



CHALMERS
UNIVERSITY OF TECHNOLOGY



Exploring Opportunities and Challenges for Artificial Intelligence within Healthcare

A Case Study at Sahlgrenska University Hospital

Master's thesis in Management and Economics of Innovation

ANNIE MILDE
SARA LOCHER

DEPARTMENT OF TECHNOLOGY MANAGEMENT AND ECONOMICS
DIVISION OF SERVICE MANAGEMENT AND LOGISTICS

CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenburg, Sweden 2021
www.chalmers.se
Report No. E2021:064

Exploring Opportunities and Challenges for Artificial Intelligence within Healthcare

A Case Study at Sahlgrenska University Hospital

ANNIE MILDE
SARA LOCHER

Exploring Opportunities and Challenges for Artificial Intelligence within Healthcare
A Case Study at Sahlgrenska University Hospital
ANNIE MILDE
SARA LOCHER

© ANNIE MILDE, 2021.
© SARA LOCHER, 2021.

Report no. E2021:064
Department of Technology Management and Economics
Chalmers University of Technology
SE-412 96 Göteborg
Sweden
Telephone + 46 (0)31-772 1000

Cover:
Illustration of Artificial Intelligence.
<https://pixabay.com/sv/illustrations/artificiell-intelligens-hj%C3%A4rnan-tror-5291510/>

Gothenburg, Sweden 2021

Exploring Opportunities and Challenges for Artificial Intelligence within Healthcare A Case Study at Sahlgrenska University Hospital

ANNIE MILDE
SARA LOCHER

Department of Technology Management and Economics
Chalmers University of Technology

Abstract

The healthcare sector is experiencing an increased burden caused by an ageing population, whereof many suffer from multiple diseases and health problems. Artificial Intelligence (AI) has been subject to major hype in recent years, and many sense its big potential for healthcare applications. Nevertheless, the uptake has been slow, and very little is implemented in clinical practice. Stemming from this, the aim of this study is to investigate opportunities and challenges associated with using AI in healthcare, as well as provide suggestions for how further adoption of AI within healthcare organizations can be facilitated. Firstly, to get an idea of the current market, a mapping of CE approved AI medical devices was conducted. As a result, 343 products were identified, mostly within the field of radiology. Moreover, a brief exploration of current research regarding AI within healthcare was performed, and it appears that the research corresponds well with the trends seen in the mapping. Additionally, bigger trends associated with AI such as precision medicine and telemedicine were identified. To understand the context of healthcare organizations and its prerequisites for adopting AI, a case study was conducted at Sahlgrenska University Hospital (SU), one of the biggest hospitals in Sweden and Europe. From this, some major opportunities and challenges associated with AI were identified. By applying technological innovation systems theory, the innovation system and its dynamics were analyzed, and areas of improvement could be identified. This was then used to derive implications for the future work with AI for healthcare organizations. Briefly, the implications regard enhanced knowledge and competence, generation and illustration of use cases, enabling infrastructure, support to develop and implement products, and stimulation of research and collaborations.

Keywords: artificial intelligence, healthcare, medical device, technological innovation systems.

Acknowledgements

This Master's Thesis was conducted during the spring of 2021 at the Department of Technology Management and Economics, Chalmers University of Technology. The thesis was done in collaboration with Sahlgrenska University Hospital.

Firstly, we would like to thank our supervisor Magnus Kjellberg at Sahlgrenska University Hospital for his guidance and support throughout the process. We hope that this thesis will bring value for the organization in their future work with AI.

We would also like to thank our supervisor at Chalmers, Petra Apell, and our examiner Henrik Eriksson, for their valuable input from an academic point of view.

A final thanks goes out to all the interview participants. Without their time and contribution, this thesis would not have been possible.

Annie Milde & Sara Locher
Gothenburg, May 2021.

Table of Contents

ABSTRACT.....	V
ACKNOWLEDGEMENTS.....	VII
DIAGRAMS.....	XI
FIGURES.....	XI
TABLES.....	XI
1. INTRODUCTION.....	1
1.1 BACKGROUND	1
1.2 AIM AND RESEARCH QUESTIONS.....	2
1.3 REPORT OUTLINE.....	2
2. THEORETICAL BACKGROUND	3
2.1 ARTIFICIAL INTELLIGENCE	3
2.1.1 <i>Definitions of AI</i>	3
2.1.2 <i>Machine Learning</i>	3
2.1.3 <i>Neural Networks and Deep Learning</i>	3
2.1.4 <i>Challenges with AI</i>	4
2.2 THE HEALTHCARE CONTEXT.....	4
2.2.1 <i>The Swedish Healthcare System</i>	4
2.2.2 <i>Healthcare Organizations</i>	5
2.3 REGULATORY CONTEXT	5
2.3.1 <i>Medical Device Regulation</i>	5
2.3.2 <i>Laws Restricting Personal Data</i>	6
2.3.3 <i>The Law of Public Procurement</i>	6
2.4 TECHNOLOGICAL INNOVATION SYSTEMS	6
3. METHODOLOGY.....	11
3.1 RESEARCH STRATEGY AND DESIGN.....	11
3.2 RESEARCH SETTING.....	12
3.3 DATA COLLECTION.....	13
3.3.1 <i>Secondary Data Collection</i>	13
3.3.2 <i>Primary Data Collection</i>	14
3.4 DATA ANALYSIS.....	16
3.5 QUALITY OF RESEARCH	16
3.5.1 <i>Validity</i>	17
3.5.2 <i>Reliability</i>	17
3.5.3 <i>Ethics</i>	18
4. RESULTS.....	19
4.1 MAPPING OF MARKET	19
4.1.1 <i>Mapping of CE Approved AI-based Medical Devices</i>	19
4.1.2 <i>Future Outlook</i>	21
4.2 MAPPING OF OPPORTUNITIES AND CHALLENGES	23
4.2.1 <i>Opportunities</i>	23
4.2.2 <i>Challenges</i>	26
4.2.3 <i>Summary of Opportunities and Challenges</i>	32
5. ANALYSIS.....	35

5.1 FUNCTIONAL ANALYSIS	35
5.1.1 <i>Summary of Functional Analysis</i>	38
5.2 FUNCTIONAL PATTERNS	39
5.3 IMPORTANT FUNCTIONS TO ADDRESS	40
6. CONCLUSIONS AND DISCUSSION	43
6.1 IMPLICATIONS FOR HEALTHCARE ORGANIZATIONS	43
6.2 THEORETICAL IMPLICATIONS.....	44
6.3 LIMITATIONS.....	45
REFERENCES.....	47
APPENDIX I: GENERAL INTERVIEW GUIDE	I
APPENDIX II: ILLUSTRATION OF DATA ANALYSIS	II

Diagrams

Diagram 4.1: Accumulated number of CE approved products.....	19
Diagram 4.2: Distribution on different product purposes.....	19
Diagram 4.3: Distribution on risk classes.	20
Diagram 4.4: Distribution on medical fields.	20
Diagram 4.5: Number of AI publications on PubMed 2015-2020.	21
Diagram 4.6: Frequency of concepts in 10.000 latest PubMed publications involving AI.....	22

Figures

Figure 3.1: Overview of research process.....	11
Figure 5.1: Illustration of functional patterns.....	40

Tables

Table 2.1: Summary of TIS functions.	9
Table 3.1: Categorization of product purpose.....	14
Table 3.2: Interview subjects.....	15
Table 4.1: Summary of opportunities and challenges.	32
Table 5.1: Summary of functional analysis.....	38

1. Introduction

This chapter gives an introduction to the research. Firstly, some relevant background to the study will be presented. This is followed by the aim and research questions of the study. Lastly, a brief outline of the rest of the report is presented.

1.1 Background

Artificial Intelligence, which henceforth will be referred to as AI, has been subject to major hype in recent years. There is no clear or unambiguous definition of AI, but generally it can be said to possess the ability to mimic intelligent human behavior (Vinnova, 2020). The technology becomes more advanced and sophisticated every day and is already used for several different purposes ranging from self-driving cars, banking, and healthcare (Tegmark, 2018). The importance of capturing the potential of AI is stressed by the Swedish Government (2018), and it is stated that Sweden aims to be at the forefront of the technological development. AI is also stated as an important source of economic growth, development in society, and something that could yield benefits in a variety of different fields in the public sector. The same is argued by the Agency for Digital Government (2020), who stresses the economic potential of utilizing AI in the public sector. Yearly savings of up to SEK 140 billion is said to be achievable if fully implemented, corresponding to 6% of the total public spending today.

It is clear that AI technology has huge potential, not least within the public sector. Here, the healthcare sector is of big importance and has subsequently been argued as an area with big prospects of using AI. An ageing and growing population puts higher pressure on the healthcare system, and at the same time, people expect access to quick, personalized, and high-quality care (Löfberg, 2020). Not seldomly, one can read about staff shortages, unsustainable working conditions, and threatened patient safety. Although the overall quality of Swedish healthcare is typically assessed as relatively high (Sveriges Kommuner och Landsting, 2018), there are major concerns regarding accessibility and waiting lines (Swedish Agency for Health and Care Services Analysis, 2021). Further, due to the recent events of Covid-19, it is clear that the healthcare sector more than ever needs to grasp every opportunity to free up resources.

Many actors are starting to realize the potential of using AI in healthcare. Subsequently, AI is receiving an increased amount of interest from life science companies, who aim to seize the potential of the technology to innovate their products. AI intended for healthcare purposes classify as medical devices in the European Union (EU) and must subsequently be Conformité Européenne (CE) approved before being placed on the market. Moreover, healthcare organizations can also develop and use their own AI algorithm in-house, as long as no commercial product corresponding to their specific needs exists (Beckers, Kwade, & Zanca, 2021). There are several potential application areas for AI in healthcare, but the most prominent as of today is within radiology. With the rise of sophisticated AI methods, large image datasets can be analyzed, and features beyond human perception can be extracted. Consequently, image analysis has come comparatively far in applying AI (Ahmad, 2021).

Despite big possibilities of higher efficiency, lower costs and higher quality, the uptake of AI in healthcare has been slow. In a mapping of AI usage in Swedish healthcare from 2019, there were only 59 AI products currently in use throughout the country, and most initiatives regarding AI were found in research projects (Socialstyrelsen, 2019). There is a long way to go to fully capture the value of AI technology within healthcare, and many hurdles are to be overcome. One big problem is how to handle

and obtain the data that is necessary for using these technologies. It also gives rise to ethical considerations regarding who makes the algorithm and their biases, the data that is used, how decision making should be made with AI, and who is held responsible if e.g., the wrong diagnosis is made (Smer, 2019). Further, issues with social acceptance of the technology, support for necessary investments, new competence requirements, and how to implement the technology also arise (Österberg & Lindsköld, 2020). Moreover, there is no comprehensive database or register with approved AI medical devices in Sweden or even Europe, making it difficult to identify available external solutions in the first place (Muehlematter, Daniore, & Vokinger, 2021). However, the European Commission is currently developing a database (EUDAMED), which when established will enhance the overall transparency on medical devices available on market within the EU (European Commission, 2021). However, it is still unclear exactly how this will look like and how complex it will be to navigate.

Concludingly, it is clear that there exist both opportunities and challenges regarding AI in healthcare. Moving forward, it will thus be important to find ways to strategically approach the area in order to accelerate the uptake of AI in the healthcare sector.

1.2 Aim and Research Questions

This study aims to investigate opportunities and challenges associated with AI in healthcare, as well as provide suggestions for how further adoption of AI can be facilitated. To fulfill this aim, it is interesting to understand what the market for AI products intended for healthcare currently look like, as well as immerse in the context of the healthcare organization and its prerequisites for adopting AI. This will be done by a mapping of the market of CE approved AI-based medical devices and future outlooks, combined with a case study regarding AI at Sahlgrenska University Hospital (SU), one of the biggest hospitals in Sweden and Europe. Furthermore, technological innovation system theory will be applied to analyze the adoption of AI and thereby identify suggestions for the future work with AI.

The research questions that this master's thesis aims to answer thus are:

- *What does the product market of CE approved AI-based medical devices currently look like?*
- *What are the major opportunities and challenges associated with AI in healthcare organizations?*
- *Based on this, what is needed to facilitate further adoption of AI in healthcare organizations?*

1.3 Report Outline

The remainder of the report is organized as follows: Theory regarding AI, the healthcare sector and organization, and some relevant regulations will be presented, followed by theory on technological innovation systems. This will be succeeded by a method description. After this, the empirical findings on the market, some research trends, and findings from the case study will be presented. Thereafter, these findings will be analyzed using theory on technological innovation systems, and lastly implications derived from the analysis will be presented together with conclusions and a discussion.

2. Theoretical Background

In this chapter, relevant theory and context to the study will be presented. This includes a brief description of AI and related concepts, some information regarding the healthcare context, associated regulatory aspects, and lastly theory on technological innovation systems.

2.1 Artificial Intelligence

To provide an understanding of AI, the technology behind it as well as some recognized challenges of using the technology will be elaborated on below.

2.1.1 Definitions of AI

As already mentioned, AI has been subject to major hype in recent years. However, AI is not a new notion, as it is said to have been founded at a workshop at Dartmouth University in 1956 (Moor, 2006). Despite this, there is still no clear or unambiguous definition of AI, and many different interpretations of the concept exist. One definition by Dobrev (2012) says that “AI will be such a program which in an arbitrary world will cope not worse than a human”. In their *National approach to artificial intelligence* (2018), the Swedish Government further states “What distinguishes AI from other automation methods is the ability of AI technology to learn and become smarter over time.” (p.4). Tegmark (2018) simply defines AI as “non-biologic intelligence”, where intelligence is phrased as the ability to achieve complex goals. Moreover, a widespread definition stems from Alan Turing, and the so-called Turing test. Here, it is proposed that for something to be or possess AI, it must pass this test. The test itself consists of a person that speaks to a computer placed behind a curtain, and if the person cannot tell the difference between that and a human being, it passes the test and thus classifies as AI (Dobrev, 2012). It is clear that AI is a wide concept but stemming from many definitions it could generally be said to possess the ability to mimic intelligent human behavior (Vinnova, 2020).

2.1.2 Machine Learning

One way to obtain AI is through Machine Learning (ML), which thus is a subset of AI. This is the main enabler for much of the AI we see today in our day-to-day life, such as Netflix, Google, Spotify, and Facebook. ML is essentially a statistical process of finding patterns in data, and “learning” while doing it (Hao, 2018). IBM (2020) describes it as follows: “In machine learning, algorithms are 'trained' to find patterns and features in massive amounts of data in order to make decisions and predictions based on new data. The better the algorithm, the more accurate the decisions and predictions will become as it processes more data.” This is achieved through utilizing historical data for a training set and a test set. A model with adjustable parameters is chosen, together with an objective function corresponding to the desired outcome of the algorithm. Then the model is trained on the training set through adjusting parameters to favor the objective function. Once trained, the model can be evaluated using the test set (NSTC, 2016).

2.1.3 Neural Networks and Deep Learning

Further, a popular ML technique is artificial neural networks, often referred to as just neural networks. As the name implies, neural networks simulate the functions of the biological neural networks in the human brain. Neural networks are built up by computational units (i.e., neurons), which are interconnected with weights, corresponding to the strength of the synaptic connections in the human

brain (Aggarwal, 2018). Typically, the neurons are organized in multiple layers, with one input layer, one output layer, and so-called hidden layers in between. The number of layers and how the neurons within them are connected determines the complexity and “depth” of the model. Here, the notion of Deep Learning (DL) appears, which is a subset of ML. DL essentially refers to deep neural networks, i.e., neural networks consisting of many layers. The major advantage of DL is its ability to handle and analyze enormous amounts of data. DL therefore excels when it comes to areas such as image recognition (IBM, 2020).

2.1.4 Challenges with AI

Although AI is a powerful technology with many potential areas of application, there exist some challenges coupled with using it. Firstly, before AI algorithms can be used, they need to be successfully trained with a large volume of data (AIDA, 2021). Beside the quantity of data, the data must also be of high quality, meaning that the data fits the intended area of application. One substantial problem is how to handle and obtain the data that is necessary for using these technologies. This regards problems with regulations, personal integrity and cybersecurity (Tegmark, 2018). Furthermore, with the need for massive amounts of data and data power comes the need for data servers and well-developed IT-infrastructures (AIDA, 2021).

