LUND UNIVERSITY
School of Economics and Management

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Swedish healthcare and the EHDS Act: Exploring blocking mechanisms

A qualitative study exploring current blocking mechanisms in the implementation of the EHDS Act in Swedish healthcare

Master thesis 15 HEC, course INFM10 in Information Systems

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PUBLISHER: Department of Informatics, Lund School of Economics and Management, Lund University

PRESENTED: May, 2024

DOCUMENT TYPE: Master Thesis

FORMAL EXAMINER: Osama Mansour, Associate professor

NUMBER OF PAGES: 126

KEYWORDS: EHDS, Healthcare, Sweden, Health Data, Technological Innovation Systems Framework

ABSTRACT (MAX. 200 WORDS):
The EU approved the EHDS in April of 2024, a piece of legislation that regulates how member states store, handle and give access to health data. It presents both opportunities and challenges for member states. Therefore, the focus of this study is to explore and identify any *current* possible blocking mechanisms in Sweden in relation to the implementation of the EHDS. The study adopts an interpretivist qualitative approach and conducted a series of six interviews with experts on the subject to gather their perceptions of Sweden's current state. The TIS framework was used to gather and divide data into its seven functions and subsequently assess each functions' strength. Based on the analyzed results, the functions *knowledge development and diffusion, resource mobilization, guidance of search* and *entrepreneurial experimentation* were identified as blocking mechanisms, with *knowledge development and diffusion* being the main one, as a perceived lack of released information and guidance by authorities was identified from the data. While this does not imply that Sweden will fail to implement the EHDS on time, our study identifies the obstacles that must be overcome to achieve this goal.

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1 Introduction

This chapter provides an overview of our study, beginning with a background on the European Health Data Space (EHDS) and the current state and challenges of accessing and utilizing patient data within Swedish healthcare. Following this, the chapter outlines the problem the study seeks to address and the purpose of the research. We then introduce our research question and the specific delimitations of the study, which are detailed to specify the focus and scope of the research. This structured presentation aims to give readers a solid understanding of the context, aims, and boundaries of our investigation.

1.1 Background

Nordic healthcare, and specifically Swedish healthcare, is at the forefront of innovation (Tucker, 2023), which has been characterized by the integration of information communication technologies for many years, or ICTS (He, 2023). However, while progress has been made in general in digitizing healthcare, there are still rigidities limiting the effectiveness of these systems. These rigidities can be considered significant when it comes to sharing health data across regions and with other organizations (European Commission, Directorate-General for Health and Food Safety, 2022b; Österberg & Lindsköld, 2020). Swedish healthcare suffers particularly in this area as it's sometimes easier to transmit health data across borders than across regions (Federation of European Academies of Medicine, 2023).

As Sweden is currently undergoing a transition into new electronic health record (EHR) systems, hopes are that interoperability between the regions will improve (Cederberg, 2023). With an aging population (SCB, 2022), which also applies to the rest of the EU (Machado & Polónia, 2022), and a lack of healthcare professionals in Sweden (Apell & Eriksson, 2023; Dagens Medicin, 2023; Socialstyrelsen, 2023b), innovation is greatly needed. While changing to a more common set of EHR systems (Cederberg, 2023) is a step in the right direction, hopes are that AI technology can alleviate some of the burden on healthcare (AI Sweden, 2024; Apell & Eriksson, 2023; Rye & Göransson, 2021)

While there's been an investment in developing innovations for healthcare from both the private and public sector (AI Sweden, 2024; Tucker, 2023; Österberg & Lindsköld, 2020), several issues or barriers hinder AI development meant to be utilized in Swedish healthcare despite a large output of research (Österberg & Lindsköld, 2020). Apell and Eriksson (2023), who studied blocking-mechanisms in Swedish healthcare AI initiatives, summarized Sweden's AI initiatives as "restricted by the system weaknesses of limited resources [data access]" (Apell & Eriksson, 2023, n.p.). As vast amount of data is required to build accurate AIs (Högberg & Larsson, 2022), it's no surprise that many studies asses the lack of access to health data to be a major barrier in the way of AI development within Swedish healthcare (Burden et al., 2023; Neher et al., 2023; Tucker, 2023; Österberg & Lindsköld, 2020).

Lack of access to health data, or more accurately the ability of sharing health data, is something that's bothering Swedish healthcare in general. These are some of the issues that the upcoming law, the European Health Data Space (EHDS), is designed to address. The

issues in question mainly concern data handling in healthcare settings, and health data access to enhance innovation (Molnár-Gábor, 2022). Moreover, Sweden's Health Data Register Act (1998:543) regulates who can access medical data, which is further complicated by Sweden's interpretation and subsequent national standards of General Data Protection Regulation (2016), (Högberg & Larsson, 2022; Österberg & Lindsköld, 2020). However, in an effort to further digitize European healthcare, the European Union's (EU) Parliament and Council have agreed on a preliminary version of the EHDS which would change the way its member-states store and transfer health data (Pagels, 2024; Sveriges Kommuner och Regioner, 2024). The EHDS has much potential for streamlining many healthcare processes and facilitating innovation within the entirety of the EU, yet health data is highly variable and even though Sweden has a wealth of health data already stored (Högberg & Larsson, 2022), adjusting to the new law will pose technical challenges (Deloitte, 2024; European Commission, Directorate-General for Health and Food Safety, 2022a; He, 2023).

1.2 Problem

The EHDS requires healthcare providers in its member states to share primary data according to specific standards and formats, which presents a significant challenge for both EU member states and IT-system providers to adapt in order to meet these requirements at both national- and EU levels. The challenges vary regionally in Sweden as regions operate different IT-systems and require adjustments due to these already existing different standards (Socialstyrelsen, 2023a). Furthermore, Tucker (2023) argues that innovation in Swedish healthcare has been hindered by a lack of resources as well as communication from healthcare practitioners. Healthcare innovation is also stifled by lack of incentives from private companies, even though Swedish healthcare is highly reliant on private sector innovation as the public healthcare sector lacks the funds (Tucker, 2023).

As the EHDS aims at putting the EU at forefront of healthcare innovation and subsequently claim independence from foreign players (Horgan et al. 2022), supporting private sector innovation would be considered important (Tucker, 2023). However, specifications of technical aspects in regards to data handling are still missing from EHDS protocols (He, 2023). Moreover, EIT Health (2023) finds a low awareness of the EHDS among key stakeholders in Sweden and echoes statements about the scarcity of required technical skillsets. Adding to the issue is the fact that current work on healthcare innovation, mainly AI solutions, are severely handicapped by Sweden's harsh interpretation of the GDPR which suffocates the access to health data (Burden et al., 2023; Neher et al., 2023; Tucker, 2023; Österberg & Lindsköld, 2020).

While efforts are being made to digitize European healthcare (He, 2023), several interoperability issues already exist between different information systems in healthcare used within the EU. The issues aren't necessarily about the transmission of information, but the dissemination of information so that it can easily be understood at different ends of the networks (Tuzii, 2022).

Laws and regulations, such as the GDPR, severely restrict the use of health data in Sweden (EIT Health, 2023; Högberg & Larsson, 2022; Österberg & Lindsköld, 2020). This is evident as "none of the 21 regions and 219 municipalities are fully able to share all their data with other Swedish regions, even though a national Swedish patient summary has been set up"

(European Commission, Directorate-General for Health and Food Safety, 2022b, pp. 56). Since requirement of anonymouse or pseudonymous health data will be introduced under the EHDS, Sweden's data lakes and faucets of health data will have to adhere to the new standards (He, 2023), which they don't support at this time (Socialstyrelsen, 2023a). While the EHDS might give the EU a chance here to establish international leadership in the field and give independence from foreign players, its success depends on the free flow of data, which itself is dependent on something less tangible: the readiness of its member-states to make use of the then-available data through robust technical infrastructure (Horgan et al. 2022).

Current blocking mechanisms, i.e. things that might slow down or hinder work to prepare for the implementation of the EHDS, have been suggested by some (Deloitte, 2024; European Commission, Directorate-General for Health and Food Safety, 2022a; Machadoand & Polónia, 2022), and some reports and preliminary road maps have been created (EIT Health, 2023; Socialstyrelsen, 2023a; Swedish eHealth Agency, 2024) in the Swedish context. However, few academic studies have been conducted to investigate the state of current efforts in Sweden. Studies conducted on an EU level, like Horgan et al. (2022), stresses the importance of the success of the EHDS in every member state to avoid dependence on foreign global suppliers of technology services, yet EU guidance on the subject is still greatly needed (He, 2023). Moveover, studies by the Government Offices, the Swedish eHealth Agency and the National Board of Health and Welfare has begun to plan for the integration of these new process into existing IT-infrastructure, however, little-to-none of this is yet to be realized (Socialstyrelsen, 2023a; Swedish eHealth Agency, 2024; Swedish Government Offices, 2024). Sweden's recent transition to a more homogeneous set of EHR systems and systems for medical terms is a step in the right direction (Cederberg, 2023; Sveriges Kommuner och Regioner, 2021; Swedish eHealth Agency, 2024), but studies investigating these efforts are scarce as well. Even though Sweden could benefit a lot from the EHDS, little is known about its current alignment, or what might hinder a successful implementation.

1.3 Purpose

The purpose of this qualitative study is to explore current possible blocking mechanisms in Sweden for the implementation of the European Health Data Space (EHDS) law, as perceived by Swedish experts working in the two of the biggest regions, Stockholm and Skåne regions. This research study aims to explore how the experts from the two different regions view and interpret the efforts currently being made and drawing from the functions of the framework Technological Innovation Systems, identify weaknesses in functions, if found. The framework is commonly used to study emergence and growth of new technological fields and their performance, and was hence viewed as appropriate. Through these investigations, the study intends to provide an overview of the potential challenges and opportunities that the EHDS law presents to Swedish governance and regional healthcare systems. This study does not indent in any way to solve any blocking mechanisms if found, but rather expose them for future studies to delve deeper into.

1.4 Research Question

In order to conduct the study, the following research question has been created.

- What do Swedish experts in the healthcare IT industry consider to be blocking mechanisms for the implementation of the EHDS in Swedish healthcare?

1.5 Delimitation

Considering time constraints and the current status of legislative progress, the study will focus solely on the potential blocking mechanisms of the *current* state of Swedish authorities and regional healthcare administrators work to prepare for the EHDS. Furthermore, only experts working in two regions were chosen as subjects to interview, although their respective organizations all have national reach and representation. Additionally, it is important to note that key conferences discussing the implications and strategies related to EHDS are ongoing as this research is being conducted. These developments will be considered to provide context and update the analysis throughout the study but will not serve as cornerstones in the body of the thesis. Given the objective to gain a comprehensive understanding of Sweden's current state of work and perceived blocking mechanisms, the participants selected for interviews will be senior leaders or decision-makers within key governmental and regional healthcare organizations. These individuals are chosen due to their direct involvement in the preparation or strategy formulation for the EHDS law.

As the EHDS is only one of many pending laws from the EU, it is considered too great of an initiative to incorporate them all into this study, and they will therefore not serve as subject to research. Additionally, this study will not explore the specific technical implementations of the EHDS across systems. Instead, it will focus on the functional, regulatory, and strategic aspects that are crucial for supporting the law's implementation. The aim is to discover how these elements can facilitate interdisciplinary collaboration and enhance digital health data practices in Sweden.

2 Literature Review

The theoretical foundation of this thesis involves a comprehensive review of scholarly literature, government agency reports and white papers on the implementation of the European Health Data Space (EHDS) in Sweden. This chapter integrates previous research on EHDS, GDPR, and Swedish health policies to build a robust understanding of the challenges and frameworks relevant to EHDS implementation. We also present the TIS framework, which will be applied in our analysis and discussion of our research question.

2.1 Demand and potential for innovation to alleviate the workload of the healthcare system

2.1.1 Demand

Sweden's population is aging rather fast, putting stress on healthcare services that struggle to keep up with increasing demand. Therefore, innovation in healthcare is a need rather than a want (AI Sweden, 2024a; Apell & Eriksson, 2023; Rye & Göransson, 2021). SCB, Sweden's agency of statistics, claims that the population of people 60 years and older is growing more rapidly than the population as a whole (SCB, 2022), further emphasizing the need for something to alleviate the workload of Swedish healthcare. As the population ages, so do chronic diseases and conditions that require medical attention (Apell & Eriksson, 2023).

