and welfare services initiative (2022). The method is based on a subset of artificial intelligence called deep learning, which in practical terms, is actually a subset of machine learning. Deep learning algorithms are structured in layers to create an “artificial neural network” (Krogh, 2008). Through these algorithms, the model developed in the MIM project analyzes data from the mammography program to decipher a logical structure similar to what a radiologist would draw a conclusion. This model aims to train algorithms to recognize complex patterns and make independent decisions based on a combination of mammograms, screening information, and breast cancer diagnoses. If the project is successfully tested and validated, the goal is to be able to classify 70% of all screening examinations as negative using automatic image analysis. The remaining 30% will still require closer inspection by two radiologists. This would free up much-needed resources, allowing the radiologists to focus on scans with plausible breast cancer.

Large amounts of image data from screening examinations and information from radiological assessments were required to devise and test the method. Involved in the project were eight breast centers. They conducted over 650.000 digital screening examinations in the program, resulting in more than 2.5 million

mammograms. The breast centers are regional specialists in diagnosing and screening breast cancer and provide radiological expertise (The Norwegian Cancer Registry, 2023). During the project's initial phase, the available data were insufficient to develop and adequately train the model for further progress. The Norwegian Computing Center stated:

We have a method in place. However, we are still in the process of collecting enough data on breasts with cancer. Fortunately, the majority of women who undergo screening are healthy. Therefore, there is limited data available on cancer cases. (Jakobsen, 2020, para. 3)

Consequently, the project was delayed while awaiting new data. By 2021, the project received more data to train a new model. The research phase of the project was concluded in 2022. Completing the research meant that the project's next stage was to apply for a CE marking (Abbreviation 3), conduct more clinical testing, and validate the developed model in order to commercialize the product. Due to extended legal processes, regulatory frameworks, and associated expenses, the CE marking has not yet been acquired. However, according to The Norwegian Cancer Registry, the project end-date has been extended to enable further development and improvement of the algorithms. The developed models and database will contribute to further research in another ongoing project, called AIforScreening (2023).

1.2.2 DoMore Diagnostics

- *improving diagnosis by utilizing AI and deep learning to automate pathology.*

To effectively treat cancer, one needs to understand the development of the disease. In this aspect, pathology plays a vital role in the precise diagnosis of cancer patients (Cooper, 2000). A pathologist is a “medical healthcare provider who examines bodies and body tissues” (John Hopkins Medicine, 2019, para. 1) and will examine tissue samples of what he or she believes to be cancer under a microscope. They will diagnose the tumor using different grading systems based on their expertise and observations. However, the grading systems’ abilities to provide a correct prognosis, and the subjectivity in using them, pose a great challenge to procuring an accurate diagnosis (Chen, 2022). Additionally, cancerous tumors are often heterogeneous, meaning that different regions of the

tumor have distinct characteristics. The tumors can encompass diverse abnormalities; some deviations might spread and be dangerous, while others might be calm and non-life threatening. In other words, predicting the progression of a patient's cancer is complicated. There are also other challenges, such as a single area of the tumor may not provide a representative picture of the cancer. This confirms that tumor heterogeneity increases the workload involved. Newer calculations show that pathologists' assessment of the severity of cancerous tumors is correct in roughly 60% of the cases (Danielsen, 2021). Because of the immense workload involved in analyzing an entire tumor, only a portion of it is sampled. Pathologists base their prognostication of various cancer on their subjective assessments. Due to the risk of overlooking potentially more dangerous tissue of cancer, many patients receive more treatment than what might be needed. This leads to overtreated patients that are vulnerable to additional side effects (DoMore, 2022). If, in these cases, the conclusion is severely incorrect, it may lead to more costs for society and potentially life-altering effects for the patient. The human brain can only do so much, and with limited resources and access to expert pathologists, the workload is becoming overwhelming for the Norwegian healthcare system to provide efficient and quality care for all cancer patients (Lea & Hatleskog, 2022). To address these challenges, The Research Council of Norway chose to nominate The Lighthouse Projects, considered beacons, inspiring and directing future initiatives to tackle significant societal challenges through advanced technology (The Norwegian Research Council, 2019). One of the projects they believed was ambitious enough to take on the challenge was the DoMore! project.

DoMore! is an artificial intelligence-based cancer diagnostics method development initiative. The research behind this initiative has improved the ability to forecast the development of cancer in a patient and administer more appropriate treatment (Skrede et al., 2020). Cancer poses a global threat, and the cases are rapidly increasing. To retrieve an accurate diagnosis, especially at an early stage of the disease is vital for any successful outcome of cancer treatment (DoMore, 2022). The ability to project the future of the disease is also crucial, and the importance of prognostic tools and markers cannot be overstated. As mentioned in the previous section, there is a need for automating diagnostic and prognostic

methods in the field of pathology. This is exactly why the DoMore! project was initiated.

In 2016, Håvard Danielsen, the director of Oslo University Hospital's Institute of Cancer Genetics and Informatics (IKI) and his research team, filed a funding request to the Research Council of Norway for the DoMore! project. They were granted 60 million Norwegian kroner over a period of five years to develop a technology that can provide each cancer patient with improved and more personalized diagnostics, thereby improving the prognosis of their treatment. Proven by pathology studies, the importance of analyzing growth patterns of tumors can provide detailed information about patient outcomes (Cooper, 2000). To utilize this information to predict better prognoses and treatment patterns, DoMore! utilizes AI and deep learning (a subset of machine learning) techniques on Big Data to develop better grading systems for tumors. The aim is to generate objective digital prognostic markers applicable to different types of cancer (DoMore, 2022). In doing so, they can access more reliable tools for determining the severity of a form of cancer based on the tumor’s activities and predict better patient prognoses.

Throughout the project's lifetime, the research team consisting of international experts in digital image analysis, pathologists, cancer surgeons, and oncology built a strong partnership for overseeing the DoMore! development (The Norwegian Research Council, 2019). The project listed a great collaboration with researchers from several esteemed institutions, including the University of Oxford’s Cancer Medicine Institute, the University of London, the University of Oslo, Helse Vest, the University of Liverpool, the University of Glasgow, UiT, the University of Stavanger, the University of Agder (UiA), as well as other departments at Oslo University. The collaborations allowed for more data to be utilized and tested throughout the research phase, having procured data from 11 454 patients diagnosed with prostate, lung, colorectal, bladder, breast, or endometrial cancer (The Norwegian Research Council, 2019). The analysis was made up of 57 326 cancer samples, amounting to a data production of around 25000TB. Through these datasets, the DoMore! team designed and developed deep learning algorithms for better cancer prognosis (DoMore, 2022). By training the computer to distinguish between these datasets, the developed methods

successfully identified distinct markers. These markers revealed a correlation between tissue samples of less severe cancer and those exhibiting more advanced stages of the disease.

The finalized methods are based on mathematical and bioinformatics using deep learning and neural networks (DoMore, 2022). Based on newer research, the algorithms can now predict a prognosis for a patient with either of the aforementioned forms of cancer. A scanner is used to analyze the tissue, and within three minutes, the test provides the results and can recommend what kind of treatment the patient should receive (The Norwegian Research Council, 2019). From their reports, the test that Danielsen and his team developed delivers an accurate prognosis for cancer patients in 88% of the cases.

With their astonishing methods, the project's research phase was concluded in 2020, and the company DoMore Diagnostics was established as a result. The firm was now ready to commercialize the products that had been developed. To be able to deliver any medical products to the Norwegian market, the company needed what is known as a CE marking. In May 2022, DoMore Diagnostics was the first company in Norway ever to obtain a CE marking for an artificial intelligence product (Omvik, 2023). They received a certification in accordance with ISO 13485, which ensures the safety and reliability of their products. The certification was conducted by DNV, one of Norway’s most recognized companies in conducting certification processes (Omvik, 2023).

Although DoMore! has successfully come this far with its development and acquired the right certification for selling its products to the Norwegian market, there are still obstacles to overcome. Elin Melby, the project leader at Inven2, one of DoMore Diagnostics' collaborative firms, stated, “The digitization of pathology is in an early phase, but in a few years, the situation will be completely different” (Andersen, 2020). As of right now, DoMore! has not managed to sell its products to the Norwegian healthcare market. Part of the charted obstacles is the regulatory systems that in some ways can limit the accessibility of buyers or training data. Once the CE marking is acquired, additional frameworks must be upheld to access Norway’s health market (The Norwegian Directorate of Health, 2022; The Norwegian Directorate of Health et al., 2022). DoMore! has managed to do what most other projects have failed to do, to get to commercialization and finalize

products to sell. However, the question remains still whether they have all they need to see these products implemented.

1.3 Motivation for the Thesis

Having witnessed people in our lives, including close friends and family, go through cancer and various forms of treatment, we have developed an understanding of what this process entails. The exhaustive process of navigating a cancer trajectory, including receiving an accurate diagnosis, communicating with multiple hospitals and healthcare professionals, undergoing various procedures across different hospitals, and managing post-treatment effects, highlights the extensive efforts involved. What we have also experienced, is that the limitations in resources within the Norwegian healthcare system are already impacting the experiences of several patients going through this journey.

As confirmed by Statistics Norway, one out of three Norwegians will have to work in the healthcare sector by the year 2060 if Norway is to meet the patient's needs with the same healthcare quality as today (Hjemås et al., 2019). In light of this information, we wanted to look for ways the healthcare sector could benefit and improve overall healthcare services for medical personnel and patients. In doing so, we both felt the urge to investigate the potential behind AI technologies and the enormous amount of ongoing research projects for solving various healthcare challenges. We hope this thesis can provide insights into the process of implementing AI technologies in hospitals, specifically focusing on cancer diagnostics and prognosis. We believe such technologies will potentially improve healthcare quality, efficiency, and ensure better outcomes for patients and their doctors.

1.4 Aim of the Thesis

Based on our motivation for choosing this topic for our thesis, we aim to gain insight into the areas we can improve and contribute to the betterment of hospital services in cancer diagnostics and treatment using AI. The thesis aims to find out what barriers and-/or elements must either be resolved or acquired for AI technologies to be implemented into the Norwegian healthcare system, with emphasis on public hospitals. Investigating *how* AI can potentially be utilized to improve efficiency and patient care is another crucial area to consider. To achieve

this, it is essential to understand the technology being introduced, its purpose, its role, and how it can be integrated into the existing hospital infrastructure. This process will help identify the barriers and facilitators of AI and uncover any limiting effects of the technology. As AI indicates an integration of new technologies, it is also necessary to investigate how AI technologies align with hospital operational structures and infrastructure to determine any opportunities or limitations.

1.5 Research Question

This thesis aims to identify the barriers and facilitating elements that affect the Norwegian hospital's ability to implement and use AI. Focusing on the AI technologies developed in our selected case studies on cancer diagnostics and optimized treatment, we have formulated the following research question:

How can hospitals implement and adopt AI technologies to improve hospital care and provide a more efficient pathway for everyone in need of healthcare services?

To answer the research question, we include a sub-question with the intention of examining the significant factors that enable or hinder AI implementation.

What are the challenges to implementing AI into public healthcare?

To address our research question(s), we have reviewed literature and recently published studies on AI adoption in healthcare settings. The thesis uses this literature to identify key factors needed for an AI implementation process to be successful. We have chosen to include seven significant factors, which we hypothesize to be determinants to successful implementation of AI: (a) AI algorithm/technology, (b) data access and structure, (c) interdisciplinary collaborations, (d) legal and regulatory frameworks, (e) AI validation and documentation, (f) procurement and economic considerations, and (g) competence and leadership. Each of these variables forms the basis for categorizing our findings.

We find that to manage the process of developing AI technologies and reaching clinical use, a successful outcome depends on several elements, which we have sectioned into the categories above. The topics related to our research question(s) and the factors that support or hinder the implementation of AI are considered very important in providing a better understanding of how hospitals can employ AI technology in Norwegian hospitals. After reviewing the MIM and DoMore Diagnostics projects, it became clear which areas enabled and limited the process of accessing the healthcare sector with their technologies. After conducting more comprehensive research, the decision of which factors to investigate in this thesis has been further reinforced. We hypothesize that the outlined variables discussed in the previous section are all crucial and have a significant impact. This thesis aims to determine the validity of this hypothesis and explore how these areas need to operate to facilitate the implementation of more AI projects.

1.6 Structure of the Thesis

The thesis follows a thematic structure. Initially, we establish the theoretical framework, including relevant information, before the theory section. Then, we divide the literature review into three categories: *AI in hospitals, public healthcare industry dynamics, and technology adoption*. In each of these sections, we cover the grounds for identifying the current AI landscape in healthcare, the industry structure and how healthcare adopts technologies. Moreover, we analyze the seven factors described above, which we identify as key influencers in whether an AI implementation takes place and is successful. Subsequently, we present our chosen methodology, research design, and findings from the case studies and interviews. We conclude the thesis with a discussion and conclusion that relates to the findings and existing literature. Finally, we recommend an alternative approach to increase the AI adoption rate in healthcare.

1.7 Classification and Definition of "AI Implementation"

As predetermined by studies reviewed on the process of implementing AI into healthcare, we differentiate between the development and implementation phases of an AI-based solution (Figure 3). The development phase entails constructing a solution based on predetermined criteria, which includes creating a model, training it, and conducting tests. In contrast, implementation is the process of

integrating a solution into a healthcare system so that it becomes a natural part of the clinical process (Makhlysheva et al., 2022). In this thesis we investigate how AI implementation can improve hospital care in Norway and the underlying barriers to AI adoption in a healthcare setting.

1.8 Limitations to the Thesis

To provide a clear focus for the research, the thesis concentrates on the Norwegian healthcare system and the ongoing development of the MIM and DoMore projects. Additionally, when discussing "AI technologies" or "AI solutions," we only refer to AI products that classify as "medical devices" or "medical devices software," reflecting the specific cases being studied (MDCG, 2019, 2021). We acknowledge that other AI-based tools distinguish from AI medical devices. The primary data source of the study is also limited to the participants in the research interviews, which include individuals directly or indirectly involved in the projects, representatives from partnering firms, healthcare professionals, professionals from legal institutions, and experts with specialized knowledge of AI deployment in the Norwegian healthcare system.

Additionally, as mentioned, the research focuses on seven variables that we have identified as the most influential to AI implementation in healthcare. Given the extensive quantity of research on AI in healthcare, we have placed certain limitations on the literature reviewed. The choices made regarding the research were based on our experience with the MIM and DoMore! projects, as well as our overall understanding of the process of introducing AI medical devices to Norwegian hospitals.

The technical aspect of the AI algorithm/technology and a comprehensive overview of the legal and regulatory frameworks have not been prioritized. However, they are recognized as vital elements for the implementation of AI in hospitals and will therefore be included in the thesis. When addressing the legal and regulatory frameworks, a generalized perspective will be taken based on insights from interviews and previous studies regarding the barriers and enablers of AI adoption in healthcare in Norway. With that said, drawing on their background in innovation and entrepreneurship, business, and project management, the authors examine the factors that impact the adoption of AI

innovations in Norwegian hospitals. They also explore the challenges involved in this process and try to identify how things can be better.

2.0 Literature Review

Our research question is how hospitals can implement and adopt AI technologies to improve hospital care and provide a more efficient pathway for everyone in need of healthcare services. To answer the formulated research question, we included a sub-question with the intention of examining the significant factors that enable or hinder AI implementation into public healthcare. “Artificial intelligence (AI) has great potential to transform healthcare, making it more efficient, equitable, and safe” (DNV, 2023, p. 3). Still, with all the amazing available AI medical equipment on the market, almost no one makes it to clinical use. Therefore, the primary focus is to reveal the barriers and opportunities of implementing AI-based medical equipment, while identifying areas where AI can improve quality patient care and improve efficiency. As the research question links to several research fields, the review is divided into three primary categories: AI in hospitals, healthcare industry dynamics, and technology adoption. The application of AI in hospitals serves as the context for our research. The category analyzing the healthcare industry dynamics is the impetus for our research question, and the technology adaption category demonstrates the "how" (to AI implementation)/ (in our question regarding AI implementation.) Together, these categories form the purpose of our research, the problem area, and the means to find a solution. By means of these categories, we will explicate the theoretical basis of the research question and explain the significance of this study in relation to prior research and theory.

To cover more grounds for the discussion section of the thesis, some of the literature included will not link directly to the research question but be applicable as part of the investigation to enable successful AI adoption. We apply the theory because we acknowledge the importance of including other areas related to the Norwegian healthcare sector to address the current approach to technology implementation. The final section of the literature review will include a

conceptual model (Figure 5) that demonstrates the link between the categories and the literature.

2.1 AI in Healthcare

2.1.1 What is AI?

Artificial intelligence (AI) is not a new phenomenon and was first introduced by John McCarthy in the 1950s. He described AI as the "science and engineering of making intelligent machines" (McCarthy, 1956, 1959). In modern times, the definition of AI has been interpreted in many ways and it varies greatly between publications. In this thesis we acknowledge AI as "computer systems that perform physical or digital tasks based on the analysis and processing of structured or unstructured data with the objective of achieving a specific goal" (The Norwegian Ministry of Local Government and Modernisation, 2020, para. 2). AI can further be described as an "umbrella term" that in simple words allows for a machine to do something that requires human intelligence, such as recognizing sounds or objects, solving mathematical problems, etc. (Apell & Eriksson, 2023). Beneath the umbrella term lie various subsets of AI, some known as machine learning, deep learning, supervised learning, unsupervised learning, neural network, and others (Butcher, 2023). For this thesis, we will limit the number of subsets of AI to machine learning (ML) and deep learning (DP) as those apply to the technologies developed in the case studies.

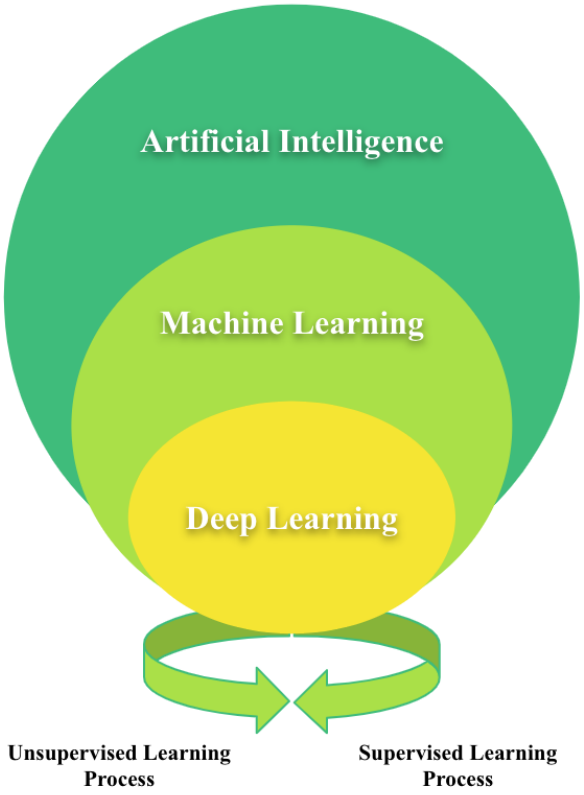
AI provides an overview of computer programs able to process big data using a programming language based on a set of "rules" or algorithms to actively perform a task. Algorithms are a logical group of instructions in the program instructed at solving a problem or completing a task, almost like a recipe (Neyland, 2019). Algorithms are aimed at optimizing its surroundings. From there, the computer programs can identify patterns, interpret them, and make new predictions based on the data entering the system (Makhlysheva et al., 2022).

2.1.2 Machine Learning

Machine learning is a form of AI that enables a machine to learn from data and make predictions. By analyzing the data over time, so-called training, it can improve its performance over time. To further develop machine learning

algorithms, we rely on the industry's ability to collect and structure big data (Peng et al., 2021). With the emergence of increased computational resources, including bigger cloud storage and improved data-sharing capabilities, there has been a significant boost in enthusiasm surrounding machine learning. And from there, the interest in ML is to develop efficient algorithms for designing models that can assist in analyzing and predicting solutions on that data (Theodoridis, 2015).

The majority of AI applied in society today are based on machine learning models, such as Google Search, Amazon, streaming services, etc. Although there are different machine learning algorithms used, the most recognized versions are known as regression algorithms and classification algorithms (Harper, 2005). The regression algorithms target different data and evaluate it to predict a certain outcome. It is a process of using "correctly identified observations and then use this learning to evaluate new observations" (Peng et al., 2021, p. 8). An example would be the model that DoMore Diagnostics has developed, where their algorithms evaluate a set of parameters to predict the outcome of a cancer patient's disease. Based on the information provided, the model then determines the most suitable treatment plan for each patient (DoMore, 2022). A classification algorithm is used to identify patterns and classify the data into groups. For instance, in an article published by the Journal of Scientific Reports on the use of machine learning for detecting heart disease, the researchers conducted a study to look for specific patterns in diagnosing heart disease, where classification algorithms were used to determine the patterns in which an electrocardiogram (ECG) gave out signals of the activity of a human heart consistent with several waveforms (2021). To analyze the ECG signals, the scientists applied machine learning. By training the datasets with the predetermined labels to detect heart disease, they could build different classification models to further cluster the patterns of variations to heart disease (Aziz et al., 2021).



Unsupervised and Supervised Learning

In an explanatory context, AI can also be characterized by its "learning process" that changes its patterns based on input data and rules imposed by human intervention (Son et al., 2023). In other words, when it comes to AI, the process of machine *learning* can be described as a continual learning process that incorporates optimized outcomes from data to model the most optimal solution. In each of the abovementioned examples, the types of machine learning algorithms are based on the type of learning process called supervised learning. Briefly explained, supervised learning makes use of trained data that includes examples of variables that would match target variables. This means that the learning process relies on prelabeled input-output pairs (Russell et al., 2010). On the other hand, unsupervised learning, as indicated by the term "unsupervised," implies that the algorithms do not need to train with target variables. Instead, they rely solely on the data to autonomously "learn" and discover new patterns (Son et al., 2023).

2.1.3 Deep Learning

Deep learning, a subset of machine learning, is another form of AI. It involves a method of organizing algorithms into layers to construct a neural network.

Through this approach, deep neural networks possess the ability to learn on their own and make intelligent decisions (Lee et al., 2017). The utilization of multiple layers in these networks form diverse models, leading to exceptionally great results when trained using big data. What distinguishes deep learning algorithms from traditional machine learning programs is their ability to perform well when dealing with vast amounts of unstructured data. The algorithms no longer need predefined labels and variables to train, instead they make calculated assumptions based on logical structures over time (Apostolopoulos et al., 2023). The design of deep neural networks mirrors the intricate network of the human brain, allowing the system to make decisions in a similar way as humans reach a conclusion (Decher, 2021). Even though deep learning models work in a similar manner to a human decision-making process, one of the most notable advantages of deep learning is its ability to identify data patterns that are too complex for humans to recognize (Lee et al., 2017).