Another problem is that of how understandable AI models actually are. Due to its complex structure, especially DL models can be hard to interpret, causing a sort of “black box” problem (Mahapatra, 2018). In other words, it is often very hard to understand why a model generates a certain result or conclusion (Rai, 2020). Moreover, ethical considerations and discussions often arise when talking about AI. Firstly, there is an overall tendency to believe that the technology is neutral. This is however rarely the case. Instead, in the entire process from design to application, biases and preferences upon which the AI relies, are being built in. Further, there is the equivocation regarding who is to be held responsible if the wrong recommendation is made, but also in the event of a cyber-attack or similar (Smer, 2019).

2.2 The Healthcare Context

In this section, some contextual information about the Swedish healthcare system, as well as a brief elaboration of healthcare organizations in general, will be presented.

2.2.1 The Swedish Healthcare System

The aim of the Swedish healthcare system is to achieve good health and healthcare on equal terms for the entire population (Swedish Research Council, 2020). The responsibility is divided by the national government, regions and municipalities, all governed by democratically elected politicians. The national government’s role is to set an overall political agenda as well as establish laws and guidelines. Sweden is divided into 21 regions which independently are responsible for organizing good and accessible healthcare for its citizens. The purpose of the regions’ self-determination is that it allows for activities to be adapted in order to suit regional conditions. Hence, the regions are responsible for the internal control of their activities as well as the financials. However, regions must nevertheless be compliant with the framework set by the national government. In addition to the 21 regions, Sweden is further divided into 290 municipalities responsible for elderly care, care for persons with physical and mental disabilities, school health, and support to individuals who have completed therapy and been discharged from the hospital.

Swedish healthcare is financed mostly by regional and municipal taxes but also by a share of the government budget. In addition, the healthcare system gets a part of its revenue from patient fees. In 2018, the regions' revenues added up to SEK 365 billion, while the costs corresponded to SEK 357 billion the same year (Swedish Research Council, 2020).

2.2.2 Healthcare Organizations

Looking at the healthcare organization in general, it may seem very similar to other large and complex organizations. However, when digging deeper it becomes evident that healthcare organizations contain dimensions that add additional complexity. Golden (2006) refers to Drucker's statement from 1993 that healthcare organizations are the most complex form of human organization we have ever attempted to manage. The complexity can partly be derived from the fact that there is a confluence of different professions, such as nurses, clinicians and administrators, but also other stakeholders such as patients and government. Typically, this implies a conflict in terms of interests, perspectives, and time horizons (Golden, 2006).

2.3 Regulatory Context

In this section, information regarding some relevant regulations regarding AI for healthcare purposes will be presented.

2.3.1 Medical Device Regulation

AI-based software that complies with the definition of a medical device (Regulation (EU) 2017/745), e.g., that it is used for diagnosis, prediction, monitoring, and treatment, is classified as a medical device in the EU. In 2017, the EU legislation for medical devices was revised. As a result, three former directives were replaced by two regulations, 2017/745 on Medical Devices (MDR) and 2017/746 on In-Vitro Diagnostic Devices (IVDR). These new regulations that enter into force on May 26, 2021 and May 26, 2022 respectively, impose stricter requirements on medical devices before they can be utilized in clinical practices (Swedish Medical Products Agency, 2021). AI products that classify as medical devices must subsequently comply with certain requirements in the MDR, which affects both commercially developed AI devices, but also devices developed by healthcare institutions for in-house usage (Beckers et al., 2021).

For commercial devices, they have to undergo a conformity assessment to demonstrate that they comply with the legal requirements, i.e., that they are safe and perform as intended (European Medicines Agency, 2021). The approval is conducted at member state level by so-called Notified Bodies that are authorized to approve medical devices and thus also AI products. Once a medical device has passed the European conformity assessment, manufacturers are allowed to place the CE mark on the device which is then allowed to be marketed in the EU (Muehlematter et al., 2021). Medical devices that have received a CE mark are also assigned a certain risk classification, Class I, IIa, IIb, or III. Class I has the lowest perceived risk while Class IIa suggests that there is a low to medium risk, whereas Class IIb and III correspond to medium to high risk (Vårdhandboken, 2019). The factors that are considered during the classification are for instance the duration it is in contact with the patient, whether it is invasive or not, and whether it emits energy to the patient. Typically, for Class I devices, the manufacturer independently can place the device on the market without involvement of a Notified Body.

As already mentioned, healthcare organizations may develop and use medical devices in-house if they can prove that there is no equivalent product available on the market. As long as the medical device is

intended for in-house use only, CE approval is not required. However, although no CE mark and no involvement of a notified body is needed, requirements on safety and documentation still apply (Beckers et al., 2021).

2.3.2 Laws Restricting Personal Data

Sweden has advantages such as the system of personal ID-numbers as well as a long tradition of recording statistics in terms of the clinical quality register, local registers and medical records (Österberg & Lindsköld, 2020). However, there are two laws that make it difficult to fully utilize this data. The first is the Swedish Patient Data Act (PDL) that regulates how personal information and medical records should be managed. The aim of this law is to protect personal integrity; however, it prevents the creation of an overview of the patient. Another prominent regulation regarding AI, is the EU-regulated General Data Protection Regulation (GDPR). The law aims to protect and regulate personal data usage, which further complicates profiling and automatic decision making (Österberg & Lindsköld, 2020).

2.3.3 The Law of Public Procurement

In Sweden there is something called public procurement which applies to the public sector and thus also for public healthcare organizations buying AI products from commercial actors. The LOU, the law of public procurement, aims to encourage competition and subsequently optimize the use of resources in society (Vårdhandboken, 2019). The procurements have to be handled professionally which implies that they must have neutral and objective requirements and be announced at special sites which the healthcare providers are connected to. This will ensure that the procurement does not automatically result in a predictable supplier and that a fair price is obtained. If the associated cost of a procurement is judged as modest, a direct procurement is allowed which means that the order can be made directly to a suitable supplier without having to announce it publicly.

2.4 Technological Innovation Systems

Even though AI within healthcare has great potential, it seems like the adoption so far has been low. To understand the underlying causes in this complex context, the socio-technical concept of Technological Innovation System (TIS) will be used. Carlsson and Stankiewicz (1991) describe the concept of technological systems: “a technological system may be described as a network of agents interacting in the economic/industrial area under a particular institutional infrastructure and involved in the generation, diffusion, and utilization of technology.”(p. 94). The bottom line is how a new technology is developed, diffused and implemented, is influenced by the whole innovation system surrounding it. Moreover, a TIS is composed by actors, networks, and institutions, where the latter comprise formal institutions (e.g., laws, regulations) and informal institutions (e.g., norms, values, expectations) - together constituting the “rules of the game” (Hekkert, et al., 2007).

In order to explain the dynamics of a TIS, the notion of functions is used by many scholars (e.g., Bergek et al., 2008, Hekkert, et al., 2007). For a well-performing TIS, the fulfillment of each of the system functions are of importance. However, the dynamics between these functions will also highly affect the outcome of the TIS. The functions in the system interact and affect each other. Sometimes these interactions can result in cumulative causation and positive feedback loops. This implies that the fulfillment or strengthening of one function may enhance another function in the system, or the system as a whole. Contradictory, if functions are not sufficiently fulfilled, the opposite may occur (Hekkert et al., 2007). The functional components of the TIS (see *Table 2.1*) will be elaborated on below.

Knowledge Development and Diffusion (F1)

This function involves the breadth and depth of the knowledge base of the TIS, as well as how knowledge is diffused and combined in the system (Bergek et al., 2008). Knowledge and learning are at the very heart of any innovation process. Thus, R&D and knowledge development are prerequisites within the innovation system and encompasses the terms ‘learning by searching’ as well as ‘learning by doing’ (Hekkert et al., 2007). Knowledge development takes place at different levels; within a firm, within an industry and within society at large (Bergek et al., 2008). Due to technological complexity and interdependencies, organizations seldomly innovate based on their internal knowledge only, but rather reach out for external knowledge as a complement. This can be accomplished by collaborations with organizations such as universities, government labs, and research institutes, which together form a knowledge infrastructure. This type of network activity constitutes a prerequisite for ‘learning by interacting’ and, once a user producer network is established, also ‘learning by using’ (Hekkert et al., 2007). This function can be evaluated using a range of different indicators, including the number of research publications, R&D projects, or through assessments by relevant stakeholders (Bergek et al., 2008).

Legitimation (F2)

Legitimation can be described as the process where the new technology, its advocates, as well as the TIS as a whole, experience increased legitimacy from relevant stakeholders. This process can occur through e.g., increased compliance of the technology and system with current rules, regulations, norms, and attitudes. In a broader sense, legitimation can be visible through adaptation to the current institutional context, changing of institutions, or the emergence of new institutions (Bergek et al., 2008). Moreover, there are many different interpretations of legitimacy in the literature, where the most prominent centers around the technology itself and the perceived benefits of using it. However, this may be hampered by uncertainty which can make stakeholders question the new technology. Here, demonstrations that confirm the benefits and performance of the technology could be important for creating legitimacy (Bergek, 2019). Legitimation can be analyzed through how well the TIS is aligned with the current institutions. Moreover, how relevant actors and stakeholders perceive legitimacy is also an important indicator (Bergek et al., 2008).

Resource Mobilization (F3)

As a TIS evolves, a range of different resources need to be mobilized. This includes financial capital and human capital in general, but also appropriate competence (Bergek et al., 2010). In addition to human and financial capital, there is typically a need for mobilization of complementary assets, such as complementary products and enabling infrastructure. The investments needed for this may be funded by long term R&D programs which seek to develop technological knowledge, as well as to allow testing of new technologies in niche experiments. However, this function can be complex to map using specific indicators over time, and thus interviews with core actors to get their perceptions of whether resources are sufficient or not can be useful to assess this function (Hekkert et al., 2007).

Guidance of Search (F4)

If a TIS is to develop, new actors must choose to enter it. In order for them to do so, there must be influence in terms of either incentives or pressure (Bergek et al., 2008). Similarly, there are mechanisms having an influence of the direction of search within the TIS. For instance, there might be influence in terms of visions, expectations and growth potential (Bergek et al., 2008). Moreover, crises, articulation of demand, success stories, and government interventions in terms of policies are all factors that highly

can affect the direction of search. Thus, guidance of search is not solely influenced either by the market or government, but rather an interactive and constant process of exchanging ideas among technology producers, technology users, and other actors (Hekkert et al., 2007). The function can be evaluated based on qualitative factors such as beliefs in growth potential, extent of regulatory pressures, and articulation of demand among leading customers (Bergek et al., 2008).

Entrepreneurial Experimentation and Management of Risk and Uncertainty (F5)

Innovation is by definition a novelty and hence associated with substantial risk and uncertainty, technically but also economically (Bergek et al., 2010). The uncertainty can be reduced by trial-and-error experimentations. Entrepreneurial actors are therefore critical for any innovation system since they are the ones who turn the potential of new knowledge into concrete actions that generate business opportunities (Hekkert et al., 2007). It is also important to test the technologies under “real-life conditions” to mitigate risks and explore how to integrate them into larger systems (Andersen, 2014).

To ensure that these entrepreneurial activities take place, there must be sufficient incentives. However, when the business opportunity is associated with a high level of risk, actors might nevertheless be hesitant to make the investment needed (Bergek et al., 2010). Thus, there is sometimes a need for governmental interference, in terms of for instance grants. Factors such as the number of new entrants as well as the number of different types of products can be seen as indicators for a promising development (Bergek et al., 2010). Moreover, the number of experiments with the new technology and the diversification of experimental activities by incumbent actors could also act as indicators (Hekkert et al., 2007).

Market Formation (F6)

For an emerging TIS, there is typically no market to be found, or it is greatly underdeveloped. Thus, marketplaces might not exist, and potential customers may not have articulated their demand or even have the competence to do so (Bergek et al., 2008). Moreover, performance in relation to price is usually low, and solutions are typically badly adapted to the context in which they will be utilized. Therefore, they may offer very small or perhaps no advantages compared to existing methods (Hekkert et al., 2007). Thus, many uncertainties still prevail and as a consequence, diffusion might be low. Due to this, it may be needed to create protected spaces in terms of nursing markets for new technologies, which allow the TIS to prosper and mature. Gradually, these smaller markets can be scaled and eventually become mature markets. To evaluate this function, it is generally of interest to look at market size, customer groups, the function of standards, and purchasing processes (Bergek et al., 2008).

Development of Positive Externalities (F7)

This refers to the generation of resources and utilities that can be utilized at a system-level, but that also can be used by actors that did not contribute to the build-up of these resources. Examples can be specialized labor and competence, complementary technologies, and specialized suppliers. This function can be seen as very interdependent from the other functions in the TIS, and rather showcasing the dynamics in the system than being a predefined function in itself (Bergek et al., 2010). Thus, this function may indicate the overall dynamics of the system.

Table 2.1: Summary of TIS functions.

Function	Description	Indicators
Knowledge Development and Diffusion (F1)	Regards the overall knowledge base and how knowledge is diffused throughout the TIS.	Number of research publications and R&D projects. Activities to facilitate knowledge exchange.
Legitimation (F2)	Refers to compliance as well as social acceptance of the technology.	The degree of institutional alignment and perception of legitimacy among key stakeholders
Resource Mobilization (F3)	Mobilization of financial and human resources, but also complementary assets such as infrastructure.	Core actors' perceptions of whether resources are sufficient or not.
Guidance of Search (F4)	Regards mechanisms that influence the direction of the development.	Beliefs in growth potential, regulatory pressure, articulation of demand.
Entrepreneurial Experimentation and Management of Risk and Uncertainty (F5)	Experimentation and testing of new products to reduce uncertainty.	Number and diversity of experimentations.
Market Formation (F6)	Refers to the market of available products.	Market size, customer groups, purchasing process.
Development of Positive Externalities (F7)	Collective utilities. Can be seen as an indicator for the overall dynamics of the system.	Emergence of specialized labor, goods, and creation of knowledge spillovers.

3. Methodology

In this chapter, the methodology of the study will be presented. This includes the chosen research strategy and design, a background to the case study, methods for data collection and analysis, as well as an assessment of the research quality. A general outline of the research process is presented in *Figure 3.1*. Firstly, an initial literature review was conducted to get an overall understanding of the research area. Thereafter, to answer the first research question, a mapping of the market of CE approved AI-based medical devices along with some major research trends was conducted. Thereafter, a case study at Sahlgrenska University Hospital (SU) with corresponding interviews was performed in order to answer the second research question. Then the data was analyzed, and subsequently, the TIS framework was applied to the findings from mainly the case study, but also some elements from the external mapping. Lastly, based on the TIS analysis, implications for the future work with AI were derived to answer the third research question. However, the research was conducted in an iterative manner and thus the process was not entirely linear.

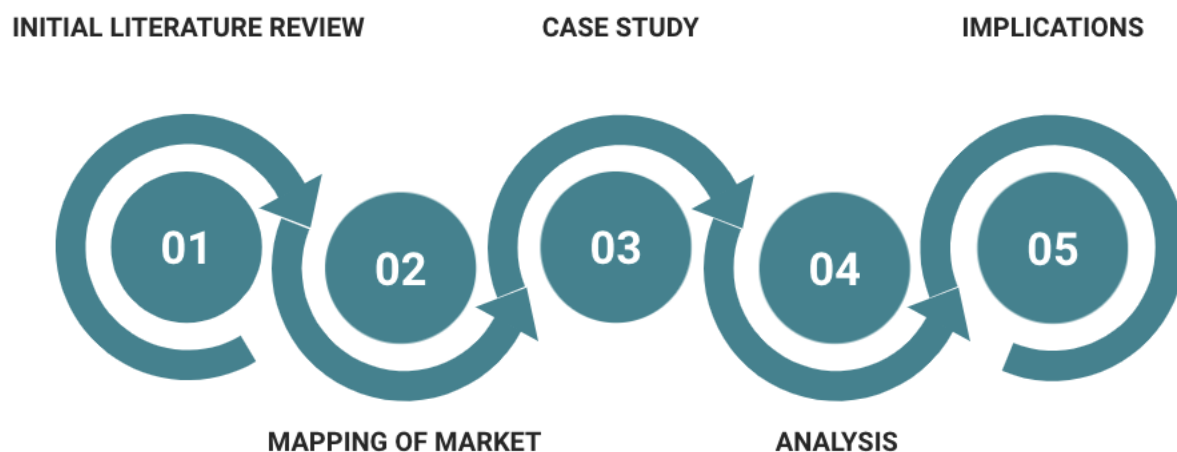


Figure 3.1: Overview of research process.