Sweden also suffers from a lack of talent in regards to both healthcare professionals as well as those who work to deliver technological solutions to Swedish healthcare (Apell & Eriksson, 2023; Dagens Medicin, 2023; EIT Health, 2023; Socialstyrelsen, 2023b). Though this is disproportionately distributed across the nation's more rural areas as compared to the bigger cities, however, all Swedish regions report a need for more healthcare professionals to some effect (Socialstyrelsen, 2023b). Now, the challenge of a heavier workload as a result of an aging population leads to a higher demand for healthcare professionals, which is an issue Sweden already faces. That is why innovation in healthcare is needed, as it could alleviate this burden without the need of greatly adding to the workforce of healthcare professionals (Apell & Eriksson, 2023).

In regards to IT-systems used in Swedish healthcare, it has been documented that the country is having problems sharing health data between regions despite efforts to combat this (European Commission, Directorate-General for Health and Food Safety, 2022b). Moreover, Sweden's interpretation of data laws, such as GDPR, has further complicated this as Sweden as a country might enforce the strictest following in the entire EU (Österberg & Lindsköld, 2020). Also, even though innovation in Swedish healthcare is reliant on private sector involvement, it's today limited in its capacity since access to health data is restricted (Tucker, 2023). At the EU level, Machadoand and Polónia (2022) states that the only way to ensure

that healthcare systems remain suitable for their purpose, is through revamping the entire system through an initiative like the EHDS.

2.1.2 Potential

Even though Sweden is quite poor at sharing and allowing access to its health- and medical data (Österberg & Lindsköld, 2020), it has large sets of health data compared to other countries going back several decades (Högberg & Larsson, 2022; Österberg & Lindsköld, 2020). Taking this into account, it is also important to note that every Swedish citizen has a personal identifiable number (PID) that is unique to every individual, further enabling the potential for data analysis (Österberg & Lindsköld, 2020). Moreover, there's a shared vision of innovation in the nordics, in which they're promoting development of AI in healthcare. This vision involves private companies to expedite development (Tucker, 2023), something that the EHDS would allow for to a greater extent than what is allowed today. Moreover, the revamping of the European healthcare system in accordance with the EHDS could establish the EU as a leading innovator in the domain (Horgan et al. 2022), including Sweden. Despite Sweden having difficulty transmitting health data, a lot of technical solutions are in place, just waiting for legal frameworks to change (EIT Health, 2023). Meaning that while much work will have to be done across all digital infrastructure in Swedish healthcare, many of the pieces are already there (EIT Health, 2023).

2.2 The EHDS and GDPR

2.2.1 GDPR implementation history - Sweden

Sweden was the first country in the world to introduce a national law on the protection of personal data, the Data Protection Act, in 1973 (Gültekin-Varkonyi et al. 2019; Iveroth, 2018). Since then, the data protection laws in Sweden have always been subject to updates and have undergone extensive revisions to address the challenges and technological changes faced by society, as illustrated well by the many legislative changes over the decades up to the more comprehensive changes that the GDPR brought, which created a more uniform protection within the EU (Gültekin-Varkonyi et al., 2019; Iveroth, 2018). This history of data protection reflects a continuous adaptation to new technologies and societal changes, while striving to maintain individual rights.

The General Data Protection Regulation (GDPR), an EU regulation, was introduced in Sweden on May 25th, 2018, replacing the Swedish Personal Data Act (PUL) (SUB, 2024). PUL, "*Personuppgiftslagen*", a Swedish law enacted in 1998 and repealed in 2018, aimed to protect individuals from having their personal integrity violated through the processing of personal data (Riksdagen, 2024). The General Data Protection Regulation (GDPR) protects EU citizens' privacy rights and gives individuals some control over what personal information is being stored and by whom. According to the Swedish Authority for Privacy Protection, IMY (2023), the ground principles of the GDPR implies that private information can only be collected for very specific and clearly stated and legitimate purposes which are necessary for the organization. They need to be stored securely and up-to-date, and when they no longer serve a purpose, they need to be deleted (IMY, 2023).

2.2.2 The integration of EHDS and GDPR

EHDS incorporates and builds upon regulations from the GDPR to regulate the processing of personal data across diverse public sectors (EHDS, 2024; Molnár-Gábor, 2022; Proso, 2024; Socialstyrelsen, 2023a). It is meant to be a complementary to earlier legislations such as the GDPR, but with a sole focus on healthcare (Horgan et al. 2022; Molnár-Gábor, 2022; Proso, 2024). Under the new framework, individuals' rights that builds upon GDPR will allow them to easily access and read their health data, share said data with a healthcare provider of their choice, add information for either themselves or dependents such as children, amend information, restrict information, and view who has access to their health data (EHDS, 2024; Proso, 2024). Furthermore, it allows for greater innovation and more efficient healthcare across the border of EU member states (Horgan et al. 2022; Molnár-Gábor, 2022). The legislation also answers a call from researchers who states that a lack of access to health data is holding back development of innovation in healthcare (Burden et al., 2023; Neher et al., 2023; Tucker, 2023; Österberg & Lindsköld, 2020), specifically AI which requires a lot of data to be trained. Österberg and Lindsköld (2020) states that the lack of access to health data is a consequence of Sweden's harsh interpretation of GDPR, which might be the harshest within the EU. While this article is a few years old, its statement about the lack of health data access is strengthened by the more recent studies (Burden et al., 2023; Neher et al., 2023; Tucker, 2023), further solidifying a need for amendments or further legislation like the EHDS that allows for access to health data for innovators.

2.3 European Health Data Space

In 2022, the Commission presented a draft of a new regulation (Proso, 2024). On March 14, 2024, the Council and Parliament reached a preliminary agreement concerning the EHDS regulation. The European Parliament's last meeting to make a decision before the election period was scheduled for April 22-25, 2024 (Sveriges Kommuner och Regioner, 2024), and the law was subsequently passed. It is expected that by the year 2030, a common European Health Data Area will exist across the Union (Machadoand & Polónia, 2022)

The EHDS aims to facilitate an environment in which data can easily and smoothly be accessed by different healthcare providers, as well as private developers, researchers and individual citizens within and across borders (Horgan et al. 2022; Molnár-Gábor, 2022).

> "*The EHDS should not be envisaged as a big European 'data lake', but as a system for data exchange and access which is governed by common rules, procedures and technical standards to ensure that health data can be accessed within and between Member States*" (European Commission, Consumers, Health, Agriculture and Food Executive Agency, 2021, pp. 11).

This is envisioned to improve efficiency within healthcare, provide increased control over one's individual health information, but also support healthcare innovation on a larger scale (Deloitte, 2024; Horgan et al. 2022; Molnár-Gábor, 2022; Socialstyrelsen, 2023a; Sveriges Kommuner och Regioner, 2024). This was partly done in response to the Covid-19 pandemic (Genovese et al 2022; Kotsareli & Tsachouridis, 2023), and answers calls for laws to allow for better innovation within healthcare, as those by (Burden et al., 2023; Neher et al., 2023; Tucker, 2023; Österberg & Lindsköld, 2020).

EHDS is also expected to contribute to achieving the goals of the EU's digital agenda (Socialstyrelsen, 2023a). As expressed by Horgan et al. (2022), this is a great opportunity for European healthcare to overcome some of the challenges that they face today and establish international leadership in healthcare innovation.

In regards to the health data itself, the EHDS specifies types of use of the health data into primary- and secondary use. Primary data use refers to healthcare providers and patients ability to access and share their information with them (EHDS, 2024; Fåhraeus, Reichel & Slokenberga, 2024; Kotsareli & Tsachouridis, 2023; Proso, 2024). While secondary use of health data refers to "research, innovation, public health, policy-making, regulatory activities and personalized medicine" (EHDS, 2024, n.p.). While individual citizens and healthcare providers will have primary use access to health data by a cross-border digital infrastructure in a common European electronic health record exchange format, those who seek secondary use of health data will have to apply for a permit from a health data access body (EHDS, 2024). These include researchers, companies or public institutions and will only come in an anonymised or pseudonymised form to protect patients privacy (EHDS, 2024). This will put technological demands on all sides of those who use and store the data (He, 2023), but also give them the opportunity for innovation which studies has pointed out as an issue (Burden et al., 2023; Neher et al., 2023; Tucker, 2023; Österberg & Lindsköld, 2020).

This also divides the EHDS and relevant actors into three categories, as explained in the subsequent sections: *2.3.1 Health Data Access Bodies (HDAB), 2.3.2 Demands on Health Data Holders, and 2.3.3 Health Hata Users.*

2.3.1 Health Data Access Bodies (HDAB)

The Health Data Access bodies (HDAB) will act as mediators between those who sit on various types of health data (health data holders) and those who wish to access it for secondary use (EHDS, 2024; European Commission, Directorate-General for Health and Food Safety, 2022c; Fåhraeus, Reichel & Slokenberga, 2024; Kotsareli & Tsachouridis, 2023; Proso, 2024; Socialstyrelsen, 2023a). This differs from accessing health data for primary use, as member states are required to set up a *digital authority*, which allows for the storing and sharing of primary use health data in accordance with MyHealth@EU (EHDS, 2024; European Commission, Directorate-General for Health and Food Safety, 2022c; Fåhraeus, Reichel & Slokenberga, 2024; Proso, 2024). However, HDABs have a dual role; they guide and support both health data holders and users and function as a national hub within a European network for secondary use. While HDABs have the responsibility to apply ethical, legal, semantic, and technical guidelines to manage data access and ensure that the data is used in accordance with applicable data protection regulations. Those organizations that are assigned this role as HDAB also have several other key functions in their respective member states which include:

Table 1: Key functions of HDABs

Key functions of HDABs in their respective member states (EHDS, 2024; Socialstyrelsen, 2023a).
● Provide information about what data is available.
● Offer a service that allows potential health data users to apply for permission to use health data. ○ Implementing standards for how this is done.
● Provide statistics upon request.
● Prepare and test the disclosure of anonymous and pseudonymous health data. ○ Issue health data to secure environments for analysis and surveilling said environment.
● Provide support and guidance for health data users.
● Connect both technically and administratively to the European hub of HDABs.

2.3.2 Demands on Health Data Holders

Those who are in possession of health data are called health data holders. They can be government agencies, healthcare providers, academic institutions, or companies that collect, store, and manage health data (Fåhraeus, Reichel & Slokenberga, 2024; Proso, 2024; Socialstyrelsen, 2023a). However, a certain set of technical demands and responsibilities fall on health data holders as well. Like HDABs, they must have a solid technological architecture that allows for secure storage as well as reliability and interoperability of the data they share, often back to the HDAB (Fåhraeus, Reichel & Slokenberga, 2024; Proso, 2024; Socialstyrelsen, 2023a).

2.3.3 Health Data User

Health data users include organizations and individuals such as authorities and researchers who use health data within the framework of the EHDS for research, innovation, and improvement of healthcare services. These users must meet specific authorization and eligibility requirements to be allowed access to data from the HDABs (EHDS, 2024; Fåhraeus, Reichel & Slokenberga, 2024; Proso, 2024; Socialstyrelsen, 2023a).

2.3.4 Possible future opportunities given by the EHDS

To reiterate, we've mentioned above what the EHDS is envisioned to give us and a short description of how that would be structured. What it specifically hopes to do is namely:

> "*to strengthen and extend the use and re-use of health data for the purposes of research and innovation in the healthcare sector; to help healthcare authorities to take evidence-based decisions; to improve the accessibility, effectiveness and sustainability of healthcare systems; to support the work of regulatory bodies in the assessment of medical products and demonstration of their safety, efficacy and quality; and to contribute to the competitiveness of the EU's industry.*" (European Commission, Consumers, Health, Agriculture and Food Executive Agency, 2021, pp. 11).

Basically, it hopes to, through the power of free flowing, structured and organized data, provide a higher standard of healthcare across the board and also improve efficiency. This development benefits not only the patients but also the healthcare providers, who gain increased access to information about their patients (Machadoand & Polónia, 2022). This enables improved coordination within healthcare and gives providers the chance to offer tailored and, thus more effective care. Through this revamping of healthcare systems, it allows for them to continue to stay suitable for their purpose in this digital age (Machadoand and Polónia, 2022). Moreover, it also aims at providing greater grounds for innovation (Deloitte, 2024; EHDS, 2024; European Commission, Directorate-General for Health and Food Safety, 2022c; Fåhraeus, Reichel & Slokenberga, 2024; Kotsareli & Tsachouridis, 2023; Proso, 2024; Socialstyrelsen, 2023a), which healthcare in Sweden desperately needs (AI Sweden, 2024; Apell & Eriksson, 2023; Rye & Göransson, 2021). For researchers and innovators, new doors open thanks to access to expanded data.