2.1.4 Drivers and Barriers of AI Implementation in Healthcare

In a comprehensive study conducted by the Norwegian Centre for E-health Research, numerous barriers and drivers were identified for AI adoption in the Norwegian healthcare system (Makhlysheva et al., 2022). The conclusions drawn in this study are rooted in empirical data collected from various national and international implementations. In another literature review by Cubric (2020), the paper covered published assessments of AI adoption in healthcare and other industries from 2005 to 2019. In this section of the thesis, we incorporate these studies to identify the drivers and barriers to AI adoption in healthcare. The next section focuses on the most prevalent factors from these findings.

Drivers to AI Implementation

There is an extensive list as to what drives the interest in AI in healthcare, with the need for increased efficiency being one of the most frequently mentioned. Healthcare systems constantly encounter challenges affiliated with a growing population, the need for specialized treatments, the provision of quality care, patient safety-and privacy, while operating with limited resources (DNV, 2023). According to the findings outlined in Cubric's review (2020), the drivers for adopting AI in healthcare correspond with economic, social, and security perspectives. From an economic standpoint, the dominant driver of AI is the

potential for improved efficiency, accuracy, and productivity by utilizing AI-based clinical decision support tools (CDS). These tools offer support to hospitals and clinicians by automating routine tasks, filter information and identify potential issues to patient outcomes or healthcare quality (Bajgain et al., 2023).

AI-based technologies can offer other various economic benefits to healthcare, including assisting in the interpretation of patient clinical information, aiding clinicians in selecting treatment plans, automate repetitive tasks, and enhance clinical decision-making (Cubric, 2020). From a social-and patient perspective, AI-based tools are expected to support clinicians by performing entire tasks, allowing doctors to focus on more comprehensive cases and spend more time with patients. Besides the potential time-saving benefits of using AI and improved resource utilization for more quality patient care, another highly important driver of AI is the use of deep learning algorithms. These models have the potential to acquire more accurate diagnosis and personalized treatment plans for individual patients. From a security perspective, considering the viewpoints of both society and medical personnel, the adoption of AI is driven by the need to follow the industry's demand for constant advancements and to improve quality care, making its use in healthcare inevitable (Makhlysheva et al., 2022).

One highly important reason for the renewed interest and shift towards more AI adoption in the healthcare industry can be attributed to one crucial factor: access to Big Data. It was identified in both studies that the rising availability of healthcare data is primarily a barrier to AI adoption (Cubric, 2020; Makhlysheva et al., 2022) due to its unstructured nature and risks relating to data security. However, one cannot avoid acknowledging that the increasing availability of healthcare data also serves as a driving force and motivating factor for adopting AI (Jiang et al., 2017).

Barriers to AI Implementation

In the study conducted by the The Norwegian Centre for E-health Research (NER) a total of 46 barriers to AI adoption was identified (2022). In the review from Cubric (2020), most barriers were linked to economic, technical, legal, and social perspectives. In this section we outline the most evident barriers from both reviews. The NER review pointed to several important factors determining whether an AI-based technology will make it to clinical use (2022). Most evident

was the low data quality that hinders proper AI algorithms to learn to perform tasks in a standardized environment. They highlight that most of the data is in "free text and is a subject to language idiosyncrasies" (2022, p. 20). Also, as outlined in Cubric's review, the current information and communication technology (ICT) infrastructure in the healthcare sector is insufficient in supporting a widespread implementation of advanced AI-medical tools (2020).

Even with access to data of high-quality, it does not necessarily mean that the AI-algorithms can be trusted in every situation. Most algorithms are developed using distinct datasets with certain parameters to match target variables. However, if there is insufficient data or not enough representativeness of diverse data for the algorithms to train from, there is a risk of implementing a model that is not adaptable or able to perform reliably in various contexts (Makhlysheva et al., 2022). Similarly pointed out by Cubric, that a major technological barrier is the risk of implementing weak AI due to "lack of training data [that] may result in performance degradation" (2020, p. 9).

Adding on to the previous point, another barrier to adopting AI is the lack of trust in the results and proof of quality assurance (validation), which oftentimes is credited to the AI-model's lack of explainability (DNV, 2023). The lack of explainability and transparency is recognized as a significant obstacle to the implementation of AI. Clinicians, who are responsible for making treatment decisions for patients, need assurance that the AI-medical tool they use to assist them, are trustworthy and reliable (Markus et al., 2021). As mentioned, deep learning algorithms are constructed with multiple layers, forming a neural network. This is what is called the "black box" phenomenon. Petch et al. (2022) define "black box" as machine learning models that are too complex for humans to interpret, as they assign values to multiple layers of parameters within these neural networks. In simpler terms, one can describe the black boxes as the actual layers in the artificial neural network. When these deep learning models lack explainability and transparency in how they reach a decision, we have a "black box problem" (Apostolopoulos et al., 2023; Markus et al., 2021). Validation, transparency, and explainability are all part of the matrix to overcoming the barriers associated with AI implementation. These elements ensure that AI-algorithms are trained properly using diverse datasets, mitigate potential biases

and enhance generalizability, and explain the reasoning behind the decisions made by AI-models. However, as pointed out by Markus et al. (2021), “the field of explainable AI has promising prospects for healthcare, [however] it is not fully developed yet” (para. 3).

According to Cubric (2020), from an economic standpoint, the most occurring barriers include the limited resources associated with the process of AI adoption, the need to maintain adequate training and quality of AI-tools, the alignment of current infrastructure to support the new tools, the inability to reuse most models, and the high cost of labeling data. Another part of the economic scope is understanding how extensive the procurement process is for a hospital. As documented in the report by Espeland et al. (2015), the healthcare sector finds it difficult to engage in innovation and determine which AI-technologies to invest in due to lack of knowledge, the hospital’s requirements for validation and transparency, cost-effectiveness, and safety. Other barriers such as legal and regulatory frameworks, ethical considerations are also important determinants that most often hinders the procurement process to ever be initiated (DNV, 2023).

Another considerable barrier is the diverging interests between the healthcare industry and other cross-industry actors involved in developing AI-technologies for healthcare purposes. When there are clear differences in needs and objectives, it can hinder successful collaboration. While the healthcare industry prioritizes improving patient care and ensuring safety and control, other actors may favor efficiency and profitability, creating differences that inhibit implementation (Espeland et al., 2015, p. 8). Furthermore, the healthcare sector has been criticized for its closed organizational structure, where the system appears impenetrable. Accompanied by strict regulations and limited flexibility in terms of procurement processes, hospitals appear to be difficult to collaborate with (Cubric, 2020; Makhlysheva et al., 2022).

To summarize, even with the immense potential and ongoing advancements in AI for healthcare, barriers remain. These barriers span economic, technological, and social perspectives with challenges such as data quality, validation and explainability of AI, missing interdisciplinary collaborations, lack of competence associated with the procurement processes, infrastructure considerations, and

regulatory frameworks. These factors, among others, make the deployment of AI in healthcare challenging (Espeland et al., 2015).

2.1.5 Big Data

A new revolution in healthcare is imminent. Technological breakthroughs to accelerate innovation can be seen with artificial intelligence, propelled by the rising availability of healthcare data and the rapid development of analytics tools (Jiang et al., 2017). Arguably one of the biggest reasons scientists believe that the healthcare industry will be most affected by the development of AI is the data-rich processes and the possibilities of improving data analytics (Apell & Eriksson, 2023). These analytics incorporate data from a variety of sources, including biomedical data (electronic medical records), research and development, financial data, and patient behavior data (IoT, IoB, etc.) (Alamgir & Mohyuddin, 2022). When the system is designed properly, healthcare analytics can generate actionable data that can lead to advances in hospital operations and service delivery, clinical results, hospital efficiency, and better allocation of resources (Apell & Eriksson, 2023). The enormous amount of data from a number of sources is difficult to manage, but it also presents an opportunity to gain new knowledge and to establish a data-driven decision-making organizational model (Marx & Padmanabhan, 2020). When advanced analytics technologies like AI and machine learning can extract insights from the data it could advance the delivery of healthcare in terms of precision, personalized patient-medicine and operational efficiency (Marx & Padmanabhan, 2020).

2.1.6 Technology Readiness – AI used in the Norwegian Healthcare System Today

The current landscape of AI-based tools available in healthcare is promising and steadily rising (Peng et al., 2021). AI is rapidly being applied to several areas to support clinical decision making, diagnostic purposes, and data analysis (Bajgain et al., 2023; Denecke & Gabarron, 2021). The number of examples of deep learning in biomedicine is also increasing and includes everything from interpreting medical images to detect cancer cells, tumors, or abnormalities in terms of lung nodules or liver masses. Areas where deep learning methods have particularly produced great results are analyzing mammograms and

electrocardiograms (ECG) (Apostolopoulos et al., 2023; Aziz et al., 2021). The field with the largest selection of available AI-tools is within image analysis and radiology. However, the adoption of AI in radiology is still in its early stages, with only a fraction of tools showing potential clinical impact (The Norwegian Directorate of Health et al., 2022).

Even with a slow adoption rate, Norway is working on several promising AI-projects. A notable example where AI has demonstrated its use can be observed at Ålesund Hospital, in partnership with St. Olavs Hospital in Trondheim, where machine learning algorithms are utilized to detect tumors in breast cancer patients. Usually, when conducting a CT scan for potentially cancerous breasts, radiologists can spend an entire day manually analyzing and outlining the tumor. By using this model, the radiology department saves enormous amounts of time as the machine can identify the tumor within minutes (Otneim, 2022). Helse Nord have implemented an AI-based product called "DirectOrgans" that uses deep learning algorithms to segment organs and tumors in CT images. The Helse Sør-Øst region acquired this year an AI-based product in radiology to help detect cancerous tumors, and the implementation work is currently underway. Additionally, at Oslo University Hospital, the MIM project led by the Cancer Registry is testing its AI models for mammography. Another notable project, DoMore Diagnostics, has successfully managed to commercialize its products with its prognostic markers to optimize workflow within pathology. Now, they have successfully brought five different products to the market, making it one of the most promising projects in Norway (The Norwegian Directorate of Health et al., 2022).

Although these projects represent a bright future for AI in the Norwegian healthcare system, most of them are still residing in a research stage (The Norwegian Directorate of Health et al., 2022). Numerous studies have highlighted the increase in available AI-based tools in healthcare, but it remains unclear how many of these tools are being adopted for clinical use. A study conducted by DNV (2023) indicates that AI has already been adopted in several areas, such as "computer vision, natural language processing (NLP), robotics, planning, scheduling and optimization, and recommender systems" (2023, p. 14). They also indicate that there is much room for improvement. The Norwegian Directorate of

E-health (2019) states that “the results from research projects have been limitedly implemented in operational use in healthcare or commercialized. The reasons for this mainly lie in regulations, financing, and the extent to which the solutions meet real needs” (2019, p. 6).

2.1.7 Legal and Regulatory Frameworks for AI in Healthcare

This thesis will provide an overview of the legal and regulatory requirements in Norway concerning the deployment of AI medical devices in healthcare. Research indicates that one of the key obstacles is navigating through several overlapping legislations to reach AI implementation, which has been perceived as complex and extensive (The Norwegian Directorate of Health et al., 2022). In this theory section, we will provide a short overview of the standardized requirements and method(s) for developing AI-based tools to facilitate their deployment in healthcare.

AI as a Medical Device

We distinguish between AI based technologies and AI medical devices. AI technologies that are considered medical devices are subject to different risk classes, requirements, a CE-marking process, and authorities responsible for enforcing these regulations. To quote the report from the Norwegian Centre for E-health Research (2022), AI as a medical device can be described in the following way:

> Software that is intended to be used, alone or in combination with other equipment, for the purpose of diagnosing, preventing, monitoring, treating, or alleviating of a disease, injury, or disability, is considered medical device software (MDSW) (18) and falls under the EU regulation for medical devices (MDR) or in vitro diagnostic medical devices (IVDR). This includes software with AI algorithms. (2022, p. 12)

With that definition, certain requirements and standards must be met to gain access to the healthcare market. Following The Medical Device Regulation (MDR), medical devices are classified into risk classes, which determine the necessary requirements before a device can be introduced to the market. In simple

terms, if a medical device provides information or assists medical professionals in making curative or diagnostic decisions, it falls into class IIa, which is a moderate-risk class. If the device could potentially lead to deaths of patients or health deterioration, it is classified as a high-risk (class III) device. While these classifications may seem straightforward, there are many rules that need to be evaluated (MDCG, 2019; The Norwegian Directorate of Health et al., 2022).

Regulatory Requirements

When discussing Medical Device Software (MDSW), which encompasses many AI-technologies, additional rules come into play. For instance, in terms of quality standards on MDSWs, the risk classification specifies how the device must address systems for quality and risk management (MDCG, 2019). In addition to providing documentation that validates the device's process and intent, as a vendor you must outline the device's design and performance. For regulatory purposes, this documentation must be sufficiently detailed to comply with ISO 13485 (2016) and ISO 14971 (2019) standards. Furthermore, if the product reaches the market, the healthcare institution needs to decide whether the device is justified in meeting the needs of a patient group that cannot be fulfilled by any other means. The Norwegian Medicines Agency may request such information and safety reports (PSUR), and monitoring the device must be conducted in accordance with the aforementioned requirements (The European Medicines Agency, 2022). To ensure the safe use of medical devices, it is necessary to identify and implement preventive and quality measures. Throughout the lifecycle of the device, regular data quality, security, and performance assessments are expected.

CE Marking

The regulatory requirements for AI medical devices include obtaining the CE mark certification for the product(s). The CE marking signifies that the medical device has complied with the requirements of the MDR and meets specific standards for performance, quality, safety, and efficiency (The Norwegian Directorate of Health, 2022). While the CE mark does not guarantee the medical device’s acceptance on the market, it serves as a significant milestone and recognition for hospitals, affirming that the product is valid and has met all the necessary requirements to be used for healthcare purposes. Obtaining the CE marking involves a comprehensive process consisting of several steps (MDCG,

2021). Without having to go into detail about the necessary actions, the most important requirements focus on confirmative validation, if it is safe to use, and if it improves patient care in terms of clinical effectiveness and cost. The foundation of AI implementation in healthcare rests upon ethical principles, privacy preservation, digital security, explainability, and accountability. Also, it is important to ensure that data access for testing and validating these devices adhere to the regulations of healthcare and data protection legislation (The Health Register Act, 2022, § 19).

Although the requirements for classifying and developing medical devices, and the navigation through various legislative frameworks can be difficult, both Norway and the EU are embracing a collaborative approach to AI in healthcare. Norway is actively shaping its digital strategy to ensure a promising future for AI implementation in healthcare settings (The Norwegian Ministry of Local Government and Modernisation, 2020). An important example of this is the recent amendment to the Health Personnel Act section 29 (2022), that came into effect in 2021. This amendment clarifies the authority to grant exemptions from confidentiality obligations, specifically allowing the use of health information in clinical decision support tools in healthcare services (The Norwegian Directorate of Health et al., 2022). This change facilitates the development and use of AI-based tools in healthcare while ensuring privacy and confidentiality. Another example that reflects the collective shift towards AI in healthcare is the introduction of the Artificial Intelligence ACT. It assures a standardized approach for utilizing AI and unifying the nations with a common regulatory framework. This initiative can help streamline the development- and implementation processes of AI-related medical tools, encouraging international collaboration and integration across nations (FLI, 2021).

AI Development Phases until Deployment

Part of understanding how a potential AI solution reaches deployment, one must look at the different phases revolving product development. This involves going through multiple stages. We provide a brief overview of the three primary stages, while acknowledging that the actual process is much more nuanced and oftentimes involves several other components (MDCG, 2021; The Norwegian Directorate of E-health, 2019). It is important to note that this thesis focuses

solely on the natural progression of AI medical devices in the healthcare domain. The product development process comprises three stages, each governed by distinct regulations. We describe them as follows:

(Figure 3: Illustration of the phases of AI development)

Research: This stage marks the beginning of an AI idea, where the foundational work is carried out. The primary objective lies in addressing a real challenge that can be handled better using AI. The research initiative is conducted either in academic institutions or via private companies, oftentimes in collaboration with healthcare institutions to access relevant data and securing the right approach. During this stage, the AI-based technology is tested in conjunction with healthcare facilities to match the needs of the targeted population the finalized product is intended for.

Product development: This stage incorporates the primary development of the product and can take place in the healthcare sector or in private companies. Extensive testing and validation are conducted to meet the requirements for obtaining the CE marking, which is necessary for potential market entry. Collaboration between healthcare institutions and tech startups is often seen during this phase to facilitate the development of the product(s). In this phase, clinical trials are carried out to assess the performance of the product. According to a report by DNV (2023), the estimated time of the different phases of development can be substantial. Typically, the development of an AI-based tool can take approximately 1-2 years, with an additional 1-2 years for validation and proof of performance. Once the testing is complete, obtaining regulatory approval for the AI-medical device can take 0.5-2 more years (2023, p. 16).

Implementation and operational use: Once a product has been approved and meets the regulatory guidelines for use of AI as a medical device, obtained CE

marking certification, and been introduced to the market, it is ready to be utilized in healthcare settings (The Norwegian Directorate of E-health, 2019). Additionally, to maintain quality and risk requirements, a management system must be established. The next step would be for a healthcare institution to adopt the AI solution into clinical practice. As pointed out by DNV (2023), this phase marks the actual implementation process, which typically takes around 0.5-2 years, depending on the specific AI technology being implemented. Once the solution is integrated into clinical practice, it can take another year before it is being used by end-users. Many studies credit the prolonged development phases as one of the reasons why so many new tools are developed and so few documented in clinical practice (DNV, 2023).

2.2 Public Healthcare Industry Dynamics

A hospital's dynamics must contribute to a quality system that can improve the organization and services of the hospital (Sundar, 2003). In this section, we focus on the present challenges of meeting industry demands in implementing AI in healthcare and the anticipated challenges in the future. We include various aspects, including hospital management processes encompassing governance, value creation, operations, and decision-making processes for healthcare institutions. Additionally, we study the critical role of the procurement process in acquiring AI technologies. Lastly, we look at the significance of interdisciplinary collaborations in managing the development and deployment of AI.

2.2.1 Global Challenges

The healthcare industry is considered one of the most crucial functions in society that requires constant imbursement of resources and continuous improvement (Vaisshalli et al., 2021). The ongoing digital evolution calls for unprecedented change, and the healthcare industry is one of the key industries dealing with significant challenges as a result (Cheng et al., 2015). Amplified by the Covid-19 pandemic and a surging global population, the hospitals are pressured “to deliver better, safer, and more cost-effective treatment” (Alamgir & Mohyuddin, 2022, p. 97). In addition to soaring pressure to deliver on quality and cost, the hospitals are experiencing massive financial restraints, limitations on skilled workforce, threats to patient safety, increased stakeholder expectations, and difficulty implementing

new technologies, necessitating modifications to internal hospital operations (Hjort, 2006). Along with the current obstacles and the learning outcomes from the pandemic, many governments are recognizing the importance of improving hospital procedures in terms of quality and efficiency. Moreover, several public healthcare organizations are contemplating and undergoing a restructuring of operational and architectural systems capable of withstanding future exponential threats (Iansiti & Lakhani, 2020). The lack of integration between information systems among departments and hospitals, motivates the replacement of traditional healthcare systems. In many ways, these systems represent a perplexing mixture of highly decentralized entities unable to synchronize with each other (Summit et al., 2003). Although the pandemic might have spiked the interest in reorganizing hospital structures and services, the realization that the system itself could be responsible for many of the issues is not a recent revelation (The Ministry of Health and Welfare, 2023).

With legacy information systems and internally developed procedures, many hospitals run modern day operations based on century-old principles, making the healthcare industry highly fragmented. Conclusively, introducing a transformative digital structure would necessitate a synchronized, thoroughly organized change across all hospital sectors, making it extremely difficult and time-intensive (Feygin, 2018). Furthermore, different healthcare procedures and departments are so diverse that a unified solution seems next to impossible. Also, there is the relative isolation of various technologies. Limited standardized technology has been utilized substantially across the healthcare industry, adding complexity, and impeding the scalability of solutions (Feygin, 2018). According to the New England Journal of Medicine (2018), the standardization of healthcare is still insufficient to allow rapid transformation. Many healthcare organizations have used different implementation strategies and approaches to overcome the limitations of a function-based structure (Toussaint & Berry, 2013). The hospitals also recognize the impetus of leaning more on an operational architecture that enables agile work methods. According to Iansiti & Lakhani, (2020), the way to do that is to acquire an integrated foundation of data for operational power decision-making with the help of software, analytics, and AI. Major changes in the design of health systems and health services will occur over the course of the

next ten years, driven by AI and machine learning, expanding consumerism, digital health, and financial restrictions (Feygin, 2018).

2.2.2 Future Change Requirements in the Norwegian Healthcare Industry

Norway ranks at the top in Europe in terms of its use of resources for health and welfare services, but challenges are anticipated (The Ministry of Health and Welfare, 2023, p. 11). A change in population composition indicates that the proportion of elderly persons is increasing; this phenomenon is also known as the elderly wave (Statistics Norway, 2019). Since Norway is considered a welfare state, the consequences of a demographic shift will present Norway with both economic and practical challenges. The fact that more people will require healthcare in the future is indicative of the difficulties associated with a shortage of medical staff, which is already seen in the district municipalities and other central areas. These challenges necessitate a new mindset, policy approach, and the willingness to implement innovative technologies as tools for change (The Ministry of Health and Welfare, 2023, pp. 11–12). These challenges create an environment for opportunities to innovate. AI introduces a spectrum of such opportunities, but it also necessitates changes in the industry's structural and operational framework. As a result of technological advancements and the need to support further quality care, medical personnel need to serve new roles in redefined positions (Land, 2019). The fact that we are already experiencing a shortage of qualified medical staff indicates that the industry needs to find alternative ways to deliver its services.

2.2.3 Hospital Structures and Management Processes

The state owns the public hospitals in Norway, but there is a division of autonomy and responsibilities among them. The decision-making authority lies with the parliament (Ringard et al., 2013, p. 16), whereas the government is responsible for determining the state budget and deciding upon the national strategic priorities (The Norwegian Parliament, 2022). In general, Norway's healthcare system is semi-decentralized, meaning that the Ministry of Health and Care, the counties, and the municipalities are all responsible for managing different parts of the system (Ringard et al., 2013, p. 18). The Ministry of Health and Care is responsible for formulating national health policies, developing reforms and

legislative initiatives, overseeing implementation, providing support to the government in decision-making, and also exercising control over the Regional Health Authorities (RHAs). RHAs are accountable for overseeing the Hospital Trust, which includes areas such as investing in hospital infrastructure, long-term care facilities, primary care, and specialist care. They also handle regulatory and supervisory functions, as well as owner arrangements. Conversely, the municipalities hold the responsibility of legislation and managing financial instruments in accordance with national acts and regulations (Ringard et al., 2013). Every Norwegian citizen is entitled to public healthcare services (Health Norway, 2019). Norway also has an implemented provision called the "right to choose a place of treatment" (Health Norway, 2019, para. 5), which grants patients the freedom to select either public or private treatment centers that have agreements with regional health authorities. The healthcare industry strives to meet people's needs in the best way possible. Hospital management is constantly seeking ways to improve their services, especially as "the healthcare industry is undergoing sweeping change" (Buescher & Viguerie, 2014, para. 1).