3.1 Research Strategy and Design

Due to the complexity of the field and the nature of the research questions, a qualitative research approach was applied. Qualitative research is suitable to capture people's opinions, views, and perspectives (Bryman & Bell, 2011), which is appropriate for the aim of this thesis. This was combined with an inductive research approach. Inductive research allows for collection of data to draw conclusions and generate theories from it. Moreover, inductive research also allows for new insights and flexibility as new knowledge emerges, and as the understanding of the research area deepens (Bryman & Bell, 2011). An inductive approach was deemed suitable for this thesis since the area of AI within healthcare is seemingly new and partly unexplored, with no well-established theories to draw from. The aim is rather to understand the situation, find patterns in the data, and generate meaning from that.

Furthermore, a major part of the research was constituted by a case study in order to immerse in the context of the healthcare organization and its prerequisites for adopting AI. Conducting a case study is a convenient approach for in-depth investigation of a phenomenon in a certain context (Bryman & Bell,

2011), which was appropriate for this thesis regarding AI within healthcare. Case studies are also especially suitable for studying contemporary phenomenon (Yin, 2014), which undoubtedly is the case for AI within healthcare.

3.2 Research Setting

The case study was performed at Sahlgrenska University Hospital (SU). SU is situated in Gothenburg and is a part of Västra Götalandsregionen (VGR). Being one of the biggest university hospitals in Sweden, SU conducts advanced research in several different areas and has specialized knowledge within approximately 25 different medical fields, and also conducts education. SU serves as the main hospital for the inhabitants in Gothenburg but treats people from all over Sweden. SU operates through several different instances, at different locations in the Gothenburg area. It is a large organization with around 17000 employees, making it one of the biggest employers in Västra Götaland. SU's vision is to provide care, research, development and education with the highest quality possible (Sahlgrenska Universitetssjukhuset, 2018).

In a mapping of AI usage in Swedish Healthcare made by Socialstyrelsen (2019), it can be seen that AI in Swedish healthcare is mainly to be found within research. Moreover, it can be seen that the regions that had come the farthest in adopting AI were Stockholm, Skåne, Östra Götaland, and Västra Götaland, where SU is constituting a big part. Subsequently, a few research and experimentation projects regarding AI are being conducted at SU. In 2020, an internal inventory at SU of current AI projects within the organization was conducted in terms of a survey that was distributed to each area manager. As a result, a total of 58 research projects distributed on several medical fields were identified.

As of today, there is no clear organization around AI at SU. Thus, there are no articulated roles solemnly devoted to AI and no specific function or unit currently exists. However, there are a few individuals that work towards driving the development and in extension accelerating the implementation of AI. Currently, a central unit, more specifically an AI competence center, is being heavily discussed. Once established, the expectation is that this will facilitate support to accelerate the implementation of AI within the organization. Moreover, meetings and discussions are being held at different levels with different stakeholders involved.

Beside the internal work regarding AI, there are collaborations and interactions with external actors. Firstly, as SU is a part of VGR, SU is directly affected by the work conducted at VGR. For instance, within VGR there is a unit called the Innovation Platform whose aim is to facilitate and stimulate innovation within VGR and thus also SU. The unit provides support and financial resources to innovation projects as well as functions as a bridge between healthcare, academia and industry (VGR, 2021). There is also an AI counsel in VGR where meetings are held regularly.

Moreover, there are collaborations with academia, e.g., Chalmers University of Technology and the University of Gothenburg. Regarding Chalmers, there is for instance collaboration through Chalmers AI Research Center (CHAIR), whose aim is to conduct cutting edge AI research beneficial for both industry and the public sector (CHAIR, 2021). Moreover, research projects are also being conducted in collaboration with AI Sweden, the Swedish National Center for applied AI. AI Sweden is funded by the Swedish government and partners in the public and private sector across Sweden, and its aim is to accelerate the usage of AI in society (AI Sweden, 2021). Some exchange is also ongoing with the science parks in close proximity to the hospital, i.e., Lindholmen, Johanneberg and Sahlgrenska science

park. Furthermore, grants for AI research can be obtained through external actors such as Vinnova, Sweden's innovation agency.

Except for collaborations, there are also connections to the external environment in terms of visions and agendas from higher instances. In 2018, the Swedish government presented their national approach to artificial intelligence. Here, they stress the importance of reaping the benefits of AI and clearly state that stakeholders in the public sector should actively support AI development and adoption. Moreover, the Research Institutes of Sweden (RISE), has developed an agenda for accelerating AI within Sweden, where AI in the public sector is argued to play a big part (RISE, 2021). There is also pressure from international instances such as the EU. In their white paper on artificial intelligence, A European approach to excellence and trust (COM/2020/65), they clearly state the importance of adopting the technology, not least within healthcare.

3.3 Data Collection

To answer the research questions, both secondary and primary data was collected. The rationale and methods used for this will be elaborated on below.

3.3.1 Secondary Data Collection

Secondary data was utilized both in the mapping of the external market of CE approved AI products and research outlooks, as well as when conducting the literature review for the theoretical background. Regarding the overall literature review, it is first important to get an understanding of the research area by reviewing existing literature (Bryman & Bell, 2011). This was done in an initial phase to get an understanding of the area and how the thesis could be done. This was followed by data collection regarding several different aspects of the thesis (e.g., AI, healthcare, regulations). The literature review was done using a narrative approach, i.e., the review was rather wide-scoped and not that in-depth focused and aimed at achieving an overview and general understanding (Bryman & Bell, 2011). This was deemed suitable for this thesis since there are a lot of different aspects and areas to cover, but also since it is appropriate when combined with an inductive approach. Moreover, literature regarding innovation systems was reviewed, since this is part of the theoretical framework in this thesis. However, literature on innovation systems regarding healthcare is sparse, so innovation system literature regarding other sectors (e.g., energy) was utilized. Through the whole literature review, databases such as Chalmers University of Technology Online Library and Google Scholar were used.

The mapping of the external market was conducted by researching several different sources. Firstly, other mappings (both Swedish and international) of healthcare related AI products were studied. Then, to investigate which products that are CE marked, the products were double-checked by researching the respective company website. Moreover, news regarding approved products were used, as well as databases for specific product categories (e.g., radiology) when applicable. In all cases, information about the identified products was obtained from the company/product website.

The products were categorized into medical field, product purpose, and risk class. The classification of medical fields has been adopted from the categorization by U.S Food and Drug Administration (FDA) (FDA, 2018) since nothing similar was found from the EU. The product purpose categorization is illustrated in *Table 3.1*. Moreover, the categories are somewhat overlapping, which caused the assessment to involve a certain degree of subjectivity and was based on the description of the manufacturer. Worth mentioning is also that some products were placed into more than one category

since there sometimes was a combination of categories, e.g., telemedicine/monitoring. The risk class classification, which is regulated by MDR, were obtained from the respective company website.

Table 3.1: Categorization of product purpose.

Product Purpose	Description
Decision Support	Advanced analysis in order to make better decisions.
Diagnosis	Tools for detecting correlations between symptoms and diseases.
Monitoring	Aids for monitoring and assessment of conditions.
Telemedicine	Applications for remote healthcare.
Workflow	Enhancement of workflow, e.g., triage, automation of tasks.
Other	E.g., robotics, prosthesis.

Moreover, since the mapping only regards products that fall into EU's definition (Regulation (EU) 2017/745) of medical devices, other AI solutions that potentially could be used within healthcare were not included. Lastly, since there is no unified definition of AI, the products have been classified as AI based on how they are described by the company supplying it (i.e., if they refer to it as AI, ML, DL etc.).

Regarding the external research outlook for AI within healthcare, a brief exploration of this was conducted to get an idea of what the future market may look like. This was done through analyzing how the number of publications involving AI-related concepts¹ has increased on PubMed, a large database collecting biomedical literature, over the last years. Moreover, a tool possessed by SU screening the 10000 latest publications on PubMed was used to identify some trends regarding research associated with AI and healthcare. The tool collects which words often coincided with AI and related concepts², and illustrates this quantitatively.

3.3.2 Primary Data Collection

During the early phase of the project, explorative meetings with the supervisor at SU were conducted. By these meetings, the scope of the project as well as an understanding of the research area and the organization evolved. Once a sufficient understanding had been obtained, 14 semi-structured interviews with both internal and external interview subjects were conducted (see *Table 3.2* below). In accordance with Bryman and Bell (2011), the semi-structured interviews were performed around an interview guide (see Appendix I), that is, a set of questions that aim to be covered during the interview. A semi-structured interview allows the interviewer to steer the interview in a desired direction and hence to some extent control the outcome while leaving room for flexibility to capture unexpected perspectives

¹ The following concepts were used: *artificial intelligence, machine learning, neural network, deep learning*.

² The following concepts were used: *machine learning, regression model, neural network, deep learning, artificial intelligence, classifier, image analysis, computer vision, statistical model, image segmentation, classification model, object detection, statistical learning, supervised model, cognitive computing, unsupervised model*.

(Easterby-Smith, Thorpe and Jackson, 2015). In accordance with Bryman and Bell (2011), the emphasis of the interviews was on how the interviewee frames and understands the issue, in other words, what the interviewee finds important to share.

The interview subjects were selected based on purposive and snowball sampling. Purposive sampling allows for handpicking of specific individuals based on their knowledge and experience within the field. Thus, as Bryman and Bell (2011) suggest, it makes sure that those that are sampled are relevant for the research questions that aim to be answered. This type of sampling was considered advantageous since the authors wanted to ensure that the interviewees had some prior knowledge of the research area to give valuable input. Moreover, the researchers wanted subjects operating in fields corresponding to what had been found in the external product mapping. Further, since the authors wanted to highlight different perspectives, input from a spectrum of professionals at different hierarchical levels was desired. The practice of viewing things from more than one perspective is called triangulation and the idea behind it is that the researcher can get a better understanding of the subject that is being investigated if viewing it from different positions (Denscombe, 2014). During the interviews, the interviewees were asked if they had someone else in mind that could be of interest to the study. Sometimes, the interviewees gave such recommendations spontaneously. Thus, a sampling where referrals were selected for interviews has also been utilized. This type of sampling is according to Easterby-Smith et al. (2015) referred to as snowball sampling, which is a useful approach when it is difficult to identify relevant interview subjects. Since the ecosystem of AI within healthcare is very complex and since key individuals are difficult to locate, this was considered an appropriate method.

Due to the Covid-19 pandemic, the interviews were conducted using digital tools such as Zoom and Teams. During the interviews, one of the authors was primarily responsible for asking questions while the other took notes. The interviews were also recorded to ensure that all data was available for analysis without any subjective interpretations.

Table 3.2: Interview subjects.

Interview Subject	Organization
Member of Hospital Board	Sahlgrenska University Hospital
Member of Hospital Board	Sahlgrenska University Hospital
Member of Hospital Board	Sahlgrenska University Hospital
Strategist	Sahlgrenska University Hospital
Clinician/Researcher Radiology	Sahlgrenska University Hospital
Clinician/Researcher Cardiology	Sahlgrenska University Hospital
Clinician/Researcher Cardiology	Sahlgrenska University Hospital

Clinician/Researcher Psychiatry	Sahlgrenska University Hospital
Clinician/Researcher Anesthesia	Sahlgrenska University Hospital
Clinician/Researcher Medicine Physics	Sahlgrenska University Hospital
Clinician/Researcher Dermatology	Sahlgrenska University Hospital
Representant	VGR (eHealth unit)
Representant	VGR (Innovation Platform)
Representant	AI Sweden

3.4 Data Analysis

After the data was collected, an inductive and iterative data analysis was performed. For the primary data obtained from the interviews, this was analyzed using CAQDAS, which is a general term for computer-aided analysis of qualitative data (Easterby-Smith et al., 2015). More specifically, the software NVivo was used for the analysis. Before the data analysis, all interviews were transcribed. The data analysis was then performed using grounded theory, in accordance with Gioia et al. (2013). Thus, 1st order concepts were coded from interview transcripts. These were then aggregated into broader 2nd order themes, and lastly aggregated further into larger aggregated dimensions. An illustration of this (obtained from NVivo), can be found in Appendix II. This methodology provides a systematic approach to conducting inductive qualitative research, which sometimes is critiqued to lack rigor. By performing inductive analysis in a structured and systemic manner, the result will be more rigorous (Gioia et.al, 2013). The obtained themes and concepts were then analyzed using technological innovation system theory.

Lastly, data analysis was also briefly conducted on the data obtained from the external mapping and the research outlook. This was done through simple quantitative assessments.

3.5 Quality of Research

The quality is of great importance when conducting research, both to make the research and achieved result useful, but also to ensure that the research process itself is conducted rightfully. Thus, the validity, reliability, and ethical considerations regarding this research will be elaborated on below. Another aspect affecting the research process is the extraordinary events surrounding the outbreak of Covid-19. This resulted in that the researchers could not be on-site at SU, and as mentioned, not conduct the interviews face-to-face. If the situation was different, the researchers may have received a deeper understanding of the prerequisites and operations at the hospital. However, since AI within healthcare

currently is at a very early stage with few products in clinical practice, it is unclear whether it would have made a difference in the results obtained.

3.5.1 Validity

The validity of a research project refers to, in simple words, if the research observes or measures what it claims to do. Validity can be divided into internal validity, referring to how well the observations made by the researchers correspond to the conclusions and developed theories, and external validity, referring to how transferable the result is to other social settings. The latter is commonly referred to as the “generalizability” of the study (Bryman & Bell, 2011). Since this research involves a case study, this inhibits the validity of the research since case studies concern a particular case in a specific context. However, since SU is one of the biggest hospitals in Sweden, assumingly sharing common characteristics with other (especially big) healthcare organizations, the result of the study could probably be useful in these settings as well. Moreover, since AI has many potential application areas, some findings and insights may also apply to other contexts.

Moreover, according to Bryman and Bell (2011), both purposive and snowball sampling have drawbacks in that they do not allow the researcher to draw any general conclusion of an entire population, thus also affecting the validity of the research. However, interviews have been conducted with several individuals within and outside the organization. By ensuring multiple perspectives to the same subject matter, validity is likely to be strengthened and subjectiveness reduced (Denscombe, 2014).

Further, another potential risk in this research is the interpretation of the interviews. Although they have been both recorded and transcribed to avoid misinterpretations, the findings had to be translated into English since the interviews were conducted in Swedish. To mitigate this, both authors took part in the translation process to get multiple perspectives and thus reducing the risk of misconceptions.

Lastly, since no extensive database exists for CE approved AI medical devices, there is a risk that some products have been missed. However, by utilizing several different sources of information this has been tried to be mitigated. Also, the general conclusions of the market were of greater interest than the specific products, and these probably still hold.

3.5.2 Reliability

Reliability refers to the dependability of the study, and hence also the results (Bryman & Bell, 2011). Similar to validity, reliability can be divided into internal and external reliability. Whereas external reliability refers to the extent that the study can be replicated, internal reliability concerns the joint interpretation of what is being observed when there is more than one observer. According to Bryman and Bell (2011), external reliability is generally difficult to obtain in a qualitative study due to the nature of it, as the circumstances and social settings will vary. Moreover, since the interviews have been semi-structured and thus allowed for some flexibility, the interview procedure may also be difficult to fully replicate. However, by providing information on how the interviews were conducted along with an interview guide, the external reliability is increased. Further, to enhance the internal reliability, the authors have worked closely together, as well as established routines and procedures of how data is to be interpreted.

3.5.3 Ethics

When conducting research, ethical considerations are of great importance. Bryman and Bell (2011) mention four ethical principles. The first one regards potential harm to the participants, including physical as well as emotional harm and stress. The second principle regards informed consent, meaning that the participant should be given information about the research and the possibility to decide whether to participate. The third principle regards the invasion of privacy and that vulnerable material should not be published. The fourth principle regards deception and implies that the researchers should be clear about what their research is.

Several attempts have been made to ensure that the research has been conducted ethically. Firstly, all the interviewees have been anonymized in the report to respect their privacy and minimize the risk of harming the participants and their integrity. Moreover, when reaching out to potential participants, a short description of the research and the reason for it were stated, so that the participants could make an informed decision about whether to participate or not. Furthermore, at the beginning of each interview a short presentation about the research was made, to further clarify what the research was about. Lastly, the decision to record the interviews (after making sure this was approved by the interviewees), minimizes the risk of participants being misinterpreted.

4. Results

In this chapter, the results of the study will be presented. Firstly, the results from the product market will be illustrated. This is followed by the results from the case study at Sahlgrenska University Hospital (SU), where some major themes regarding opportunities and challenges associated with AI will be presented.

4.1 Mapping of Market

In order to answer the first research question, a mapping of the product market was conducted. Below, the results from the mapping of CE approved AI-based products along with an exploration of associated research trends will be presented.