As two services have already been implemented (ePrescription and patient summaries) under the eHealth Digital Service Infrastructure (eHDSI) umbrella, the EHDS have somewhat of an existing infrastructure to go off of as it progresses. Furthermore, Katehakis et al. (2016) explained that this is something that would greatly benefit the eHealth domain's efficiency. This platform supports cross-border health data exchange, and has grown to 10 member states using one or both services, with a vision of reaching more (European Commission, Directorate-General for Health and Food Safety, 2022a). Furthermore, the EHDS will build upon the framework put forward by the Data Governance Act (EU Commission, 2022).

2.3.5 Challenges we face to get there

While there is hope that the EU will become a competitive leader within healthcare innovation as a consequence of the EHDS, there are also several challenges Sweden along with the rest of the EU have to face in order to get there. These challenges can be categorized into: technological challenges, Variation in stakeholders engagement and expectations, and ethical challenges (Deloitte, 2024; European Commission, Directorate-General for Health and Food Safety, 2022a).

The technical challenges that Sweden and the EU face in regard to the EHDS are varying. While the EHDS puts emphasis on the requirement of anonymisation and pseudonymisation of data, it gives no further explanation of what that means (He, 2023). In addition, the construction and maintenance of a technical infrastructure pose a major challenge (Machadoand & Polónia, 2022). This infrastructure must be ubiquitous and robust enough to support effective sharing and use of health data, not only within individual member states but also between them. Achieving this requires extensive collaboration among various actors in the healthcare sector (Deloitte, 2024; European Commission, Directorate-General for Health and Food Safety, 2022a; Machadoand & Polónia, 2022). And Sweden has proven slow at this point in the past as "none of the 21 regions and 219 municipalities are fully able to share all their data with other Swedish regions" (European Commission, Directorate-General for Health and Food Safety, 2022b, pp. 56), which in caused by a legal framework that doesn't allow for it (EIT Health, 2023), but a current wide variety of EHR systems could also cause difficulty in extracting and aggregating data in the short term (EIT Health, 2023).

Variation in stakeholders engagement and expectations poses a challenges since involves promoting and facilitating effective cooperation and information exchange, which is crucial for ensuring that EHDS achieves its goal of improved and more cohesive healthcare across borders (Deloitte, 2024; European Commission, Directorate-General for Health and Food Safety, 2022a; Machadoand & Polónia, 2022). While the Nordic countries are more willing to share their data, some others aren't. (European Commission, Directorate-General for Health and Food Safety, 2022a).

Ethical challenges mostly center around questioning what information should be saved, how much of it, and who has access to it. Firstly, it is important to follow the GDPR-principle of data minimization, also known as only saving what you need for the period of time you need it. As the EHDS serves as a complementary legislation to the GDPR (Horgan et al. 2022; Molnár-Gábor, 2022; Proso, 2024), this is an important aspect. This is followed by a wide variety of public trust in different institutions that might get access to their health data. Safeguarding individuals' privacy should be a main concern for governing bodies (Karacic, 2022). However, a lack of access to health data might also lead to a growing frustration among leading health innovators, thus depriving the individual of better treatment and diagnostic tools (European Commission, Directorate-General for Health and Food Safety, 2022a), and the one of the EHDS' purposes is to cater to both the right to privacy as well as allowing for innovation (Horgan et al. 2022).

2.4 Current work on EHDS infrastructure

2.4.1 The Government Offices and The Swedish eHealth Agency: a plan for a national digital infrastructure

As a guidance of how Sweden should tackle the challenges and ambiguity of its current digital infrastructure in relation to healthcare, the Swedish eHealth Agency (2024) decided to put forward a "road map" of sorts. This is in part due to today's infrastructure which is viewed as less-than-optimal, but also in reaction to the EHDS, as the road map hopes to align its digital infrastructure with the upcoming regulation (Swedish eHealth Agency, 2024). This correlates with other reports and studies suggesting that significant changes of new technological standards will have to be made in order to comply with the EHDS (EIT Health, 2023; Machadoand & Polónia, 2022). Today, Inera AB is responsible for about half the regions' technological infrastructure, but the Swedish eHealth Agency plans to limit their role significantly, by only using certain tools and services they offer moving forward (Swedish eHealth Agency, 2024). However, this road map only stretches to 2028, stating that more resources will have to be allocated by then (Swedish eHealth Agency, 2024). Leaving much uncertainty on the table still. Furthermore, the report is not a situation report assessing the actual readiness of implementing the EHDS, but rather a proposal of funding etc. to build the necessary infrastructure upon the existing one. This is quite important as Guthmuller, Paruolo and Verzillo (2021) summarize that the EU tends to rely on regulations, thus providing guidelines and norms, and facilitating networks, rather than actual monetary funding. Implying that each country will need to fund their own infrastructure and creating value as mentioned, which Guthmuller, Paruolo and Verzillo (2021) consider to be a great contribution.

Sweden's Government Offices have assigned an investigation to the Ministry of Health and Social Affairs. This investigation has a different scope than the Swedish eHealth Agency, and is actually overseeing their road map to see if it's feasible, the allocated funds are sufficient, and if other agencies need to be involved (Swedish Government Offices, 2024). Which Guthmuller, Paruolo and Verzillo (2021) views as important in this matter. Moreover, the assignment involves recommending one or more authorities to be responsible for the storing and sharing of health data, a HDAB. However, the investigation results are still unpublished.

The Nordic countries have launched a collaborative project, the VALO project, in an effort to align the countries IT-infrastructure in regards to sharing and storing health data (Nordiska Ministerrådet, 2024). This correlates well with the findings of Guthmuller, Paruolo and Verzillo (2021) who state that collaboration and sharing of knowledge of best practices is a key to creating value from the EHDS law, and Hägglund et al. (2023) who find that international collaboration is needed to ensure that socio-technical and contextual factors are considered. The VALO Project is an ambitious initiative focused on the secondary use of health data, encompassing activities such as research and innovation in healthcare. This project is distinguished by its collaborative structure, involving multiple Nordic countries. Sweden, led by the Swedish eHealth Agency, plays a pivotal role by leading one of the main work streams (Silvestri, 2024). The project was initiated on February 1, 2024, and is intended to conclude on April 30, 2026. It aims to conduct specific experiments (pilot projects) to generate evidence of the benefits of this collaboration. It also will focus on the synergistic advantages of developing a Nordic platform within the European Health Data Space framework while avoiding overlap with ongoing EHDS activities. The project's planning is based on the assumption that Nordic cooperation offers unique benefits, which will be verified through concrete experiments based on using unique Nordic health and social data and registries, prioritizing efficiency and security (Nordiska Ministerrådet, 2024).

2.4.2 Healthcare IT-systems and the EHDS

In order to comply with certain coding standards of medical terms, the EHDS will require all member states to use an international system known as Snomed CT, which determines global standards for health terms (Swedish eHealth Agency, 2024). Today, many of the medical terms are published as PDF-files, requiring manual handling of the information which is considered a low level of automation (Swedish eHealth Agency, 2024). However, some regions have adopted Snomed CT or similar systems as a way to promote cohesiveness in medical language (Fahlen & Rosenqvist, 2010), as opposed to free text-journals of a patient's medical journal (Sveriges Kommuner och Regioner, 2021). In fact, Sweden had initiated a similar project in collaboration with Snomed CT in order to create a common coding standards for medical terms, but it was halted due to the EHDS. (Swedish eHealth Agency, 2024).

While Sweden's been in the progress of investigating systems to enhance interoperability and efficiency, there is no national EHR system in Sweden as its healthcare is decentralized (Fragidis & Chatzoglou, 2018) and regions use different EHR systems (Wretborn et al. 2021). However, half of Sweden's regions are in the transition to phase out old EHR systems. The transition will incorporate a cohesiveness among EHR systems, as only three or possibly two of them will be used across all of Sweden's regions. As opposed to nine different systems, which has been the case in the years before (Cederberg, 2023). While it is important that EHR systems are integrated to an architecture that enables transference of health data in accordance

with EHDS (Swedish eHealth Agency, 2024), technical specifications for that are yet to be released (He, 2023).

2.4.3 EU and Sweden's current alignment with the EHDS

In an article discussing the opportunity presented by the EHDS, Horgan et al. (2022) conclude that the success or failure of the EHDS will partly depend on each member state's readiness to implement the necessary infrastructure and procedures. However, an assessment of said readiness is somewhat unknown. As the EU commission themselves states through their website, as of May 2022, that there's an ambiguity to each member state's readiness (EU Commission, 2022). Two thirds of the member states handle ePrescription and patient summaries online, though only a few of these have the ability to send those across borders. Ten member states support sharing of ePrescription and patient summaries through MyHealth@EU (European Commission, Directorate-General for Health and Food Safety, 2022a), however, eleven member states still use paper prints for prescriptions (EU Commission, 2022).

Moreover, the secondary use of health data is restricted across the EU, and so is its readiness to implement the EHDS (EU Commission, 2022). Databases are often small and only exist in a few member states (Tuzii, 2022). To deal with this, an undertaking of legislating national laws has taken into effect, yet none of them have any connection to each other on an EU-level as they are fragmented and disruptive in relation to oneanother (EU Commission, 2022). Although, some countries have created authorities within them to be responsible for access to health data, such as Findata (Finland), Health Data Hub (France), Forschungsdatenzentren (Germany) (EU Commission, 2022). In order to prepare the EU for the cross-border sharing of health data for secondary use a joint effort between member states called TEHDAS has been launched (Richards, 2022) and is expected to keep releasing recommendations for technical aspects (EIT Health, 2023).

Sweden has also begun to structure its healthcare-digital infrastructure in order to be compatible with the EHDS, as described in *2.5.1 The Government Offices and The Swedish eHealth Agency: a plan for a national digital infrastructure and 2.5.2 Healthcare IT-systems and the EHDS*. However, just how ready and prepared Sweden is, along with the rest of the EU, and what might hinder the development is still subject to a knowledge gap.

2.5 Summary of the the EHDS in the Swedish context

It is evident that Sweden's lack of healthcare professionals, coupled with a rapidly aging population, poses severe challenges on its healthcare system (AI Sweden, 2024a; Apell & Eriksson, 2023; Apell & Eriksson, 2023; Dagens Medicin, 2023; Rye & Göransson, 2021; Socialstyrelsen, 2023b). Some hope that innovation, such as AI, will alleviate some of this burden, yet Sweden is quite poor at sharing health data, which is important to train an AI. Even within its own borders as regions are having trouble sharing health data between them (European Commission, Directorate-General for Health and Food Safety, 2022b, pp. 56). These are some of the problems that the EHDS hopes to alleviate (Deloitte, 2024; EHDS, 2024; European Commission, Directorate-General for Health and Food Safety, 2022c; Socialstyrelsen, 2023a; Swedish eHealth Agency, 2024).

The use of health data will be categorized as primary- and secondary use. Where primary use is for healthcare providers, and secondary is if for research and innovation purposes. The flow of data will be structured and controlled by health data access bodies (HDAB), but some technological demands will be put on the health data holders as well (EHDS, 2024; European Commission, Directorate-General for Health and Food Safety, 2022c; Socialstyrelsen, 2023a). Since Sweden has a long standing tradition of collecting and storing health data, it should provide a good base for innovation in the form of AI (Högberg & Larsson, 2022; Österberg & Lindsköld, 2020).

Sweden's municipalities and regions have expressed a positive stance towards the ambition of the European Health Data Space (Swedish eHealth Agency, 2024; Sveriges Kommuner och Regioner, 2024), but they argue that the proposal is too far-reaching, where national health care should remain a national concern (Sveriges Kommuner och Regioner, 2024). The European Health Data Space does not only pose significant challenges but also requires substantial investments. It also represents a significant opportunity to achieve the necessary interoperability for health data within our country's borders (Deloitte, 2024; European Commission, Directorate-General for Health and Food Safety, 2022a; Silvestri, 2023; Socialstyrelsen, 2023a).

Several initiatives have been undertaken to prepare for when the EHDS goes into effect, most significantly by the Swedish eHealth Agency which is tasked with coming up with a plan for a digital infrastructure to comply with the EHDS. However, other projects such as VALO, which aims at facilitating collaboration between the nordic countries in relation to the EHDS, and the Swedish Government Offices' mission to oversee the plan out forward by the Swedish eHealth Agency, helps the effort (Nordiska Ministerrådet, 2024; Swedish eHealth Agency, 2024; Swedish Government Offices, 2024). Moreover, Sweden's efforts to create a more cohesive digital infrastructure across the country in regards to EHR systems and systems for coding standards of medical terms (Cederberg, 2023; Sveriges Kommuner och Regioner, 2021; Swedish eHealth Agency, 2024) makes for interesting steps towards an IT-infrastructure which may or may not be able to comply with the technical requirements of the EHDS.