Efforts to manage both cost and quality performance relate to the importance of value creation (Pfannstiel & Rasche, 2017; Rasche, 2010). Most hospitals typically operate using business models that prioritize value chain configuration (Pfannstiel & Rasche, 2017). These hospitals aim to provide patients with tailored solutions that address their individual needs, while also employing standardized medical procedures that benefit both healthcare professionals and patients, reflecting the value shop configuration. However, Pfannstiel and Rasche (2017) point out that hospital governance systems often fail to explore potential solutions and opportunities for business model innovation, which can ultimately lead to value destruction. Furthermore, according to Fjeldstad et al. (2020), the current healthcare system is not built for growth. To address this, they propose a networked architecture that can effectively bring together and leverage the resources of healthcare professionals, patients, family members, and other stakeholders involved in healthcare delivery and improvement (Fjeldstad et al., 2020).

2.2.4 Resource Management

Planning, organizing, and leading resources, as well as budgeting within various departments and initiatives, are all components of the resource management process necessary for an organization to achieve its goals (Fjeldstad et al., 2020). Healthcare is a highly specialized domain that leverages human and technological resources to improve health. To ensure effective and efficient patient care, resource management plays a crucial role in the allocation of capital funds within hospitals. Budgeting serves as an internal part of the planning process, enabling public hospitals to deliver quality care across all departments. To achieve measurable results in the healthcare sector, management employs short-term strategies such as cost, law, and tax dumping (Pfannstiel & Rasche, 2017). There are two distinct types of budgeting involved in the management process at hospitals. Operational budgeting involves the allocation of funds for operational expenses, primarily personnel and training, which constitute a significant expenditure in the healthcare industry. Capital budgeting relates to the procurement of materials, infrastructure, supplies, and technology. Both budgets are interrelated and need a balanced approach to ensure optimal outcomes (Syntellis Performance Solutions, 2021). As part of the natural budgeting process of hospitals, cost reduction initiatives play an important role in generating income (Kaplan & Haas, 2014).

Because the public hospitals are mostly funded by the allocated resources from the Norwegian Government, there have been limited resources to pursue innovative projects, such as acquiring or developing AI medical devices (Anderssen, 2019). That is why, in terms of AI implementation, financial resources have been scarce (Chomutare et al., 2022). AI technologies typically entail significant costs, that include everything from developing the algorithms, to clinically testing them, to implementation, validation and acquiring CE marking (Makhlysheva et al., 2022). Proven to be one of the primary obstacles that hinders the commercialization of many AI research projects is the unforeseen and substantial costs involved. Securing adequate funding to support the entire implementation process of an AI system has been identified as the foremost crucial factor for successful AI implementation among Nordic countries (Makhlysheva et al., 2022, p. 35).

Procurement Processes and Economic Considerations

The procurement process in healthcare requires a high level of expertise in medical knowledge, legal concerns, economic considerations, and understanding how the acquired product or service will impact the hospital structure (The Ministry of Health and Welfare, 2023). In relation to the procurement of an AI solution, the hospital can choose between different approaches for their acquisition. The healthcare institution can either develop a specific AI technology in-house, acquire a commercial CE marked AI technology from another company, or do a "hybrid" approach of both. There are obvious benefits and challenges with either of these methods but what applies to all of them is that the process itself is comprehensive (Makhlysheva et al., 2022). It is never a straight-forward initiative to integrate AI solutions in healthcare, mostly because it has to solve a potential problem, or improve the situation for which the AI is intended. According to the Norwegian Directorate of E-health (2019), in any case where AI is acquired it needs to meet the requirements for safety and performance for medical equipment. The developer of the AI technology is responsible for documenting these requirements. The hospital must also determine whether the technology safeguards the trust between patient and medical personnel through controlling the quality of training data, methods used in the development phase, its performance, and explainability (Makhlysheva et al., 2022). All of the abovementioned points must be presented in the procurement process (The Norwegian Directorate of E-health, 2019).

Most often what occurs in the procurement process concerning AI, is that the hospital has limited knowledge of how to proceed to buy these solutions. The risk of buying an AI medical device that is e.g. not representative of the population in which it is intended for, or to know how generalizable AI algorithms are, whether the validation process is inconclusive, or that the AI solution is addressing a specific need is significant (Makhlysheva et al., 2022).

As highlighted in the report published by the Norwegian Directorate of E-health (2022) the frequent challenges with procurement processes is that they "require cross-disciplinary competence, which is a combination of juridical, IT, economical, and clinical expertise, to choose the right solution" (p. 18). It also

necessitates the need for the involvement of healthcare professionals who already have limited capacity to desist. Most often, the bottleneck is the healthcare organization as it is considered fragmented in terms of decision-making and financing. Studies have shown that missing interdisciplinary teams are hindering action to be initiated. The report indicates the main issues being lack of funding beyond a research stage for AI, that the vendors are unsure of the profitability of the solution, and the extensive cost for implementing, validating, and altering the infrastructure to fit the AI solution (Makhlysheva et al., 2022). Additionally, the report by The Norwegian Center for E-Health Research (2022) states that "there should be a streamlined process for public procurement that is understandable, coordinated, and effective for healthcare organizations" (p. 42).

Given the complexity of different requirements and regulatory frameworks involved in the procurement process of AI, standardization is necessary. Different initiatives aim to simplify these processes, such as the introduction of the AI ACT by the EU (FLI, 2021), and the collection of regulatory frameworks by The Norwegian Directorate of Health (2023). Other parties have also taken steps to facilitate the process. For instance, a UK Government unit responsible for NHS policy and practices has published a guide called "A Buyer's Guide to AI in Health and Care" (Joshi & Cushnan, 2020). This guide outlines ten crucial questions to consider when acquiring an AI product. Due to the ethical and legal considerations inherent in AI development and use, the report highlights the importance of "cooperative procurement" processes (Makhlysheva et al., 2022, p. 42). Competence networks like the Norwegian Network for AI in Healthcare (KIN) and interdisciplinary guidance service can provide clarity on the necessary assessments for procurement projects. Sykehusinnkjøp HF is "one of Norway's largest procurement organizations for the specialist healthcare service" that can also contribute to raising the necessary procurement-related competence (Makhlysheva et al., 2022, p. 42).

2.2.5 Interdisciplinary Collaborations

Interdisciplinary collaboration is when professionals from diverse professional backgrounds work together to foster the development of cross-disciplinary competence and practice (The Norwegian Directorate of Health, 2018). By combining several competencies, you will be able to acquire more knowledge and

see the situation from multiple perspectives. When it comes to implementing AI in the healthcare industry, interdisciplinary collaboration can be crucial for the sake of clinical assessment and technology expertise. The development of healthcare technologies requires interdisciplinary collaborations in particular (Krause-Jüttler et al., 2022). In a report jointly published by the US Government Accountability Office (GAO) and the National Academy of Medicine (NAM) (2022), the findings pointed to how AI adoption in healthcare depend on national motives that promote collaboration and resource sharing among various stakeholders, including "healthcare professionals, regulators, technology providers, payers, research organizations, and patient groups" (2022, p. 44). The report emphasizes the importance of involving cross-disciplinary collaborative teams prior to initiating the procurement process. This approach can enable the scalability of AI products/services by providing an opportunity to apply their products across different units and institutional settings, overcoming a common barrier for AI providers (The Government Accountability Office & The National Academy of Medicine, 2022).

2.3 Technology Adoption

While rapid AI adoption is seen across most industries, the healthcare sector is lagging behind (Batra et al., 2019). Even though studies have identified several obstacles to AI implementation in healthcare, what determining factors affect AI technology adoption in healthcare remains unknown (Keel et al., 2018). Drawing from extensive literature on technology adoption, this section demonstrates how AI implementation occurs based on the technology's characteristics and market saturation. We will use specific frameworks to address these elements.

Geoffrey A. Moore's *Technology Adoption Life Cycle* introduces a framework for describing the technology adoption lifecycle (2014). Moore's cycle recognizes that different individuals and industries have distinct psychographic profiles when it comes to adopting new technology (2014, pp. 12–16). An important aspect of Moore's model is the concept of "crossing the chasm", which refers to bridging the gap between the "early adopters" and the "early majority". Successfully crossing this chasm is a significant challenge as it requires addressing the characteristics and concerns of the mainstream market to achieve broader acceptance. Outlined in previous sections of the literature review, there are several

obstacles to AI adoption in healthcare (DNV, 2023; The Norwegian Directorate of E-health, 2019). These obstacles, particularly the structural environment of healthcare institutions, make it difficult to introduce AI. Despite the immense focus on digitizing healthcare and the positive attitudes towards AI implementation, the current adoption rate indicates that the healthcare sector falls within the "late majority" category according to Moore's framework (2014). This suggests that the industry is awaiting technology standardization before embracing AI fully. While most healthcare institutions align with the "early majority" group, driven by pragmatism and the desire to solve specific problems, overall, the industry's cautious approach requires more evidence of the AI's effectiveness and validity, forcing it to currently reside in the "late majority" category (Anderssen, 2019; Apell & Eriksson, 2023; Krishnamoorthy et al., 2022; Moore, 2014).

2.3.1 Disruptive Innovation

With their dynamic model of innovation, Afuah and Utterback (1997) suggest that "as the technology evolves, so do the industry structure, attractiveness and critical success factors" (p. 183). With the rapid advancements in AI technologies across various domains, healthcare institutions and its governing officials are compelled to redefine the structural boundaries, standardize data systems, and prioritize digitization and technology (The Ministry of Health and Welfare, 2019). However, the factors influencing the overall adoption rate of AI in healthcare remain unclear (Keel et al., 2018). To grasp the complexity of AI adoption, it is vital to determine whether the technology is disruptive or continuous. Christensen et al., (2015) describes disruptive innovation as the process by which a new product or service can eliminate the existing product or service. Continuous or sustainable refers to incremental technological advancements that expand upon existing products and services. The healthcare industry has undergone significant changes since the emergence of Big Data and the potential of AI models to leverage healthcare data (Chomutare et al., 2022). In the article by Christensen et al., (2015) the authors indicate that disruption is a gradual process, with the technology evolving over time before achieving disruptive impact (p. 47). In Moore's (2014) book, he emphasizes that a disruptive innovation must "change our current mode of behavior or to modify the products and services we rely on" (p. 12). As newer

machine learning models surpass old AI models, the literature labels some of these AI innovations as disruptive. To enable the use of these disruptive AI technologies, it is important to understand *how* the existing infrastructure and workforce needs to be modified to benefit from its adoption. Moore (2014) highlights in his framework the challenges involved in crossing the chasm and points out that the way in which the industry will adopt AI, depends on how technological evolution pushes the industry to transform.

2.3.2 S-curve

The S-curve, also known as the technology life cycle, is a framework first introduced by Foster (1987) that explains the pattern of technology development and market growth over time. It is also a model to illustrate the relationship between the rate of technology adoption and market saturation. According to Foster, once technological innovations are introduced to the market, growth tends to be slow. With the steady improvement of the technology, it gains acceptance, and growth accelerates, often leading to rapid implementation. Foster differentiates the different stages to which technology is adopted and labels them as ferment, takeoff, maturity, and discontinuity (1987). Referencing Foster's definitions of each label of the technology lifecycle, we can determine where certain AI technologies are positioned. AI in healthcare is not a new phenomenon, and with the emergence of advanced machine learning algorithms and deep learning networks, the original AI technologies that emerged early in the 1970s when it was first introduced in a healthcare setting, has reached the discontinuity phase, where new S-curves (new technologies) are replacing the existing ones, and creating disruption (Christensen et al., 2015; Ghassemi et al., 2021).

AI technologies differ greatly in terms of the type of technology being developed. In this next section we exclusively label those technologies capable of assisting in medical decisioning such as diagnosing, prognostics, and recommendations for treatment. Applying Foster's S-curve, this AI category resides between the ferment and takeoff stages (1987). In some areas, the technology is still in its early stages, such as the development of machine learning algorithms and deep neural networks where adoption is limited. However, as other technologies are adopted in several healthcare settings around the world, for instance in pathology and cancer detection for image analysis, the technology S-curve has gained some

momentum and is adopted by more healthcare institutions (The Norwegian Directorate of E-health, 2019). In this phase, the takeoff phase, having overcome technical obstacles and the ability to meet the needs of the clinicians and patients, the products have been adopted by the early majority. This also indicates that there is a rapid growth in production and is quickly moving towards full market adoption. We can see this development supported by the ongoing development of AI-products (DNV, 2023).

2.3.3 Competence and Literacy

To effectively adopt and utilize AI-based technologies, healthcare institutions need a workforce with a combination of clinical knowledge and technical expertise (DNV, 2023). However, these institutions seldom have the necessary skill sets. It is therefore important to bridge the competence gap to facilitate a successful implementation of AI. To use AI technology safely and confidently, there must be an understanding of what the technology implies and an in-depth knowledge of its applications.

In their article on AI governance, Papagiannidis et al. (2023) suggests that failure to implement AI-medical tools can be attributed to a lack of understanding the technology and its implications, resulting in a gap between intent and action. This indicates that healthcare decision-makers are also struggling with lack of competence to even initiate AI implementation (Amershi et al., 2019). In 2015, an OECD analysis report projected that Norway would have one of the lowest job elimination rates due to automation (The Norwegian Ministry of Local Government and Modernisation, 2020). The reason being Norway's emphasis on extensive workplace training, regardless of the educational background, making it one of the leading countries in this regard. The National Health and Hospital Plan 2020–2023, places particular importance on educating medical professionals and motivating their active participation in the adoption of AI to ensure success (The Ministry of Health and Welfare, 2019).

Another important aspect of the competence challenge linked to AI implementation, is to confirm the technology's validity. In other words, the clinicians need expertise in AI algorithms and their explainability to ensure accurate evaluations. A Harvard Business Review article by Wilson & Daugherty

(2018) emphasizes the importance of understanding how an AI-medical device processes inputs to generate outputs, thereby validating its medical recommendation. As previously mentioned, knowledge about the explainability and validity of AI devices is paramount in establishing trust in the algorithm's recommendations. Such competence is also vital once the device is operative, where clinicians must continuously monitor the systems to ensure proper functioning (Wilson & Daugherty, 2018). Suggested in the report by DNV (2023), is that developers of AI should include training on result affirmation, impact evaluations, the population used for training, expected mistake margin, statistical knowledge, and method explainability. Multiple studies show that when adopting AI into healthcare, the entire healthcare institution must be redesigned, incentivized, and invest in upskilling and reskilling the workforce (Apell & Eriksson, 2023; DNV, 2023; Petersson et al., 2022).

When it comes to the adoption of transformative technologies and reshaping the entire healthcare organization from what we know today, there is a significant learning process involved. The article by Cohen & Levinthal (1990) highlights the importance of knowledge acquisition, stating that organizations must leverage both external and internal information to enhance their innovative capabilities. They refer to this as absorptive capacity, which means "recognizing the value of new, external information, assimilating it, and applying it to commercial ends" (Cohen & Levinthal, 1990, p. 129). Even though the public healthcare industry is governed by the state, which may not face the same competitive pressures as the private sector, there is often a tendency to wait for others to take the first step.

In Afuah & Utterback's article, the authors describe the prevalent tendency of industries to become complacent and accustomed to their present state, which often leads to overlooking creative ideas for innovation (1997). To engage and foster a culture of openness, effective communication with external and internal environments is significant. If the institution is to achieve efficient learning across all of its departments, AI knowledge must become an understood language (Cohen & Levinthal, 1990).

2.3.4 Culture and Acceptance

To implement and adopt AI in the healthcare sector, where the technology can be used to assist in medical decisions, such as diagnosing patients, both the healthcare professionals and the patients must accept the technology. According to a survey conducted by Fountaine et al., (2019) implementing AI presents both cultural and organizational barriers, for example, the professional's fear of becoming obsolete, as well as professionals having high expectations for quality and also expecting results unrealistically fast. Fountaine et al. emphasize the importance of aligning cultural change to avoid those barriers and suggest involving end users in the development of the system, as they are the ones who will use it operationally (2019). It is also important to be critical of the suggestions the systems make. The outputs are simply suggestions calculated by the algorithm meant to offload work for the clinicians, and each case will be unique (Fountaine et al., 2019). Whether positive or negative, employee perceptions can significantly influence technology acceptance, which in turn impact the innovation outcomes and performance of an organization (Lichtenthaler, 2019, p. 40). Apart from the abovementioned factors contributing to implementing AI, several studies indicate that most clinicians, despite cultural and social diversity, express that they are in favor of widespread adoption of AI in healthcare (Krishnamoorthy et al., 2022). However, the occurring argument that concerns cultural and acceptance of AI implementation, is uncertainty avoidance. Uncertainty avoidance coincides with the concept of trust. Trust in the system refers to an individual's inclination to place their trust in AI technologies when used in healthcare applications (Krishnamoorthy et al., 2022).

2.3.5 Responsibility for Using AI

For users to accept AI algorithms' ability in making life-altering decisions, or providing clinical proposals, it is essential to establish trust and reliability. The level of trust placed in the algorithm depends on its application, whether it is used for logistics, predicting diagnoses, or recommending treatments for patients. The latter two carry significant implications, as highlighted by McAfee and Brynjolfsson (2017) in their book *Machine, Platform, and Crowd*, where they note that most patients do not want to be diagnosed by a machine (p. 89). If an AI medical device makes the wrong decision or misdiagnoses a patient, the outcome

could be life-threatening. In such cases, the question of liability and responsibility arises. The big discussion is determining who holds the legal and ethical responsibility; i.e., the supervising medical professional, the medical institution, the AI provider, the certifying authority, or the patient themselves.

Benny Chan (2022, p. 376) discusses in the *American Journal of Law and Medicine* that there are three distinct stakeholders at the forefront of the question of responsibility regarding the use of artificial intelligence in healthcare. These are clinicians (users), manufacturers of the AI system (providers), and institutions (hospitals). Chan first introduces the clinicians as the users of the AI system. A question frequently raised is the level of responsibility a clinician holds when an AI device misdiagnoses or recommends the wrong treatment for a patient. Chan signifies that the progress made in machine learning algorithms and deep neural networks has led to clinicians being wary about trusting the performance of AI. Their hesitation stems from a lack of understanding the inner structure and functioning of the algorithms, as well as the relevant medical expertise that supports them (2022, p. 376). However, the purpose of implementing AI in clinical practice is not to replace clinicians but to offer qualified assistance, within its inherent limitations. Therefore, when assessing the output and deciding whether to approve or reject the AI's recommendations, the clinician's presence and expertise is essential (Chan, 2022, p. 376). According to Ryan (2020), AI itself cannot be held accountable for its actions. In contrast, liable AI places the burden of responsibility on those who develop, deploy, and use these technologies (2020, p. 17). The AI developer constructs the algorithms designed to perform specific tasks. However, once the system is in use, the manufacturer has little control over its functioning and how clinicians interpret and utilize the system's assessments. While the AI developer possesses knowledge of the system, they are not the ones using it, even if they are in charge of its programming and improvements. The last stakeholder in this responsibility discussion, as outlined by Chan, is the institution. The institutions, which are typically represented by hospitals, do not directly use the algorithms or make decisions based on the conclusions that the system draws. Chan concludes that for the purposes of liability, this is considered a mutual commitment (2022, p. 376), despite the fact that determining who should be reliable is a difficult undertaking.

2.3.6 Leadership and Governance

AI adoption necessitates solid organizational processes, which are fostered through clear leadership and governance (DNV, 2023). It requires a well-defined strategy to identify the needs of the healthcare institution and its personnel. This involves assessing whether and how AI can solve specific challenges, and evaluate potential benefits and risks associated with adopting AI technologies. Also, a comprehensive plan should be in place to manage the implementation and utilization of AI-medical tools both within the organization and from its distributors (DNV, 2023). What this entails is that the healthcare industry needs encouraging leaders and managers to drive innovation and AI adoption. Despite the extensive research on the role of leadership in promoting innovation in organizations, there is a lack of studies specifically focusing on how leadership approaches can cultivate a culture of innovation in healthcare (Weintraub & McKee, 2018, p. 1). The healthcare industry is constantly under pressure to innovate, especially in terms of improving procedures for diagnosing and treatments. The need to digitize the industry for more efficient and high-quality patient care further motivates innovation. Also, the introduction of new care models necessitates potential adjustments to established roles in order to harness the benefits of these models (Weintraub & McKee, 2018). In their study, Weintraub & McKee (2018) identifies several frameworks important to address with innovation strategies. They highlight that to ensure the advantages of integrating an innovation strategy to deploy AI technologies, it requires the leadership to have specific expertise with innovation in healthcare, administrative and technical skills acquired in all the innovation phases (2018, p. 139). They refer to four identified phases selected by Tidd and Bessant (2020), called "Search, Select, Implement, and Capture". These phases are distinguishable from each other, and the leaders need expertise acquired from all of them to be successful.

A study conducted in 27 hospitals in the UK found that the relationship between leaders and members of the institution, particularly the healthcare professionals, was a significant source to promote innovation (West & Anderson, 1996). This study underscores the importance of creating a strong and collaborative relationship between decision-makers responsible for implementing AI and the

individuals who are expected to use it. The leader-member exchange (LMX) theory focuses on the relationship between the leaders and their followers. This theory highlights the importance of mutual trust and respect, empowerment, and leadership support in enhancing the effectiveness of the innovation process (Graen & Uhl-Bien, 1995). By cultivating positive leader-member relationships, the healthcare institution can create an environment that fosters innovation and encourages its team members. In Germany, a study was conducted to examine the factors influencing innovation capability in hospitals. The findings revealed that having a "well-structured, formalized, and strategy-oriented environment" was vital (Liebe et al., 2017, pp. 142–146).

Although the existing literature emphasizes the importance of a positive leadership-member relationship and clear structures for AI implementation, there are other elements to consider (DNV, 2023; Weintraub & McKee, 2018). For instance, AI technologies have the potential to impact several aspects of a hospital's structure. Therefore, leaders must identify the strategic priorities related to AI adoption, which often necessitates a multidisciplinary approach within the leadership team to make informed decisions. Once the strategic priorities are established, leaders should create governance and implementation plans for AI adoption while ensuring alignment with the strategic priorities (DNV, 2023).