4.1.1 Mapping of CE Approved AI-based Medical Devices

AI and its possibilities within healthcare have, as already mentioned, gained substantial interest over the last years. As a result, several AI-based medical devices have been commercialized and approved for clinical use in the EU. The mapping aims to illustrate what the market of CE approved products currently looks like in terms of the number of products, as well as the distribution on medical field, product purpose, and risk class.

During the mapping, 343 CE approved AI products for use in healthcare were identified. The characteristics of the products are illustrated in the diagrams below. On the 343 identified products, there were 284 different actors ranging from small startups to large corporations. Moreover, the number of approved products has steadily increased in the last five years, as illustrated in *Diagram 4.1*. Only 13 of the identified products were approved in 2015, whereas a total of 343 is approved as of today.

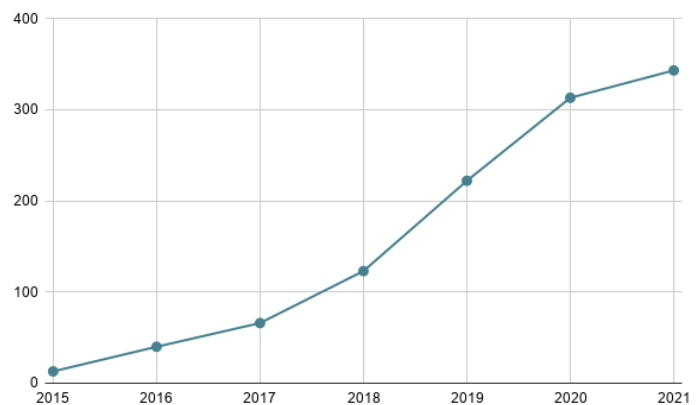


Diagram 4.1: Accumulated number of CE approved products.

To get an idea of how approved AI products are to be used in clinical practice, the product purpose was investigated. Looking at *Diagram 4.2*, the distribution of different product purposes can be seen. The most prominent type regards decision support, where 41.3% of the products fall into. Many of these products concern image enhancements for better and simpler analysis. Moreover, 20.8% of the products are for diagnosis, and 14.3% for telemedicine and remote care with AI components. 11.4% is within monitoring

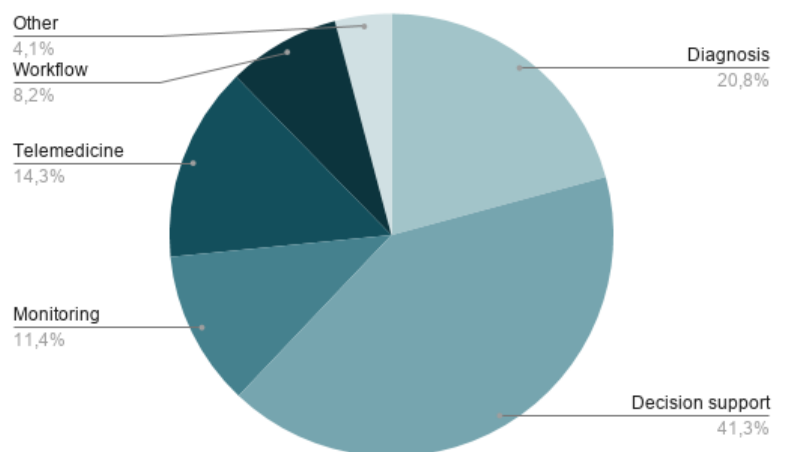


Diagram 4.2: Distribution on different product purposes.

with AI assessment, and 8.2% of the products regard workflow by e.g., improving triaging and sorting out abnormalities automatically. The last 4.1% fell in the “Other” category, and examples of products here are “smart” prosthesis, robotics for surgery, and Virtual Reality glasses for rehabilitation.

When possible³, the risk classification was also noted. The distribution of the different classes is illustrated in *Diagram 4.3*. Here, it can be seen that a majority of the products, 54.1%, belong to Class IIa, and 40.4% of the products Class I. Very few products are classified as Class IIb and Class III products. As mentioned earlier, Class I and Class IIa correspond to the lowest risk classifications, and it can thus be concluded that almost all identified products are classified as low-risk products.

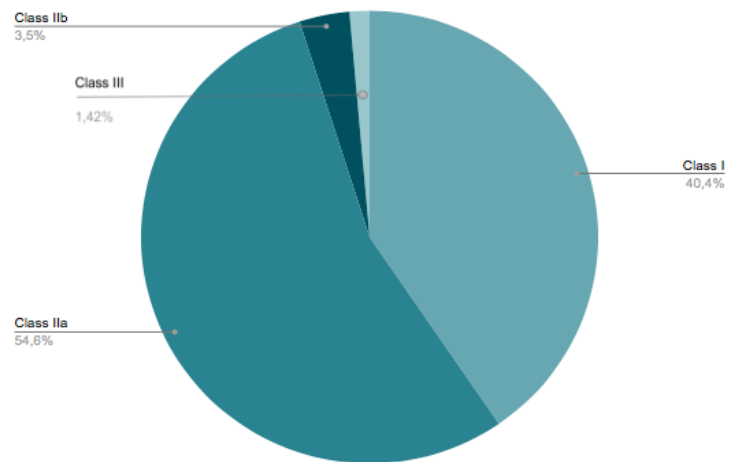


Diagram 4.3: Distribution on risk classes.

The distribution of different medical fields among the identified products can be found in *Diagram 4.4*. As already mentioned, radiology is one of the prominent application areas of AI within healthcare. This goes well in line with the mapping of CE approved products which revealed that 53.1% of the products are found within the field of Radiology. Most of the identified products utilize scans from CT (Computed Tomography), MR (Magnetic Resonance), Ultrasound and X-ray for image analysis of for instance lungs, breasts, brains and bones.

More specifically, they hold features to detect abnormalities, do measurements and quantifications, as well as to enhance overall visualization. Thus, they can be used as decision support for diagnosis, treatment and surgical planning. Some of the products, such as those which detect and flag for abnormalities, operate fully automatically. However, most of the devices have to be used in interaction with a radiologist. Moreover, it could be seen that the market has responded to Covid-19 by developing AI-based software that utilize CT and X-ray scans to detect and analyze Covid-19 related abnormalities in the lungs.

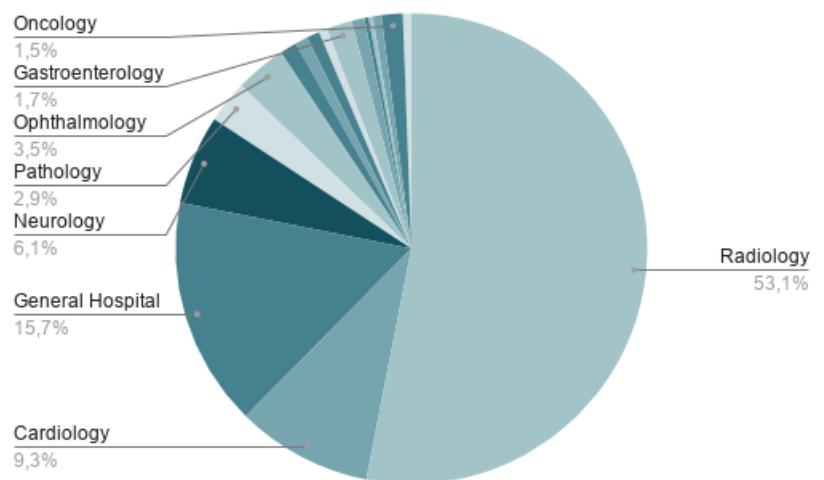


Diagram 4.4: Distribution on medical fields.

Another prominent area of application regards Cardiology, corresponding to 9.3% of the total products identified in the mapping. Among the products, a majority focus on assessing and interpreting ECG data. Moreover, many of the products here lie within telemedicine and monitoring, where several products are intended for home usage.

³ Risk classification was found for 141 products.

Furthermore, a few products, 6.1%, are found within Neurology and mostly regard decision support and diagnostics. The products have diverse application areas ranging from pain assessment to depression treatment. Many products also regard early detection of dementia and Alzheimer's disease. Moreover, Pathology composes 2.9% of the total products in the mapping. Most products regard decision/diagnostic support from analyzes of various kinds of tissue. Furthermore, a few of the identified products, 3.5%, can be found within Ophthalmology. Here, many of the identified products are intended for diabetic retinopathy detection, and a few for diagnosis of other eye-related diseases.

16.3% of the identified products do not correspond to any specific medical field and were therefore placed within the field General Hospital. For instance, there are products whose aim is to monitor, often by the utilization of smart devices that patients with for instance diabetes and asthma can use at home. Moreover, there are products that function as digital health centers to which patients can turn to get a first assessment as well as treatment advice based on their symptoms. Lastly, there is a group of products that have a direct impact on enhancing the workflow. For instance, some regard the medical record system while others seek to facilitate prioritizing of patients and improve triaging by utilizing patient history.

4.1.2 Future Outlook

As illustrated above, there are some AI-based products currently available on the EU market, and more are constantly being approved. To get a brief idea of how this relates to current research, some major themes and trends have been identified which will be illustrated below.

4.1.2.1 Current Research

Starting with trends in medical research, some patterns can be identified. Firstly, the publications involving AI (or associated concepts) have steadily increased. This can be seen in *Diagram 4.5*, where the number of publications over the last five years is illustrated. An exponential growth, especially in the last couple of years can be seen, corresponding well to the hype surrounding AI lately.

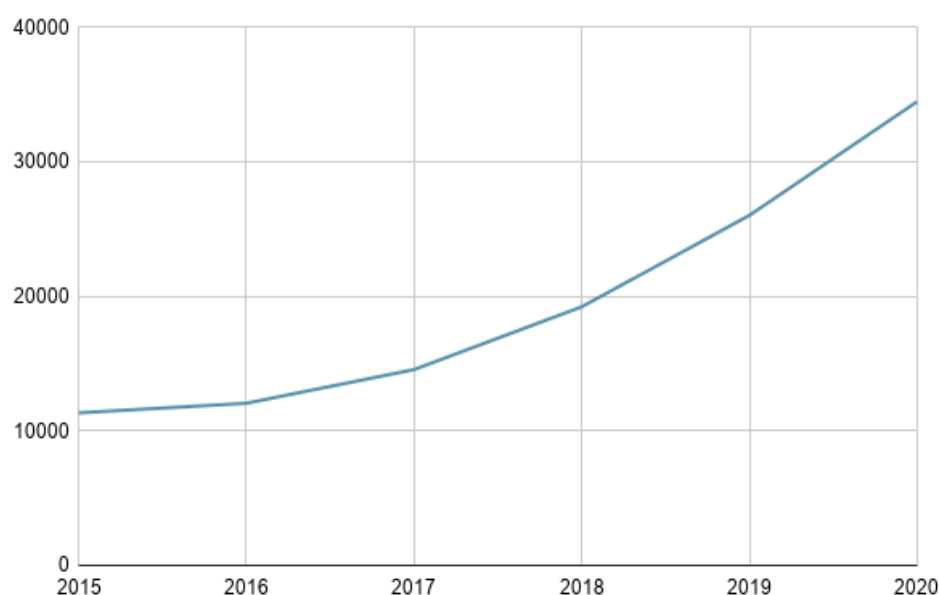


Diagram 4.5: Number of AI publications on PubMed 2015-2020.

Moreover, by analyzing some recent research, the list in *Diagram 4.6* could be obtained. It can be seen that besides surgery and medicine, two very wide concepts, public health, pathology, epidemiology and radiology are frequently appearing. Public health (and related concepts such as world health, global health and community health) is probably often appearing since the possibilities with AI are thought to revolutionize healthcare and being able to give higher quality care to more people. Regarding pathology, this was also one of the areas that had several CE approved products. The same goes for radiology, where more than half of the products in the mapping were categorized into. Considering epidemiology, this has probably been a popular term partly due to Covid-19. Regarding the other terms that were recurrent, they were also present in the mapping of approved products. Precision medicine, which can be enhanced by AI, is thought to be one area with great prospects in healthcare. Precision medicine seems to be a very evident trend in recent research while not explicitly appearing in the product mapping. However, many of the available products may be used for that purpose, since they utilize large amounts of data for better and more precise assessments and recommendations. This, and other major areas which are thought to have big prospects in AI enabled healthcare, will be described below.

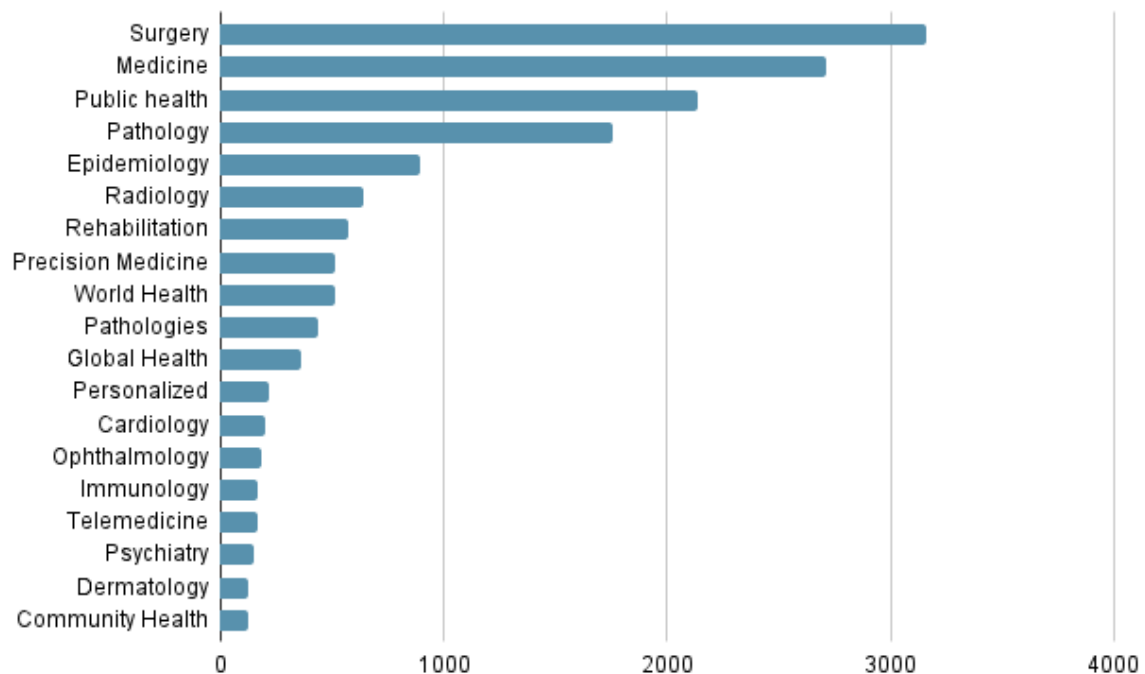


Diagram 4.6: Frequency of concepts in 10.000 latest PubMed publications involving AI.

4.1.2.2 Bigger Trends

Beside the identification of prominent application areas which have been described above, the authors also noticed some underlying big trends that partly are being enabled due to AI. Historically, healthcare has been designed for entire populations. Thus, the focus has been to create solutions that can treat a large number of people with similar symptoms (Mesko, 2017). However, in the near future, AI is predicted to result in a paradigm shift toward precision medicine, sometimes also referred to as personalized medicine. US National Library of Medicine describes it as an emerging approach for disease treatment and prevention that considers individual variability in genes, environment and

lifestyle (Krittanawong et al., 2017). Hence, treatments can be tailored to each individual rather than the one-size-fits-all approach. In turn, better healthcare outcomes are likely to be achieved.

Moreover, with the advancement in technology that has taken place lately, new possibilities with e.g., wearables, internet of things, cloud products, and robotics have paved the way for a new wave of digital health and telemedicine. Telemedicine can be described as “the application of transferring medical information through interactive digital communication to perform consultations, medical examinations and procedures, and medical professional collaborations at a distance” (Pacis, Subido Jr & Bugtai, 2018, p.1). Telemedicine is thought to provide more cost-efficient care to more people, and to make the overall healthcare logistics much more efficient. Here, AI is a cornerstone of handling the vast amounts of data from e.g., wearables or apps, and information sharing, thus paving the path for successful implementation of telemedicine throughout the healthcare sector (Pacis et al., 2018). Moreover, in times with pandemics like Covid-19, telemedicine is of great importance to provide care but still minimize the spread of the virus (Portnoy, Waller, & Elliott, 2020). The most common application today is patient monitoring (e.g., via sensors, apps or wearables), but also remote consultation and diagnostics. In the future, more advanced products of telemedicine and AI such as intelligent assistance and self-diagnostics through medical devices are thought to have great prospects (Pacis et al., 2018).