2.6 Technological Innovation Systems Framework

The Technological Innovation System Framework (TIS) originated from Swedish scholars in the 90s, structuring components that contribute to the development, diffusion, and utilization of innovations (Carlsson & Stankiewicz, 1991). It stresses that technological systems are defined by competence and knowledge, rather than the flow of goods and services. Since its inception, it has seen further development by other scholars, including some of them introducing the concept of "functions" (Bergek et al. 2008; Hekkert et al. 2007; Johnson & Jacobsson, 2001). As described by some of the experts of TIS:

> "*The TIS approach is an often-applied framework to study the emergence and growth of new technological fields and their performance. The approach has been used for a broad range of studies including but not limited to novel technologies that carry the promise of improving sustainability.*" (Markard, Hekkert & Jacobsson, 2015, n.p.).

The quote comes from an article discussing criticism towards TIS and its growing popularity as well as continuing development. They also address the prospect for TIS as an approach for

analysis of socio-technical transitions, stating that the approach indeed has some applicability in this endeavor, but would benefit from further development in this area (Markard, Hekkert & Jacobsson, 2015). Using the TIS framework, Apell and Eriksson (2023) studied blocking mechanisms of healthcare innovation in Sweden, specifically artificial intelligence, and used its functions to determine strengths and weaknesses of the healthcare system. This type of research is typical for the TIS framework that is usually incorporated in studies of radical innovation (Bergek et al. 2015). Our thesis paper intends to use the TIS framework similarly to Apell and Eriksson (2023) by investigating blocking mechanisms in Swedish healthcare when preparing for the EHDS. The TIS-functions used by Apell and Eriksson (2023) are depicted in the table 2 and further explained in the subsequent sections *2.6.1 - 2.6.7.* This table gives an overview and displays the names of each function in the TIS framework and provides references used when explaining each function below.

Table 2: TIS functions

Function	Name	References
F1	Knowledge development and diffusion	Apell & Eriksson, 2023; Hekkert et al. 2007
F2	Legitimation	Apell & Eriksson, 2023; Bergek, 2019
F3	Resource mobilization	Apell & Eriksson, 2023; Bergek, 2019; Hekkert et al. 2007
F4	Guidance of search	Hekkert et al. 2007
F5	Entrepreneurial experimentation	Apell & Eriksson, 2023; Bergek, 2019; Bergek et al. 2008; Hekkert et al. 2007
F6	Market formation	Apell & Eriksson, 2023; Bergek, 2019; Hekkert et al. 2007
F7	Development of positive externalities	Apell & Eriksson, 2023; Bergek, 2019; Bergek et al. 2008; Hekkert et al. 2007

2.6.1 Knowledge development and diffusion

Knowledge development and diffusion are the processes of broadening and deepening the knowledge base of a TIS, and creating new knowledge by sharing information between actors. In the case of this thesis, knowledge development is Sweden's process of creating knowledge of implementation strategies, available technologies, procedures etc. when it comes to implementation of the EHDS. Knowledge development is usually created by universities, research institutes, and companies, and are often publicly funded (Bergek, 2019). This can be assessed by the number of publications on the subjects, as well as the assessment of experts in the area (Apell & Eriksson, 2023). Knowledge diffusion is characterized as the exchange of information in networks, "learning by interacting" for example (Hekkert et al. 2007, n.p.). In this study, the extent of knowledge development and diffusion will be determined by the opinion of interviewed experts on the subject of EHDS, to which extent they perceive general knowledge and awareness is sufficient, and how well they share that knowledge.

2.6.2 Legitimation

Legitimation refers to the TIS achieving regulative, normative and cognitive legitimacy in the eyes of relevant stakeholders. That means that if the TIS is perceived to be legitimate, it complies with laws and regulations, societal norms (morally acceptable), and expected behavior (Apell & Eriksson, 2023; Bergek, 2019). Legitimation is closely connected to the perceived benefits of the TIS, which can be undermined by disappointing results in the early development, but in emerging industries it can be strengthened by gaining certificates or by being given grants for its efforts. Also, perceived impact on health can either weaken or strengthen the legitimation (Bergek, 2019). As the EHDS is an upcoming legislation, the legal aspect of legitimation will be partly disregarded since the systems created for integration with the EHDS will likely comply with it. The questions formulated to determine legitimation concerns the perceived benefits and acceptance of the EHDS, as well as in any major objections exists.

2.6.3 Resource mobilization

Resource mobilization is exactly what it sounds like: the acquisition of required resources which are needed for the TIS, specifically funding, human resources (manpower and competence), and infrastructure (Apell & Eriksson, 2023; Bergek, 2019; Hekkert et al. 2007). Sufficient resources are necessary to make production possible, and besides acquisition of human capital, monetary capital and infrastructure, it can also be exemplified by long-term R&D programs (Bergek, 2019; Hekkert et al. 2007). In the case of the EHDS, which incorporates both the primary- and secondary use of health data, this entails resource mobilization for both the public sector, the Swedish regions and municipalities, as well as the private sector. To determine resource mobilization, this study concerns itself with what kind of resources are being invested at this time, and where they come from, as well as development of infrastructure.

2.6.4 Guidance of search

As resources are almost always limited, including time, specific focus for development is often chosen (Hekkert et al. 2007). Therefore, guidance of the search refers to the mechanisms influencing the choice of strategic and technological path moving forward that most positively affect the specific wants of users (Hekkert et al. 2007). Estimation of this function will therefore be judged on whether efforts are being put into the right place, and if different fractions across the country influence this direction for differing purposes.

2.6.5 Entrepreneurial experimentation

Entrepreneurial experimentation refers to the trial-and-error experimentation with new technologies, applications, and strategies (Apell & Eriksson, 2023; Bergek, 2019). Entrepreneurs are essential to a TIS as their role is to turn potential into new business opportunities, and their presence is a prime indicator of good performance of a TIS (Hekkert et al. 2007). Uncertainty is a fundamental feature of technological and industrial development, and entrepreneurial experimentation is the main factor in reducing these uncertainties (Bergek et al. 2008). Some associate entrepreneurs with small or new firms, however, in this context

they can be any kind of actor who experiments with the new technology in question (Bergek, 2019). To examine entrepreneurial experimentation, interviewees were asked if and to what extent experimentation has begun, as well if it's considered to be a sufficient amount.

2.6.6 Market formation

Market formation refers to the opening of a space in which goods and services can be exchanged in semi-structured ways (Apell & Eriksson, 2023; Bergek, 2019). This also includes an articulation of demand, as well as the creation of a protected space for the technology, such as laws, regulations and policies to enhance use and development (Bergek, 2019; Hekkert et al. 2007). It can also be judge on market size (Bergek et al. 2008), which in the purposes of this thesis will be interpreted as number of organizations in the TIS.As the EHDS is yet to go into effect and hence no real exchange of goods and services yet, this aspect will mainly be judged on the national policies Sweden chooses to adopt, as well as the amount of organizations entering the space for this preparation. Market formation will therefore be assessed by questions meant to discern if a sufficient amount of organizations and authorities are working on the preparation for the EHDS, as well as if regulations or incentives exist to promote the EHDS and create a protected space.

2.6.7 Development of positive externalities

"Development of positive externalities refers to the creation of system-level utilities" (Bergek, 2019, n.p.), which basically entails positive things revolving around the TIS, such as pooled labor markets, complementary technologies, specialized suppliers and even entry of new firms into the market (Bergek, 2019). This can be assessed by looking at the establishment of international standards being set and the formation of formal networks between actors (Apell & Eriksson, 2023). Development of positive externalities is a function not always included in the TIS framework (Bergek, 2019), which might be because it works through strengthening the other functions and is thus not independent (Bergek et al. 2008). It will nonetheless be included in this paper to get a comprehensive view of the TIS as possible. As international standards are the foundation from which the EHDS is built upon, this paper will assess the development of positive externalities by the extent to which network and collaboration has been formed, and if any unforeseen recurring topics emerge throughout the interviews that don't totally fit into other functions as we see them.

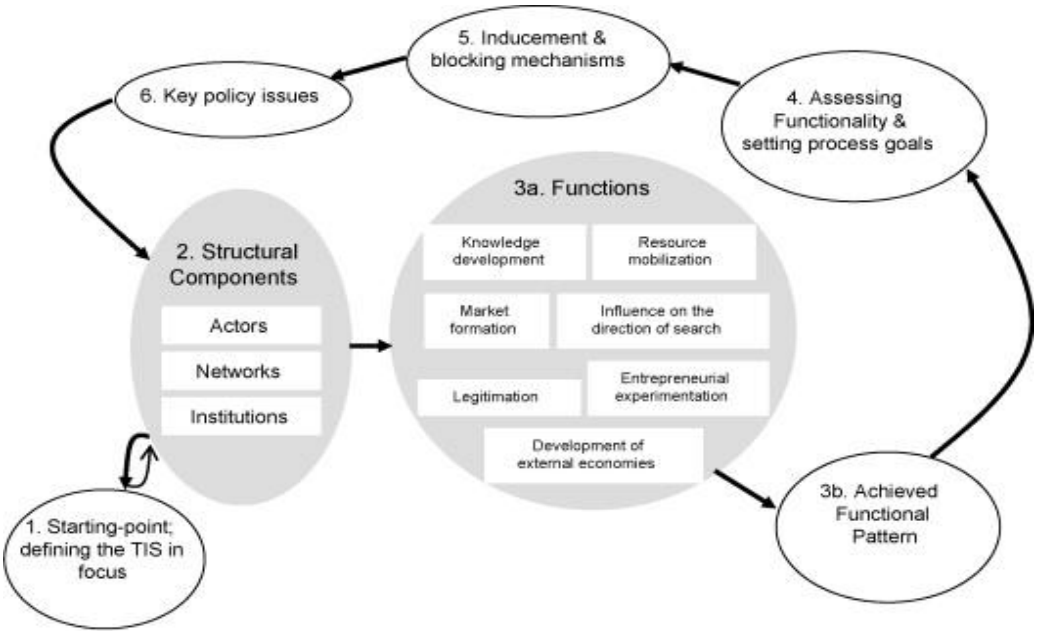

Fig 1. "The scheme of analysis" (Bergek et al. 2008).

2.6.8 Motivation and criticism for the use of TIS framework

Over the last few decades technological innovation systems framework have gained notoriety in the academic sphere (Bergek et al. 2015), which focuses on understanding how the innovation system around a particular technology functions (Bergek et al. 2008; Carlsson and Stankiewicz, 1991; Hekkert et al. 2007; Markard & Truffer, 2008). Furthermore, "these approaches have proven to be instrumental for informing a wide range of pressing public policy problems" (Bergek et al. 2015, n.p.). This thesis paper uses the functions approach as part of the TIS framework since it has been described as the most influential conceptual part (Markard, Raven & Truffer, 2012), and has been used by over 200 published papers as of 2019 (Bergek, 2019.

Moreover, TIS has been widely used to study emerging technological fields (Markard, Hekkert & Jacobsson, 2015), much in line with the study by Apell and Eriksson (2023), as mentioned under *2.6 Technological Innovation Systems Framework.* And is often used "to identify shortcomings and to derive recommendations for the design of policies in support of a specific technology" (Markard, Hekkert & Jacobsson, 2015, n.p.). Furthermore, the TIS framework is primarily used in studies with a qualitative approach (Walrave & Raven, 2016), which is in line with this thesis paper.

However, most studies incorporating the TIS framework puts much focus on sustainable innovation (Bergek, 2019) which this paper isn't directly in line with. Although, there's been a rise in interests of studying sectoral transformation and socio-technical transitions using the TIS framework. Furthermore, Markard, Hekkert and Jacobsson (2015) published a paper responding to six frequent criticisms against TIS where they identified four areas that could benefit from improvement and further development. They include geographical considerations, the interaction between a TIS and its existing institutional structures, micro-level processes such as those discussed in *2.7.7 Development of positive externalities*, and analysis of socio-technical transitions.