3.0 Research Methodology

In this chapter, we will present the selected methods and procedures for collecting and analyzing data, along with an explanation behind our choice of methodology. In addition to explaining and justifying our chosen research methods, approach and design, we will also detail the process of selecting and sampling for our two-case study design. Furthermore, we will address ethical considerations regarding privacy. To highlight different aspects of the research question, we include it here: *How can hospitals implement and adopt AI technologies to improve hospital care and provide a more efficient pathway for everyone in need of healthcare services? What are the challenges to implementing AI into public healthcare?*

For this thesis, we used a two-case study design comprising two separate projects developing AI machine learning models for developing cancer diagnostics and treatment optimization. Each case represents an individual project that is required to follow the same regulations for developing AI medical devices to gain access into the Norwegian healthcare market. Through generalization, we aim to identify variables that may exist in similar cases (Yin, 2014). We chose a case study approach since our research question involves understanding "how" something occurs, investigating a contemporary phenomenon (Yin, 2014, p. 11). Case studies are known for their in-depth examination of specific individuals, groups, or institutions. Considering that our study examines Norwegian hospitals or the Norwegian healthcare industry in general, the case study research design is most suitable. By selecting two distinct research projects as case studies, we want to understand the experiences of the involved subjects. Hence, the case study design can be considered a qualitative study (Flick, 2007).

3.1 Research Design

The research design can be viewed as the logical framework that connects the empirical data to the research question and the overall objective of the study (Yin, 2014, p. 28). The research design should be tailored to fit the research question and how the study attempts to collect and analyze data. There are three types of research designs, descriptive, exploratory, and causal. The first design focuses on describing a situation and understanding causal relationships (Jacobsen, 2005, p. 101). The exploratory research design is utilized in cases where the investigated topic has limited prior research areas. A causal research design aims to measure the impact of causal factors (Jacobsen, 2005). In our study, we have chosen an exploratory research design as a result of the limited studies detailing the reasons behind why the AI adoption rate in hospitals have been so low and why so few AI research projects make it to clinical use. The objective of the thesis is to acquire more insights into the determinants of AI implementation in healthcare, which we have sub-categorized into three research fields: AI in hospitals, public healthcare industry dynamics, and technology adoption. When targeting an exploratory research question, it benefits the study to select a method that can encapsulate the subtleties and intricacies of the subject matter. As the exploratory design enables a deeper comprehension and knowledge of the phenomenon (cases) being studied

(Yin, 2014, p. 30), we justify our reasoning for choosing this design for our research.

3.2 Research Approach

Considering research approaches, there are two distinct types of reasoning: inductive and deductive. The choice of reasoning depends on whether an established theory is being used. Inductive reasoning involves reaching a general conclusion based on specific observations (Streefkerk, 2023). On the other hand, deductive reasoning means acquiring a specific conclusion from a general idea supported by existing literature (Streefkerk, 2023). In this study, we have used a hybrid approach that combines elements from both deductive and inductive reasoning. The reason for adopting a hybrid approach is that we utilize existing theories derived from prior research on artificial intelligence in healthcare, public healthcare industry dynamics, and technology adoption. Additionally, we also rely on data collected through interviews, enabling us to obtain specific primary data from the projects (cases). The chosen method will guide the data collection process. The conclusions drawn from the data collection will encompass both a generalized understanding of the subject matter derived from existing theory, a clarification of our hypothesis, a set of assumptions, an explanation of the phenomenon, and new empirical data that contributes to the establishment of a new theory.

3.3 Research Method

Recognizing the importance of collecting pertinent data to effectively address the research question, we have chosen to use a qualitative research method for collecting primary and secondary data. The research centers around a two-case research study that meets the distinct requirements in classifying as a case study design, making a qualitative research approach highly appropriate (Creswell, 2012; Yin, 2014, p. 19). The study focuses primarily on conducting comprehensive interviews with individuals affiliated with the companies serving as the foundation for our case studies. Nonetheless, we must also conduct interviews with other stakeholders directly or indirectly involved in the cases to gather substantial information about all aspects of our research area. The diversity of respondents is a result of the discoveries made through interviews with the companies involved in the cases, enabling us to learn more about the research

topic and get closer to finding out the "how" of the research question. Additionally, to understand the challenges related to implementing AI in healthcare identified during the interviews, we need to assemble comprehensive information from various sources and documents. This will help us understand the terminology and intricacies surrounding the implementation of AI in healthcare, which we can subsequently use to analyze further in the findings and discussion sections of the paper.

3.4 Two-case Study

Case studies are frequently used to enable researchers to improve their knowledge of the phenomenon while maintaining a holistic and pragmatic perspective (Yin, 2014, p. 4). By using real-life cases as anchors for knowledge, the researcher can obtain a pragmatic perspective. In this study, we have decided to focus on two different cases that share some similarities, aiming to acquire a more profound understanding and avoid drawing conclusions based solely on a single phenomenon. Moreover, we wanted to gain insights from two cases in different phases for us to understand how the companies reached their current positions, while also gaining perspective on the challenges faced by the companies overcoming subsequent phases. Straits and Singleton (2018) state that several carefully selected samples will justify the accuracy of the information in a case study, which will also avoid the pitfall of generalizing every AI implementation in hospitals based on one case study. To ensure a straightforward and effective analysis of each case and its respective challenges, we will limit the number of cases included in the study.

3.4.1 Case Selection and Sampling

Information for the discussion will mostly come from the interviewees and by reviewing and analyzing previous research. Therefore, it will be important that the respondents are pertinent to the perspective of the proposed field of study. Before a sampling of the interviews can be selected, we need to have a clear picture of the population (Kenneth Bailey, 1982; Straits & Singleton, Jr., 2018). Before creating the sampling frame, we will go through a selection process in which the target population is chosen.

Geographically and explicitly, the target population will primarily be limited to Norway-based research projects and private start-ups working with AI. As stated earlier, we will focus on a two-case study. These research projects (later startups) (Description under 2.2.4 second topic: Procurement processes and economic considerations) will have certain criteria to be able to answer our research question. The most important criteria is that the cases are developing AI medical devices for healthcare purposes and aim to implement them into a clinical setting.

Our sample frame is, as mentioned, determined by a set of AI-specific criteria. The operational criterion is that the AI technology can contribute to changing internal processes, strategies, or potentially alter the healthcare industry with an AI implementation process. As the AI landscape for the healthcare sector is considered extensive, we will choose cases that specifically target AI medical devices for cancer diagnostics and treatment. To meet the criteria of distinguishing between two case studies residing in different stages, we have chosen cases based on their positioning in the AI product development process where the end objective is to integrate their products in hospitals (Figure 3). We will therefore choose one project that is in the product development phase and another that has transitioned into the operational phase and is compliant with ISO 13485 certification for its products. The latter case has acquired the CE-mark for its AI machine learning models and is ready to be implemented in clinical settings.

With these criteria in hand, the embedded case studies will be based primarily on the following projects described in the introduction:
a) Machine Learning in the Mammography Program (MIM), and
b) DoMore Diagnostics

Both projects focus on the implementation of AI medical devices to enhance hospital services and improve cancer diagnostics and treatment for both medical personnel and patients.

3.5 Data Collection

Primary data will provide us with more precise information that is particularly relevant to our research question, given that this question also refers to knowing how something can be done moving forward. Before the two cases were

established, we had several discussions with academics concerning our topic to narrow it down, as the scope of the field is considered highly advanced and complex. During these discussions it was concluded that we needed to conduct more research to fully understand the implementation of AI medical devices in the healthcare industry. This research ultimately led us to the two cases a) MIM and b) DoMore Diagnostics. For our research on the cases, we have used both primary and secondary qualitative data.

3.5.1 Qualitative Primary Data

To get first-hand information for our case-study, we have collected data from interviews. By adopting this approach, we can dedicate more attention to acquiring a comprehensive understanding of our topic. The selection criteria for the interviewees were based on their direct or indirect involvement in the respective cases a) and b), as well as our aim to gather insights from professionals who have experience or potential involvement with AI technology in healthcare. To maintain control over the interviewees, we compiled a schedule of which informants we spoke with and when (Appendix 1).

Subsequently, we developed an interview guide (Appendix 2) to be used during interactions with informants. The interview guide will help us ensure thorough preparation, maintaining the relevance of questions, and organizing them systematically to facilitate the collection of essential data (Straits & Singleton, Jr., 2018, p. 293). The interview questions were categorized to address specific aspects tailored to different interview groups, such as clinicians, enabling us to cover both general questions and those specific to each category. From there, the interview guide was customized based on our research hypothesis and existing theories related to AI in healthcare, with the flexibility to adapt and incorporate new information and theories discovered throughout the research process. The interview guide was shared with the respondents prior to the scheduled meetings.

Most of the interviews were held in person lasting approximately 1 hour each. However, when the informants were not able to meet in person, they were completed via Microsoft Teams. To learn more about the challenges faced by the projects, we opted for semi-structured interviews. By conducting semi-structured interviews, we were able to frame our interviews with predetermined questions

and redirect the questions if the direction of the interview changed. This "balance(s) adaptability with rigor, but not rigidity" (Yin, 2014, p. 75), and gives the respondents some free reins to lead us in a new but relevant direction. Researcher Robert K. Yin emphasizes the importance of the questions: "Research is about questions, not about the answers" (2014, p. 74). We conducted semi-structured interviews with lawyers, directorates, agencies, departments, AI communities, registries, incubators for health startups, scientists, radiologists, and pathologists, where the common denominator was that they all were directly professionally involved in some way or had in-depth knowledge about the two cases. Additionally, we completed several unstructured interviews with key experts in AI, involving lawyers, professors, and clinicians. However, these interviewees were not involved or had prior knowledge about the investigated cases. The interviews either gave us direct insight into the respective cases or referred us onward to more relevant informants.

To accurately cite the interviews, it is vital that the transcription of the interview is accurate; therefore, the interviews were transcribed straight after they were conducted. The interviews were conducted with one researcher transcribing while the other interviewed, so that the "researcher [...] creates a rich dialogue with the evidence" (Yin, 2014, p. 73). After conducting and transcribing the interviews, we edited corrections made from fresh memory to ensure quality control (Straits & Singleton, Jr., 2018, p. 417).

3.5.2 Qualitative Secondary Data

The collection of secondary data in this study involves gathering information from various literature sources, including reports, documents, articles, and research studies. Utilizing secondary data has proven to be a resource-efficient approach since it comprises existing data, as opposed to the data we needed to collect, process, and analyze ourselves from the interviews. However, it is worth noting that analyzing different documents can be time-consuming due to the extensive literature not specifically tailored for our study. Conducting a thorough literature review has been crucial for our research, ensuring that we identify high-quality published documents, including peer-reviewed and other reputable sources. This is especially important in a developing field where some research may exhibit biases if it is conducted by the same researchers who collected the data.

3.6 Processing and Analysis of Data

The primary qualitative data, which is based on the interviews, will be the main source of information, while the secondary data will be used to supplement or question the study. In the beginning, we asked for permission to take voice recordings during the interviews, but we found it very time-consuming, which is why after a couple of interviews we decided to transcribe in real-time. Since we are following a qualitative research method, we will use Creswell & Plano Clark's steps to analyze the research. The steps are "preparing the data for analysis, representing the analysis, interpreting the analysis, and validating the data and interpretations", in the form of a conclusion (2011, p. 204).

3.6.1 Coding

For the step of preparing the data for analysis, we generated codes for a better overview of the findings. Coding involves sifting through, organizing, and categorizing your data. The data was coded to provide an outline of the patterns and tendencies of the data for further examination. It will assist with data reduction so that irrelevant information gathered from the interviews can be eliminated (Tjora, 2020, p. 197). Coding can be an iterative process, which means that constructing, refining, and enhancing the data is an ongoing process (Software Quality, 2022). The more frequently data is analyzed, the more information can be extracted from the data. For the coding of the transcribed interviews, we highlighted the various findings with colors, and added it to a self-made coding system based on our preferences for the study. In consideration of the research question, we developed a coding system based on the following concepts: *Technological understanding, organizational contingency, obstacles and challenges, potential benefits and implementation strategies.* The coding systems used for analysis are detailed in Appendix 3.

3.7 Quality Control of Data Material

Prior to conducting the research, several factors were taken into account to ensure the production of a high-quality study. Four principles, namely case-study construct validity, internal validity, external validity, and reliability, have been identified as widely utilized for ensuring the quality of empirical data (Yin, 2014, pp. 45–46). It is important that the research is correct in terms of reliability and

validity. During our research, we had to be aware that the analysis could be subject to errors. The errors must be predicted beforehand and mitigated as best as possible. During interviews, respondents may not understand the meanings of the questions in both a literal and figurative sense, which is called cognitive processing. As a result, it is critical that the questions are concise and specific so that the respondent is not misunderstood, which is why we chose to have interviews in person instead of surveys (Straits & Singleton, Jr., 2018).

3.7.1 Validity

Validity is explained by Straits & Singleton (2018) as "goodness of fit" (p. 89), if the research is measuring what it is meant to measure. In order to determine if the research is valid, three segments have to be evaluated. The first principle determines whether the study has the "correct operational measure" (Yin, 2014, p. 46). This means to collect enough data to support the measurement variables. In our study, we have incorporated this principle by collecting data from several professions within the same industry. The second principle is internal validity. Yin (2014) explains it as a "problem of making inferences" (p. 47), this means that the researcher makes a conclusion based on perhaps one interview. To mitigate this, we have asked for a deeper explanation of statements. For instance, if an interviewee from case b) presented a statement about regulators, we conducted interviews with the entity directly involved in the regulatory agency to ensure we made an accurate affirmation. The third principle is external validity which emphasizes whether the research is generalizable or not. Looking at the descriptive nature of our case study research, which focuses on the "how" aspect of the research question, it is important to incorporate strategies that enhance external validity (Yin, 2014, p. 48).

3.7.2 Reliability

The final principle involves ensuring the trustworthiness of the research. If the research is trustworthy, the same conclusion should be reached if the exact same case study is replicated, thus minimizing the study's errors and bias (Yin, 2014, p. 49). To ensure the reliability of the study, we interviewed a number of respondents directly and indirectly involved in the cases. To ensure the quality of the secondary research, we gathered data from reliable search engines encompassing published academic studies reflecting our research area, which we analyzed

critically. However, with two cases, it is difficult to predict the influence of the same or other variables on a potential third case.

3.8 Privacy and Ethical Considerations

Safeguarding the privacy of the respondents is a critical aspect that has been taken into account in this study. Ethics refer to standards of right and wrong, whereas research ethics implies the application of ethical principles to scientific research (Straits & Singleton, Jr., 2018, p. 479). Yin (2014) highlighted the responsibility of researchers to exercise special care and sensitivity when conducting a case study, as outlined in the National Research Data guidelines (p.78). In this research, it means informing the respondents about the study, ensuring the protection of privacy and maintaining confidentiality during the entire process. To ensure that the respondents' privacy were protected, we requested and submitted a registration form to Sikt for the processing of personal data prior to collecting the data (Appendix 4). Sikt's registration ensures that students and researchers comply with the regulations for processing personal data (Sikt, n.d.).

4.0 Findings and Discussion

In this chapter of the thesis, we will examine the correlations between the theoretical framework of the thesis and the findings derived from the interviews and case study research conducted on the MIM and DoMore Diagnostics projects. Through this analysis, we uncover the barriers and driving elements that affect the implementation of AI in hospitals. We discuss, using both theory and empirical evidence, how each factor influences the success rate of AI adoption in healthcare. During the investigation into the case studies, we will integrate the empirical findings with relevant theories from our literature review to gain insights into how the identified barriers and drivers have influenced the respective project's development of AI technologies and why their implementation in hospitals has not yet been realized.

The subsequent sections are organized in a similar sequence as the theoretical review to maintain a coherent progression. From there, we will assess the seven key categories identified in our hypothesis as critical factors for achieving

successful AI implementation in healthcare: (a) AI algorithm/technology, (b) data access and structure, (c) interdisciplinary collaborations, (d) legal and regulatory frameworks, (e) AI validation and documentation, (f) procurement and economic considerations, and (g) competence and leadership. Additionally, the discussion will include other pertinent subcategories derived from the findings. Quotations from the participants will be presented in italics and with indentation.The discussion will serve as the foundation for addressing the research question of the thesis: "*How can hospitals implement and adopt AI technologies to improve hospital care and provide a more efficient pathway for everyone in need of healthcare services*?". It will also outline the subquestion of our thesis, namely *what the challenges are to implementing AI into public healthcare*.

4.1 Discussion and Findings Linked to Subcategories in Theory Section 1: AI in Healthcare

AI Technologies' Impact on Healthcare and its Surroundings

The results show that all respondents believe that AI technology is of great importance for the healthcare industry to be able to respond to the challenging demands of society, both in terms of efficiency and improved patient care. The healthcare sector already depends on technology on a daily basis, and although the rate of AI adoption has been insignificant, the future holds promising prospects.

> *«When I think of AI, I think of the possibilities it offers for better treatment and newer treatment, more efficient treatment.»*

The respondents generally agree that AI has the potential to reconstruct the entire hospital organization by influencing how administrative tasks, procedures, decision-making processes, and treatments are carried out.

> *«The advantage is that it enables more efficient treatment, either by requiring less human resources in some areas or by restructuring human resources. New type of treatment and doing specific tasks that humans are unable to do. E.g. The DoMore project which deals with an analysis tool*

at such a specific level that it is impossible for humans to see in order to recommend better treatment.»

These statements are supported by the Norwegian Health and Hospital Plan for 2020-2023 emphasizing the importance of the state providing support to the hospitals in digitizing their operations and utilizing technologies, such as AI to take advantage of the opportunities these new technologies provide (The Ministry of Health and Welfare, 2019). Similarly, the respondents point out that AI can also help medical professionals in allocating more of their time focusing on their patients.

«We can analyze information more quickly and perhaps bring in new information than we have done so far, we get to know more about the patient, and faster. We can also get help to use the resources correctly on the right patient.»

There are, on the other hand, limitations to how it is believed that AI can have an impact on healthcare *right now*. What keeps surfacing is the notion of "future AI" and how AI can alter the healthcare industry in the years to come. Even though we have proof that AI is already being developed to the point where it could do that even now. This argument is supported by theory, that although AI has the *potential* "to transform healthcare, making it more efficient, equitable, and safe, there are hundreds of AI-based tools available on the market today, and yet few get adopted into clinical practice because of numerous barriers and challenges" (DNV, 2023, p. 3). Evidently, also discussed a lot in the included studies pointing to AI in healthcare, the tendency is always to look at the AI's "potential" and not so much as how the already developed AI tools are contributing to making a difference (Halamka & Cerrato, 2020; OECD, 2019; Saunes et al., 2020; The Norwegian Directorate of E-health, 2019). We can argue that AI technologies are expected and anticipated to have a great positive impact on the healthcare industry, however, there is little evidence to address whether AI is impacting the healthcare industry already. We acknowledge that other countries such as Sweden, England, Denmark, the USA, and others have gotten further in their implementation of certain AI tools, and therefore do not apply to the same

argumentation as for the Norwegian healthcare industry (Alamgir & Mohyuddin, 2022; The Norwegian Directorate of E-health, 2019).

The data analysis and literature review indicate that the Norwegian healthcare industry has displayed little evidence of AI implementations, which inhibits us in evaluating the precise impact of AI on healthcare. However, we also have to consider the potential timeframe in which AI can demonstrate its economic and societal value (Apell & Eriksson, 2023). Presently, most advanced AI medical device models are developed and specialized in solving a single problem or performing a single task (DNV, 2023). Since most of these have not been implemented in healthcare due to various obstacles, one can argue that because there are so few user cases to verify AI's impact on healthcare, this is also furthering the uncertainty of adopting AI. Nevertheless, Norway has made significant efforts to promote and foster a digitized healthcare industry, which will most likely serve as a foundation for enabling AI adoption in the coming years (The Norwegian Directorate of E-health, 2019). What does align with the findings from interviews and theoretical analysis is the shared motivation for AI to positively impact healthcare but also that it is difficult to project exactly what that impact will be.

> *«From my point of view, it is an absolute yes. I also believe that most people in the healthcare industry are positive about using AI if it can prove to make things more efficient.»*

> *«If it is a type of machine learning, I'm optimistic, but I'm also one that's optimistic about such technology.»*

As stated, even without implementation, AI proves that its perceived future value is already contributing to a positive shift towards more digitization and technology. Supported by numerous studies anticipating groundbreaking changes in the healthcare industry, are stating that "AI may reach or even exceed human-level cognitive functions" (DNV, 2023, p. 6), or that "machine learning is the primary capability behind the development of precision medicine" (Davenport & Kalakota, 2019, para. 14). The authors argue that despite the challenges associated with AI adoption, it is expected that AI will overcome them and excel

in the healthcare domain as well. So the question may not be how AI *currently* impacts healthcare, but rather how AI development can support, trigger and promote a digitized transformation of the healthcare industry, which can influence AI implementation and adoption over the next few years.

Distinction Between AI as a Medical Device vs. AI-based Tools

Arguably, even with few specialized user cases, the majority of studies conducted to review the presence of AI in healthcare have primarily focused on AI solutions that are classified as medical devices, differing between low, moderate and high risk classes (Aziz et al., 2021; Biller-Andorno & Biller, 2019; Du‐Harpur et al., 2020; The Government Accountability Office & The National Academy of Medicine, 2022). In doing so, they might have overlooked or failed to investigate the AI-tools that do not fall under the distinction of a "medical device". As indicated in the report done by DNV (2023), there are some examples of AI-based tools integrated in healthcare such as "computer vision, natural language processing (NLP), robotics, planning, scheduling, and optimization, and recommender systems" (2023, p. 14). In general, these categories aim to improve operations and patient experiences without interfering or intended to be used on patients to alter procedures involving e.g., diagnosing, monitoring, or treating diseases (The Norwegian Medicines Agency, 2021).

> *«I think all hospitals are using AI in one way or another, they just don't know it.»*

Even with multiple sources documenting that AI is being used every day in healthcare settings, it is important to clarify that in this thesis, our reference to "AI implementation" specifically pertains to technologies that meet the criteria of "medical devices" as defined by The Norwegian Medicines Agency (2023). We do however want to emphasize the important value of recognizing the existence of other AI-tools related to healthcare. This acknowledgement contributes to the overall conclusion of affirming the already integrated AI-tools in the healthcare field.

Implications of AI Adoption Linked to Risk Classes

As mentioned in the previous section, we argue that there exists a distinction between implementing AI solutions that qualify as medical devices and those that do not, owing to the extensive requirements for reaching clinical use. This leads us to believe that the implications of implementing an AI medical device that resonates in a moderate-to-high-risk healthcare class must also differ (The Norwegian Medicines Agency, 2023). This thesis focuses on two case studies developing advanced AI machine learning algorithms to assist cancer detection and treatment optimization (DoMore, 2022; The Norwegian Cancer Registry, 2023). The type of AI models that the MIM and DoMore projects have developed classify as moderate to high-risk AI medical devices (MDCG, 2021). We can claim that due to the fact that both project's objectives are to help with cancer detection and treatment, which would implicate how radiologists and pathologists would work with cancer patients, the AI solutions fall under risk class IIa, also known as moderate-risk class. However, because these algorithms also might jeopardize or implicate how and if a patient receives certain treatment, which could alter the patient's health situation, it is also classified as a class III, or a high-risk class (MDCG, 2019; The Norwegian Medicines Agency, 2023). In accordance with the Medical Device Regulations, a medical devices' "conformity assessment is the process demonstrating whether the requirements of the MDR relating to a device have been fulfilled. The higher the class of the device, the greater the involvement of a notified body in conformity assessment" (MDCG, 2021, p. 5). Put simply, it can be affirmed that different classes entail varying implications, risks, and performance measurements. This, in turn, could perhaps lead to more questions and uncertainty.