As elaborated on above, AI plays a vital role within precision medicine as well as telemedicine. By utilizing AI to enhance precision medicine and telemedicine, healthcare has a considerable potential to become more predictive and in extension also more preventive. Mobile AI devices can provide personalized support for maintaining healthy behavior, improve adherence in prevention programs as well as give health care providers valuable insights (Rowe & Lester, 2020). In such a way, they extend the reach of primary care and also enable effective self-regulation. By moving towards more preventive healthcare, the burden of healthcare systems can be decreased, and more effective and cost-efficient healthcare can be achieved.

4.2 Mapping of Opportunities and Challenges

To answer the second research question, a case study at Sahlgrenska University Hospital (SU) was conducted. The identified opportunities and challenges associated with AI are presented below. A summary of these can be found in *Table 4.1*. One overarching theme from several of the interviews is the high level of complexity that is associated with AI within healthcare. This is explained by the interviewees to be caused by the many interconnected issues and factors surrounding AI. There is the problem of accessing data, the legal barriers, the technical aspects and so on, and all of them will have to be addressed to successfully implement AI. One of the interviewees highlighted the importance of understanding this complexity: “It's important not to narrow down and instead get a complex and comprehensive picture of various factors. Sometimes people tend to be focused on one thing, now we just have to change the laws and it will solve everything, or now we will whip people so they want to change so that will solve everything. But they go hand in hand”. Subsequently, many of the themes elaborated on below are interconnected and interplay with each other and do not exist in isolation from each other.

4.2.1. Opportunities

Below, the identified themes that were assessed as opportunities will be presented.

High Expectations on AI

One theme that could be derived from almost all of the interviews was that people have high expectations on AI within healthcare, and they see a big potential for what the technology can facilitate. This regard both external interest as well as within the hospital. Many participants base this upon the challenges that the healthcare sector is facing, with an increasingly ageing population, whereof many suffer from multiple diseases and health problems, combined with a constant struggle with sparse resources. As one of the participants phrased it: “Our entire healthcare system is on the verge of collapse, everyone over 80 we try to keep alive with multiple diseases. Here is your diabetes, your epilepsy and so on. When all of these counteract it becomes extremely hard, even economically”. Several of the respondents think that AI could be one important solution to these challenges. One of the members in the hospital management argued that “It is a strategically important area for the hospital. We think it will be important in order to manage the challenges that healthcare is facing.”

Another recurrent theme from the interviews is the amount of time that could potentially be saved with AI. Many interviewees see AI as a way to liberate time by letting AI aid or automate some of the tasks. Many of the clinicians described “simple” but time-consuming tasks in their clinical practice which today is done manually. Here, they see big potential for AI which would allow them to instead focus on tasks where their time is more valuable. This is in line with what the people in management roles wish for as well since they hope to be able to handle more patients. Some participants, mainly clinicians, also highlighted the quality enhancements AI could enable, in terms of a “second opinion”. They described how sometimes daily form, gut feeling, and subjectivity could influence decision making. Thus, having AI tools as support could result in improvements for both patients and healthcare professionals in their working life.

In terms of areas where AI seems to have great prospects, almost all participants mentioned image analysis. More specifically, radiology and pathology were argued as areas where AI could be highly utilized, which also corresponds to the results of the mapping of CE approved products. This also rhymes well with the fact that there are or will be a shortage of both radiologists and pathologists, which was further highlighted in the interviews. Moreover, AI products for decision support were argued to be desirable. Several clinicians wish for AI tools to analyze data from journals to be able to base their decisions on more data. On a similar note, precision medicine was highlighted in several of the interviews as having big potential with the use of AI technology. Clinicians hope for better ways to find which treatments that would work for a specific patient, which sometimes today was described as more of a trial-and-error process. Moreover, switching to more preventive and predictive ways of conducting healthcare was also identified as a big opportunity with AI. Linked to this, remote care and telemedicine were brought up. Lastly, most of the participants talked about AI for clinical purposes, but some respondents highlighted the potential for more administratively focused AI, not least since this may be easier to implement.

Possibility to Purchase AI products

As could be seen in the product mapping, there are in fact over 343 CE approved products that could potentially be applied in healthcare organizations. Moreover, as mentioned above these products correspond to medical fields where AI is welcomed and desired. Although very few, or possibly none of these are implemented at the hospital as of today, most of the people interviewed stated that they are positive to adopt these kinds of products, as long as they answer to real-world problems. AI becomes increasingly sophisticated, and many of the participants highlighted the power of the technology itself, and as one of the participants put it: “Machine learning is here to stay. Once you have opened that door

there is no going back”. Concludingly, many of the respondents realize the power and potential of the technology and are open to commercially developed AI products. However, as will be elaborated on further related to challenges, implementing “off the shelf” solutions are not seamless, and is associated with many challenges. Just because there exist products does not mean they are valuable and solve the problems that actually need to be solved. However, the fact that there exists a market for these products and that the respondents have a positive outlook on it represent an opportunity to look further into.

Overall Positive Attitude towards AI

In addition to the high expectations on AI and its importance for future healthcare, the overall attitudes towards actually implementing and using AI among the interviewees turned out to be positive. All of the interviewed clinicians expressed a positive attitude towards AI, and their perceptions are that clinicians, in general, are positive and curious about AI. Many of the interviewees, both members of the hospital management but also clinicians, pointed out that the hospital management has a very positive attitude and a strong desire to accelerate the application of AI within the organization. There is no clear vision regarding AI formulated in written text, however, many mentioned a vision in that sense that it is a strategically important area where “... the hospital wants, should and will be in the front seat of the development”. An interview subject claimed that a clear vision combined with a strong leadership is absolutely crucial when it comes to digital transformations. On the other hand, other interview subjects raised the aspect of being a bit cautious not becoming too visionary, as there is a risk of losing respect and motivation among co-workers further down in the organization. One of the interviewees put it: “I think it is important to play down the notion of AI and at the same time not put up too big visionary prospects of something that isn’t there yet. Because otherwise it easily results in disappointments and even resistance that in the end slows down the development”.

Promising Collaborations

Something that most interview participants brought up when talking about AI activities, was that several projects and initiatives are conducted in collaboration with other actors. Many participants mentioned collaboration with Chalmers and CHAIR. The importance of utilizing the knowledge from academia was stressed, and the proximity to Chalmers was mentioned as a big advantage and asset in the forthcoming work with AI. One participant stressed that “I think it is of great importance to utilize our united forces”. Except for Chalmers, collaboration with AI Sweden was mentioned by several participants, as well as collaboration with the science parks in Gothenburg. Collaboration with Region Halland, which is in some ways at the forefront of AI in Swedish healthcare, was also brought up. Here, some participants mentioned a collaboration with AI Sweden and Region Halland regarding distributed or federated learning, focusing on ways to overcome the legal barriers of moving sensitive data over the regional boundaries by training models locally and aggregating the results nationally. This particular project was mentioned as very promising, and one participant said that “If it works it's actually a breakthrough since we very neatly can overcome the legal barriers that right now causes a lot of trouble”. Most participants stressed these sorts of collaborations as very important, and a prerequisite in avoiding “reinventing the wheel”.

Furthermore, other types of activities involving information sharing were also brought up. All in all, most of the participants stressed information sharing as crucial, and that even more united efforts are necessary. Some participants also brought up the opportunity of collaborating more with commercial actors. The possibility to utilize knowledge from other industries, e.g., automotive and self-driving cars, was also mentioned as a way to gain technical know-how and valuable insights.

Considerable Research Activity

Even though AI is at an early stage when it comes to healthcare, the interviews showed that there is quite much activity going on. Apart from projects with external actors such as academia, government and other regions, there are also several AI-related projects within the organization. This regard both strategic discussions but also more hands-on research projects and experimentation. Based on the inventory from 2020, there exist 58 projects spread across several medical disciplines. For instance, there is a big project within radiology where the aim is to eventually implement deep learning algorithms that will facilitate the segmentation of brain lesions, a time-consuming task that currently is being performed manually by radiologists. There is also a project within dermatology where a research team has developed a promising algorithm used to detect malignant melanoma. Apart from projects related to image analysis, there is for instance a project within psychiatry where a research team is working on an algorithm that can predict which patients that are at risk of needing recurrent care after leaving the hospital. Thus, actions can be taken in advance which hopefully can reduce the degree of re-enrollment of patients.

During the interviews, many referred to the research project SCAPIS. SCAPIS is a massive and unique national project which is a collaborative effort between six Swedish universities and university hospitals, of which one is SU. The aim is to predict and prevent cardiovascular disease and chronic obstructive pulmonary disease, through collecting data from 30,000 individuals. Within the project, AI algorithms will be used mainly to analyze images, but to some extent also statistical data. The algorithms used for analysis can later potentially be used in clinical practice, even though this is not the main objective of the project. However, since the register of data is made available to external research projects, there is a possibility that others can utilize it to develop useful AI algorithms.

Several of the interviewees highlighted that even though some of the research projects do not result in an algorithm that can be utilized in clinical practice, it is not a waste of resources since it leads to important insights that can be utilized in future projects. Moreover, many interviewees highlighted that research and experimental efforts were very important to illustrate the potential and value of the technology, since healthcare professionals are very “evidence-driven”.

4.2.2 Challenges

Below, identified themes assessed as challenges will be presented.

Insufficient Knowledge of AI

Despite that the overall attitude towards AI is perceived as positive, many of the interview participants stressed that there is a lack of knowledge of what AI is and what it could mean. Many of the participants said that they do not think that people know at all what the technology is, and thus do not understand the potential it has to improve their work and healthcare overall. Consequently, people are not very interested in, or able to, contribute to the acceleration of implementing it. Many of the interview participants also said that they think some people are scared that their jobs will disappear. However, almost all the interviewees stressed that this will most likely not happen. AI is rather thought to be a complement or aid, and a way to handle more patients with the same amount of resources. Several participants stressed that information about what AI is and what impact it could have should be spread so that people get an informed position about it and why it is important and valuable, and to avoid misconceptions. Some interviewees mentioned that there are a lot of discussions and hype going on at higher levels, whilst people further down in the organization typically lack the digital prerequisites as well as the knowledge to express what they want from AI. Thus, to bridge the gap, some requested more

discussions where co-workers from clinical practice, but also patients, are involved. Some respondents also said they think AI should be further integrated into the education for healthcare professionals, so the new graduates have some knowledge about AI and are updated on the topic. In general, it seems like it is much up to the individual to keep up with research and the development of AI.

Lack of Illustrative Use Cases that Solve Real Problems

One thing that was brought up as a problem in most of the interviews was that very few AI products are implemented at the hospital as of today. A few interviewees could mention one or two products, but most participants had no examples of AI used in clinical practice. Subsequently, many argued that there is a lack of illustrative use cases. Further, many respondents highlighted the importance of AI corresponding to real-world problems and showing how it could improve healthcare and facilitate the profession. The participants stressed that although being visionary and prospective about AI, concrete examples are needed; “I think in many respects it would be positive if you had a solution presented for you instead of a potential vision.” Many of the interviewees argued that precursive use cases are one important measure to spread information and motivate healthcare professionals when it comes to AI and show how it could help them in their work: “I think you need to be quite driven there and show benefits in the form that it is very labor-saving for example”. Moreover, if a few such cases were illustrated, some interviewees argued that this could accelerate the implementation further. “I think it can be a bit of a ketchup effect, the technology does exist, and we have shown in many research projects that it works well. But we have not really taken the big step yet”.

Moreover, many interviewees highlighted that AI solutions should not be implemented unless they are valuable and address real problems. One of the members of the management group stressed “In my world I do not want to force cool solutions on the organization to problems they do not feel they have; I want problems from the organization I can help solve.” Another participant said “I am very positive towards purchasing useful products. But there is quite much overselling. There are a lot of products out there that are garbage. The AI element does not really add anything, it is more for selling” One of the interviewees even described AI solutions that have been implemented but does not add that much value: “the ones I have seen so far have not been useful. They provide information that no one wants, low-hanging fruit”.

All in all, many respondents stressed that illustrative use cases where AI solutions are implemented and solve real problems could be very important in the forthcoming work with AI, not least to motivate and showcase the potential it has. Here, many interviewees said they thought driven individuals throughout the operation would be an important part of this: “we need pioneers in the various professions who also show all the benefits”.

Problems with Access to Data

It became clear in the interviews that one of the big challenges surrounding AI is the struggle to access the necessary data. As one of the participants phrased it “If AI is the rocket, data is the fuel”, and subsequently it will be very hard to implement AI on a broader scale without access to sufficient data. This problem is of course very connected to the legal issues further elaborated on below, restricting the usage of personal data. One of the interviewees mentioned the risk of intruding on personal integrity and argued that: “There is no such thing as anonymized data, there is only a question of how much data you are provided with. If you only have enough data points, there will be a risk that you can identify a single individual”. Some participants also stressed that there can also be problems with the quality of the data, especially regarding the data in the journals with unstructured free text. Problems with data

format were also mentioned, e.g., pathology glasses are not digitized yet so that data is not possible to use for AI purposes. Further, data sharing was brought up, and how it is unfortunate that healthcare data cannot easily be shared with e.g., Chalmers with high competence and knowledge within AI, who could probably develop good AI solutions. Lastly, infrastructural problems with data from many different sources were also described as a challenge.

No Clear Process from Research to Implementation

One thing that was brought up by many of the respondents, despite without it being an explicit question (interview guide in Appendix I), was the wish and need for a clear process from research to implementation. As mentioned earlier, there is a lot of research activity regarding AI, and some of these projects may result in useful solutions. However, it seems like nothing, or very little, actually makes it to implementation and most of it stays as research. “We must have a system for what is successful, 70-80 per cent of all pilot projects become nothing. How should we get all projects to be implemented in clinical practice? We have no good culture to do that.” Similar opinions were expressed by several respondents. Especially clinicians/researchers expressed a wish for support and a clear process: “So also building some kind of golden road or if you say that this is how you do it, these steps need to be taken and there are routines for that and turn to this.”, and another respondent said “If the healthcare wants it in, you must have support on how to proceed, it may be there today but probably not clear enough”.

Taking an algorithm from research to clinical practice is seemingly a very complicated process. Moreover, many respondents argued that the researchers that often come up with these solutions (themselves included), are above all interested in the research itself. “I think many, at least I, are so curious about what's around the next corner, I just want to continue doing research. I'm not commercially driven, I don't have that motive. I think that could be an obstacle to some research not going on to the next stage, it's about ‘now that I have solved it, it was fun. I think that can be an obstacle.” Similar opinions were expressed by other respondents regarding the process of commercializing “so everything must be CE marked and everything, and a researcher can't do that and may not have an interest in it.” Worth mentioning is that some interviewees raised the question if such activities are even motivated for the healthcare organization. Instead, some respondents argued that collaborations with commercial actors that potentially can come in at the end of a research project and take over the commercialization process may be a better alternative.

Technical Obstacles

Most respondents agreed that when it comes to AI, the technology itself is not the main concern. However, there are other technical obstacles surrounding it that several respondents brought up. One such thing is digitalization, which many respondents argued was not as forthcoming within healthcare as they wished for. One participant said: “We are not digital. If you are not digital, there is no point in doing AI. Our digital support is lousy, our systems do not talk to each other”. Another argued that since the healthcare organization is not made for or use for these kinds of technologies, thus making it hard to assimilate; “we don't have an organization built for this at all.” Moreover, respondents said that there may also be infrastructural problems, e.g., when integrating AI solutions in existing systems, since they may not be compatible; “if you bring in an app, it should be compatible with our entire computer system etc. So, it becomes very complex”. Thus, even if the AI technology is sufficient, the surrounding technological infrastructure may not be.

Lack of AI Competence

The lack of appropriate competence was a theme frequently brought up during the interviews. One of the respondents underlined the fact that healthcare traditionally has relied upon competencies centered around the human, whereas technical competence has been of less importance. However, during this new era, many of the respondents stress the need for in-house competence. One of the interviewees argued: “We must have our own technical competence, but we shall not spend time on writing algorithms, that should those at for instance Chalmers do”. Instead, the interviewees mentioned that they need AI competence to test and validate products that potentially can be used in clinical practice, as well as sufficient competence among decision-makers in general. Several participants also talked about competence at the regional purchase unit that deals with procurements of products that have been developed by external actors. “The experts will probably always be somewhere else; however, we need a decent competence when we purchase products. Otherwise, there will be too big of an unbalance, so we need a kind of interpreter that can translate healthcare and the world in which we operate to the real experts”. Another respondent is on the same track and argued that: “We must increase the competence among the purchasers within the region, if they do not know what AI is, it will never be purchased and thus reach the hospitals”.