Socio-technical transitions can be defined as “technological changes that transform the way society functions such as transportation, communications, and housing are realized” (Nesari et al. 2022, n.p.), and is therefore the criticism most applicable to this study. The major criticism or shortcoming of the TIS framework in regards to socio-technical transitions is that it is too rigid to be applied to larger sector transformations and the interaction of multiple technologies, which is typical for large sector transformations (Markard, Hekkert & Jacobsson, 2015). However, Markard, Hekkert and Jacobsson (2015) are confident that the TIS framework is well equipped to deal with socio-technical transitions since, through functions as the base for TIS evaluation, it reveals system weaknesses and blockage.

2.7 Summary of Literature Review

Table 3: Literary Summary: EHDS and TIS Framework Context

Element	Factors	References
Background of the need for innovation that led to the EHDS	Aging population	AI Sweden, 2024; Apell & Eriksson, 2023; Rye & Göransson, 2021; SCB, 2023
	Lack of healthcare professionals	Apell & Eriksson, 2023; Dagens Medicin, 2023; EIT Health, 2023; Socialstyrelsen, 2023b
	Rigidities in existing technological and regulatory environments	European Commission, Directorate-General for Health and Food Safety, 2022b; Tucker, 2023; Österberg & Lindsköld, 2020
History of data sharing	GDPR and Sweden’s harsh interpretation	IMY, 2023; SBU, 2024
	EHDS as a compliment to the GDPR with sole focus on healthcare	Burden et al., 2023; EHDS, 2024; Horgan et al. 2022; Neher et al., 2023; Socialstyrelsen, 2023; Tucker, 2023; Österberg & Lindsköld, 2020
The EHDS	How it works	Deloitte, 2024; EHDS, 2024; EIT Health, 2023;EU Commission, 2022; European Commission, Consumers, Health, Agriculture and Food Executive Agency, 2021; European Commission, Directorate-General for Health and Food Safety, 2022a; European Commission, Directorate-General for Health and Food Safety, 2022c; Fåhraeus, Reichel & Slokenberga, 2024; He, 2023; Kotsareli & Tsachouridis, 2023; Machadoand & Polónia, 2022; Molnár-Gábor, 2022; Proso, 2024; Socialstyrelsen, 2023a; Sveriges Kommuner och Regioner, 2024
	How it can help and challenges to get there	Deloitte, 2024; EIT Health, 2023; European Commission, Consumers, Health, Agriculture and Food Executive Agency, 2021; European Commission, Directorate-General for Health and Food Safety, 2022a; European Commission, Directorate-General for Health and Food Safety, 2022b

	Sweden's current alignment	Cederberg, 2023; EIT Health, 2023; EU Commission, 2022; European Commission, Directorate-General for Health and Food Safety, 2022a; Fahlen & Rosenqvist, 2010; Fragidis & Chatzoglou, 2018; Nordiska Ministerrådet, 2024; Silvestri, 2024; Sveriges Kommuner och Regioner, 2021; Swedish eHealth Agency, 2024; Swedish Government Offices, 2024; Wretborn et al. 2021
Technological innovation systems (TIS) framework	Dissemination of its factors	Apell & Eriksson, 2023; Bergek et al. 2008; Bergek, 2019; Hekkert et al. 2007
	Criticisms and applicability	Apell & Eriksson, 2023; Bergek, 2019; Bergek et al. 2008; Carlsson and Stankiewicz, 1991; Hekkert et al. 2007; Markard & Truffer, 2008; Markard, Hekkert & Jacobsson, 2015; Markard, Raven & Truffer, 2012; Nesari et al. 2022; Walrave & Raven, 2016

The chosen categories for *Table 3 - Literary Summary: EHDS and TIS Framework Context* are drawn from the literature on the EHDS, most importantly from official reports and website articles published by the EU commission (EHDS, 2024; EU Commission, 2022; European Commission, Consumers, Health, Agriculture and Food Executive Agency, 2021; European Commission, Directorate-General for Health and Food Safety, 2022a; European Commission, Directorate-General for Health and Food Safety, 2022b; European Commission, Directorate-General for Health and Food Safety, 2022c), but also the Swedish eHealth Agency and the National Board of Health and Welfare (Socialstyrelsen 2023a; Swedish eHealth Agency, 2024). Even though these reports come from respectable sources, academic literature was also incorporated to further corroborate statements and discuss findings. As the EHDS is a quite new topic much available information comes from these kinds of sources, since academic literature takes longer to create.

The "background of the need for innovation that led to the EHDS" aspects of the summary are viewed as context to what led up to the legislation, and the "current AI innovation" is further background to display an interest and progress, but need for more available health data in order to innovate. "History of data sharing" ties into the compliment for GDPR, as strict data laws are what has halted much of innovation within healthcare, as well as rigidities in existing IT-infrastructure. "The EHDS " has a number of subcategories which explain how the EHDS is currently planned to work, as well as the challenges and opportunities that we face. Moreover, it also contains literature on what work is currently being done in Sweden to enforce required IT-infrastructure. Lastly, "Technological innovation systems (TIS) framework" is sub categorized by what it is and how it works, as well as dissemination of applicability and criticism. This is done in order to give insight into the chosen framework and to be transparent about why it was chosen.

3 Methodology

This chapter presents the research strategy and philosophy underpinning our study, detailing the design, scientific approach, and data collection methods employed. It provides an overview of the methods chosen for gathering and analyzing data, as well as the analytical procedures used to interpret the empirical findings. Additionally, this chapter discusses ethical considerations and addresses potential research limitations, ensuring a thorough understanding of the framework guiding our investigation.

3.1 Research Philosophy

Lee (2004) underscores the importance of philosophical inquiry in research, particularly useful for improving the understanding of information systems and enhancing fundamental research methodologies. According to Lee (2004) and Hassan, Mingers & Stahl (2018), addressing philosophical questions is important for ensuring that research is not only technically strong but also meaningfully placed within a broader societal and ethical context. Their views collectively emphasize the vital role that philosophy plays in strengthening the integrity and depth of research across various disciplines.

This study adopts the interpretivist philosophy aiming to understand and identify potential current blocking mechanisms in Swedish healthcare regarding preparation for implementation of the European Health Data Space (EHDS) law. As described by Goldkuhl (2012), the interpretive philosophy provides a comprehensive framework for understanding the subjective and social dimensions of information systems phenomena, emphasizing this phenomenon, Mingers (2004) points out the significant role of human interaction and interpretation in shaping this framework. According to Mansour et al. (2009) & Lee (2004), researchers using the interpretive approach aim to deeply understand information systems phenomena by progressively recognizing and including the social and organizational aspects of their subjects.

Further supporting the use of interpretivism in our methodology, Goldkuhl (2012) emphasizes the connection between qualitative research and interpretivism. He argues that interpretive methodologies are highly effective for studying the adoption and use of information technologies within organizational contexts. These methodologies are particularly adept at exploring the subjective experiences and meanings of individuals, making them well-suited for analyzing complex social and technical phenomena, where understanding human factors is important. This perspective is important as it ensures that our study not only captures the technical aspects of EHDS implementation but also delves into the human experiences and organizational dynamics involved.

Similarly, Levers (2013) explains that the interpretivist approach leads to research outcomes based on the researcher's personal understanding of the data, shaped by their independent thought processes, unhindered from external reality. This underscores the relativistic nature of the findings, where outcomes are constructed through the researcher's subjective perspective rather than discovered as objective truths.

Based on these insights, we have determined that interpretivism is an appropriate theoretical framework for our research. Our focus is on exploring and identifying possible blocking mechanisms in Swedish healthcare for the implementation of the EHDS law, particularly from the perspective of experts working in two of the biggest regions in Sweden, how well the healthcare sector can adopt and integrate this law, emphasizing the importance of considering both personal perceptions and organizational capacities in this context.

3.2 Research Approach

The choice of research strategy for our thesis is based on the current scope and the time constraints we need to comply with. Therefore, we have chosen to conduct a qualitative interview research. Qualitative research can vary considerably, and the concept is broad and interpreted differently by different researchers (Ahrne & Svensson, 2015). Despite these variations, there are common core characteristics, especially concerning the role of the researcher, where according to Ahrne & Svensson (2015), in qualitative research the researcher is much closer to both the environment and the people being studied compared to quantitative methods. This is particularly relevant for our work, where we aim to explore experiences, perceptions and opinions. Ahrne & Svensson (2015) further explains that qualitative methods also offer great flexibility, allowing the researcher to alternate between data collection and empirical analysis, which we intend to utilize to create a more adaptable research design that allows for different approaches to achieve our purpose.

According to Denscombe (2018), qualitative research is limited to fewer subjects and objects but allows for a deeper understanding of the phenomenon being studied, unlike quantitative studies that are based on numbers and are more static. This is applicable to our study because we are seeking answers to a complex issue only experts on the matter would be able to give us. Qualitative research treats social realities as complex phenomena that cannot be analyzed in isolation from their environment (Rienecker & Jørgensen, 2014). This means that when we investigate the possible blocking mechanism in Swedish healthcare regarding the implementation of the EHDS law, we must consider the context. We adopt a wider perspective where various factors and actors are considered before making judgments about the generalizability and transferability of our research. Therefore, a qualitative approach is suitable for our purpose and our research questions.

According to Johnson & Onwuegbuzie (2004), qualitative research requires considerable time and resources because interviews need to be planned, processed, and analyzed. Given the critical role of resources in shaping research strategy, our study had a limited scope. The limited resources further shaped our strategic approach and the execution of the research. The time source affected both the variety of topics we could look into and how deeply we could analyze them. Guest et al. (2006) emphasizes the importance of carefully determining the number of interviews in a research study. Consequently, following the recommendation of

Marshall et al. (2013) to conduct a minimum of six interviews to obtain meaningful data, our research includes six interviews.

3.3 Data Collection Methods

Interviews have been chosen as the method for data collection in our study. This choice is rooted in the specific nature of our research question. The method of interviews is particularly effective, as highlighted by Denscombe (2018), because it allows for the exploration of how values influence the perceptions and experiences of those involved with exploring the possible blocking mechanism in Swedish healthcare for implementation of the EHDS law. We chose semi-structured interviews to prioritize flexibility and depth in our study. According to Brooks, Horrocks, and King (2018), this flexibility allows researchers to adjust their questions and focus as new insights and patterns emerge during the interview process, leading to a deeper understanding of the topic.This adaptability is especially valuable in the study of topics with limited research or incomplete understanding, such as our topic dealing with a law that has not yet been enacted. Patton (2014) emphasizes that this flexibility ensures that researchers remain open to new discoveries and perspectives, which is essential to our research.

3.3.1 Littereture view

According to Recker (2021) a literature review is considered to be of great importance in all studies as it facilitates the process of understanding the existing literature in the field and the existing theoretical. Rienecker & Jørgensen (2014) explain that while searching for literature can start with Google, it is important to include various search databases for a systematic search in a study. They emphasize that to effectively understand the content of studies, one should read the abstracts. Oates (2006) highlights that internet sources can be unreliable, so a careful judgment when selecting information to include, is crucial. Therefore, on the academic side of the research, we focused on academic literature discussing the EHDS from both a Swedish and EU legislative perspective. As shown in Table 3, we used literature discussing the background of the need for innovation that led to the EHDS, the history of data sharing, the EHDS itself, and the Technological Innovation Systems (TIS) framework.

The initial literature review revealed a general lack of academic studies on the implementation of the EHDS in Sweden. We attribute this to the relatively new nature of the topic, as the EHDS has not yet been implemented. Therefore, to find more specific information, a search was conducted on Google. The information found came from major stakeholders in the field, such as preliminary studies by the National Board of Health and Welfare (Socialstyrelsen) and the eHealth Agency (E-Hälsomyndigheten), which propose a roadmap for implementing a national digital infrastructure for healthcare. We also found reports from the EU commission to be of value, as they disseminate their understanding of the current state of the EU and its member states in regard to the EHDS. This was considered relevant as they are the ones drafting the legislation, but to ensure no biased opinions prevailed we corroborated statements with academic literature where possible. Thereby, the literature review includes reports by these large authorities and white papers discussing the subject.

3.3.2 Pilot interview

According to Majid et al., (2017), an effective way to start the interview process in qualitative research is by conducting a pilot interview. Furthermore Chenail (2011), states that pilot interviews in qualitative research serve as a critical step to test interview protocols and identify potential researcher biases. These interviews allow the researchers to refine their methods on a smaller scale to ensure the procedures work as planned, ultimately enhancing the reliability and effectiveness of the research methods before embarking on larger studies. Therefore, a pilot interview was conducted with Stefan Jovinge, President of Research and Education at Scania University Hospital. Insights gained from this interview significantly influenced the shaping of the literature review and the interview guide. Additionally, new insights from the field led to a change in the study's focus towards exploring potential barriers to the implementation of the European Health Data Space (EHDS) law in Sweden. A follow-up interview was conducted with Stefan Jovinge to obtain complete reflections on themes that were subsequently integrated into the interview guide.