«You are afraid of making mistakes.»

Noted in several of the findings and literature assessments, it was observed that there is a sense of apprehension surrounding AI and uncertainty about its implications and risks. It may be evident, but it is worth noting that as the risk-class of a medical device enhances, so do the associated risks and requirements for its usage (MDCG, 2021). Another intriguing notion is that the risk class often correlates with the level of autonomy exhibited by an AI medical device (Makhlysheva et al., 2022). In both the MIM and DoMore projects, the studies have showcased how their developed models could benefit the healthcare

sector. Since these models act as “assisting tools” to help the radiologists and pathologists in performing their jobs, it can be argued that most people would not perceive these models as too risky. Moreover, this suggests that the autonomy level of the AI model is also seemingly low if in fact these elements correlate. On the other hand, despite the progress made in the MIM project towards obtaining CE marking and the ongoing efforts of DoMore to implement its products in Norwegian hospitals, it is not unlikely that there may still be remaining obstacles to overcome.

The Importance of Data Access, Quality, and Structures

Extensive datasets are confirmed to be a significant factor in processing and generating results for AI and machine learning (Apell & Eriksson, 2023). One of the many challenges that was mentioned in the interviews was the lack of data access due to strict rules on data sharing and privacy policies within healthcare institutions.

> *«There are ethical considerations associated with protecting privacy, which is a natural aspect of the development of AI towards health today.»*

Another respondent, affiliated with an incubator firm that assists entrepreneurs in navigating the intricacies of AI development and adoption, expressed the following:

> *«Collecting data is somehow easier in the early stages. However, as soon as the company is established and is no longer in the research phase, where they are no longer a research endeavor at a hospital, the collection of data becomes more complex.»*

Supported by literature, with the development of AI medical devices, one of the notable opportunities and challenges lies in the availability of Big Data for training and validating AI algorithms to perform specific tasks (Jiang et al., 2017). Given that a significant portion of healthcare data is unstructured and varies between hospitals and institutions, it becomes difficult to generalize the outcomes of these algorithms (Makhlysheva et al., 2022). As the findings from the interviews point to, although it might be manageable to gain access to substantial

data for developing, testing, and validating an AI medical device, as soon as that project moves over to the operational phase (market), most data becomes restricted and therefore unreachable (Figure 3). This can also imply that if e.g., an AI machine learning algorithm is developed to assist the radiology department in detecting cancerous tumors through image analysis, disparities may arise between the trained datasets and the datasets that the algorithm is expected to decipher. One can therefore argue that this is also a reason as to why so many finalized AI medical devices never make it to implementation (DNV, 2023).

What might also be important to note is the differences between the required data necessity for a conventional software implementation versus an AI medical device software implementation. Arguably, one of the most occurring arguments to why AI is so difficult to both implement and understand its effects, is that AI-based tools "adapt their logic over time to change how the task is carried out" (DNV, 2023, p. 12). Conventional software on the other hand, procures the same results each time with the same underlying parameters. It is also recognized that AI algorithms learn better over time, by being exposed to more data. This further exemplifies the need for proper access to more qualified data even after it reaches implementation.

> *«When we come to use AI in the health sector, it is expected that such [testing,]validation, and ethical analyzes and responsibility have already been approved during the process (development phase).»*

Needless to say, AI deployment requires a whole different approach when it comes to expecting a finalized product to be delivered at the doorstep of a healthcare institution. Arguably, it needs an environment where it can learn to excel its performance by being exposed to more sets of data. However, this type of approach has normally never been required in the healthcare domain (Ghassemi et al., 2021).

Data Discrimination and Biases in AI

The topic of available and quality data resurfaces as one of the primary obstacles for successful development of AI (DNV, 2023; Feng et al., 2022; Feygin, 2018; The Norwegian Directorate of E-health, 2019). However, it also relates to how an

AI solution is equipped and trained to distinguish between different datasets to avoid discrimination and biases when delivering its results. Frequently, machine learning algorithms are developed with limited data samples that may not be representative of the intended audience (Zou & Schiebinger, 2021). An AI machine learning algorithm needs to train on extensive datasets from various populations (e.g., gender, race, age, patient profiles etc.) for it to be applicable to all patients. In most cases, AI medical devices are developed and tested within specific environments, due to the limited data available, particularly concerning the population groups that the algorithms need. Take an example, an AI medical device is developed in-house at a hospital in Norway, and we anticipate that the hospital did not partner with other international institutions for data sharing purposes. Due to data sharing restrictions, the device would most likely be trained solely on the Norwegian population. However, once the model enters the market, it requires extensive training to ensure that the device will produce consistent outcomes regardless of the population it was initially trained for. This oftentimes brings questions of biases and discrimination into the picture. This confirms the challenges associated with data sharing during the operational phase (The Norwegian Directorate of E-health, 2022).

The strict regulations surrounding the acquisition of large datasets often restrict access to diverse data sources that could provide a more holistic view of the patient. Consequently, this could result in an inaccurate representation of the patient population during the training and testing of AI algorithms, potentially leading to defective models (The Government Accountability Office & The National Academy of Medicine, 2022). While it may be assumed that models untrained for shifts in population demographics would yield unsuccessful outcomes, there have been instances where models have performed exceptionally well after testing with different datasets (The Research Council of Norway, 2022). If however, the data causes the models to perform inaccurately, it can cause speculation of whether the model is discriminating against certain populations or if the developed AI algorithms are based on human biases (Char et al., 2018). The findings further corroborate the idea that some AI algorithms might show signs of discrimination.

«There are some limitations with current systems, which means that not everyone is equal, but everyone is treated equally.»

The discrimination often becomes an obstacle to address in the development and implementation process of AI medical devices because both anticipating and exposing underlying biases is very challenging (Char et al., 2018). According to a published article from Harvard written by Katherine J. Igoe, this challenge can be classified as "algorithmic bias" (2021). There is a unanimous acceptance among the respondents that discrimination should be taken seriously and actively mitigated.

«Typical challenges with AI are about discrimination, and one of the things that must have [been] confirmed at the time is that it does not take place.»

During the development phase of an AI device, biases of developers, researchers, and designers can emerge if they select target variables and indicators without taking into account the social determinants of health and other unpredictable factors (Leslie et al., 2021). The issue of understanding the different needs of care related to ethnicity has been consistently mentioned by multiple respondents, indicating that it is one of the most difficult challenges associated with data and human biases. In a study that focused on ethnic differences in ECG measurement (Mansi & Nash, 2004), distinct variables were discovered. This means that in countries such as Norway, where a relatively population-specific genetic structure exists (Mattingsdal et al., 2021), using genetic information solely from this population can introduce biases in diagnostic tests.

Let us assume that a patient from a different continent undergoes an ECG test using an AI model trained using data from the local population, it may inaccurately interpret the patient's heart condition and assume a heart defect. Conversely, if the patient receives an ECG test with an AI model trained with data from a similar genetic background, it may show a different result. This demonstrates how the choice of data collection and testing methods can result in different outcomes, potentially leading to discrimination against specific ethnicities, genders, or other social determinants. While this issue carries great

importance, being aware of the potential risks can assist AI developers and clinicians in addressing it. Several informants support the argument that implementing more AI models could potentially promote greater equality among populations and provide larger datasets for training purposes.

> *«[An] AI solution in healthcare gives more justice when you have such tools, it becomes equal for everyone, which is good with a data-driven solution.»*

Establishing better data sharing methods to the point where it becomes a standardized practice in developing and validating AI medical devices to avoid potential errors, such as discrimination and biases, may still be a long-term goal. However, we can argue that it plays a crucial part in fostering more AI implementation in healthcare. Research examining the impact of AI on equality suggests that "developers test the prediction accuracy for various demographic groups" to avoid these questions (Glauser, 2020, para. 8). To mitigate the problem, Katherine J. Igoe emphasizes the need for broader and more diverse teams in data collection, analysis and research (2021, para. 15). To address these concerns, a variety of data should be available to facilitate the standardization and non-biased development of AI solutions. That calls for more standardized data systems and better national and international collaboration (The Norwegian Directorate of E-health, 2022).

Determining Factors of AI: Explainability, Validation, and Documentation

The foundation of AI implementation in healthcare undoubtedly rests upon ethical principles, privacy preservation, digital security, explainability, and accountability. Also, it is important to ensure that data access for testing and validating these devices adheres to the regulations of healthcare and data protection legislation (The Health Register Act, 2022, §19). Perhaps the most crucial element during all phases of AI development, is to document every aspect of the technology, validate its performance, and verify the AI model's ability to showcase explainability (Wilson & Daugherty, 2018). For an AI algorithm to provide recommendations to clinicians and earn their trust, it is imperative to establish validity. Consistent with the findings, AI outcomes are associated with both ethical concerns and hesitance regarding trust.

> *«What worries us a little is that, for example, healthcare personnel and others may think that the algorithm is always conclusive. We are afraid that in the long run an idea will take hold, that it will become facile, that it will become dangerous.»*

As outlined in the theoretical section, one of the main barriers to AI adoption is the lack of trust associated with AI that requires the developers to prove its accuracy and validity (Fuhrman et al., 2022). However, with the comprehensive regulations associated with implementing AI in healthcare, several of the respondents support that the technologies developed are more than adequate to be used in clinical settings. This confirms what Foster (1987) highlighted in the S-curve, where the market becomes more accepting as the technology evolves.

> *«It is not the AI solution itself that has uncertainties, but the paranoia surrounding it.»*

One way to confirm an AI's validity is to acquire the CE marking. To produce and sell a medical device in Norway, the vendor must have a CE marking certificate for that product, which indicates that the medical device has met the MDR requirements (The Norwegian Directorate of E-health, 2022). As highlighted in the literature review, even with a CE marking, there might be other regulatory restrictions that need to be addressed before it can be implemented in Norwegian hospitals. However, one could argue that once an AI developer has managed to get their product CE marked, most of the hard work of documenting and ensuring the safety and quality of the medical device is completed (MDCG, 2021).

Despite that most AI technologies are well documented and its performance validated through extensive testing, more often than not, the biggest issue is to ensure the AI's explainability and transparency. Explainability refers to the AI algorithm's ability to explain how it reaches its conclusions (Fuhrman et al., 2022). In the findings, several of the respondents point to the importance of understanding the technology, but also for the clinicians to trust in the recommendations provided.

«Must convince the clinicians that this really works.»

When it comes to convincing the hospitals and clinicians of an AI's quality and performance measurements, it can be argued that the AI developers/vendors who most likely will "win the race" of making it to implementation, are those who excel in providing and incorporating validation, transparency, and explainability. These elements are crucial throughout the research, development, and operational phases.

How Two Projects can Differ: A Process Evaluation of The MIM and DoMore! Projects

The MIM Project

Researching the case studies clearly shows differences in terms of challenges in accessing data. During the initial research phase of the MIM project, what occurred as one of the main challenges was accessing enough data for developing their AI model for detecting cancer in mammography scans (The Research Council of Norway, 2022). Arguably, this delayed the progress of moving the project further to be able to verify, test, and validate the AI model for commercialization.

«It does not seem as if Norway is the country that finds the simplest solutions when it comes to data sharing and AI so far.»

Although the project managed to access more data and move the project further, the extensive requirements for testing and validating the AI model to obtain the CE marking prolonged the process.

«The CE marking must be applied for, but we lack the resources to test it and make it commercially available.»

The process of moving away from the product development phase to the operational phase has been demonstrated to be quite comprehensive for many research teams.

«Hospitals are a closed market.»

«It often takes a long time to reach such an implementation because there are so many requirements along the way to get it clinically implemented.»

There might be uncharted territories to move through to be granted access to reach a greater market. The MIM project developed their ML algorithms based on Norwegian datasets. However, as confirmed in their reports, "the model has been tested on datasets that were not used for the development of the algorithm. The results are promising and show that there is great potential to increase the sensitivity of mammography screening by detecting more breast cancer [...]" (The Research Council of Norway, 2022, para. 6). Whether the product is scalable or not is another concern for projects like MIM to consider.

«The Norwegian Medicines Agency sets strict rules for developing algorithms in-house. There may be many obstacles on the way, such as these algorithms might only be allowed to be used within the healthcare institution for which they were developed.»

Even with the MIM project's promising results, there are obvious concerns that might hinder the product from reaching clinical use. Adequate funding plays a crucial role in determining whether AI research projects have the necessary resources to complete the development phase and cross over to the operational phase (Makhlysheva et al., 2022). The MIM project was granted 8 million NOK to develop their AI models. However, the high costs associated with AI development raise questions as to whether it is worth the process of acquiring a CE marking if the product cannot be scaled (The Research Council of Norway, 2022). It is likely to assume that, if acquiring a CE marking could take several years including more rigorous testing, many research teams do not make it to clinical use (Makhlysheva et al., 2022). In these instances, developers may also lack incentives to conduct further evaluations on their models.

«If the Norwegian Medicines Agency says that we will never get this approved internationally, then there is no point in continuing to spend resources on it.»

Effectively managing implementation and maintenance costs presents a significant challenge when deploying AI in healthcare. Although the MIM project has completed its research phase and have currently not acquired a CE marking, it is reasonable to assume that the valuable AI models they have already developed will contribute to further research into machine learning in the mammography program. The most recent update on the MIM project indicates that the end date in REK (Regional Committees for medical and healthcare research ethics) was extended due to the need for further development, validation and improvement of the algorithms. Given the critical nature of detecting breast cancer and reducing the workload of the radiologists, we can hope that the immense work undertaken in this project will continue.

The DoMore! Project

Throughout the research and development phases of the DoMore! project, it was emphasized that there were challenges associated with collecting data but that they eventually found an *"ok way of working this out"*. As one of the "Lighthouse Projects" chosen by The Research Council of Norway (2021), one might claim that this project had a different starting point than many other research projects. We might also claim that the reason as to why the research team managed to find its way through the regulatory landscape was their smart move of initiating international collaborations from the beginning. Additionally, as highlighted in the findings, the project had an amazing team with diverse expertise that could handle more aspects associated with developing deep learning algorithms than perhaps others.

> *«We have been a team that has worked very well together. We have been positively disposed to implementing it.»*

An important distinction between DoMore! and other projects is the support it received in terms of financial funding. The project was granted 60 million NOK, which is conceivably more than many other projects (The Research Council of Norway, 2021). Perhaps it can be assumed that their process of meeting the regulatory needs, which landed them the CE marking certification, was somewhat less troublesome. However, as the literature confirms, even with enormous

datasets and enough resources to reach the operational phase with an AI medical device, the requirements concerning documentation, validation, and explainability are the same.

> *«We went through CE-marking of the product so legally we are allowed to sell it, but still, we are not selling computers, there needs to be a lot of things and a place for clinics to be able to start using it.»*

Notably, the DoMore! project resides in the operational phase and has achieved commercialization, however there seems to be other obstacles in terms of getting it implemented.

> *«Still there are several processes we must go through and convince the clinicians that this really works. This means that we must do additional validation processes.»*

As previously mentioned, the findings highlight the challenge of obtaining substantial data after a product reaches the market. The literature supports this viewpoint, stating how difficult it is for developers to assess both the costs for post-market evaluation and the additional validation of the product (The Government Accountability Office & The National Academy of Medicine, 2022).

> *«There are differences in how open the hospitals are to new technology. Our other challenge is that radiology has been digitalized for decades, CT, MR, X-ray has been there for a while, there are many companies working with AI on them. But when it comes to pathology, they are still working with microscopes.»*

Confirmed by the company, DoMore Diagnostics, the firm has managed to conduct several more tests and validation processes post-market. Now, we can assume that whatever challenges ahead are interconnected with the healthcare industry's perspective.

How Legal and Regulatory Frameworks Could Potentially Drive AI

With our research and findings, we have realized that regulatory mechanisms for developing medical devices and their implementations into the Norwegian

healthcare industry are not easy to navigate through (Sharma et al., 2022; The Norwegian Directorate of Health et al., 2022).

> *«In Norway, obtaining permission to integrate diverse instruments is a lengthy process. If you attempt to communicate with a regulatory third party, you will be added to the queue.»*

Although many studies point to a comprehensive portfolio of legal frameworks as one of the primary reasons why most research projects fail to reach clinical use, we must not disregard the fact that these frameworks also serve to stabilize the risks and uncertainties associated with AI. It can be argued that these frameworks also provide reassurance to clinicians, as they outline the medical device's quality level, intended purpose, and guidelines for how one should approach these devices (MDCG, 2021). The frustration of many regulations from different entities has been addressed from several informants. On the other hand, the regulations are made to ensure patient safety. The informants recognize the need for regulations and says the following:

> *«I would say that from a regulatory perspective and a patient safety perspective, it is important that there exists such regulations, and that there is no free access when it comes to selling medical products, which could be very costly for society.»*

There is a regulatory test environment called the regulatory sandbox that focuses on helping organizations with the different frameworks related to developing AI-devices. According to The Norwegian Data Protection Authority, *"the regulatory sandbox aims to promote greater understanding of regulatory requirements and how AI-based products and services can meet the requirements imposed by data protection regulations in practice"* (2021, para. 4). The informants acknowledge the sandbox, but emphasize the need for additional assistance.

> *«A GDPR and regulatory sandbox exists, but what we need is to set up a health legal sandbox where you get help juggling the legal laws and rules.»*

As emphasized by several respondents, the presence of these "rules" in the development of AI medical devices is justified. However, considering that the healthcare industry has been criticized for being fragmented and closed to the market, perhaps these regulations could contribute to promoting standardization and offering clear value propositions for the adoption of new AI technologies. With the Government already pursuing a new digital strategy and the EU introducing the AI ACT, a law aimed at classifying and applying collective rules for different risk categories of AI, significant changes may occur if these regulations collectively have the ability to modify the market and provide a clear approach to introducing AI in healthcare (FLI, 2021; The Norwegian Ministry of Local Government and Modernisation, 2020).

«We need legislation, but we also need a better interpretation of it.»

How the Market is Affecting Norway

The Norwegian Directorate of E-health reports that the implementation of AI projects has been limited due to regulations and stringent procurement procedures (2019). Several respondents express that there is a growing culture of hesitancy among developers focused on the healthcare sector, due to privacy concerns. Others acknowledge the potential benefits and effectiveness of AI, however, they are apprehensive about accidentally breaking any rules. Moreover, some believe that the vast assortment of regulations facilitating the implementation of AI in healthcare, and the challenges of maintaining control, are discouraging them from proceeding with the process.

«There has been a culture that nothing is legal and everything is difficult.»

Arguably, the stringent regulations associated with AI development in hospital care may result in a decrease in the number of AI devices intended for clinical use. Some of the respondents claim that the healthcare system is conservative, whereas one informant suggests that the perceived culture has been formed through years of experience working on AI projects, and that the tendency suggests that *"nothing is legal and everything is difficult"*. Therefore, some might believe that this perspective has led to a prevailing sense of fear of making

mistakes within the Norwegian healthcare system. On the other hand, another respondent provides insight into the rationale behind the existing regulatory landscape:

> *«It is well regulated and has a high safety focus, which can be perceived as conservative and resistant to change if you have not been in charge yourself. But if you use words like safety focus, patient safety focus or well-regulated, it is no wonder it is strict. It is not us who have decided that it should be so strict, it is for good reasons that the law is the way it is and it is often drawn up on the basis of things where mistakes have happened.»*

A document by the European Commission, which focuses on the approach of artificial intelligence towards excellence and trust, details how regulations concerning AI are essential to instill user-confidence in the technology (2020, p. 3). What may be an obstacle with prolonged legal processes and limited accessibility to the market, is that companies developing AI medical devices may abandon the Norwegian market and seek opportunities elsewhere. As noted by one of the respondents, companies might choose to *"travel to, i.e., Germany, because they may have already fixed these issues"*. Possibly another reason for considering expansion into foreign markets, as explained by one respondent, is the fairly small market size in Norway. If the effort is greater than the reward, it is only natural to consider exploring prospects abroad.

> *«Norway is a small country and a small market, with these barriers, it puts them in this situation. Am I willing to put this in a small market? Why don't I go to Germany or the US, where the market is 10-50 times bigger than in Norway. Is that worth all my time and resources?»*

4.2 Discussion and Findings Linked to Subcategories in Theory Section 2: Public Healthcare Industry Dynamics

How the Healthcare Industry Becomes a Unified Entity

Highlighted in the literature section, a hospital's dynamics must contribute to a quality system that can improve the organization and services of the hospital (Sundar, 2003). As indicated, hospitals are pressured to procure better, safer, and more cost-effective treatments (Alamgir & Mohyuddin, 2022). With the anticipated challenges of the future there needs to be some changes to the current systems. But how is Norway changing a system that seemingly is very fragmented and unsynchronized, and how should it be governed? As promised in the new hospital plan, Norway is vigorously working on a transformative digital structure that hopefully can help the regions and municipalities to become more synchronized (The Ministry of Health and Welfare, 2019). However, it appears to be a very difficult task (Feygin, 2018). Evidently, changes are already happening in designing both old and new healthcare institutions, and AI is driving forward action plans to speed up this process (Feygin, 2018). The findings have highlighted the lack of defined organizational governance and standards for introducing various AI tools, which may also inhibit trust.

> *«It is difficult to navigate, many times there are [AI] solutions that do not fit the needs of that particular healthcare institution as it varies greatly in the region. That is a barrier.»*

An important condition for the safe integration of AI medical devices in clinical environments is that the device must effectively address a particular task or problem area that the institution needs assistance with (Sutton et al., 2020). Several respondents find it difficult to understand the needs of hospitals and effectively communicate the technology they have developed. It is possible to believe that at times, even the decision-makers within hospitals may not be fully aware of what they need.

> *«When their companies meet with a healthcare institution, they find that they are [often] unable to formulate and present [the technology] in such a way that the hospitals would understand it. It is often the case that they understand what the solution entails, but perhaps do not understand how it should fit into their systems.»*

Presumably, the main interest for hospitals to actively acquire AI medical devices is to improve patient care, and to manage cost and quality performance (Pfannstiel & Rasche, 2017; Rasche, 2010). While this may be true, it all comes back to the planning and managing the industry's value creation. Pfannstiel and Rasche (2017) argue that the governance systems often fail to explore potential solutions and opportunities for business model innovation because of how the industry is built. One respondent addresses the "maze" of systems by stating a simple but important fact:

> *«There are many integration questions here.»*

Consequently, this requires a governance process in the healthcare system that lays the groundwork for a strategic action plan. According to a study on *Governance Model for AI in Healthcare (GMAIH)*, the authors argue that the primary components of a successful governance model for AI is "transparency, trustworthiness and accountability" (Reddy et al., 2020, p. 493). Even though it can be argued that these models and frameworks are important to facilitate AI implementation, they are not real action plans. As the study highlights, the primary objective is to see how this model "integrates into clinical workflow" to benefit both patients and the hospital (Reddy et al., 2020, p. 495). As the respondents also emphasize, there needs to be a clear structure and a plan to implement AI.