Resistance to Change

Although there does not seem to be a big resistance to AI per se, many respondents brought up that there may be a resistance to the change process the transformation AI in healthcare will imply: “Change management in healthcare is not an easy thing. I think that many are positive to AI, but I think that many are not positive to the process itself, which they may consider necessary to get to the finish line.” Some respondents talked about an inherent wish among hospital workers to maintain status quo, and a fear that these kinds of change processes may be exhausting and time-consuming. One of the respondents said: “There is a resistance to change in everything. So that if you could choose, you would have chosen your traditional way of working”. However, some respondents highlighted that this is not necessarily a bad thing, since it is important for healthcare professionals “not to buy everything” as one participant phrased it. At the end of the day, people's health and lives are on the line, and some respondents said that a certain amount of skepticism may be sound. However, since AI has such potential and could be crucial to cope with the future demands on the healthcare sector, participants said it will be important to be able to motivate for this change: “Acceleration of AI clinically is like any type of change process. It is required that you work partly with attitudes to why I should do this, it is just a cost-saving, what is it doing that facilitates my job and, in the end, makes my patient feel better.” Another participant said: “You have to push because you may not see the result so clearly now but then we have to do motivational work, also you have to get some answers on ‘what’s in it for us’”.

Legal Barriers

The aspect of legal barriers such as GDPR, PDL and MDR was something many of the respondents raised as a big obstacle to the use of AI within healthcare. Due to these regulations, it is currently very difficult to get access to data, which in turn inhibits the development and utilization of AI algorithms. Even though several of the interviewees recognize the need for regulations like these to protect the privacy and security of people, some argue that it sometimes goes to exaggeration. “I have been in meetings with authorities that get completely blinded by GDPR and cloud act, while in Holland they have said that ‘we can never let personal integrity have a higher priority than saving a human life. If we can show that we can save lives with this data, then personal integrity must stand aside’”. Several interviewees claimed that the law must keep up with the technological development if AI for real is to

make its way into clinical practice. Otherwise, there is a risk that the hype of AI will die. One of the respondents phrased it: “There is always a fear regarding the notion of AI winter. There is a discussion whether it’s a hype that eventually will die. Then I believe that it’s the red tape of law that will kill it”. However, some mentioned that the event of Covid-19 has speed things up and thereby proved that some flexibility regarding these areas is possible.

Public Sector Drawbacks

Some of the challenges derived from the interviews can be traced back to the fact that healthcare foremost is part of the public sector. In Sweden, healthcare is managed at a regional level and several respondents were quite critical to how this structure affects AI development. “The regional structure is a structure that hasn’t benefited this area, quite the opposite. There is quite much competition among the regions, everyone wants to be in the lead, incredibly little cooperation between the regions today”. Even though some acknowledged that it is getting better, many still insisted on the need for more collaboration across regions. “Sometimes it’s almost like they outplay each other, I don’t think it is with bad intent, but I think that there would have been more strength in the negotiations if we were to cooperate. Not at least in the requirement specification during public procurements”.

The concept of public procurement was highlighted as a considerable challenge by several of the respondents. “In Sweden, we have the law of public procurement and it isn’t always the best method for this type of transformation. You specify your requirements and then suppliers get to come up with offers. Not very suitable for things that are a bit fuzzy and difficult to define”. The same interviewee also argued that: “If we do not put pressure on the suppliers and demand for instance AI diagnostic tools as part of the radiology equipment, then it will never happen. That’s how the format looks like in Sweden and that’s also part of the reason why it goes so slow to roll out innovation in the public sector”.

Another theme that could be derived from the interviews that somehow can be connected to the public sector was the aspect of decision making. Some of the respondents were quite critical towards how we tend to make, or perhaps not make decisions in Sweden. One of them phrased it: “I think we have a quite anxious climate when it comes to decision making, we are very consensus-driven. That’s not necessarily the best way to drive transformations. Some will probably have to step forward and be clear about that we have to do this and then get people to follow”.

Trade-off between Operational and Strategic Efforts

Another aspect brought up by interviewees is the fact that the healthcare sector to a large extent is financed by taxes. However, it was surprisingly few that raised money as a challenge, in fact, a few even argued that it was relatively easy to receive the financial means needed for projects regarding AI. However, respondents from the hospital management did mention the difficulty to think long-term and handle the trade-off between the strategic and operative work. “You are struggling with the strategic on the one hand and the operative on the other. People with my type of position are supposed to think of the strategic, but we are also occupied by operative issues, especially during a pandemic when you need to focus on solving acute problems. Then these types of questions get in the shadow”. Another interviewee put it: “From my perspective, it is about how we can realize value today, not in 5-10 years”.

Moreover, the lack of time within healthcare was often brought up as a challenge. Many expressed that healthcare professionals are under big pressure and that there simply is not enough time to think of AI and assist various IT projects. One of the respondents put it: “The further down in the organization you are, the more occupied you are by daily problems”. One participant also expressed that even if products with elements of AI are purchased, there is not enough time to effectively incorporate them into the

daily routines. “A while ago, we bought a new MR camera and then an AI-based software to identify lesions was included. It’s purchased and demonstrated but it isn’t implemented in the sense that it’s used in clinical practice. Everybody gets overwhelmed, but if we had devoted a week to sit down and learn how it works, then perhaps we could start to use it and it may bring some value”.

Insufficient Possibilities for Testing and Validation

Many of the interviewees believe that a majority of the AI products ahead will be purchased from external commercial actors rather than developed in-house. Many referred to the difficulty of the process of taking a product all the way from research to CE approval as a reason for this argument. However, as good as all the respondents were positive towards commercial products, but many also underlined the complexity of buying products from external actors. One of the interviewees stated: “There are tons of apps out there and people might wonder why we don’t just buy them, but it’s not quite as simple as that”. An additional shortcoming mentioned was the lack of local adaptation. Another respondent argued: “We need to identify products and see which of them that are valuable to us. We need support in the organization in terms of routines and testbeds to evaluate whether a certain product is useful or not”. Thus, many stressed the need for testing and validation of products prior to implementation, both to see if it is a valuable solution but also for safety reasons. A participant argued: “You must have an evaluation step before you take in something, and I think, and I have said that the hospital should have a bank. Here we have 1000 lung X-rays with two tumors, find the two, go ahead and test. Here we have people who are healthy in their kidneys, 500 healthy and 40 sick. It must find 35 of them otherwise we do not want to buy this tool.” Moreover, possibilities for testing and validation were also requested for internally developed solutions.

Uncertainties and Ethical Considerations

Several ethical issues were brought up during the interviews. One issue regards the data that has been used to train an algorithm. One participant raised the concern of unethical AI and referred to algorithms that had been trained on data from white people and therefore did not work on black people. Similarly, some algorithms were claimed to have been trained on data from men and therefore did not work on women. Furthermore, considerations regarding “whose fault is it” were raised, and the uncertainty regarding the fact that AI can make mistakes. One participant brought up an example of when this occurred. “There was a case with a diagnosis application that had been trained on around a thousand individuals. The problem is however that some diseases do not have a frequency of 1 out of 1000, but perhaps 1 out of 2000 or even 3000. What happened was that this tool missed a rare meningitis and the patient in question was happily sent home”. If an AI application commits a mistake like this, then there is the question of who there is to blame. Many of the respondents argued that will be impossible to sue an algorithm, thus it is either the producer, but most likely, a healthcare professional that in the end will be held responsible. Naturally, as some mentioned, this causes a certain degree of skepticism and even reluctance to adopt such products.

Another concern brought up during the interviews regards the black box problem. One interviewee highlighted that it is not enough to just be presented with a result. Instead, one must understand why and on what parameters the AI has based its suggestion. One of the respondents mentioned that a leading company is training an algorithm based on American medical journals. However, American patients are not identical to Swedish patients, which must be kept in mind when considering adopting products like this. Problematically, as one of the respondents argued, there is typically weak transparency of the data that has been used to train algorithms which creates uncertainties regarding these aspects.

Suppose the development of AI eventually reaches a stage where it can be implemented in a safe and ethical way, then according to the respondents, it gives rise to new concerns. For instance, some of the respondents mentioned the aspect of the overload of information an AI application can generate. Consequently, it may result in much additional work for healthcare professionals, as well as an inability to reach a decision. Some of the interviewees also questioned where in the workflow AI products are optimally integrated and how they should be combined with current processes. During discussions like this, one respondent underlined the importance of having the patient's perspective in mind.

4.2.3 Summary of Opportunities and Challenges

Below in *Table 4.1*, a summary of the identified opportunities and challenges can be found.

Table 4.1: Summary of opportunities and challenges.

Opportunities	
High expectations on AI	There are high expectations on AI and its potential.
Possibility to Purchase AI products	A market of 343 CE approved AI products exists, thus making AI products available for purchasing.
Overall Positive Attitude Towards AI	The overall attitudes towards actually adopting and implementing and AI seem to be positive.
Promising Collaborations	A lot of projects, initiatives and information exchange are initiated.
Considerable Research Activity	There is quite a lot of research activity within different fields and within a range of different projects.
Challenges	
Insufficient Knowledge of AI	Many people know too little about AI, potentially hampering the implementation and leading to misconceptions.
Lack of Illustrative Use Cases that Solve Real Problems	Very little AI is implemented in clinical practice, and subsequently there are no precursive use cases.
Problems with Access to Data	Access to data is highly restricted due to regulations, inappropriate data formats and difficulties to share data.
No Clear Process from Research to Implementation	Insufficient support and routines to take research to clinical practice.
Technical Obstacles	The current technological infrastructure is not well adapted for AI solutions.

Lack of AI Competence	AI competence within the hospital is currently insufficient, making it difficult to develop solutions and to test/validate products.
Resistance to Change	There may exist a resistance to the change process the transformation towards AI in healthcare will involve.
Legal Barriers	Legal regulations such as MDR, GDPR and PDL restrict the development and usage of AI within healthcare.
Public Sector Drawbacks	The regional structure, public procurement and a consensus mindset were argued not to be favorable for AI development in Swedish healthcare.
Trade-off between Operational and Strategic Efforts	It is hard to devote resources to uncertain and long-term projects. This is especially prominent within healthcare where resources tend to be limited.
Insufficient Possibilities for Testing and Validation	There is a lack of established routines and infrastructure to test and validate AI products.
Uncertainties and Ethical Considerations	There are some uncertainties associated with AI, e.g., ethical considerations, transparency, how it fits into current work processes.

5. Analysis

To answer the third research question, and subsequently derive implications for the future work with AI in healthcare, the empirical findings have been analyzed using the TIS framework. As described in the theoretical background, the TIS framework can be utilized to analyze the development and diffusion of a certain technology and thus evaluate the performance of a certain technological innovation system. Here, the TIS framework will be applied to analyze the system associated with AI in healthcare, and more specifically to understand why the adoption of the technology within healthcare has been rather low. However, since this study has its main focus on one particular healthcare organization, the analysis will focus mainly on the activities within the organization and the part of the TIS that directly interacts with it.

5.1 Functional Analysis

The functions of the TIS were analyzed with a combination of data. Mostly, qualitative data from the interviews with relevant stakeholders was utilized, but also data from the external mapping as well as secondary data regarding the organization and its context. A summary of the functional analysis can be found in *Table 5.1*.

Knowledge Development and Diffusion (F1)

Based on the interviews, there is a lack of knowledge regarding AI among healthcare professionals within the organization. It seems like it is up to each individual to keep up with the latest science, but since many expressed a high workload within healthcare, this is not always highly prioritized. Thus, co-workers may not fully understand the potential of AI. Contradictory, some respondents argued that there is a lack of sufficient knowledge of the healthcare context among commercial actors, since some products that exist on the market are not seen as valuable by healthcare professionals.

On the positive side, based on the qualitative interviews and the inventory from 2020 of AI-related projects, there seems to be considerable research activity going on within the organization which subsequently expands the knowledge base. Further, some degree of knowledge diffusion tends to occur within the external network in terms of collaborations with e.g., academia and instances such as AI Sweden. Moreover, as earlier illustrated, there has been a significant increase in the number of external publications regarding AI in medical research in general. This demonstrates that the general knowledge base is constantly expanding, something which may indirectly influence SU's knowledge base as well.

Legitimation (F2)

Most interviewees perceive the overall attitude towards actually using and implementing AI as positive. This regards both hospital management as well as clinicians/researchers. However, several aspects can be regarded as weak when it comes to legitimation. Firstly, there does not seem to be much of an institutional alignment regarding AI and healthcare. It is clear that many relevant actors and stakeholders see issues with current legislation, and although they did not imply that this was necessarily wrong, many of the respondents claimed that it does not fully keep up with the technological development. Furthermore, although the perceived attitudes towards AI are positive, it became clear that there always exists a certain resistance to change which may inhibit the adoption. There also exists a lot of uncertainty regarding AI, for instance how it can be used in a safe and ethical way, how it will affect the work of healthcare professionals, and how to overcome some of the technological difficulties.

Resource Mobilization (F3)

Regarding financial resources, some interviewees claimed that it is in fact relatively easy to get funding for AI projects. Funding can be obtained either from the internal organization or external instances such as Vinnova. Regarding investments from within the organization, the struggle between strategic and operational investments was brought up. Moreover, since healthcare in Sweden is funded by tax money from the public, some respondents brought up that it sometimes may be hard to motivate and legitimate investments where it is somewhat uncertain what they will give, as with AI. Several respondents also argued there is a lack of time to work with AI to the extent it would be necessary. As mentioned earlier, one interviewee described a product including an AI element that actually has been implemented, but since no one had the time to familiarize themselves with it, the AI element remains unused. As another interviewee said, healthcare professionals are “always running”. The same goes for people in managerial positions who constantly have to balance AI-related work with other strategically important areas.

Moreover, access to data, which is one of the main prerequisites for AI, seems to be a substantial problem. Both due to the restrictions to use patient data, but also since some data may be in improper formats. Furthermore, the current technological infrastructure and complementary assets were argued to be deficient in many ways. Another resource that seems scarce is AI competence. Subsequently, many respondents argued that more specified competence and roles are needed throughout the organization, from IT to management to purchasing. Although everyone does not need to be prominent AI experts, they must understand the external experts in order to successfully implement the technology. Linked to this, a concrete example of resource mobilization is the AI competence center that is under development at the hospital, which aims to support AI development and implementation. Externally, another example is AI Sweden which may support organizations like SU in the implementation efforts.

Guidance of Search (F4)

As already mentioned, the healthcare sector faces great challenges and requires innovative ways to overcome these. One of the most recurrent themes from the interviews was the high expectations on AI among both clinicians/researchers and management personnel. They coherently expressed that they believe in this technology and see big potential in it. Subsequently, decision-makers seem to have realized the importance of prioritizing AI. Thus, there exists some guidance from the hospital management in the sense that strategic work is performed in terms of discussions, collaborations and by the construction of an AI competence center. However, there is no clearly articulated vision regarding AI for the hospital.

Moreover, there is guidance from higher instances in the sense that AI is highly encouraged by the government, which is visible through e.g., an AI agenda and entities such as AI Sweden. Although some guidance exists internally and externally, it seems rather vague, and there is a potential risk that it stays with expectations and discussions rather than concrete actions. Further, there seems to be a lack of guidance from those who will interact with the technology, that is healthcare professionals (and patients).

Entrepreneurial Experimentation and Management of Risk and Uncertainty (F5)

One thing that became evident during the interviews is that a considerable amount of experimentations is being conducted within the hospital. During the inventory made in 2020, 58 projects distributed on different medical fields were identified, and more have likely been initiated since. Even though few projects reach clinical practice, they still provide opportunities to learn more about the technology and

mitigate uncertainties coupled with it. Many projects and initiatives are also conducted externally and in collaborations with different kinds of actors, e.g., academia and government instances. Looking at the external market, another positive indication for this function can be seen in the increased number of healthcare related AI products that exist on the market, and the many commercial actors that have entered the market. As could be seen in the product mapping, the products have also become more diversified compared to foremost existing within radiology and image analysis, which also could be seen as a sign of accelerated entrepreneurial experimentation.

However, there are some factors that seem to hamper the strength of this function. Firstly, many interviewees argued that if internal research projects are to result in solutions implemented in clinical practice, there should be a clearer process and support for this. Moreover, many argued that both when it comes to in-house development at the hospital, and experimentation with products purchased from external actors, there is a need for better possibilities to test and validate the algorithms to reduce uncertainty and facilitate implementation. Linked to this, another weakness is the lack of successfully implemented AI products within the organization.