3.3.3 Respondent selection

According to Recker (2021), selecting the appropriate participants is an important aspect, which we find essential in our work. Patton (2015) explains that the scope and size of a study are influenced by several factors, categorized into three main areas: the research objectives, the available resources, and the nature of the research itself. We started the process early to ensure that a diversity of organizations is included. We chose to use expert sampling, a non-probability sampling method which Bhattacherjee (2012) describes as where respondents are selected based on their specialized knowledge of the subject matter, in our study: the EHDS and the Swedish healthcare system. This choice was motivated by the need to delve deeply into the possible blocking mechanism of the implementation of the EHDS law within Swedish healthcare. Initially, we were uncertain about which specific companies or organizations to contact, but we knew that stakeholders within the healthcare sector and the authorities responsible for implementing Sweden's digital laws would be involved.

Sampling, choosing respondents carefully, enables the collection of targeted and meaningful data that is directly relevant to our research question (Bhattacherjee, 2012). By focusing on these specific groups, we increase the chances of gathering data that is not only informative but also allows for a controlled and thorough analysis of the collected information. Bhattacherjee (2012) states the importance of noting that while expert sampling provides access to high-quality insights from knowledgeable experts, the results from this type of sampling are not generalizable to a larger population. However, this limitation is acceptable within the scope of our study, which aims to understand specific dynamics and preparations within an area of expertise rather than drawing broad conclusions about the entire population. This targeted approach ensures that we gather rich, contextual insights from those directly shaping and impacted by EHDS-regulations in healthcare.

After researching empirical information about EHDS and its implementation, we began identifying and contacting key actors—such as those who had published articles or posted on LinkedIn about their participation in EHDS-related conferences. We focused on companies and individuals who were central within the digitized Swedish healthcare system. By selecting respondents based on their roles and direct involvement in the subject, we ensured that they had relevant and in-depth knowledge of the technical and organizational aspects of EHDS.

The participants were carefully selected and contacted via LinkedIn and email, chosen for their professional relevance and active involvement in both healthcare and digital knowledge, as well as their participation in the implementation decisions of the EHDS law. This selection process and the communication methods were strategically chosen to engage individuals who are well-informed about the EHDS law and the level of digitalization in Swedish healthcare, and who are positioned to influence its implementation. After selecting relevant companies for our study, we created an email template and a brief LinkedIn message in Swedish, which we sent to potential respondents. However, a number of the individuals contacted declined to participate, expressing uncertainty about the subject of the EHDS law. The initial communication with participants aimed to establish a solid foundation for informed consent, clearly outlining the research objectives and ensuring transparency regarding the rights of participants to anonymity and their preferred formats for interviews—whether face-to-face or through digital platforms like Zoom or Google Teams. This approach highlights the adaptability of the research and its sensitivity to the needs and concerns of the participants, emphasizing the importance of ethical considerations and the comfort of participants in qualitative research.

Since the respondents provided insights into the subject area, which they identified as being new and not yet implemented, some of them preferred not to be the first to publicly comment on the subject. Consequently, they requested anonymity, leading us to include only their roles and the size of the organization of those in the documentation. The anonymity perspective will be explained in section *3.5 Ethical Considerations.* Organizations that chose not to remain anonymous in the study include Sveriges Kommuner och Regioner (SKR**)**, Region Skåne, and Social styrelsen. The details about all the respondents and the interviews are listed in the following tables, *Table 4: Summary of Respondent Details* & *Table 5: Summary of Interview Details* .

Table 4: Summary of Respondent Details

Respondent	**Role**	**Organization**	**Organization size (≈ Employees)**
R1	AI Transformation Strategist	Organization 1	70
R2	Healthcare Transformation Strategist	Organization 1	70
R3	Healthcare Director	Organization 2	415 000
R4	Head of Unit, Department for Analysis and Investigation	Organization 3	280
R5	President of research and education	Region Skåne	37000
R6	Strategist	Sveriges Kommuner och Regioner	440
R7	Senior Consultant	Socialstyrelsen	700

Table 5: Summary of Interview Details

Respondent	Interview Date (DD/MM/YYYY)	Communication Channel	Duration (minutes)
R1 & R2	16/04/2024	Teams	58 min
R3	25/04/2024	Physically	50 min
R4	28/04/2024	Skype	52 min
R5	06/05/2024	Teams	58 min
R6	06/05/2024	Teams	54 min
R7	08/05/2024	Zoom	52 min

3.3.4 Design of the Interview Guide

According to Recker (2021), qualitative research includes a broad array of data types and various forms of communications. The most common method for collecting qualitative data is through interviews, which Recker (2021) describes as “conversations with purpose”. It allows researchers to gather deep insights from key informants with specialist knowledge due to their roles within the study context.

The choice of semi-structured interviews as a methodology reflects a strategic decision aimed at providing both flexibility and depth (Recker, 2021). This approach aimed to create an environment where participants can freely and openly share their experiences and thoughts about Sweden's healthcare, particularly in the context of implementing the EHDS law, without limitations.

Our research guide serves to support our research question and aim, and in order to ground our work in existing research and promote scientific quality we originally took inspiration from a study mentioned earlier in this study by Apell and Eriksson (2023). They used the Technological Innovation Systems (TIS) framework in their study to assess “system-blocking mechanisms for AI healthcare technology innovations” (Apell and Eriksson, 2023, n.p.) in Sweden and based this on the framework's functions. This then led us to base our interview guide on research by scholars on the TIS framework (Bergek, 2019; Bergek et al. 2008; Hekkert et al. 2007) and used the functions of the framework they describe as the foundation.

The following table, *Table 6 - Interview Guide - Themes*, outlines the interview questions divided into themes based on the TIS framework. It is further broken down into sub-themes that clarify the aim for each question, in order to provide a clearer picture.

Table 6: Interview Guide - Themes

Theme	Subtheme	Factor
Introduction		1. Can you tell me a little about yourself, your workplace, and your daily tasks?
		2. Would you say that Sweden is on track to meet the demands imposed by the EHDS?
Stakeholder Analysis		3. Which research organizations are the main players in today's development of innovation systems for healthcare?
		4. Which organizations are the main players in today's development of systems that support the EHDS?
		5. Which organizations are the main players in the implementation and development of these technologies? (**Also Resource mobilization)**
		6. Which regions or government initiatives are leading in this matter?
Knowledge development and diffusion	Actual current knowledge	7. Where would you say the level of knowledge about the EHDS in Sweden and Swedish healthcare stands? This could be among researchers and experts, but also other people affected by the EHDS.
		8. How well are people currently sharing information and best practices regarding the EHDS?
	Extent to which knowledge is shared	9. How would you rate the research base, meaning the amount of research, regarding EHDS in Sweden?
		10. How knowledgeable are both private and public actors in integrating their systems with the EHDS' pseudonymized data?
	Research	11. Who are the major contributors of knowledge in Sweden when it comes to managing EHDS and developing the technology it requires?
		12. How are people informed about EHDS and its implications and consequences?
Legitimization	Perceived benefits	13. What do you think about the acceptance of EHDS in healthcare?
		14. How do you view the end product of EHDS, more positively or negatively?
	Perceived drawbacks	15. What are the main objections people have against EHDS?
Resource mobilization	Monetary resources	16. What type of resources are being invested in technology to handle the demands of EHDS?
	Human capital	17. What resources and investments are currently available to tackle the demands of EHDS, and are they sufficient?
	Technical infrastructure	18. Where do the largest investments in EHDS come from? - Who are the biggest investors in EHDS technologies?

Guidance of search	Direction of development	19. Do you think that the current focus is on the right sub-goals? That is, are we on the right track with the correct priorities?
	Influence on development	20. Do various authorities, such as politicians, industry leaders, or appointed experts, set healthy goals in preparation for EHDS?
		21. What are your goals when it comes to preparing for EHDS?
Entrepreneurial experimentation	Amount of experimentation with potential new technical solutions	22. Can you tell us about any initiatives by organizations, institutions, or companies aimed at working with technology and processes specifically for EHDS?
		23. Do you think that technology supporting EHDS regulations for data management has begun to be experimented with and to a sufficient extent?
	Experimentation with existing technical solutions	24. How have Swedish organizations generally reacted to the technical demands that EHDS imposes?
		25. How important do you think entrepreneurship and innovation from the private sector will be in the preparation for EHDS moving forward?
Market formation	Number of organizations in the TIS	26. Do you think Sweden is promoting the preparation for EHDS with incentives or new regulations?
		27. Do you believe that enough organizations are working on preparing for EHDS? - For example, private entities that will be able to use the data, or authorities that will build the infrastructure.
	New organizations entering the TIS	28. What market opportunities and barriers do you think exist today for Swedish organizations in developing technologies for EHDS?
		29. How well is the market preparing for these opportunities and barriers?
Development of positive externalities	Forming of formal networks	30. Do you think there are established networks among various actors working on this (the preparation for EHDS), and how well do they function?
	Potential barriers hindering efficient networks	31. How does the collaboration between healthcare and industry work in the preparation?
		32. Are there any laws or other regulations that currently prevent effective cooperation and/or networking among relevant actors in preparation for EHDS?
Final Questions		33. How prepared are organizations working in healthcare to manage data in the way that EHDS intends?
		34. How far would you say Sweden is from being able to share and use data in the manner intended by EHDS?

This structured approach helps in organizing the research data efficiently, allowing for a clearer analysis of the various themes and subthemes related to the study. Each question is categorized based on its relevance to these themes, ensuring that the research findings are systematically presented and easy to interpret.

3.3.5 Transcribing

Transcribing is a time-consuming process, but it provides valuable close interaction with the information (Denscombe, 2018). According to Linneberg & Korsgaard (2019), transcribing the collected data is a relevant approach for documenting an interview (Linneberg & Korsgaard, 2019). It helps capture detailed conversations during interviews, making them easier to manage and analyze. This process is important for understanding and discussing the overall results of all the interviews (Oates, 2006).

The data collected in this study was obtained through interviews, which were recorded and later transcribed by the authors. To start, the audio files were transcribed using Whisper, an open-source Automatic Speech Recognition (ASR) model, with the authors initially focusing on the accuracy of the content rather than grammatical correctness. Later, the authors verified the transcription along with the audio to ensure the information was correct and then deleted the files from the website. Due to the poor quality of some recordings, one of the interviews was transcribed again using the AI tool Klang.ai. This transcription was later deleted from the source to secure the data. Therefore, it should be noted that not all words could be identified. We have marked those places with 'XXX'. All the interviews can be found in Appendices 2 through 7. The transcription Appendix includes two tables, the first one includes a brief description of the interviewees, including their names, respondent codes, and organizations. Additionally, the transcript table includes the participants' initials and last names, the dialogue (questions and answers) and the codes; which will be further explained in section *3.4.1*.

3.4 Data Analysis

According to Recker (2021), collecting data in qualitative research involves handling a large amount of complex and unstructured data. According to Patton (2015) & Recker (2021), this large amount of data often tends to be unique in various ways. Patton (2015), explains that the analysis phase in qualitative research involves being able to access all the collected data, which may include filtering out the data to the most important and relevant to the purpose of the research. By reviewing our data multiple times and working together in our analysis, we strived to ensure that our results were reliable and valid. Our data from interviews, in addition to providing answers to interview questions, provides an overall picture of the complex reality within Swedish healthcare based on the participants' experiences in the field, which is further discussed in the discussion section.

3.4.1 Coding

As Recker (2021) mentions, to understand the data, it has to be structured. In order to set a structure to pour data, the method of coding was chosen. Recker (2021) describes this method as a way of organizing raw data in detail into different categories. This method is relevant to our research because the interviews each lasted over 50 minutes and had a lot of information to organize. By categorizing this information, we could find patterns more easily and better address the study's aim and structure the information.

Linneberg and Korsgaard (2019) highlight two different coding approaches, inductive and deductive. Inductive coding involves developing codes and categories directly from the data,

while deductive coding involves creating codes and categories based on the researchers' prior knowledge from the literature and the study's scope. Deductive coding is most appropriate for studies where theoretical themes are directly prevalent (Linneberg & Korsgaard, 2019). In our case, this applies to the TIS framework, which provided us with seven functions.