> *«If you are to have a well-functioning system, it must be well integrated and work with all solutions. Data must flow between the systems and have the same login.»*

Assuming we can achieve standardized systems and structured healthcare data, this model may further support a business plan for integrating AI by requiring transparency in decision-making, to align objectives and needs from both the hospital's perspective and the commercial industry perspective. Another important argument to achieve better AI governance is the monitoring and reporting of the medical device's quality and performance, which will safeguard the validity and accountability of the implementation (Reddy et al., 2020).

AI vs. Existing Infrastructure

During the literature assessment, it was identified that the lack of proper infrastructure in the healthcare industry was increasingly becoming a strong barrier to further AI implementation (Makhlysheva et al., 2022). The research focused on two distinct categories that proved to be a challenge, both the operational infrastructure and the existing ICT infrastructure (2022). The report stated the following:

> The available IT systems and setups in healthcare organizations are outdated and not able to handle the nowadays load with browsing in several clinical systems or simultaneous access to a remote system, not even talking about the demanding needs of recent technologies. (2022, p. 27)

Several respondents have described how AI medical devices require a whole different support system of integrated data flow. They also claim that the AI machine learning models are, more often than not, much different than conventional tools and methods. One of the respondents from the DoMore! project highlighted the following:

> *«On the pathology side, quite a lot of infrastructure is required, there are images that are quite large, it can be perhaps 100 GB per image when they unpack. It takes a lot to analyze those images. I think most hospitals struggle with building stock, poor data connections, etc. There is a lot of infrastructure that needs to be updated before you can use things like that for approved use.»*

Confirmative to this statement is that most AI technologies require a sizable amount of data to continuously train its performance over time (DNV, 2023). Generally, this results in better accuracy. However, as the findings corroborate, the current systems are not suitable for several of them.

To promote acceptance and utilization of AI by the hospitals and clinicians, it seems essential to secure and integrate them into the established infrastructure. However, it appears that this is a challenging task as most of the operational and

ICT infrastructures are not designed to accommodate AI. Most healthcare institutions operate with different systems, making it even more difficult to apply the integration experience from one site to another (Nguyen et al., 2022).

> *«Everyone must have a common language and interpretation of the (...) infrastructure process.»*

An article published by the New England Journal of Medicine highlights the importance of undergoing a digital transformation by taking a proactive approach to make changes happen sooner (Zimlichman et al., 2021). Norway is already proceeding with a national action plan to promote the digital strategy in place (The Norwegian Ministry of Local Government and Modernisation, 2020). However, even if this shift is opening up some doors for AI, it does not automatically change the industry's structure and operations. It also depends on how the industry is able to follow the new guidelines. Arguably, the strategies need to address real challenges with a step by step plan to properly employ AI into healthcare, as well as a maintenance plan once it has been developed. As the literature highlights, "it takes years before a developed AI system can be released for clinical use" (Makhlysheva et al., 2022, p. 24).

> *«If society moves in a certain direction, there will be a small window to influence it.»*

In the literature evaluation, Fjeldstad et al. (2020) emphasized that the current structure of the healthcare system is not designed for extensive progression and growth. Reviewing this argument, it seems as though the authors believe that the industry, which is so vast, and so tangled up in rules and current operational methods, does not have the ability to transform itself as other industries. Some respondents confirm this statement, saying that:

> *«[There are] many practical challenges with standardization and platforms etc. All hospitals have their own system and ways of doing things. Big job with standardization and digitization which has only just started.»*

While these observations may be true, Fjeldstad et al. (2020) also addresses potential solutions as to how these challenges can be solved. The authors look for the industry to take on a "networked organizational structure" (p. 2). They argue that this approach has the potential to enable value creation in the form of research and knowledge building, claiming that this form of organizational architecture "has the potential to facilitate the diverse types of interaction required for clinical care, improvement, and research" (p. 3).

The majority of the findings agree that it is no longer a question of "if" but rather "when" AI will become part of routine clinical care (Reddy et al., 2020). Nevertheless, there are some concerns that need to be addressed. Without proper regulatory and standardized systems in place, alongside a well-defined infrastructure to ensure the quality and transparency of AI, "rapid progress in development and deployment of AI models could lead to unsafe and morally flawed practices in health care" (Reddy et al., 2020, p. 493). Several respondents point to how the external technological environment is pushing forward AI adoption. However, if the aforementioned arguments are correct, it is reasonable to assume that the current healthcare industry environment presents obstacles to the broad adoption of AI. If this is true, then perhaps the healthcare industry might consider temporarily shifting its focus from AI implementation and instead concentrate on prioritizing the digitization transformation of the sector as the initial step. By ensuring the establishment of these elements, the industry might build a stronger foundation for more efficient integration of AI technologies in the years to come.

Procurement and Economic Considerations

As repeatedly found in the findings of the interviews, the procurement process in healthcare organizations is extremely difficult to understand and navigate. According to the report by the Norwegian Center for E-health Research, the "procurement process requires cross-disciplinary competence, which is a combination of juridical, IT, economical, and clinical expertise, to choose the right solution" (2022, p. 18). This means that the process involves many different parties with different interests and requirements, that all have to support the regulatory frameworks for introducing AI, meeting specific needs of the hospital, and ensuring the safety of the patients. Similarly to the regulatory landscape, the

procurement process could also drive AI implementation if it becomes “easily” manageable. However, it could also be the ultimate barrier for both AI vendors and hospitals.

> *«What becomes important for the hospitals (...) is good acquisition processes (...)There is a separate regulation that states that medical equipment must be suitable for the [specific] purpose.»*

Outlined in the findings, there is limited research on the procurement of AI medical devices. Perhaps not that strange if one assesses the challenges of understanding all the legal requirements, the process of documenting and validating the AI medical device, which would all have to be presented during the acquisition. The Ministry of Health and Welfare acknowledges the challenges associated with AI procurement and emphasizes that the right mix of expertise is crucial for the process to be successful in order to acquire relevant products and services for healthcare institutions (2023). Espeland et al. (2015) reimburses this statement, stating how inadequate knowledge of procurement processes makes it difficult to implement AI in healthcare.

> *«Competence in laws and regulations and an understanding of the customer's role would help a lot.»*

> *«In a procurement process, there are two laws to deal with: the Norwegian Procurement Act and The Liability Act. [It] would have been easier if there had been instructions.»*

One respondent, with a comprehensive understanding of procurement in healthcare, argues that the adoption of AI necessitates different attributes among the decision-making individuals across the board.

> *«You have to work interdisciplinarily to find the right way.»*

It was further indicated that the healthcare institutions have had a tendency to develop AI medical devices in-house or in collaboration with a commercial vendor instead of investing in products developed solely by startups. We can

argue that there are many reasons for this approach, namely access to more data if developed in the healthcare institution, more control, validation of the product, and testing in a familiar environment (Makhlysheva et al., 2022). However, several believe that another reason for this choice is the confusing procurement model.

> *«This has resulted in a large number of start-ups, but only a few will scale.»*

> *«The economic procurement model is not fully adapted to test out smaller solutions.»*

Without guidance, hospitals lack the resources and expertise to fulfill all of the required responsibilities in the process of procuring AI technologies (The Norwegian Directorate of E-health, 2022). Another respondent suggests:

> *«[We] may need a common framework for the procurement of AI medical equipment. [It] does not need to be a checklist, but more about what considerations and assessments must be made, [which] must be assessed on a case-by-case basis.»*

The findings validate that most believe that the procurement process for AI medical devices is highly intricate, requiring clinicians to uphold a thorough understanding of all its aspects. As there are many risks associated with AI to begin with, and that most AI implementations require time and much resources, it is important to avoid potential mistakes. As mentioned by several respondents, the clinicians who should be leading these projects are already struggling with limited capacity, resulting in innovation being deprioritized.

> *«To be successful, I believe that healthcare professionals must be in the driver's seat.»*

Even with hospitals wanting to implement different AI solutions, they often lack a well-defined strategic plan and the necessary resources to do so. In simpler terms, the hospitals do not possess the capabilities or resources to fulfill all the required

roles in acquiring AI technologies without assistance. The literature continues to address the importance of involving early collaboration between healthcare institutions and AI vendors to aid the procurement process (Makhlysheva et al., 2022). It could be said that national and international initiatives, such as the AI ACT and the guide to procuring AI in healthcare, are helping the countries in standardizing the process of procuring AI in healthcare (FLI, 2021; Joshi & Cushnan, 2020). Additionally, if the focus is to foster further AI adoption, then perhaps the Norwegian Government, along with The Ministry of Health and Care should prioritize allocating more resources to allow for a more interdisciplinary procurement process of AI, while also outlining clear instructions to help the clinicians and AI vendors in the process.

Accessing Early Interdisciplinary Collaborations

A broad acceptance amongst the respondents is the need for interdisciplinary collaborations in all the phases of developing and implementing AI in healthcare. Even though AI is not an unfamiliar term for most individuals in the industry, its implications and how to determine what AI should contribute to is not an easy job to manage on your own. Several AI vendors have difficulty understanding how their products can address real healthcare needs. Likewise, the clinicians have a hard time understanding what the AI products can offer. Therefore, it is only natural that early collaboration between clinical users, other healthcare stakeholders, and AI vendors should define the clinical workflow and determine which products they need and when the AI outcome should be provided (Fjeldstad et al., 2020; Makhlysheva et al., 2022).

> *«It is important that healthcare personnel take part in defining the issues. It is useful to have the needs and issues defined in a research context as early as possible. [...] There is a lot in such a phase that can seem very exciting and interesting, but you can become a little too ambitious or want to go for something else that may not meet [your] real needs. They must therefore help steer the research towards needs.»*

Although early collaboration between these actors seems like a natural part of AI development and acquisition where the objective is to meet healthcare needs, the

findings indicate that hospitals are difficult to collaborate with due to the strict regulations and procurement processes (Cubric, 2020; Makhlysheva et al., 2022).

> *«It is very difficult to get into the hospitals than the primary health service.»*

> *«Big tech companies invest heavily in health technology, but then they usually avoid hospitals because of the demanding process to come up with something that can be implemented.»*

The findings are consistent with Espeland et al. 's (2015) assertion that the absence of interdisciplinary collaborations serves as a barrier to the implementation of AI. Enabling early cross-industry collaborations would foster trust-building between clinicians and AI vendors and allow them to establish a proper project plan to align their needs and interests. Moreover, one of the respondents stressed the significance of complete transparency in the process of integrating AI devices in order to build trust between industries.

> *«Cooperation between the supplier and the health service requires a certain amount of transparency in order to gain that trust.»*

While the commercial industry and other stakeholders may advise medical professionals to engage in the early stages of AI research and development, the findings indicate that clinicians are already overwhelmed with their existing workload, leaving them with limited time to review potential projects for collaboration.

> *«Health personnel are also a challenge with such research projects, as they have very little time to work on such projects.»*

Stressed by several medical professionals is the challenge of missing resources to allocate time for participating in AI initiatives. The trend seems to indicate that cross-industry collaboration with healthcare institutions becomes feasible when medical professionals take it upon themselves to educate and familiarize themselves with the technology during their free time. Even in the case of the

MIM project, the researchers described the difficulty of managing multiple roles without the availability of extra resources to move the project forward.

> *«The other big challenge is that no one really has time to do this, they have to do it out of personal interest.»*

> *«When it is ready to implement the solutions, the challenge is a lack of people who can do the work, so that it becomes like an additional task and right expertise.»*

Owing to the aforementioned arguments, one could contend that building a strong relationship between stakeholders from the healthcare industry and the tech industry would benefit the AI implementation process. These collaborative engagements would also lead to improved understanding and trust among clinicians regarding AI medical devices.

> *«It's hard to get people to start using something new, it's easier if people are involved from the start and they feel they own it.»*

The representatives from DoMore! emphasizes the importance of building trust between the end-user and the developer. While their products are now commercialized, their new objective is to conduct further testing in order to present convincing results and prove to the clinicians that their product is valid.

> *«The approach is to have partnerships and then we start with them collecting samples where they know the outcome of the patients so that we can show that we are working on their data and that it is safe to use. (...) Once we have done enough of these studies, we can go through the guidelines of the clinics on how to treat their patients.»*

Consequently, focusing on establishing a good bond between the healthcare and tech industries would aid in mitigating the risk factors associated with AI technologies, including patient safety, data security, end-user competence, validity, and trust. Even with excellent cross-industry collaborations, there is evidence to suggest that these projects may benefit from additional expertise from

other fields. Due to the array of regulations and the potential for errors in AI implementation, the importance of national support is vital (Cubric, 2020). One of the respondents said is so well:

> *«What we need is a "Saul Goodman"* (Abbreviations 4)*, a slick lawyer who helps find the way through the bureaucracy.»*

4.3 Discussion and Findings Linked to Subcategories in Theory Section 3: Technology Adoption

The Driving Force of Competence and Acceptance

Existing theories from previous chapters identified missing competence as one of the greatest barriers to the implementation of AI devices in healthcare (Chomutare et al., 2022). Arguably, when dealing with something unfamiliar, in this case certain AI technology, most individuals are more likely to avoid applying them or struggle with how to utilize them effectively. Unquestionably, all organizational changes require some form of additional knowledge. While the technological landscape in healthcare continues to rapidly evolve, it inevitably becomes difficult for medical professionals, patients, and other stakeholders to fully comprehend the potential of these advancements and how to approach them. As previously discussed, the competence of AI will indicate whether someone trusts its outcomes. However, some of the respondents argue that medical professionals cannot be expected to have this competence without proper education and training.

> *«Can't expect healthcare personnel to have in-depth knowledge of AI and how it happens.»*

The respondents also point to the importance of helping bridging this gap in order for the medical staff to be confident in AI's performance. However, another respondent also pointed to the current issue with allocated time to properly educate the clinicians. He notes that:

> *«A general practitioner does not have time to attend a course to learn how to use an algorithm that only deals with a small part of the population. [Only] specialists have time for that.»*

Expertise and acceptance play crucial roles in enabling healthcare professionals to validate and operate AI devices for medical purposes (Wilson & Daugherty, 2018). One of the respondents highlighted how important it is for a clinician to understand how AI algorithms are constructed, which also allows clinicians to evaluate and provide recommendations. Another discussed that even with competence regarding how the algorithms are developed, it is also important for the clinicians (the end-user) to possess the ability to monitor the device's operational status.

> *«You will get more and more advanced equipment, it is probably important for health personnel in general to have a basic understanding of technology.»*

Another interesting revelation in the findings that point to acceptance and trust in AI is that most clinicians are not apprehensive about utilizing AI as long as these medical devices function as "support tools" and maintain the ultimate decision-making authority with the clinician(s) in charge. This observation could further affirm that, even with the positive changes brought about by AI, most clinicians do not blindly embrace the notion that AI will always procure the best results or that it will be the ultimate solution for everything. Instead, it seems as though they maintain a healthy skepticism while remaining open to its potential positive impact. While these arguments point to the level of acceptance, they also shed light on the limited knowledge that clinicians may have regarding certain AI technologies. From an AI developers perspective, who have conducted testing and validation of their products, can easily confirm their product's validity. However, while presenting these statistics to clinicians might help them understand the technology, it does not necessarily ensure that both parties are on the same page. As one of the respondents noted, perhaps an obvious observation, is that most often clinicians and AI vendors differ in their knowledge, mindset and interests.

«They must (...) have a real interest and knowledge about [AI] to be able to use it properly.»

Another respondent pointed out, despite how impressive a technological product might appear, the healthcare professional's primary objective is to safeguard their patients. Even if an AI vendor attempts to explain how their products can assist clinicians in achieving this goal in a different way or even more accurately, it may not align with what the clinicians believe to be the best way. Inevitably, it all comes down to effective communication and knowledge sharing between these industries in order to learn from each other. One respondent expressed how AI vendors should handle the introduction and implementation process, stating:

«It is not about being first [to implement], but about building competence in the hospitals.»

Arguably, to mitigate the competence factor as a potential barrier to AI implementation, both industries need more training. Outlined in the findings, the healthcare industry should receive more education and knowledge about the technology advancements that may be integrated into clinical operations. Similarly, the tech industry needs to become better acquainted with how to effectively share knowledge with medical professionals and adapt technologies to fit with established practices. One of the respondents expressed this viewpoint by stating:

«Health personnel need training.»

«If you want to get in, you must do everything you can to adapt the technology to the hospitals.»

This topic was uncovered in a qualitative interview study with healthcare leaders in Sweden, where one of the main concerns was the lack of technological expertise amongst the clinical workforces (Petersson et al., 2022). The challenge at hand was due to the absence of existing knowledge and the lack of educational programs to prepare medical personnel for the future. Additionally, the authors mentioned how there is a need for adequate training to ensure the safe and

effective utilization of AI-medical devices. One of the respondents addressed this issue by saying:

> *«Top management must create a routine so that the clinicians and healthcare personnel have time to familiarize themselves with it and put it to use.»*

Confirming Responsible Parties

A surfacing notion with AI medical devices is the question of who is responsible for the product. As previously highlighted, if a clinician is to base its recommendation on an AI algorithm's ability to make life-altering decisions, there needs to be full transparency and trust in the device. However, several respondents point to how the issue of responsibility also limits the hospitals eagerness to initiate AI implementations.

> *«There are probably some challenges on the way, including responsibility. Who is responsible when an algorithm makes a decision or has helped make a decision.»*

Safety and privacy concerns may hinder some clinicians from fully embracing the idea of an AI technology making critical decisions on behalf of patients. This argument was expressed by another respondent:

> *«Many people do not dare to bet on AI projects due to responsibility and privacy concerns.»*

These arguments are further supported by the authors McAfee and Brynjolfsson (2017), claiming there are many ethical questions, not just concerning the alterations in clinical practices as a result of adopting AI, but also for patients. Arguably, a big threat is that AI could misinterpret its presented variables, e.g., a cancerous image, and proclaim that the patient is healthy, leading to a misdiagnosis and potential threat to the patient's health. In these instances, the respondents point to how important it is to be transparent about the AI product's liability and validity. Drawing parallels to Geoffrey Moore's framework on technology adoption (2014), it is evident that some clinicians can be categorized

as “early adopters” who are eager to leverage new technology to improve healthcare services. However, other respondents have expressed how clinicians are reluctant to assume responsibility for AI algorithms in diagnostic, prognostic, and treatment decisions, suggesting they align more with the “late majority” category, as described by Moore (2014). Due to the inherent complexity of the different varieties of machine learning models, including both hardware and software within the field of AI, it is difficult to determine an exact timeline for their widespread adoption. As Moore emphasizes, one of the key obstacles in the adoption of technology is to successfully cross the chasm, meaning that the technology itself has to match with the mainstream market before it can be accepted (2014). This brings us back to the ethical considerations surrounding AI and the question of responsibility, specifically determining who should be in charge.

> *«Getting people to accept that, I think, has a lot to do with responsibility, who is ultimately responsible when an algorithm has made a decision.»*

> *«Responsibility and ethics related to AI. It is not a disadvantage, more of a challenge. When we come to use AI in the health sector, it is expected that such validation and ethical analyzes and responsibility have already been approved during the process.»*

What the findings corroborate is that someone will ultimately need to take responsibility for the AI medical device’s outcomes and determine whether its performance is accurate or wrong. In line with Ryan’s (2020) research, the distribution of responsibility in the context of AI is very difficult. Although the AI vendors would initially bear responsibility during implementation, integration, and testing in specific environments, once the device is deployed, it would be difficult for the vendor to remain the responsible party. As pointed out by one of the respondents, the vendor cannot be held accountable for how clinicians interpret and use the AI system once it has been turned over to them. One of the respondents also assumes the difficulty of the healthcare industry agreeing to this.

> *«Passing the entire responsibility over to the hospitals might be difficult for people to accept.»*

What remains difficult is that there are no easy answers to determine ethical concerns with utilizing AI and how much responsibility should rest upon the different stakeholders involved. As long as AI algorithms function as "support tools" for medical professionals, it can be argued that the AI device itself cannot be held accountable for its recommendations as the clinicians make the final decision. However, in terms of regulations, there may come a day where the healthcare industry would need clearer guidelines.

> *«I think the responsibility must lie locally, but then you need some overarching national plan that can help drive it in the direction you want to drive it.»*

Leadership Requirements

What all the abovementioned sections also indicate is the need for a clearer leadership structure in order to facilitate AI adoption. Regardless of the discussion on whether to slow down the focus on AI and to rather initiate more action plans for the digitization of the healthcare industry, it ultimately requires alternative leadership styles. In the report conducted by DNV (2023) it was identified that:

When it comes to adopting AI, leadership must be responsible for: determining if and how AI can create value, defining strategic priorities regarding what they want to achieve by adopting AI, developing a plan to achieve the goals, and identifying and setting measures to track progress and value. (2023, p. 47)

In other terms, for any access to the healthcare industry and the hospitals, the decision-makers must take an innovative approach. One of the respondents pointed to the leaders of a hospital noting that:

> *«Someone needs to take responsibility to implement [AI].»*

With the healthcare industry being so fragmented and semi-decentralized, often operating with analog equipment, it can be difficult to innovate (Feygin, 2018). This has been reflected in the findings referencing the limited time each clinician has to spend on innovative projects of any kind. Additionally, since most hospitals

do not have the budgets and allocated funding to focus on AI specific implementations, there appears to be many obstacles within the healthcare domain that could potentially hinder innovation. According to Weintraub & McKee in their study on leadership for innovation in healthcare (2018), they highlight the significance of fostering the right leadership styles to allow for innovation to occur. As there exists a hierarchical system of leaders in healthcare, one of the respondents stresses how the enablement of AI adoption must come from the highest rank.

> *«The initiative to adopt something must lie at the top level, because it is the higher level that makes decisions. Top management must create a routine so that the clinicians and healthcare personnel have time to familiarize themselves with it and put it to use.»*

If we address the spectrum of AI technologies, it could be wise to evaluate their potential impact by classifying them as disruptive innovations (Christensen et al., 2015). Although not every AI technology could be labeled a disruptive innovation, it is important to identify those that fundamentally alter how medical procedures are carried out. Moore (2014) calculates that disruptive innovations have the capacity to reshape industry infrastructure, necessitating adjustments from the workforce and leadership to accommodate these implementations.