Market Formation (F6)

The product mapping shows that 343 CE approved AI products intended for healthcare currently exist on the market and new products keep adding to this list. Even though products were identified within a range of areas, it became evident that some areas are more mature than others (e.g., radiology). Thus, there is indeed an external market, albeit small. Looking internally at the hospital however, there are very few products that actually have been implemented in clinical practice. The reason for the low adoption of AI products can to some extent be explained by the fact that it is difficult to get an overview of the market as there currently is no database that collects all CE approved products in a convenient way. Besides, interviewees were not fully aware of the products that exist on the external market and the organization seems to lack sufficient routines in how to search for externally developed AI products. Hence, even though some of the products currently on the market could be of value, as for now they are not being identified in the first place. Lastly, some respondents argued that public procurement is not an ideal purchasing process for complex technologies like AI, and therefore may have an inhibitory effect on the adoption.

Development of Positive Externalities (F7)

As mentioned earlier, this function is foremost a reflection of the other functions' dynamics in the TIS, but there are still some examples of how this function is visible. Firstly, except contributing to the knowledge base in general, some research projects may lead to other collective utilities. The most distinct example is SCAPIS, where the data and results are open for others to utilize. Further, the many collaborations and information exchanges that are going on will certainly improve the knowledge for the whole system, creating cluster-like dynamics. However, restricted collaboration with other industries may hamper the positive externalities that could be possible. The same goes for collaboration between regions which today seem sparse. The reason behind this was partly explained by the fact that data is not allowed to leave a certain region. However, it also became clear that there is a sense of competition between the regions which might hinder knowledge diffusion to take place in an effective way. The deficient degree of data sharing may also hamper the positive externalities for the system as a whole, thus solutions such as federated learning will be important as counteractions.

5.1.1 Summary of Functional Analysis

Below in *Table 5.1*, a summary of the functional analysis is illustrated.

Table 5.1: Summary of functional analysis.

Function	Strengths	Weaknesses
Knowledge Development and Diffusion (F1)	Increased research and collaborations with external actors.	Lack of AI knowledge in the healthcare organization. Lack of healthcare insights among AI developers.
Legitimation (F2)	Positive attitude towards AI.	Deficient institutional alignment. Resistance to change. Uncertainty regarding the technology.
Resource Mobilization (F3)	Relatively easy to get funding for AI projects.	Economical trade-offs. Lack of time. Deficient technological infrastructure. Restricted access to data. Lack of AI competence.
Guidance of Search (F4)	High expectations. Strategic work/discussions performed at a high level by a network of actors.	Vague directives and no vision. No clear articulation of needs by healthcare professionals.
Entrepreneurial Experimentation and management of Risk and Uncertainty (F5)	Ongoing experimentation. Collaborations with different kinds of actors. Increased number of products on the external market.	Lack of clear internal process. Lack of possibilities to test/validate. Lack of illustrative use cases in the organization.
Market Formation (F6)		Very few products are implemented. No routine to identify and implement products.
Development of Positive Externalities (F7)	Results from open-access projects such as SCAPIS. Knowledge exchange takes place within the network.	Restricted collaborations with industry and other regions.

5.2 Functional Patterns

It seems fair to argue that AI within healthcare is a complex area with many interconnected aspects, which was also highlighted by many of the interviewees. Subsequently, there are probably connections to be found between most functions in the system. However, some may be more visible and direct than others, and these dynamics will be elaborated on below. The identified functional patterns are illustrated in *Figure 5.1*.

As seen in *Figure 5.1*, Knowledge Development and Diffusion (F1) influences Legitimation (F2). This is visible since the understanding of AI within healthcare is connected to the attitudes and perceptions of the technology. At the same time, the knowledge gaps that exist, e.g., deficient AI knowledge, and the fact that many healthcare professionals have a very vague idea of what AI means, could instead hamper legitimation as it may cause skepticism and resistance to change. The lack of knowledge further makes it difficult for healthcare professionals to articulate their needs and what they want from AI to decision-makers and in extension commercial actors. Thus, Knowledge Development and Diffusion (F1) also influences Guidance of Search (F4).

Further, it was argued that the lack of institutional alignment and the current uncertainties surrounding AI may inhibit the incentives to invest resources into it. Moreover, it seems like strict regulations, public procurement and the requirement of CE approval have a direct inhibitory effect on the market. Thus, Legitimation (F2) influences Resource Mobilization (F3) and Market formation (F6). Resource Mobilization (F3) in turn influences Entrepreneurial Experimentation and Management of Risk and Uncertainty (F5). This is visible since resources are devoted to projects regarding AI where, in addition to experimental projects, the AI competence center is a concrete example. On the other hand, scarce resources, restricted access to data as well as deficient technological infrastructure and competence may weaken this. Further, both hospital management and higher instances such as the government articulate high expectations on the technology and clearly emphasize that this is an important area where resources should be deployed. Thus, Guidance of Search (F4) influences Resource Mobilization (F3). However, the somewhat vague directives from government and hospital management as well as the absence of articulated needs from healthcare professionals may weaken this.

Moreover, some experimental projects might result in useful solutions and thus contribute to expanding the market. Hence, Entrepreneurial Experimentation and Management of Risk and Uncertainty (F5) has an influence on the function of Market Formation (F6). On the other hand, the lack of experimentation and implementation of commercial products influence Market Formation (F6) negatively. Even though most projects do not end up in a useful application, they still contribute to expanding the knowledge base. Thus, Entrepreneurial Experimentation and Management of Risk and Uncertainty (F5) also influences Knowledge Development and Diffusion (F1). When it comes to the healthcare organization, there also seems to be a direct connection from Entrepreneurial Experimentation and Management of Risk and Uncertainty (F5) to Legitimation (F2). This stems from the “evidence-driven” culture and proximity to research and experimental results, as well as the urge for success stories from experimentation. Concrete examples of AI that actually have reached clinical practice and add value can illustrate how uncertainties can be overcome, and consequently strengthen the legitimacy. If some projects result in successfully implemented products, then many interviewees believe that more would follow. Moreover, successful experimentation can demonstrate that there is indeed a return on investment which further may strengthen legitimation.

Regarding Development of Positive Externalities (F7), although this is more of a result of the system as a whole, it can be seen that this is influenced by Entrepreneurial Experimentation and Management

and Risk and Uncertainty (F5) which is especially visible through projects such as SCAPIS, whose collected data has been made openly accessible to others. Moreover, Knowledge Development and Diffusion (F1) also influences this function since the diffusion of knowledge in the system and between actors create spillovers and thus strengthens the system as a whole. Contradictory, limited collaboration with other regions and industry may weaken it.

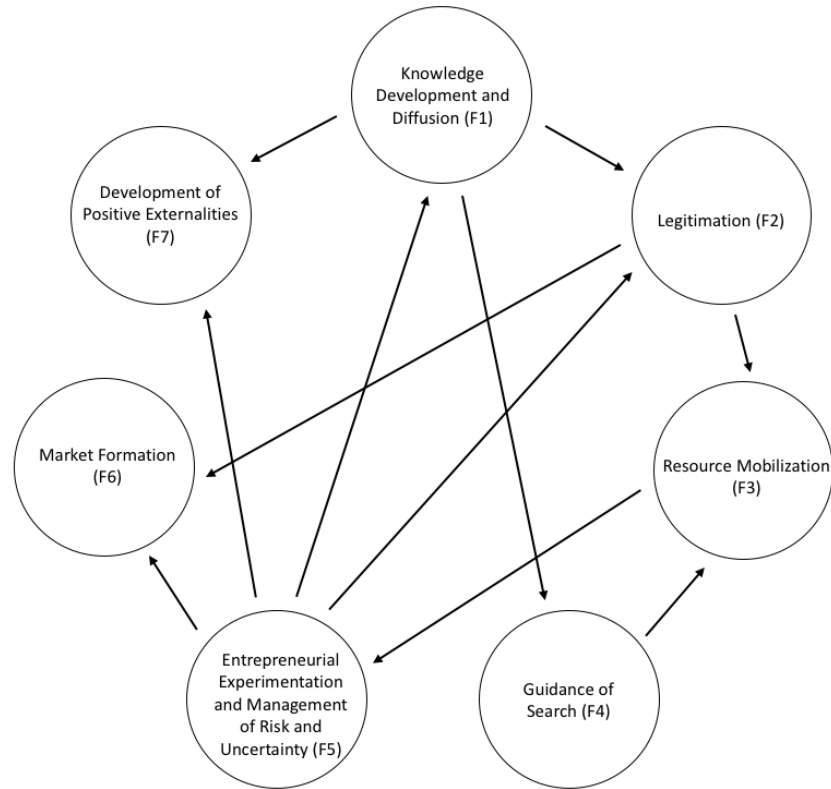


Figure 5.1: Illustration of functional patterns.

5.3 Important Functions to Address

As can be seen in *Figure 5.1* and the analysis of the functional patterns in the TIS, some system functions influence multiple functions and can therefore be argued as more important than others to address. It is clear that Knowledge Development and Diffusion (F1) and Entrepreneurial Experimentation and Management of Risk and Uncertainty (F5) are very central for the system dynamics, as they together have an influence on most of the other system functions. It can further be seen that Entrepreneurial Experimentation and Management of Risk and Uncertainty (F5), Knowledge Development and Diffusion (F1) together with Legitimation (F2) and Resource Mobilization (F3), form a feedback loop. The same goes for Knowledge Development and Diffusion (F1), Guidance of Search (F4), Resource Mobilization (F3) and Entrepreneurial Experimentation and Management of Risk and Uncertainty (F5). Thus, these functions and their connections may form virtuous cycles reinforcing themselves if functions are sufficiently fulfilled, or vicious cycles if not. This could also act to reinforce the system as a whole since both Market Formation (F6) and Development of Positive Externalities (F7) in turn are influenced by these cycles.

Consequently, addressing the weaknesses associated with the most central functions may have a strong positive influence on the system as a whole. Here, research support and possibilities for testing and

validation may strengthen Entrepreneurial Experimentation and Management of Risk and Uncertainty (F5). Also, if experimentation can result in some illustrative use cases of implemented AI, this could in turn strongly enhance Legitimation (F2) and in turn also Resource Mobilization (F3). These two latter functions are associated with institutions such as laws and regulations, which may need altering (or ways to bypass this such as by federated learning). When it comes to Resource Mobilization (F3), AI competence, data access, and enabling infrastructure is of importance. Further, to strengthen Knowledge Development and Diffusion (F1), more general knowledge about AI is needed throughout the organization as well as continued collaboration efforts. Lastly, clearer directives both internally at the hospital and externally may strengthen Guidance of Search (F4).

6. Conclusions and Discussion

The aim of this study was to investigate opportunities and challenges associated with AI in healthcare, as well as provide suggestions for how further adoption of AI can be facilitated. Firstly, a mapping of the market of CE approved AI-based medical devices was conducted. As a result, 343 products were identified, mostly within the field of radiology. Moreover, a brief exploration of research regarding AI within healthcare was performed, and the research seems to correspond with what could be seen in the mapping. Additionally, bigger trends associated with AI such as precision medicine and telemedicine were identified. Furthermore, by conducting a case study at a Sahlgrenska University Hospital (SU), some major opportunities and challenges associated with AI in healthcare were identified. By applying the TIS framework, the innovation system and its dynamics were analyzed, and thus areas of improvement could be identified. This was then used to derive implications for future work with AI in healthcare. These implications, together with a discussion regarding theoretical implications and limitations of the study, will be presented below.

6.1 Implications for Healthcare Organizations

Based on the empirical findings and the TIS analysis, some implications for moving forward with the AI-related work have been derived. Some interventions regard the system as a whole, for example, evaluation of current legislation to facilitate further institutional alignment. Moreover, clearer directives and action plans on a national level seem desired, as well as more transparency of which AI-based medical devices that exist on the market, e.g., a national or European database. There are also some aspects of public sector, e.g., decision making, regional structure, public procurement, scarce resources, which may be hard to alter. However, there are some areas the healthcare organization actually can influence that are likely to facilitate the adoption of AI, and these will be elaborated on below.

Enhance In-house Knowledge and Competence: One important challenge to address is the lack of AI competence and AI knowledge. The opportunities with high expectations and positive attitudes regarding AI can be utilized to spread knowledge about AI throughout the organization. This could counteract misconceptions (e.g., that it will steal all the jobs) and make people understand how AI potentially can enhance healthcare both for patients, the organization as a whole, and the working lives of healthcare professionals. Regarding AI competence, there may not be a need to hire several AI experts, however, it will be crucial that people throughout the organization have a sufficient technical understanding of AI. This regards many functions, both decision-makers as well as personnel working with for instance purchasing and testing. It could be achieved by establishing new roles, as well as educating the current workforce. Moreover, united action with academia to include AI elements in the education of future healthcare professionals could be beneficial. By having sufficient knowledge and competence in-house, it will be easier for the healthcare organization to articulate their needs, test and validate AI products, but also to negotiate with commercial actors.

Generate and Illustrate Successful Use Cases: Although the expectations and hype regarding AI may be a good thing to accelerate the adoption, it could also become counterproductive if not backed up with real-life examples. There is a certain amount of skepticism regarding AI and change in general, and to overcome this and further legitimize the technology, resources should be devoted to facilitating a few successful implementations. These can thereafter act as forerunners when it comes to overcoming the uncertainties and demonstrate how AI can add value and solve real-life problems, which has shown to be an important cornerstone in the legitimation of the technology. Moreover, this could be an important aspect in the motivational work in the actual implementation of AI.

Enable Sufficient Technological Infrastructure: There is currently no sufficient infrastructure in place to test and validate AI products for either internally developed solutions or external ones. Even though there exist available products on the market, before these can be implemented in clinical practice, one has to assure that they are safe to use and bring actual value. Facilitating testing possibilities and support therefore seems motivated. Moreover, the full potential and spectrum of AI will never be realized unless the prerequisite in terms of digital infrastructure is in place. As already mentioned, there is a limitation to data access partly due to the fact that healthcare is not fully digitized. Thus, parallel to considering AI, there is an urge to work with digitalization. Otherwise, systems will not be able to effectively communicate with each other and some products that could be purchased from commercial actors will have no value as they require a certain degree of digital prerequisites. However, this is a comprehensive matter due to the complexity and size of the organization.

Improve Support for Development and Adoption of AI products: In the mapping of the external market, 343 CE approved products were identified, and new products are continuously being approved. Thus, there is an opportunity in buying solutions from commercial actors, especially within the area of radiology. However, even though some products theoretically could be purchased and bring value today, there seems to be a lack of a sufficient process in how these solutions reach clinical practice. That is, at least to the authors' acquaintance, there is no clear routine in how to identify available solutions, no routine as well as infrastructure to test and validate products, and lastly no routine in how to implement and effectively integrate them into the workflow. As mentioned earlier, in those cases no adequate product exists on the market, in-house development may be conducted. However, there seems to be a lack of support to take internally developed products from research towards implementation, if this is what the hospital aims to do. Researchers are not necessarily interested in this, and thus need proper support to be able to take their research to the next step. If routines and support for these areas could be created and effectively communicated, the organization could better take advantage of internal projects as well as what exists on the market. Once support is in place, it is also important to communicate it in an effective way so that people become aware of its existence and thus utilize it.

Stimulate Further Research Projects and Collaborations: One identified opportunity regards the research and experimentation efforts that already have rather high activity, and that further acts as cornerstones in accelerating AI adoption. Thus, continued efforts to stimulate current and future research projects are recommended. Elaborations on new ways to bypass current barriers regarding data, such as federated learning, seem especially motivated. Moreover, projects regarding AI in combination with remote products, e.g., telemedicine, could be of interest. Especially since this seems to be a research trend and prominent on the market, but also since it is thought of as a solution to improve and streamline healthcare operations. Moreover, a further opportunity regards collaborations with different kinds of external actors. This is a good source of knowledge exchange, both for the organization and the network as a whole. The collaboration efforts are perceived as useful and thus important in the further work with AI. However, more collaboration with commercial actors seems motivated, both when it comes to articulation of needs, but also in the process from research to commercialization. Lastly, more collaboration should also be conducted between regions in order to share ideas and best practices. Similarly, useful insights may also be obtained from industry.

6.2 Theoretical Implications

As mentioned earlier, the literature applying TIS in a healthcare context is to the authors' acquaintance sparse. By this study, TIS has proven to be valuable for analyzing the dynamics in an innovation system within the healthcare sector. Moreover, this analysis was centered around the specific healthcare

organization. Thus, rather than exploring all activities and actors of the TIS, the authors chose to focus mainly on the organization itself and the part of the TIS that directly interacts with it. As a consequence, the boundaries of the innovation system are rather vague and unspecified. However, it is still argued to be a useful tool to analyze the interconnectedness and system dynamics and is suitable for analyzing the complex system surrounding AI within healthcare. However, since this is a single case study, more research is needed to evaluate and elaborate further on the functional dynamics in a healthcare context. Moreover, including more perspectives in the data collection could also be valuable to get a deeper as well as a more diversified understanding of the area.