Nowell et al. (2017) describes thematic analysis as a method that simplifies the identification and analysis of patterns, creating structure in the empirical data. This approach is mainly characterized by the researcher's creation of themes and sub-themes, which organize the data and provide a detailed description with minimal changes. In this study the TIS framework was used to organize our thematic analysis in accordance with Apell and Eriksson (2023), Bergek (2019), Bergek et al. (2008) and Hekkert et al. (2007). We started by dividing the research questions into the seven functions of the TIS framework and then further broke these down into sub-themes, as shown in Table 7. This setup allowed us to color-code the interviewees' responses according to these subcategories, which helped streamline both the tracking and analysis stages. By matching similar responses, we could visually organize the data and more easily spot patterns and links between different themes. In the appendices, the highlighted text matches one or more subcategories from the TIS framework's functions. To make the coding easier to read and use, we used unique codes to these subcategories and grouped them under broader supercategories, i.e. the functions. When multiple functions apply to the same piece of text—a paragraph, statement, or sentence—we use the most relevant color for highlighting, though less relevant codes are also listed in the code column. This approach helps us see which TIS functions are more or less evident and helps identify any significant differences.

Table 7: Data Coding Structure

Function	Color	Sub-themes	Code ID
Knowledge development and diffusion	Red	Actual current knowledge	KDD
		Extent to which knowledge is shared	
Legitimation	Orange	Perceived benefits	LG
		Perceived drawbacks	
Resource mobilization	Green	Monetary resources	RM
		Human capital	
		Technical infrastructure	
Guidance of search	Blue	Direction of development	GS
		Influence on development	
Entrepreneurial experimentation	Magenta	Amount of experimentation with technical solutions	EE
		Experimentation with existing technical solutions	
Market formation	Pink	Number of organizations in the TIS	MF
		New organizations entering the TIS	
Development of positive externalities	Gray	Forming of formal networks	DPE
		Potential barriers hindering efficient networks	

3.5 Ethical Considerations

The ethical framework of our study is grounded in principles of integrity, trust, and respect. These principles, which are fundamental to any research involving human participants and data, guide our compliance with the ethical perspectives offered by Oates (2006) and Patton (2015).

Oates (2006) highlights the importance of a participatory approach, emphasizing the respect for participants' autonomy and dignity. This aligns with our goal to actively and respectfully engage participants, acknowledging their essential contributions and upholding their organization. His focus on informed consent, confidentiality, and the unconditional right to withdraw underpins our ethical standards. Building upon this, Recker (2021) emphasizes the importance of informing participants about how their data will be managed, stored, and protected to ensure confidentiality and anonymity, in order to maintain their privacy.

Wiles' (2013) principles were followed to obtain full consent from the participants. They were informed about the research aims, ensured anonymity for those who requested it, provided with details about their participation, and informed on how to withdraw from the study. Additionally, each interview began with the participant's permission to record the session, in line with Wiles' (2013) recommendations.

Thereby we shared information about respondents' citations and opinions used and checked for consent during and after the interviews. Patton (2015) emphasizes the importance of being clear about ethical issues and considering the research's impact on participants. His approach focuses on understanding and sensitivity, stressing the researcher's duty to avoid causing harm and prioritize participants' well-being. To preserve anonymity, we took measures to prevent respondent identification and securely stored the research data (Patton, 2014). These actions included anonymizing personal information, using unique codes for respondents, and ensuring that all data was stored in secure, access-controlled environments. By implementing these actions, we aimed to protect the privacy and confidentiality of those participants who wished to remain anonymous throughout the research process.

Additionally, according to Recker (2021), it is important to fully share all study results openly, without hiding or omitting any findings. In that manner, respondents were informed via mail about the transcription of their interviews and contacted to review their data and share any thoughts about potential misunderstandings, as detailed in Appendix 8. Adopting these ethical perspectives, our study's methodological framework is designed to be transparent, participatory, and reflexively ethical, ensuring that our participants feel valued and understood throughout the research process—from initial contact to the final presentation of our findings.

In summary, our study uses important ethical theories to ensure the research is both ethically correct and methodologically strong. This approach improves our research design and makes sure our work not only adds to academic knowledge but also offers practical advice for implementing the EHDS law in Swedish healthcare. By meeting academic standards and addressing the needs of healthcare workers and policymakers, our findings are designed to be useful and impactful.

3.6 Scientific Quality

This study is a qualitative study conducted through semi-structured interviews. According to Saunders, Lewis, and Thornhill (2009), using qualitative research methods with semi-structured interviews can make risks to validity, reliability, and generalizability. Therefore, careful preparation of the interviews and thorough documentation have been prioritized throughout the process. Saunders, Lewis, and Thornhill (2009) further explain that reliability can be achieved with detailed documentation, which allows for what Bhattacherjee (2012) explains, if the study were to be recreated, the results achieved should be substantially similar. To further measure the concrete results and ensure they align with the study's purpose, validity is a key factor (Recker, 2021).

3.6.1 Validity & Credibility

According to Oates (2006) and Rienecker & Jørgensen (2014), a study with high validity indicates that the correct process has been followed, ensuring that the intended measurements have been accurately captured. To achieve this, we used reliable databases such as Lund University's library page (LubSearch), Diva-Portal, and IEEE Xplore Digital Library to find academic literature. Additionally, we consulted books and LinkedIn posts from professionals in relevant fields. We also used Google Scholar, with settings filtered to display only peer-reviewed articles, ensuring the high quality and relevance of the academic sources. Peer-reviewed articles undergo a process where experts in the same field review the research to confirm its accuracy and relevance before publication, as described by Elsevier (2024). Furthermore, due to few studies having been done on our topic, we complemented the literature with reports and white papers from respected organizations such as the EU Commission, government agencies and research institutions, and also a few news articles.

According to Saunders, Lewis, and Thornhill (2009), conducting high-quality interviews enhances the credibility of the research. This is why the researchers in this study were well-prepared to conduct interviews with a guide to follow. LeCompte and Goetz (1982) believe that this approach helps maintain some consistency in the semi-structured interviews, which facilitates replication of the study and improves external reliability (LeCompte and Goetz, 1982). The authors had also pre-negotiated with interviewees about the intended duration, which was between 50-60 minutes. During the scheduling of the interviews, the participants had the opportunity to review the study's purpose and ask additional questions to feel prepared for the interviews, with the option to decline if they found the subject too unfamiliar. These preparations were made to maintain the study's goal of enhancing participants' validity.

Additionally, we used member checking, allowing respondents to review the translated data for accuracy and to confirm their statements or propose any changes to their expressed views. This was done to give interviewees the chance to confirm the accuracy of statements and withdraw any information they did not want published (Creswell, 1994). Birt et al. (2016) describe this method as a way to confirm, validate, and assess the reliability of qualitative findings. By implementing these measures, we aimed to preserve the integrity and validity of the data, ensuring it accurately reflects the participants' perspectives. To ensure the validity of the data, the authors contacted the respondents after the interviews,

3.6.2 Reliability

Stenbacka (2001) argues that achieving validity in qualitative studies can be challenging, but reliability helps ensure the study's scientific quality. The reliability of the study can be assessed by examining the quality of the data measurement (Oates, 2006). Reliability implies that the same results should be achievable with repeated measurements, even if different researchers conduct them (Oates, 2006; Rienecker & Jørgensen, 2014). To minimize issues with reliability during the transcription of raw data, a careful process was carried out using the AI tools, Whisper, and Klang.ai, combined with review and revision of the transcription text. In order to ensure data security, the transcription was later deleted from the source. The thematic analysis was also conducted independently by both authors. By presenting the complete raw data in the appendices, we ensure that the reliability of the work is not affected by our note-taking or memory of the conversation. Finally, pilot testing was conducted to ensure the clarity of the interview questions.

3.6.3 Bias

Patton (2015) highlights that readers should consider potential researcher bias before reviewing the study. One potential bias we identified in our study relates to the language of the interviews and the study itself. The interviews were conducted in Swedish, allowing respondents to express themselves fluently. However, since the study is presented in English, the responses had to be translated. This translation process was carefully managed to minimize errors and preserve the original meaning.

4. Results

In this chapter, the results of the study are presented, based on findings from coding and thematizing the interviews. A table is provided to facilitate navigation through the work. Note that respondents 1 and 2 work for the same organization and were interviewed together, therefore we will consider their individual statements to be true for both of them. I.e. When we write "all respondents", but only R1 gave a statement on the issue, we consider R1 to speak for R2, unless R2 objects to the statement in question, and vice versa. Furthermore, at the end of each subcategory a short summary will be given to ease the reading experience.

Table 8: Interviewee Guidance Framework

Respondent	Organization	Role
R1 & R2	Organization 1	Healthcare Transformation Strategist
R3	Organization 2	Healthcare Director
R4	Organization 3	Head of Unit, Department for Analysis and Investigation
R5	Region Skåne	President of Research and Education
R6	Sveriges Kommuner och Regioner	Strategist
R7	Socialstyrelsen	Senior Consultant

4.1 Knowledge development and diffusion

4.1.1 Knowledge development

All respondents, except respondent 3, attest to there being a general lack of knowledge of how to implement the EHDS in Swedish healthcare to a certain extent, mostly due to a lack of specifications and guidelines being set.

While Respondent 3 says that there are not a lot of organizations currently working on preparations for the EHDS, but that there is activity among hospitals and regions, but said activity "*can consist of reading up on what's going on, trying to understand, and trying to see what we currently have*". Respondents 1, 4, 5, and 6 attribute this lack of information on how to move forward with the EHDS to the EU along with the Swedish government as they haven't released enough information for them to go off of yet. However, Respondent 7 simply explains that they've been waiting for more information which couldn't be given until the legislation was passed in April of this year. Which is neatly summarized by Respondent 6 as follows:

"*We don't know what we're supposed to do, or what will be required of us. Not even the governing authorities knows, at least not publicly.", "Yes, and we are trying to be a bit cautious. So far, we don't know exactly what is required. There are so-called preliminary texts that we naturally base our work on, but they are no official documents guiding us*" (Appendix 6: # 9, #24).

However, respondent 5 takes a more definitive stance, stating that "*They're [both the public and private sector] not knowledgeable [on this matter] at all. It's like, if you imagine a formula-1 race and we're somewhere in the back of the lineup due to us not taking the opportunity to modify GDPR*" (Appendix 5: # 22). Respondent 5 continues to state that confusion exists since the drafts of the legislation available to the public keep changing, which is strengthened by Respondent 7, who says that their knowledge has been based on the draft from 2022 until the legislation was approved in April and that negotiations, and therefore information, has before then been behind closed doors. Thus, keeping them out of the loop.

To reiterate, there's a general lack of knowledge regarding the EHDS across Sweden which is mostly due to the EU and governing Swedish authorities not releasing information. However, efforts are being made by relevant parties to inform themselves.

4.1.2 Knowledge diffusion

Regarding if the extent of which knowledge is shared is viewed as sufficient or not, the respondents gave split answers. Respondent 7 said outright that the sharing of information is "*not good at all* " (Appendix 7: # 56), while respondent 1 expressed that the collaboration "*isn't that well working as of yet*", which is strengthened by Respondent 4, who says that "*it could definitely be better, considering that they now basically have a finished EHDS regulation [...] so more active contributions are needed*". Furthermore, Respondent 4 identifies Vinnova as a skilled innovation agency and a research consortium involved in EU-funded projects.

Respondent 5 alluded to there being a lot of confusion at this time and them waiting patiently for the report by the Ministry of Health and Social Affairs in order to take the next steps.

However, respondents 3 and 6 insist that there's a good amount of information flowing between relevant parties, whereas Respondent 3 cites the eHealth Agency's and the National Board of Health and Welfare's work on informing organizations about the EHDS. Where Respondent 6 says that the regions are doing good work on informing and helping each other.

It should also be noted that all respondents state in some form that information sharing and collaboration is a recognized need and efforts are being made to mitigate this. Respondent 6 stated, "*Obviously, you can always do more, but I think we're starting to get better at it*" (Appendix 6: # 19).

In short, information sharing is limited and some are waiting for the report by the Ministry of Health and Social Affairs. This issue is also being dealt with to some extent as it is viewed as a recognized need.

4.2 Legitimation

4.2.1 Perceived benefits

All Respondents stated that they believe there to be a general positive view on the the EHDS, as the perceived benefits are seen as needed. Respondent 2 mentions the potential for the EHDS to reduce administrative burden, while respondents 4, 5 and 6 strengthen that, they also perceive the potential benefits for innovation as strong.