> *«The top management must reshape the organization to allow clinicians more time.»*

As outlined in the findings, there is consensus among the respondents that the development of AI technologies is pushing the healthcare industry to transform itself. One respondent notes how the leaders will have to take a proactive approach to facilitating the entry of AI technologies into healthcare. Another respondent addresses the importance of placing clinicians in the “driver’s seat”, recognizing their role as key drivers of AI adoption. While leadership changes appear to be deemed necessary, the respondents acknowledge that the specific approach may vary depending on the situation. It could be argued that the main element of effective leadership involves providing flexibility and support for

clinicians and AI vendors. Ultimately, to accelerate the adoption of AI, the industry needs leaders who are dedicated to transforming it.

4.4 Findings Implications

In our study we have investigated how hospitals can implement AI technologies to improve their healthcare services and facilitate a more efficient approach for the industry to deliver quality services. We have also identified drivers and barriers to successfully achieve AI integration into clinical use. The selected case studies, the MIM and DoMore! projects, have provided us with the details of how two distinct projects have managed to navigate through the process of developing an AI medical device with the objective of reaching the market. The evidence from this thesis indicates that the seven key factors we initially hypothesized to be determinants of successful AI implementation have been confirmed to be accurate. However, certain implications are more prominent than others. The findings highlight three implication categories that constitute a better approach to AI adoption in the current healthcare setting.

- ➢ Building a standardized platform for data transparency and availability
- ➢ A collaborative approach for mapping regulatory frameworks for AI development
- ➢ Integrate a networked organizational structure with emphasis on AI leaders and interdisciplinary collaborations

Building a standardized platform for data transparency and availability

The abovementioned data reflections summarize the barriers and potential benefits of utilizing AI for medical purposes. It boils down to data quality and availability which determine whether an AI medical device will be able to excel in delivering transparent, valid, documented, unbased, non-discriminatory, and explainability in its performance outcomes. To confirm these elements, it requires machine learning algorithms to be tested on extensive datasets in different environments, preferably on different populations. This will also provide the end-user (clinicians or hospitals) a certification of the AI model's performance and basis for recommendations. As mentioned in the discussion, trust and acceptance can

hinder the adoption of AI if clinicians cannot understand how an AI technology determines its outcomes. The respective parties can avoid these uncertainties if they are allowed more data to train the models. Therefore, the state should facilitate an easier approach for sharing data between healthcare institutions and their respective partners. They would also need to investigate a way to create a safe environment for data sharing once the AI products have reached the market. This argument specifies the challenges associated with data sharing firstly in the research phase, and then in the operational phase (Figure 3). The initiatives outlined in the report conducted by the Norwegian Directorate of E-health (2022) emphasize the action plans for allowing more data sharing. If these initiatives are carried through, the healthcare industry along with the tech industry would have better opportunities to implement AI. It is important to note how safety concerns are top priority, which has been a reason for the limited data sharing to this point. One place to start would be for the state to initiate a cross-industry collaboration project involving the healthcare institutions, the tech industry, and municipalities, to orchestrate an interplay of data design and protection. Norway is already working towards a transformative digital structure that can help collect healthcare data in a standardized manner. Although this is a difficult task, it will be more difficult to introduce modern technology if the existing system is not built to accommodate it. Therefore, the best way to start is to build a common platform for collecting and sharing data.

A collaborative approach for mapping regulatory frameworks for AI development

The findings indicate a "push-pull" dynamic in relation to the regulatory frameworks for developing AI medical devices. While we argue that the regulatory landscape is difficult to navigate and understand, they act as certificates in confirming an AI's quality and performance measurements. It verifies to the stakeholders involved in either industry that each AI medical device is approved based on the same parameters. Therefore, instead of working against the regulations, we must find a way to work alongside them. The current situation is claimed to hinder several medical professionals and tech developers from fully comprehending the list of different regulations, as they are overlapping with one another and governed by different agencies. As a consequence, a culture has

emerged where tech companies avoid approaching hospitals, and medical professionals are hesitant in utilizing AI. Consequently, we need a clear mapping and overview of the AI regulations from the research stage to commercialization, and final integration. The agencies must help the industries understand how to meet the requirements and advise them on how to approach the process. This requires a collaborative approach between the agencies and stakeholders from the healthcare and tech industries. This will further help each party to review the frameworks as assisting guidelines in developing AI for healthcare and facilitate a broader acceptance for AI adoption.

Integrate a networked organizational structure with emphasis on AI leaders and interdisciplinary collaborations

The last implication touches upon several areas for improvement to facilitate more AI implementation. While we distinguish between them, they all ultimately trace back to the organizational structure of the industry in which they reside. The findings outlined the need for flexibility and adaptability in the existing healthcare infrastructure to enable AI medical devices in clinical settings. It emphasized how AI vendors are attempting to adjust their models to fit this infrastructure. Another aspect that needs attention is the competence and knowledge sharing capabilities within these industries. The encouragement of cross-industry collaborations and interdisciplinary teams was identified as crucial to creating a better environment for AI adoption. In the hierarchical structure of the healthcare domain, the findings affirm the importance of developing capable AI leaders and establishing an AI governance model. With the question of ownership, the challenge is determining which stakeholder is responsible for the AI product.

We found that to address these barriers, the healthcare industry must change its overall structure when approaching AI. This necessitates a “networked organizational architecture [that] aligns fundamental activities of the healthcare system” (Fjeldstad et al., 2020). By embracing this structure, hospitals and other entities in the healthcare system can foster collaboration and communication among specialists, enabling more effective research and development efforts. The framework also addresses how we can change leadership approaches to rely less

on established hierarchy structures currently existing in healthcare and rather introduce an "actor-oriented" organization (Fjeldstad et al., 2020, p. 3). This will ultimately allow for shared responsibilities and potentially more AI leaders to drive AI adoption. It also requires the state to allocate more funding to hospitals engaging in AI and innovation. For these projects to excel and become fully integrated, they need to be supported throughout the entire product development process to operational use in a clinical setting. To succeed in these elements, the responsibility must be shared between the actors working on introducing AI, which calls for strong interdisciplinary teams and cross-industry collaborations.

5.0 Conclusion

The primary objective of this thesis has been to investigate the obstacles hindering the implementation of AI technologies in hospitals and to determine how healthcare institutions can successfully employ AI medical devices to enhance the quality of healthcare services for all stakeholders. To address the research question, the study has evaluated the significance of seven key determinants that were hypothesized, based on published literature, to be decisive in successfully navigating the phases of AI product development. The results have been obtained from qualitative research using a two-case study approach. The case-study research conducted is derived from two projects developing machine learning models to advance cancer diagnostics and optimize treatment. We chose to examine the MIM and DoMore! projects, partly because of our desire to discover the potential of AI in enhancing cancer-related areas, and to evaluate the projects' different experiences in the AI development process. Both projects had the same objective of acquiring a CE marking for their AI models to facilitate market entry and be utilized for clinical purposes. We conducted a total of 20 interviews, consisting of 14 semi-structured interviews with individuals from both projects and other key experts. These interviews included healthcare professionals with AI experience, healthcare agencies, companies involved in quality assessment and qualification of medical devices, lawyers, and representatives from startups developing AI devices for healthcare. The remaining six interviews were unstructured and provided additional insights into various aspects related to the thesis. Our objective was to determine the underlying factors that drive or hinder

AI implementation based on the findings and provide a strategic plan that would enable a successful approach to adopting AI in the current healthcare domain.

There are many risk factors involved in every aspect of the AI development phases, which limit the number of research projects that transition into the market. Our study underlines the significance of standardizing data systems and data sharing policies between healthcare institutions, their partners, and AI vendors to enable more AI development. We found that creating a common platform based on transparency and openness allows for training AI machine learning algorithms to a level where the associated risk factors of AI technologies can be mitigated. Regulatory frameworks play a crucial role in the development of medical devices, and with limited guidelines for AI-specific products, a majority of developers hesitate to collaborate with hospitals due to the complexity of navigating overlapping regulations. Our study highlights the importance of mapping the regulatory landscape for all stakeholders, enabling a better understanding of the necessary requirements, and receiving assistance from responsible agencies.

As outlined in the literature review and reinforced by the research findings, the current healthcare structure is not designed to accommodate an extensive digital transformation. Our study emphasizes how the healthcare industry needs to adapt its organizational structure to align with more innovative efforts. We therefore propose a networked organizational architecture. By embracing this structure, the industry can gradually foster a culture of innovation and acceptance for AI, enabling more effective implementation efforts. Additionally, our study reveals that AI, with respect to healthcare, necessitates the merging of different industries, including healthcare, technology, local and state governments, and public agencies. This requires a different approach to cross-industry collaboration and interdisciplinary teams working to bridge the competence gap and enable better knowledge-sharing capabilities. Moreover, our research supports the notion that hospitals require dedicated AI leaders and an AI governance model to motivate further AI integration and establish policies regarding product responsibility and ownership. In conclusion, our research provides a valuable approach to helping the healthcare sector employ more AI projects.

5.1 Reflections Concerning the Conclusion

Although efforts to increase AI adoption in healthcare can be viewed as a collective undertaking, incentives must come from both the government and top management. Reflecting the ownership and decision-making authority of hospitals, there are limitations to what a hospital is capable of influencing without support from legal authorities. Considering the involvement of various public actors in hospital operations, it becomes evident that if the goal is to prioritize AI implementations, the state must allocate adequate resources and time for this purpose. The state should also assume a more significant role in owning the research projects aimed at reaching the market, encompassing the entire development process up to final integration. The AI leaders intended to drive these initiatives must have better authority over allocated budgets, along with expert teams and a dedicated workforce to see these projects through. It is also important to assess whether a national plan for increased AI adoption should involve all hospitals or focus on those that have already digitized significant parts of their operations. As mentioned in the findings and conclusion, some hospitals may initially prioritize digitization efforts and postpone the implementation of AI products to accommodate existing infrastructure. Although it seems to be a race in society to achieve a higher AI adoption rate, for the time being, efforts might be better utilized in modernizing the industry.

5.2 Suggestions for Further Studies

With our research, we hope that we can share some further insights into the process of AI implementation from a healthcare perspective, highlighting the underlying factors necessary for the successful integration of AI medical devices during the transition from the research phase to the operational phase. We also hope that our findings can serve as a foundation for further studies in this field. Future research could delve even deeper into each of the determining factors outlined in this thesis, offering a more comprehensive understanding. Additionally, it could be interesting to explore the potential drivers and barriers to AI implementation in other countries, particularly those that have made significant progress in adopting AI. Even though our thesis did not extensively cover all financial and economic aspects, it would be relevant to explore this

further. We recognize that the financial scope plays a substantial role in obtaining the CE marking and sustaining the long development process associated with AI. It might also be relevant to gain insights from the commercial industry's perspective and how they perceive the economic aspect of AI in healthcare.

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Appendices

Appendix 1: List of interviewees

Date	Interview	Proffession
14.03.23	Unstructured interview	Proffesor specialized in healthcare technologies and practices
14.03.23	Unstructured interview	Proffesor specialized in healthcare management
16.03.23	Unstructured interview	NORA
21.03.23	Unstructured interview	Proffesor specialized in health technology
24.03.23	Unstructured interview	NORA
27.03.23	Unstructured interview	NORA
19.03.23	Semi-structured interview	MIM
20.03.23	Semi-structured interview	MIM
20.04.23	Unstructured interview	NORA
21.04.23	Semi-structured interview	DoMore Diagnostics
21.04.23	Unstructured interview	NORA
21.04.23	Semi-structured interview	MIM / The Cancer Registry
21.04.23	Unstructured interview	Proffesor specialized in healthcare management
26.04.23	Semi-structured interview	DNV and doctor
28.04.23	Semi-structured interview	The Directorate of Health / Doctor
28.04.23	Semi-structured interview	The Directorate of Health
02.05.23	Semi-structured interview	The Norwegian Medicines Agency
04.05.23	Semi-structured interview	Aleap
04.05.23	Semi-structured interview	DoMore Diagnostics
04.05.23	Semi-structured interview	Jurist and lawyer
Aleap:	Incubator for health startups in the Nordics	
DNV:	Risk management company	
MIM:	Machine learning in mammography programme	
NORA:	Norwegian Artificial Intelligence Research Consortium	

Appendix 2: Interview Guide

Interview Guide

Section 1: Participant Information

1. What is your name and job title and organization/department?
2. What does AI mean to you in reference to healthcare?
3. How many years of experience do you have in the healthcare industry?
4. Have you worked with or developed AI technologies in healthcare

before?

Section 2: AI Technologies in Healthcare

5. What are your thoughts on using AI technologies to improve hospital care?
6. (Follow up question): Do you believe that AI technologies can help provide a more efficient pathway for everyone in need of healthcare services? If so, how?
7. In your opinion, what are the advantages and disadvantages of using AI in healthcare?
8. How do you think AI technologies can help reduce healthcare costs?

Section 3: Implementation Challenges

9. What are some of the biggest challenges facing hospitals in implementing AI technologies?
10. How can these challenges be addressed?
11. What ethical considerations should be taken into account when implementing AI technologies in healthcare?
12. How can healthcare providers ensure that AI technologies are being used safely and effectively?
13. How is the implementation of AI technologies dependent on hospital infrastructure?
14. To what extent are data access and quality structure determining factors in deploying AI technologies?

Section 4: Ongoing studies: (MIM and DoMoreDiagnostic - Histotype Px Colorecta)

15. Can you, in short, describe the AI technology you are developing/have developed for this study?
16. How do you think that this technology will improve healthcare services for patients and-/or medical personnel?
17. How far have you come in terms of implementing/completing the project?
    - If completed: Are you seeing expected results?
    - If not completed: Are you confident that it will be implemented?

18. What is your overall experience with introducing AI technologies in public hospitals?
    - Barriers and enablers?
19. Are you familiar with any other AI technology projects that didn't work or were not implemented?
    - If so, what did not work?
20. How do you manage the risks associated with the adoption of the new technology, such as the potential for errors?

Section 5: Hospital management and adoption of innovations

21. In your opinion, what role should healthcare professionals play in the development and implementation of AI technologies in healthcare?
22. How do you ensure that healthcare professionals are adequately trained to use new AI technologies?
23. In what ways is the management team/leadership style affecting the rate of the implementation of AI?

Section 6: Conclusion

Is there anything else you would like to add?

Thank you for your contribution!