6.3 Limitations

Firstly, one limitation of the study regards the vague definition of AI. This caused a certain degree of subjectivity to be present throughout the study. However, since this an inductive and qualitative study, together with AI in healthcare being at a rather early stage, the authors did not want to narrow down the definition and thus risk limiting the perspectives and views on the topic. Moreover, the findings and implications are very general and likely still hold regardless if a more specific definition of AI is applied.

Another limitation of the study regards generalizability. Since this is a case study based on a limited amount of data, this must be considered when drawing on the results and making conclusions. Moreover, since this study has its focus on Swedish healthcare, the findings may be hard to generalize to healthcare organizations in other countries as the prerequisites such as rules, regulations, and how healthcare is organized, may differ substantially. However, many aspects may be applicable to other contexts, especially to other big healthcare organizations in Sweden.

Moreover, the number of interviews was quite limited, and the participants were somewhat biased since they all were interested and knowledgeable when it comes to AI. Thus, their views and opinions are not representative of the entire organization. This selection of interview subjects was however done purposely, as the authors wanted to get as much relevant information as possible from a limited number of interviews and ensure that the interviewees actually had some knowledge about AI. Further, since this study foremost included clinicians/researchers and management personnel in the hospital, a broader variety of interview subjects could have been valuable. As mentioned above, more perspectives e.g., patients, IT professionals as well as people with legal knowledge could have been useful.

Regarding the external product mapping, there is a risk that some approved products were missed due to the lack of a database for approved AI products. However, the general conclusions regarding the market probably still hold. Additionally, since there is no clear definition of AI, there is a certain amount of subjectivity involved in the assessment of whether something can be regarded as AI. Moreover, a deeper analysis of the market, e.g., regarding market size, actors and their characteristics, could have given a more thorough understanding of the market. However, since the aim of the study focuses on AI coupled with healthcare organizations, the actual technology and the availability of products are of more interest for them. Additionally, the focus has been on AI for clinical purposes. However, looking further into other types of AI aids than medical devices (e.g., for administrative and logistic purposes) could be of interest, since such products may in fact be easier to implement. Lastly, AI and AI within healthcare are incredibly fast-moving areas, thus some information may eventually become outdated, which is especially true for the information regarding the external product market.

References

- Agency for Digital Government. (2020). *Främja den offentliga förvaltningens förmåga att använda AI*. Agency for Digital Government.
<https://www.digg.se/4a3a73/globalassets/dokument/publicerat/publikationer/framja-den-offentliga-forvaltningens-formaga-att-anvanda-ai.pdf>
- Aggarwal, C. C. (2018). *Neural Networks and Deep Learning*. Springer. <https://doi.org/10.1007/978-3-319-94463-0>
- Ahmad, R. (2021). Reviewing the relationship between machines and radiology: the application of artificial intelligence. *Acta Radiologica Open*, 10(2), 1-7. <https://doi.org/10.1177/2058460121990296>
- AIDA. (2021). *Analytic Imaging Diagnostics Arena (AIDA)*. LiU. Retrieved from <https://liu.se/forskning/aida>
- AI Sweden. (2021). *Accelerating applied AI in Sweden*. <https://www.ai.se/en>
- Andersen, A. D. (2014). No transition without transmission: HVDC electricity infrastructure as an enabler for renewable energy?. *Environmental Innovation and Societal Transitions*, 13, 75-95. <https://doi.org/10.1016/j.eist.2014.09.004>
- Beckers, R., Kwade, Z., & Zanca, F. (2021). The EU medical device regulation: Implications for artificial intelligence-based medical device software in medical physics. *Physica Medica*, 83, 1-8. <https://doi.org/10.1016/j.ejmp.2021.02.011>
- Bergek, A. (2019). Technological innovation systems: a review of recent findings and suggestions for future research. In *Handbook of Sustainable Innovation* (pp.200-218).
- Bergek, A., Jacobsson, S., Carlsson, B., Lindmark, S., & Rickne, A. (2008). Analyzing the functional dynamics of technological innovation systems: A scheme of analysis. *Research policy*, 37(3), 407-429. <https://doi.org/10.1016/j.respol.2007.12.003>
- Bergek, A., Jacobsson, S., Hekkert, M., & Smith, K. (2010). Functionality of Innovation Systems as a Rationale for and Guide to Innovation Policy. In *The Theory and Practice of Innovation Policy*. Edward Elgar, Cheltenham (pp.117-146). <https://doi.org/10.4337/9781849804424.00013>
- Bryman, A., & Bell, E. (2011). *Business Research Methods* (3. ed.). Oxford University Press.
- Carlsson, B., & Stankiewicz, R. (1991). On the nature, function and composition of technological systems. *Journal of Evolutionary Economics*, 1(2), 93-118. <https://doi.org/10.1007/BF01224915>
- Chalmers AI Research Center. (2021, 3 May). *Chalmers AI Research Center*. Chalmers. <https://www.chalmers.se/en/centres/chair/Pages/default.aspx>
- Denscombe, M. (2014). *The Good Research Guide: for small-scale social research projects* (5. ed.). McGraw-Hill Education (UK).
- Dobrev, D. (2012). A Definition of Artificial Intelligence. *Mathematica Balkanica, New Series*, 19, 67-74. *arXiv preprint arXiv:1210.1568*.
- Easterby-Smith, M., Thorpe, R., & Jackson, P. R. (2015). *Management and Business Research* (5. ed.). Sage.
- European Commission. (2020). White paper on Artificial Intelligence. *A European approach to excellence and trust*. EU. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0065&WT_mc_id=Twitter

- European Commission. (2021). *Medical Devices - EUDAMED*. EU. Retrieved 2021-05-05 from https://ec.europa.eu/health/md_eudamed/overview_en
- European Medicines Agency. (2021). *Medical Devices*. EU. Retrieved 2021-05-10 from <https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices>
- FDA. (2018, 31 August). *Device Classification Panels*. <https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels>
- Gioia, D. A., Corley, K. G., & Hamilton, A. L. (2013). Seeking Qualitative Rigor in Inductive Research: Notes on the Gioia Methodology. *Organizational research methods*, 16(1), 15-31. <https://doi.org/10.1177/1094428112452151>
- Golden, B. (2006). Transforming Healthcare Organizations. *Healthc Q*, 10(10-9), 4. <https://doi.org/10.12927/hcq.18490>
- Hao, K. (2018, 17 November). *What is machine learning?*. MIT Technology Review. <https://www.technologyreview.com/2018/11/17/103781/what-is-machine-learning-we-drew-you-another-flowchart/>
- Hekkert, M. P., Suurs, R. A., Negro, S. O., Kuhlmann, S., & Smits, R. E. (2007). Functions of innovation systems: A new approach for analysing technological change. *Technological forecasting and social change*, 74(4), 413-432. <https://doi.org/10.1016/j.techfore.2006.03.002>
- IBM. (2020, 15 July). *Machine Learning*. Retrieved 2021-02-17 from <https://www.ibm.com/cloud/learn/machine-learning>
- Krittanawong, C., Zhang, H., Wang, Z., Aydar, M., & Kitai, T. (2017). Artificial Intelligence in Precision Cardiovascular Medicine. *Journal of the American College of Cardiology*, 69(21), 2657-2664. <https://doi.org/10.1016/j.jacc.2017.03.571>
- Lopez-Jimenez, F., Attia, Z., Arruda-Olson, A. M., Carter, R., Chareonthaitawee, P., Jouni, H., ... & Friedman, P. A. (2020). Artificial Intelligence in Cardiology: Present and Future. *Mayo Clinic Proceedings*, 95(5), 1015-1039. <https://doi.org/10.1016/j.mayocp.2020.01.038>
- Löfberg, A. (2020, 22 June). *AI – det intelligenta sättet att snabbt effektivisera vården*. MedTech. <https://www.medtechmagazine.se/article/view/724759/aidetintelligentasattetattsnabbteffektiviseravarden>
- Mahapatra, S. (2018, March 21). *Why Deep Learning over Traditional Machine Learning?*. Towards data science. <https://towardsdatascience.com/why-deep-learning-is-needed-over-traditional-machine-learning-1b6a99177063>
- Mesko, B. (2017). The role of artificial intelligence in precision medicine. *Expert Review of Precision Medicine and Drug Development*, 2(5), 239-241. <https://doi.org/10.1080/23808993.2017.1380516>
- Ministry of Enterprise and Innovation. (2018). *National approach to artificial intelligence* (N2018.36). Government Offices of Sweden. https://www.regeringen.se/4aa638/contentassets/a6488cceb6cf418e9ada18bae40bb71f/national-approach-to-artificial-intelligence.pdf?TSPD_101_R0=088d4528d9ab200048765afd5c64e4f8987ad92a7d5abbe0b8406a0132c632a6756a499da3b19fe908a49a1e2d143000546b9dda3d05b285d1ab5adfa33aee44e5ea46546358629625985439612d2440c51a77759878eed626bf242252c265d9
- Moor, J. (2006). The Dartmouth College Artificial Intelligence Conference: The Next Fifty Years. *AI Magazine*, 27(4), 87-87. <https://doi.org/10.1609/aimag.v27i4.1911>

- Muehlematter, U. J., Daniore, P., & Vokinger, K. N. (2021). Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): a comparative analysis. *The Lancet Digital Health*, 3(3), e195-e203. [https://doi.org/10.1016/S2589-7500\(20\)30292-2](https://doi.org/10.1016/S2589-7500(20)30292-2)
- National Science and Technology Council Committee on Technology (NSTC). (2016). *PREPARING FOR THE FUTURE OF ARTIFICIAL INTELLIGENCE*. https://obamawhitehouse.archives.gov/sites/default/files/whitehouse_files/microsites/ostp/NSTC/preparing_for_the_future_of_ai.pdf
- Pacis, D. M. M., Subido Jr, E. D., & Bugtai, N. T. (2018). Trends in telemedicine utilizing artificial intelligence. *AIP conference proceedings* 1933 (1), 040009. <https://doi.org/10.1063/1.5023979>
- Portnoy, J., Waller, M., & Elliott, T. (2020). Telemedicine in the era of COVID-19. *The Journal of Allergy and Clinical Immunology: In Practice*, 8(5), 1489-1491. <https://doi.org/10.1016/j.jaip.2020.03.008>
- Rai, A. (2020). Explainable AI: From black box to glass box. *Journal of the Academy of Marketing Science*, 48(1), 137-141. <https://doi.org/10.1007/s11747-019-00710-5>
- Regulation (EU) 2017/745. European Parliament, Council of the European Union. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745>
- RISE. (2021). *AI-agendan för Sverige*. <https://www.ri.se/sv/ai-agendan>
- Rowe, J. P., & Lester, J. C. (2020). Artificial Intelligence for Personalized preventive Adolescent Healthcare. *Journal of Adolescent Health*, 67(2), S52-S58. <https://doi.org/10.1016/j.jadohealth.2020.02.021>
- Sahlgrenska Universitetssjukhuset. (2018, 20 February). *Om Sjukhuset*. <https://www.sahlgrenska.se/om-sjukhuset/>
- Smer. (2019). *Artificiell intelligens – löftesrik teknik med etiska utmaningar*. https://smer.se/wp-content/uploads/2019/06/Smer-konferensrapport_2_webb.NY-REV.pdf
- Socialstyrelsen. (2019). *Digitala vårdtjänster och artificiell intelligens i hälso- och sjukvården*. <https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/ovrigt/2019-10-6431.pdf>
- Steiner, D. F., Chen, P. H. C., & Mermel, C. H. (2020). Closing the translation gap: AI products in digital pathology. *Biochimica et Biophysica Acta (BBA)-Reviews on Cancer*, 1875(1), 188452. <https://doi.org/10.1016/j.bbcan.2020.188452>
- Sveriges Kommuner och Landsting. (2018). *Svensk sjukvård i internationell jämförelse*. <https://meetingsplus.regionjh.se/welcome-sv/namnder-styrelser/regionstyrelsen/mote-2018-09-25/agenda/20180601-svensk-sjukvard-i-internationell-jamforelsepdf?downloadMode=open>
- Swedish Agency for Health and Care Service Analysis. (2021). *Vården ur befolkningens perspektiv*. <https://www.vardanalys.se/rapporter/varden-ur-befolkningens-perspektiv-2020/>
- Swedish Medical Products Agency. (2021, 28 January). *Regulatory frameworks for medical devices*. Retrieved 2021-05-04 from <https://www.lakemedelsverket.se/en/medical-devices/manufacture/regulatory-frameworks>
- Swedish Research Council. (2020, 25 February). *The Swedish healthcare system*. Retrieved 2021-02-17, from <https://www.kliniskastudier.se/english/sweden-research-country/swedish-healthcare-system.html#>
- Tegmark, M. (2018). *Liv 3.0: Att vara människa i den artificiella intelligensens tid*. Volante.

- Yin, R. K. (2014). *Case Study Research Design and Methods* (5. ed.). Sage.
- VGR. (2021). *Innovationsplattformen*. <https://www.vgregion.se/ov/innovationsplattformen/>
- Vinnova. (2020, 1 April). *AI for a sustainable society*. <https://www.vinnova.se/en/m/artificial-intelligence---ai/>
- Vårdhandboken. (2019, 17 September). *Märkning*. <https://www.vardhandboken.se/arbetssatt-och-ansvar/medicintekniska-produkter/markning/>
- Österberg, M., & Lindsköld, L. (2020). *AI for better health - A report on the present situation for competitive Swedish AI in the life sciences sector*. Swelife. https://swelife.se/wp-content/uploads/2021/01/AI_for_better_health_final.pdf

Appendix I: General Interview Guide

Swedish:

Vad är din roll och hur ser ditt arbete ut på SU?

Vad händer inom AI på ditt område och hur stöter du på det i ditt arbetsliv (om alls)?

Vet du om någon AI produkt som används kliniskt?

Vad har du för förhoppningar och förväntningar på AI inom sjukvården?

Vad är din uppfattning om den generella inställningen till AI på SU/ditt område?

Hur tror du det kommer påverka ditt arbete som verksam inom vården?

Vad tror du är största anledningarna till att det inte används mer i sjukvården idag?

Vad tror du skulle behövas för att accelerera användandet av AI inom sjukvården?

Anser du att de resurser som behövs finns, och om inte vad saknas (tid/pengar/kompetens)?

Hur ser du på att köpa in lösningar vs. utveckla internt?

English Translation:

What is your role and how does your work look like at SU?

What is happening regarding AI within your medical field and how do you encounter it in your work life (if at all)?

Do you know any AI products that are used in clinical practice?

What are your expectations and prospects on AI within healthcare?

What is your perception of the overall attitude towards AI at SU?

How do you think AI will affect your work?

What do you think are the main reasons why it is not utilized more in healthcare today?

What do you think are needed to accelerate the usage of AI within healthcare?

Do you think the resources needed to implement AI currently are sufficient? If not - what is missing?

What do you think about purchasing products from external actors vs. developing solutions in-house?

Appendix II: Illustration of Data Analysis

Challenges								Opportunities													
Public Sector Drawbacks				Testning och validering				Uncertainties of AI al...				High Expectations				Overall Positive Attitude Towar...					
Sverige är litet ...		Tid att ägna s...		Upp...		Gap...		Implement...				Risker med ...		Ethi...		Alla har in...		Lack of Kno...			
Beslutsstagande		Pengar		Covid-19		Operativt vs s...						AI generer...		USA		Råd...		Initi...		Få in AI i ut...	
		AI - var i fl...										Pati...									
No clear process from research to clinical practise				Legal Barriers				Problems with Data				Technologic...									
Process från forskning till ...				Juridiska problem				Problem med ac...				Digita...									
				Samarbete ko...																	
Need for prospective use cases																					
Visa på fördelar		AI måste ma...		Enskil...				Resistance to change				Lack of AI Competence									
								AI Kompetens				High level of ...									

DEPARTMENT OF TECHNOLOGY MANAGEMENT AND ECONOMICS
DIVISION OF SERVICE MANAGEMENT AND LOGISTICS
CHALMERS UNIVERSITY OF TECHNOLOGY

Gothenburg, Sweden
www.chalmers.se



CHALMERS
UNIVERSITY OF TECHNOLOGY