Appendix 3: Coding

Profession	Object 1 Professor in Tech	Object 2 Professor in Tech	Object 3 MIM	Object 4 DoMore Diagnostics	Object 5 Doctor and certification	Object 6 Doctor, health directorate, researcher	Object 8 Researcher, certification	Object 9 Incubator: Project cordinator	Object 10 Incubator: Head of strategy	Object 11 Do More Diagnostics CTO	Object 12 Do More Diagnostics Quality regulatory	Object 13 The Norwegian Medicines Agency	Object 14 Oncologist and researcher within pathology
Technological understanding: The code may contain citations or paragraphs that testify to the respondent's knowledge and adoption of AI technology. This can shed light on knowledge deficits that can impede the implementation of artificial intelligence.	- Professor of technology in health, department of computer science. I Before AI, I worked a lot with bioinformatics, which is actually a type of AI, but more aimed at biology and gene data technology. I have worked in collaboration with researchers for such projects.	- Professor in Digitalisation	- MIM project - I have not developed, but constructed image data to create an algorithm that will find the negative examinations	- Has previously worked with or developed AI technology in the health service	- Have not worked directly with AI, but has supervised individual projects in the national guidance service in artificial intelligence: administration, i.e. the Norwegian Health Authority, the Norwegian Medicines Agency, the Directorate for Health and the e-Health Directorate. Administered the health law with AI, particularly within AI as medical equipment.	- Works with the coordination project better use of AI within the healthcare system, and has primarily focused on the health personnel side and ethics in the use of AI.	- Doctorate: AI in Healthcare.	- Insight into health south-east's strategy about their approach to adopting with AI. - We mostly have companies within medical equipment and digital health. One with medical equipment also works with diagnostics. We do not work on any projects related to cancer, but we do have insight into the project Helse Sør-Øst is working on together with Do More Diagnostics.			- Not worked with AI- - I understand a little about AI, but limited with my professional background in terms of what I know about AI without being able to spend a lot of time on self-study. Can't expect healthcare personnel to have in-depth knowledge of AI and how it happens. What happens inside the black box, there is something terrifying about it.	In our research work, we are doing some AI, and a good deal of machine learning in research right now.
Organizational contigency: Codes may include statements indicating whether or not an organizations readiness to employ AI. This may involve administrative support, technological resources, and cultural acceptance.	- Usually, researchers do not have the opportunity to implement something that is put into use, which means that many of the diseases we have worked with are often serious things such as cancer treatment/cancer diagnosis. And such research requires a great deal of work and documentation and strict requirements to ensure that it actually works and is safe and clinically validated before implementation. Therefore, it often takes a long time to reach such implementation because there are so many requirements along the way to get it clinically implemented to be able to diagnose various diagnoses. - Hospitals are a closed market and keep others out. - From the research side, there is still a focus on **specialized areas and not just cancer as a disease, but** specific diagnoses such as breast cancer and brain cancer. - When it is ready to implement the solutions, the challenge is a lack of people who can do the work, so that it becomes like an additional task and right expertise - The economic procurement model is not fully adapted to test out smaller solutions - It must come from the top and it must be pushed down from managers. They must also have a real interest and knowledge about this to be able to use it properly		- Resources and means to make the MRI algorithm parallel at the screening and become uncertain if they cannot use it in the program in a prospective clinical setting. If the Norwegian Medicines Agency stops this, one can question why millions are allocated to develop algorithms if it cannot be further researched and only used in a healthcare organisation. - The CE marking must be applied for, but because we lack the resources to make it commercially available, this algorithm should initially be used only in Norway. This will be very expensive. - If the Norwegian Medicines Agency says that we **will never get this approved** internationally, then there is no point in continuing to spend resources on it	- In this project, this has not been a problem. - **DoMore** have now finished the research phase and validation phase and the model has been handed over to DoMore, after which they have obtained a CE certification and a patent for the product (model) to be commercialised. - I believe that **DoMore** only requires a hospital that wants to use it.	- **DoMore** is a Norwegian-led project, they will **know the roles** they will be willing to, so they will probably have an easier entry than a newcomer - If you have not worked with responsibility for CT in an emergency department, it can be perceived as conservative, but if you use words such as safety focus, patient safety focus or well-regulated for 1. it is not us who have decided that it should be so strict, it is of good reasons the law and it is often created on the basis of things that have happened as mistakes.	- **Resources**: I think there will be challenges in adopting AI. I don't think that the individual doctors will use it, but the various hospital departments.	- The interpretation in Norway is to be afraid of making mistakes, we interpret strictly, the culture is that you point at each other, the Norwegian Data Protection Authority was very angry with the previous manager. - We have a culture that sets the tone in Health Norway, a data protection officer who has reigned supreme for many years, and has established a culture that **nothing is legal and everything is difficult.** - **MIM**: As long as the enthusiast (object 3) remains energized and motivated, the project will eventually enter a commercialization phase.		- One of the things we observe about AI-focused companies entering the incubator is that, while they typically have access to the necessary data in the early stages, they become more complex once they establish a company: Because they are no longer a research endeavor at a hospital where they had access to their data with relative ease. - Cultural acceptance: Everyone wants to be able to work more effectively and have a better work environment. But they are afraid they will **break any rules.**	- If you can automate some of the tasks that are time consuming, then a pathologist can do more investigation, so you become more **efficient**, it doesn't have the same cost as hiring a person. - We went through **CE-marking** of the product so legally we are allowed to sell it. - A lot of things and a place for clinics to be able to start using it. - Next step is that we must do additionally validation processes. - If the hospitals are positive to implement DoMore depends on clinic to clinic, some are **skeptical about new technology**, and others are **interested and want to work with us.** - Most of the hospitals still works with **microscopes like in the old days** because it is a lot easier to focus and move around. - We are in the process of doing this validation, studies, potentially it can be used after that. But there are several aspects of things we must do before we can use it day to day in the clinics. - For a company it's hard to get access to the data it needs to train models like ours, then you need to **find and acquire all the data**, that's difficult for us - but **I think we found an ok way of working this out.**	- We have what we need from a patient perspective of regulatory rules. - We have been a **team that has worked very well together**. We have been **positively disposed to implementing it.**	Information about the process: Health information the first thing you come across, regulations I own a lot with where there is a requirement that you need clinical testing and validation, this must be applied for before you get started, requires so much documentation to be allowed to start with the clinical trial. Then you may have to visit a technical control and a competent body, to get to a process where you have finished equipment to be sold, and if you are going to have it on the market to the EU, you must have the CE mark, and if you are going to have it on the market in the USA, then you have to have it FDA-approved, etc. I think that for many of those who come to TEK, the health aspect becomes another filter where you have to take many considerations in terms of patient safety and the part that you are not ready to deal with.	- I think all hospitals are using AI in one way or another, they just don't know it. **Infrastructure:** - I think that within X-ray and radiation therapy, many places have a relatively decent infrastructure. It is as if there is perhaps a question of upgrading the technology park a little, better graphite cards, etc. Then you will be able to start using and perhaps develop some AI - On the pathology side, quite a lot of infrastructure is required, there are images that are quite large, it can be perhaps 100 GB per image when they unpack. It takes a lot to analyze those images. There, I think most hospitals struggle with building stock, poor data connections, etc. There is a lot of infrastructure that needs to be updated before you can use things like that for approved use.
Obstacles and challenges: Identify and code statements that discuss potential challenges or obstacles that may arise during the implementation of AI technology in the healthcare industry. This may involve technical obstacles, a lack of training, staff disagreement, or ethical concerns.	- It is very difficult to get into the hospitals, than the primary health service - Big tech companies invest heavily in health technology, but then they usually avoid hospitals because the demanding process to come up with something that can be implemented. - Microsoft has made a deliberate wager against hospitals, lost, and did not manage to enter the market. - Working towards cancer diagnosis, requires at least 10 years of development and often a customer group of 200 people a year (since cancer diagnoses are so specified and dependent on the person). - Responsibility and **ethics** related to AI, It is not a **disadvantage**, more of a challenge. When we come to use AI in the health sector, it is expected that such **validation** and ethical analyzes and **responsibility** have already been approved during the process - It is not the AI solution itself that has uncertainties, but the paranoia surrounding it. - Many people do not dare to bet on AI projects due to **privacy concerns.** - **MIM project**, it took years to work through bureaucracy and regulations to get through one phase to the next. - The leaders of the project have to do a lot and use a lot of resources to deal with data security, law and personal data regulations. - Health personnel are also a challenge with such **research projects, as they have very little time** to work on such projects. - The other big challenge is that no one really has **time** to do this, they have to do it out of personal interest	- Three different regulations that must be followed to implement AI: Procurement regulations, CE regulations, Medical standards - **Data access** in research stages	- Disclaimer - Some of the challenges with implementation are how they will use it, **validation**, technical implementation and specialist expertise will be reduced in the long term - Legemiddelverket develops algorithms with tight usage requirements. Since such algorithms can only be employed within the healthcare facility that created them, there may be several impediments. To determine if this initiative can continue, must consider the consequences. - **Access** and **law.** - Many lawyers make decisions on something they do not understand what it is. - Directorates are uncertain, and you have the **Norwegian Data Protection Authority** on your shoulders. - You are afraid of making mistakes. - Users of the service (radiologists and women in the mammography program) they are not negative, but they do not know what it is, so they are also not positive about being read by AI.	- Many practical challenges with standardization and platforms etc. all hospitals have their own system and ways of doing things. Big job with standardization and digitization which has only just started. Then all the **legal** stuff comes in addition - **Privacy**, there is also a risk that data can go astray, so you must be able to **validate** that the systems are working. Take care not to become too vulnerable to one system and not become helpless.	- What we have experienced with **MIM** is that they have struggled to **obtain data**. - With **MIM**, we have experienced that they are struggling to get approval to continue testing with the various hospitals to **validate** whether the data machine learning is good - Medical staff **run and run** and can't make it - resource allocation in health is different than it was 15 years ago, we have less to worry about and will continue to do so. So that the expectations of what you can get help with will be adjusted in parallel. So it's a multi-part process. We have the world's best healthcare system, but we probably can't afford to have what means that there are things we can't afford to continue with in 10 years and 15 years. Maybe we can do more of what we do now in the future than what we do now in the future with the help of AI. AI can help us with the change in what we offer, less extensively. We have done almost everything for everyone right to the end, and it has been important to have money for that. But now the wave of elderly people is coming and medicine costs a lot, cancer medicine costs a lot, so we end up in a place where we have to prioritize a bit.	- **Ethical conserns:** what **worries** us a little is that, for example, healthcare personnel and others may think that the algorithm is always conclusive. We are afraid that in the long run an idea will take hold that it will become **facile**, that it will become **dangerous**. - If society moves in a certain direction, there will be a small window to influence it, so it may be difficult to alter what is encoded. In the event that some groups come out worse in five years, it will be more difficult to alter that. - I think the challenge is **competence among hospital staff** and some **lack** of **clarity** in relation to the **regulatory system.** - A general practitioner **does not have time** to attend a course to learn how to use an algorithm that only deals with a small part of the population. Specialists have time for that. - **If only the manufacturer with a commercial interest is to be trusted, the task will be difficult.**	- **Different** and **strict interpretation** of the **law** compared to, for example, Denmark. - In Norway, obtaining permission to integrate diverse instruments is a **lengthy process**. If you attempt to communicate with Sykehuspartner or hospital system tools, you will be added to the queue.	- It is very difficult to get into the hospitals, than the primary health service - Big tech companies invest heavily in health technology, but then they usually avoid hospitals because the demanding process to come up with something that can be implemented. - Microsoft has made a deliberate wager against hospitals, lost, and did not manage to enter the market. - Working towards cancer diagnosis, requires at least 10 years of development and often a customer group of 200 people a year (since cancer diagnoses are so specified and dependent on the person). - Responsibility and **ethics** related to AI, It is not a disadvantage, more of a challenge. When we come to use AI in the health sector, it is expected that such **validation** and ethical analyzes and **responsibility** have already been approved during the process - It is not the AI solution itself that has uncertainties, but the paranoia surrounding it. - Many people do not dare to bet on AI projects due to **privacy concerns.** - **MIM project**, it took years to work through bureaucracy and regulations to get through one phase to the next. - The leaders of the project have to do a lot and use a lot of resources to deal with data security, law and personal data regulations. - Health personnel are also a challenge with such research projects, as they have very little **time** to work on such projects. - The other big challenge is that no one really has **time** to do this, they have to do it out of personal interest	- Norway is a small country and a **small market, with these barriers, puts them in the situation "Am I willing to put this in a small market, why don't I** go to Germany or the US where the **market is 10-50 times bigger then in** Norway. Is that worth all my time and resources. - **This has resulted in a large number of start-ups, but only a few will scale; we must have a large number of start-ups** in a conduit from which **approximately five will scale and** become an international business. **Some actors are successful in** procurement processes because they **hold a position.**	- **Must convince** the clinicians that this really work. - Can't really do all the **documentation** that is required for every small project, you have invested a lot of **time** and work that doesn't pay off.	- The challenges lie in **reaching our users,** for better or for worse - The health system is very **conservative**, naturally enough. Another challenge lies in the **dialogue between industry and the research communities.** There is a poor alignment between academics and the requirements that Norway, Europe and the USA give to the research part of the products.	- From a medical equipment perspective, one of the challenges is that our regulations are such that when you started in the early 2010s with a new regulation in the EU that was adopted in 2017 and came into force in 2021. So a lot has happened as means that those **regulations are not adapted to the regulations we have now.** It could be a challenge for manufacturers of medical equipment with AI. - Typical challenges with AI about **discrimination** and one of the things there that must have confirmed at the time that it does not take place, but it may not be a big risk. - The lack of human contact can be a challenge, especially for the elderly. - Classic developers of medical equipment, those who know the regulations etc. are a type of category and those who know the process, you also have the others, technologies etc. that do not come from health, but they enter health because opportunities and money, they also have to deal with other parameters that they might not have to deal with in another type of technology.	- There are probably some challenges on the way, including **responsibility.** Who is responsible when an algorithm makes a decision or has helped make a decision. - **Getting people to accept that,** I think has a lot to do with responsibility, who is ultimately responsible when an algorithm has made a decision. - If we are going to use that type of technology, then you feel that you are sitting with bad technology because it is so obvious that there is something better. It becomes **difficult for people to accept.** - The challenge is that patient information is **owned by patients,** that is natural and nice, but at the same time very **guarded**. It is difficult to use a large part of the patient information for projects and to **validate** things. I think that the doctors are softened a little, and must be softened a little more, so that we can use it. - **Discrimination.** - Getting the nurses involved in something is almost completely impossible as the nurses don't have **time** (they run their ass off). - **Time, interest and ability** prevent healthcare personnel from being sufficiently trained in the use of AI. - There are some limitations with the current system, which means that everyone is not equal, but everyone is treated equally.
Potential benefits: Statements that discuss the prospective benefits of using AI technology in hospitals. This may include improved patient care, improved efficiency, cost savings, or other advantages.	- When I think of AI, I think of the possibilities it offers for better treatment and newer treatment, more efficient treatment. - From my point of view, it is an absolute yes that AI will improve hospital services. I also believe that most people in the healthcare system are positive about using technology if it can make things more efficient. - The advantage is that it enables more efficient treatment, either by requiring less human resources in some areas or by restructuring human resources. New type of treatment and doing specific tasks that humans are unable to do. E.g. **The DoMore project** which deals with an analysis tool at such a specific level that it is impossible for humans to see in order to recommend better treatment. - Customized treatment. - Possibility to treat more people. - Technology can scale so that more people have the opportunity to receive such treatment. - Easier to focus on patients and that doctors do not analyze many healthy breasts.		- More efficient services, safer and more stable - Reduce the interpretation volume for radiologists so that they are spared reading screening images, and spend their time on other tasks - Less screening work means they can expand the age group to younger and older than the current group. - AI provides neutral targets	- The AI tools can be useful to release the work of the experts.	- We can analyze information more quickly and perhaps bring in new information than we have done so far, we get to know more about the patient, and faster. We can also get help to use the resources correctly on the right patient.	- Areas we know can be approved is antibiotica resistance. Think AI will contribute to benefits when it comes to antibiotic resistance. Use smarter, get less resistance.	- AI solution in health gives more justice when you have such tools, it becomes equal for everyone, which is good with a data-driven solution.	- Norway is a welfare state, with that comes the challenge that the procurement process is up to each municipality.		- You may be able to spend a little more time up front on **better treatment** and in the **long term reduced costs.**	- The most important saving is **quality of life**, because we reduce the number of patients who have to undergo significant side effects and the complex follow-up regime that chemotherapy gives, it is a **health cost for society.**		- Don't know what's behind it, but have to reckon it's a type of machine learning, so I'm optimistic that AI will improve hospital service.
Implementation strategies: The code may include remarks that provide suggestions or strategies for implementing AI technology in hospitals effectively. This may include statements regarding the need for training, the need to change the culture of the company, or the need to involve a number of stakeholders.			- AI and humans must complement one another, not supplant one another. - Someone needs to take **responsibility** to implement - **Health personell needs training** - **Stakeholders:** lawyers, PACS suppliers and IT staff are the bottleneck	- To the extent that there is an opportunity to be able to offer the same service and platform in order to also be able to collaborate better across hospitals, then there would have been an opportunity to make a better contribution. Provision should be made for that. - **Testing and validation** - It is important that healthcare personnel take part in defining the issues. It is useful to have the needs and issues defined in a research context as early as possible, and there health personnel must say something about the focus. There is much in such a phase that can seem very exciting and interesting, but where you can become a little too ambitious or want to go for something else that may not meet real needs. They must therefore help steer the research towards needs. - An openness is needed to form experience. Needs a culture where learning along the way is accepted.	- It's going to provide a great tool, but I might be biased as I'm a doctor, but I'd like to think that healthcare professionals should be a bit in the driver's seat. - There are two steps after CE marking. The Act on public procurement and the extent to which the CE marking is regarded as good enough. - **Competence** in **laws** and regulations and an **understanding** of the customer's **role** would help a lot. - In a procurement process, there are two laws to deal with: the Norwegian Procurement Act and The Liability Act. Norwegian Procurement Act would have been easier if there had been instructions, now the nursing homes have to figure out what to sell. - To be successful, I believe that healthcare professionals must be in the driver's seat.	- I think all hospitals are using AI in one way or another, they just don't know it. **Infrastructure:** - I think that within X-ray and radiation therapy, many places have a relatively decent infrastructure. It is as if there is perhaps a question of upgrading the technology park a little, better graphite cards, etc. Then you will be able to start using and perhaps develop some AI - On the pathology side, quite a lot of infrastructure is required, there are images that are quite large, it can be perhaps 100 GB per image when they unpack. It takes a lot to analyze those images. There, I think most hospitals struggle with building stock, poor data connections, etc. There is a lot of infrastructure that needs to be updated before you can use things like that for approved use.	- **Cooperation** between the **supplier** and the **health service** requires a certain amount of transparency in order to gain that trust. - It is not about being first, but about **building competence** in the hospitals. - A GDPR and regulatory sandbox exists, but what we need is to set up a **health legal sandbox** where you get help juggling the legal laws and rules. - Could have benefited from reassessing the entirety of health advice from a health data perspective. - If you are to have a well-functioning system, it must be well integrated and work with all solutions. Data must flow between the systems and have the same login. - I think it is important that **healthcare personnel** are **involved**, both to get the data part correct and clinically coherent, but also for the **user experience** that it should work in use. - It is also important that those who work with **technology understand** the **clinic** and their **needs**.	- Where does the responsibility lie? Then we are into **training** - Easier to think long-term than individually, then the value chain concept comes into play. Everyone must have a common language and interpretation of the procurement and infrastructure process. - I think work is being done to adapt to the new legislation that is coming and the AI ACT that will influence and lead to clearer guidelines for more predictability around AI. - We need **legislation**, but we also need a better **interpretation** of it. - Healthcare professionals should play a role in the development and implementation of AI. What is often the challenge is all the hierarchies that exist in a hospital. There are many, heavy joints. Then it is easier for those who will use it (hospital staff and patients) to take part in it. - The initiative to adopt something must lie at the top level, because it is the higher level that makes decisions.Top management must **create a routine** so that the clinicians and healthcare personnel have **time to familiarize** themselves with it and put it to use.			- Many tasks today require the processing of a lot of data, for example digital images etc. It is clear that is a great resource, but it is clear that **it will never take away the need for clinicians,** there **must be one at the end**, but **must have a sorting ahead of the medical review.** This could apply to many modalities, not just digital images.	- You have to **work together interdisciplinary** to find the right way to use it. - What becomes important for the hospitals rather than from my perspective in relation to what I work with is good **acquisitions**, especially those that has become very important. There is a separate regulation which states that the health and care service medical equipment with a medical purpose must be medical equipment that is suitable for the purpose. - It becomes important to have **routines and frameworks** when acquiring. - I believe that it requires increased **competence** and that with **multidisciplinarity**, that you must have **well-composed teams.** - Discrimination on various grounds becomes extremely important. The border against **ethics**, this with **data and privacy.** I am thinking a little back to what we have talked about to what extent human presence can be replaced. - You will get more and more advanced equipment, it is probably important for equipment in general to have a **basic understanding of technology.** - If this is to be ensured in a good and holistic way, then one should think holistically about having a common strategy from the top. - May have to have a common framework for the procurement of medical equipment with AI, does not need to be a checklist, but more about what considerations and assessments must be made, must be assessed on a case-by-case basis.	- In order to implement, one must **increase the competence** among the employees, **the digital competence.** - Anyone can look at a picture, but what many people hope for is to be able to make a recommendation based on absolutely all the information in the patient record, but that is going to be extremely abstract, and there is no one who can verify it in a way, unless you develope new algorithms that also say what they based decisions on. - It's hard to get people to start using something new, it's easier if **people are involved from the start** and they feel they own it. - Must **increase general competence** and get the **right people interested**. It's not just about time, you have to **recruit the right people,** get them to stay, get them **interested and facilitate them.** - I think the **responsibility may lie locally**, but then you need some overarching national project that can help drive it in the direction you want to drive it.
Can AI help reduce healthcare costs?	Yes, absolutately!	Yes, if it is used on the right things	Do not think so. The providers of AI services will price it completely against the costs of human services	Possibility of it. Contribute to the total expenditure by making a contribution. Can, in principle, make our existing health services more efficient and resilient. Assist us in locating the appropriate treatment for the	- Yes, but there are some prerequisites that must be in place. - I don't know if kroner and ere will get cheaper, but I think we can get better at using resources better.	No, I do not think so. There is something about the way we want to be, I don't think we can reduce it, you realize when you work there that there is no room for it	Yes absolutely.	Yes I believe so.		Yes, I think so – and the most important contribution is to be able to improve patient care.	- Yes, but the most important saving is quality of life-	There will be large one-off costs and maintenance costs. In the very long term, there will probably be savings.	I know that politicians have high expectations for this. You have to believe that in the long term it can replace a number of functions, perhaps especially within what I work with, within image analysis on the pathology side,

Appendix 4: Assessment of processing of personal data (SIKT)

Sikt

Notification form / MSc Entrepreneurship and innovation / Assessment

Assessment of processing of personal data

Reference number
207841

Assessment type
Automatic

Date
27.01.2023

Project title
MSc Entrepreneurship and innovation

Data controller (institution responsible for the project)
Handelshøyskolen BI / BI Oslo / Institutt for strategi og entreprenørskap

Project leader
Sheryl Winston Smith

Student
Julie Liland

Project period
18.01.2023 - 03.07.2023

Categories of personal data
General

Legal basis
Consent (General Data Protection Regulation art. 6 nr. 1 a)

The processing of personal data is lawful, so long as it is carried out as stated in the notification form. The legal basis is valid until 03.07.2023.

Notification Form

Basis for automatic assessment
The notification form has received an automatic assessment. This means that the assessment has been automatically generated based on the information registered in the notification form. Only processing of personal data with low risk for data subjects receive an automatic assessment. Key criteria are:

- Data subjects are over the age of 15
- Processing does not include special categories of personal data;
  - Racial or ethnic origin
  - Political, religious or philosophical beliefs
  - Trade union membership
  - Genetic data
  - Biometric data to uniquely identify an individual
  - Health data
  - Sex life or sexual orientation
- Processing does not include personal data about criminal convictions and offences
- Personal data shall not be processed outside the EU/EEA, and no one located outside the EU/EEA shall have access to the personal data
- Data subjects will receive information in advance about the processing of their personal data.

Information provided to data subjects (samples) must include

- The identity and contact details of the data controller
- Contact details of the data protection officer (if relevant)
- The purpose for processing personal data
- The scientific purpose of the project
- The legal basis for processing personal data
- What type of personal data will be processed and how it will be collected, or from where it will be obtained
- Who will have access to the personal data (categories of recipients)
- How long the personal data will be processed

- The right to withdraw consent and other rights

We recommend using our template for the information letter.

Information security
You must process the personal data in accordance with the storage guide and information security guidelines of the data controller. The institution is responsible for ensuring that the conditions of Article 5(1)(d) accuracy and 5(1)(f) integrity and confidentiality, as well as Article 32 security, are met.

Table of Figures

Figure 1: Subsets of AI

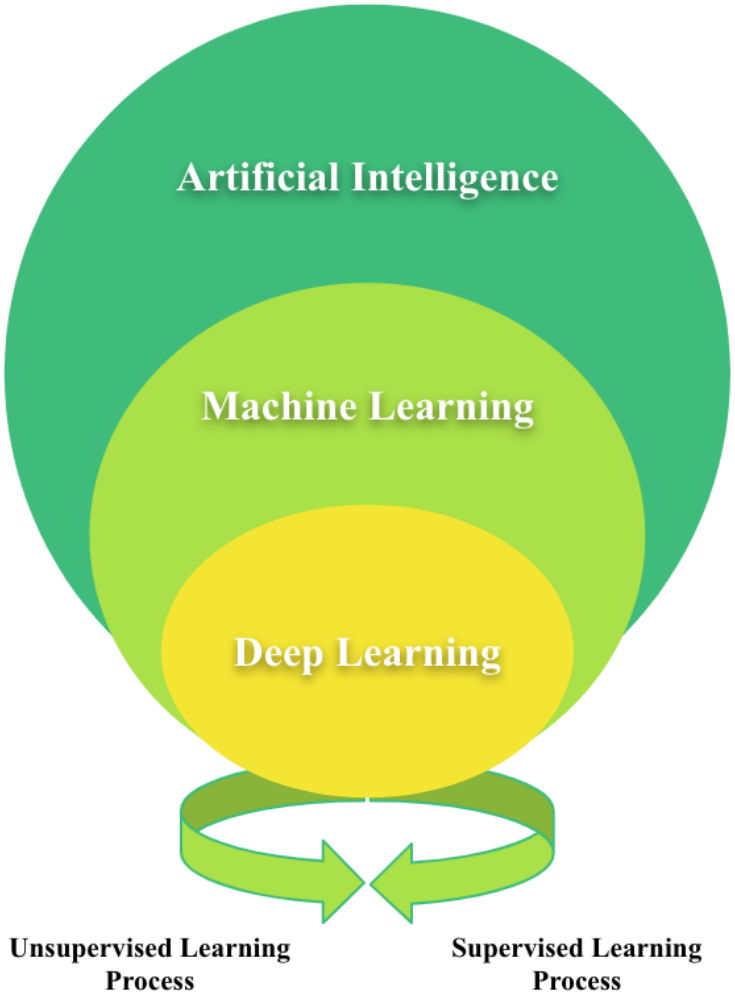

Figure 2: Unsupervised and Supervised Learning

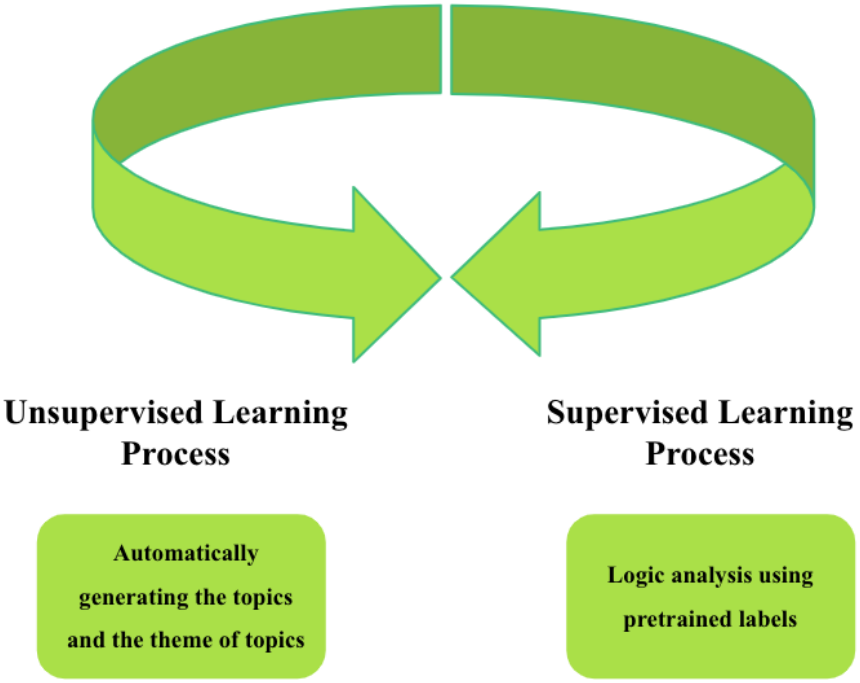

Figure 3: AI development phases until deployment

Figure 4: S-curve

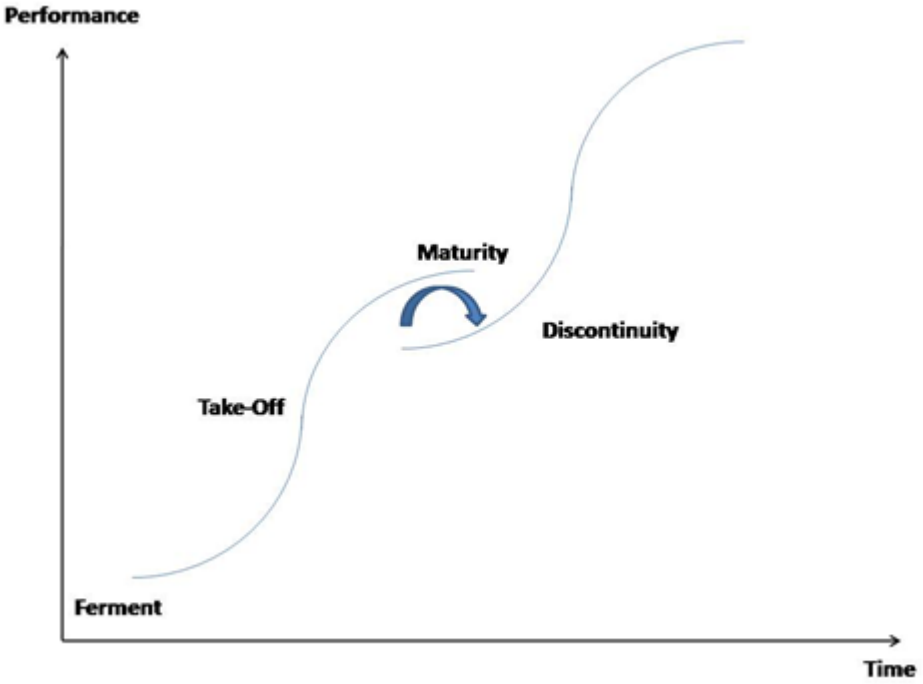

Figure 5: Conceptual Model