Stated "*[in a] safe way to be able to share health data for both today's healthcare, as well as tomorrows*" (Appendix 4: # 49), and "*we're positive to that health data will be used to help other patients*" (Appendix 6: # 39) "*I believe that this is a great opportunity to improve healthcare*" (Appendix 5: # 66).

Interestingly, though, Respondent 1 stated that hospital staff doesn't know or feel that the EHDS is too far removed from their daily job, with Respondent 1 saying that "*they don't give a shit*" (Appendix 2: # 101) and explains that they look forward to the EHDS' potential to alleviate a lot of administrative burdens. Which is strengthened by Respondent 2. Respondent 6 attribute the lack of knowledge to hospital staff not having time to think about the EHDS, and rather focus on their daily tasks.

In general, all results point towards a positive outlook on the EHDS and its perceived benefits.

4.2.2 Perceived drawbacks

Respondent 2 doesn't know of or hasn't heard of any objections to the EHDS as of yet. Respondent 4 said that there is a *generally* positive outlook on the EHDS but did not expand on what perceived drawback that could entail. Respondent 6 explains that there have been discussions on all levels about safety concerns when transmitting data to other countries, and goes on to state "*We've had varying thoughts on the proposal and so on, but we're positive in general*" (Appendix 6: # 39). Respondent 5 says that, in line with Respondent 2 and 4, they haven't heard many negative reactions to the proposal. However, they say that there are those who propagate for the harshest interpretation of the GDPR, and said interpretation is not compatible with the EHDS.

To summarize, there hasn't been much blowback in the form of protests against the EHDS. Data shows that those perceived drawbacks that exist are related to the GDPR and interoperability.

4.3 Resource mobilization

4.3.1 Monetary resources

All respondents attest to there being an ambiguity to where funding should and will be coming from in preparation for the EHDS, again citing that they haven't gotten sufficient guidance and information from the EU and Swedish government. Furthermore, Respondents 3, 4, 5, 6 and 7 state that there's currently a lack of funding in these efforts at this moment, and since it's been unclear as to exactly what the EHDS will entail, because of that

Respondent 4 and 7 explain that the regions have been careful not to engage in potentially misguided projects, as to not accidentally waste tax money.

Moreover, Respondents 5 and 7 stated that current external monetary resources are mainly coming from Vinnova and the EU, however, organizations are also spending money internally in order to best prepare for the EHDS. interestingly, Respondent 6 also claims that the state will have to compensate the regions for their work, at least partly, but you shouldn't count on the EU to contribute with monetary funding.

In short, there's an ambiguity to where future funding will come from, and current funding is insufficient. With results pointing towards current funding coming from Vinnova and the EU to some extent.

4.3.2 Human capital

Respondent 3 states that Swedish healthcare can probably manage the implementation of the EHDS on domestic human capital (competence), but might fall short in certain niche areas. This is not something that Respondents 2, 4, 5, or 6 agree upon, as they all argue that Sweden suffers from a lack of talent in this area, not a lack of competence but rather the amount of competent professionals, which means you have to put the existing competence to use in the best way possible. However, Respondent 7 recognized that there's a general lack of knowledge in regard to the know-how of the implementation of the EHDS as the specifications haven't been released yet, but they say that "*these specifications that will come in relation to the primary use of data [...] they aren't like, they're not news and we'll leave it at that*". Respondent 7 seems to be alluding to a point strengthened by Respondent 4, who says that the best-case scenario would be if the technological standards that are set won't be too hard to meet, although, this is in reference to secondary use of data.

Most respondents attest to there being a lack of talent when it comes to the implementation of the EHDS in healthcare. The responses that didn't fully agree with this still recognized it to a certain extent.

4.3.3 Technical infrastructure

In regard to how prepared Sweden's technical infrastructure is, Respondent 1 states that "*it varies*" throughout the regions. Respondent 3 says that:

"*Sweden's come pretty far in regard to infrastructure, I would say. We have a number of nationwide services that function well*" (Appendix 3: # 17).

Respondent 3 goes on to say that some tools that need to be in place but aren't at this moment, like Snomed CT among others. However, as different regions are transitioning into more commonly used EHR systems, the work to abide by technological standards that include the use of Snomed CT is underway. This is strengthened by Respondent 6 who says:

"*We consider that we have a [sound national] digital infrastructure [...] Sweden has a long-standing history with data, quality registers, and other registers [...] it is because we have such a long history of data and everything built to support it [...] which means that we have a lot of, as you know, different systems. We have different EHR systems with different data sources etc.*" (Appendix 6: # 9).

Respondent 4 says that Sweden needs to build up its technical infrastructure carefully with the right support in the EHR systems, and that there's a lot of talk about current lack of interoperability. Respondent 7 agrees that adjustments have to be made in our digital infrastructure to comply certain standards of the EHDS. However, they think that we're going in the right direction, but Sweden needs to ramp up the pace by implementing some of these standards, for example, if we're going to reach our goals, and that the government hasn't done enough in that sense up to this point. While Respondents 6 and 7 say that the transition into new EHR systems is in line with the implementation of the EHDS, Respondent 5 says that "*it isn't enough*" (Appendix 5: # 62).

To reiterate, Sweden has a sound foundation of technological infrastructure. However, since its longstanding history of digitizing healthcare these systems are numerous and not always coherent, thus requiring adjustment and integration efforts.

4.4 Guidance of search

4.4.1 Direction of development

In the question of whether Sweden's heading in the right direction in terms of a plan and resources being put to use in the right places, the respondents gave split answers. Respondents 2, 3, 4 and 6 said that they believe that we're going in the general right direction, with Respondent 6 stating that:

"*I believe that we definitely have a plan. [...] we're working steadily now towards looking at different things with investigations and all the different projects related to the EHDS and now all the other projects within national projects. I think we definitely have a plan towards the goal you think you have considering our circumstances [...] we're on the track"* (Appendix 6: # 27).

However, they later followed that up by saying "*We don't have any sub-targets [to hit] since we don't have a [final] goal*", alluding to the lack of official texts to guide their efforts. They further point out that several organizations, regions and municipalities have created their own "*road maps*" which is great, but "*we request a joint flight plan [...] otherwise this will be much harder to execute*" (Appendix 6: # 91).

Conversely, respondents 5 and 7 don't think that Sweden has a plan. Respondent 5 thinks that "*I think a lot of people got taken by surprise. In some of my lectures I talk about that when you're talking in Stockholm with the regions there were a lot of them that hadn't started anything [projects to prepare] or knew nothing [about the EHDS]*" (Appendix 5: # 84). While Respondent 7 thinks that we're heading in the right direction, when asked if Sweden's got a concrete plan, they answered:

"*Absolutely not, the Government Offices* ***just*** *appointed an investigator at the beginning of the year*" (Appendix 7: # 68).

Which, as they point out, isn't all that strange but rather logical as the EHDS was approved just this year in April. They further emphasize that work has begun but they haven't been able to take much decisive action until recently when it was approved.

In summary, the text highlights a division in perceptions regarding Sweden's direction in healthcare planning. Some see progress, while others perceive a lack of a coordinated and clear plan, indicating differing opinions among respondents about how well Sweden is managing its healthcare planning. Some respondents believe that Sweden is making progress and is on the right track with its plans and projects, while others feel that there is a lack of a clear and unified strategy, leading to uncertainty and a lack of coordination. It is evident that there is a significant difference in how the involved individuals view the situation.

4.4.2 Influence on Development

Respondent 3 believes that there's too much discussion at times, and according to Respondent 7, when discussing matters of national infrastructure in general, the dialog between agencies can be a bit hostile. The dialog itself is in reference to national infrastructure which in turn supports the EHDS but is not specifically about the EHDS. They go on saying that:

"*We take a pretty harsh line of dialogue between the state and SKR. But if we look at what they actually want, then they want the same thing [as us] but kind of in a different way. So I'd say that the dialog is often more hostile than it needs to be*" (Appendix 7: # 114).

Respondent 4 sort of alludes to a similar point, explaining that "*[there's] often a constructive dialog but they might not always agree with everything that you propose. However, they do also give positive feedback with some of which has affected our report*" (Appendix 4: # 63), which does seem typical for inter-agency collaboration.

Overall, these statements show a need for better communication to improve cooperation and efficiency between agencies in the healthcare sector. This could mean having more focused discussions, building better relationships to reduce hostility, and encouraging constructive feedback to ensure all viewpoints are heard.

4.5 Entrepreneurial experimentation

4.5.1 Amount of experimentation with technical solutions

Respondents 6 says that the process of thinking has started, but much remains to actually be done, stating,

"*We are starting to sketch out different solutions for data hubs and other things. But we haven't really thought it through. We're popping up different ideas. This might work. But we haven't fully thought it through*".

Respondent 7 expanded by saying:

"*I'd say that we've begun experimenting in a few places here and there, but not in large. But, yes, there are actors who've begun experimenting*" (Appendix 7: #118).

They further emphasize that we're ahead of many other member states due to existing functions and environments within the country.

Furthermore, Respondents 2, 3, 4, 5 and 7 all state that the amount of experimentation is small and spread out in fractions across the country, which can be summarized by Respondent 7 and 5 who says about the extent of experimentation:

"*I'd say that in a few places here and there but not on the whole"* (Appendix 7: #118).

And "*I don't know on the national level, rather those who are doing something [experimentation] are [regions] Halland, Skåne and VGR*" (Appendix 5: #116).

However, Respondent 7 highlights that Sweden has a good starting position compared to many European countries.

Moreover, Respondent 5 provides an example of beta versions of EHDS being tested in other countries, emphasizing that Sweden is not actively involved in these tests due to harsh interpretations of the GDPR, stating:

"*Sweden is poorly prepared, and this is based on where we stand today, and on how we have handled such situations in the past*" (Appendix 5: #12).

To summarize, these statements reveal that while there is some initial thinking and idea generation about data hubs and other solutions, there is a significant gap in actual experimentation and implementation. The progress is slow, and the experimentation efforts are fragmented and limited to certain regions. Strict GDPR interpretations further hinder Sweden's involvement in broader European testing efforts, contributing to a sense of being unprepared. To move forward, there needs to be more coordinated national efforts, increased experimentation, and a balanced approach to GDPR compliance that enables innovation.

4.5.2 Experimentation with existing technical solutions

The technologies supporting EHDS, including technical standards such as HL7 and Snomed CT, are discussed by Respondents 3 and 4. They emphasize the importance of these standards for ensuring accurate data transfers. Respondent 3 further expresses concerns about Sweden not being fully prepared to implement these technologies, noting,

"*then there are certain aspects that we are not keeping up with, and it somewhat relates to data formats. I believe it is more your area—the parts about information, definitely Snomed CT 10, ICD11, which are not fully utilized, and this varies somewhat*" (Appendix 3, #17).

Building on Respondent 3's opinion, Respondent 5 identifies "datalakes" as a potential opportunity for advancing technologies related to EHDS. However, they note that the implementation of such technologies has yet to begin, stating: "*[Well, what I'm describing with data lakes is actually a technology that could support EHDS... but it's not in place yet*]" (Appendix 5: #118). Specifications and standards for infrastructure to support the secondary use of health data is actually a project that Respondent 4 is working on at this moment.

Several Respondents, namely Respondents 3, 5, 6, and 7 mentioned the regions' current transition into new EHR systems as experimentation in line with the EHDS. However, this also complicates things a little as Respondent 6 says:

"*I believe that [changing EHR systems] is totally in line with the EHDS. Although, it's a question if it wouldn't have been better if the EHDS were to come five years later since this will make for a parallel process, implementing the EHDS and changing EHR systems. Although this can be both an advantage and disadvantage*" (Appendix 6, #71).

Respondent 7 added to that by stating:

"*This is a process that has been going on for nearly 12 years to update our EHR systems, but at least it has begun and is ongoing [...] it's going the right direction, we've made the right investments, men it's going too slow [...] if we're to reach our goal before its like a hard law [referring to the EHDS] the we need to pick up the pace*" (Appendix 7, #98).

Overall, these statements indicate that while there are promising technical solutions and ongoing efforts to align with EHDS, significant challenges remain. These challenges include the full implementation of important technical standards, the slow progress of transitioning to new healthcare EHR systems, and the need to accelerate the adoption of supporting technologies like data lakes.

4.6 Market Formation

4.6.1 Number of organizations in the TIS

Discussing support and if enough organizations are working towards the preparation for the EHDS, Respondent 1 expresses disappointment over the lack of support for stimulating cooperation between hospitals and technological innovation, stating "*There is no designated actor.*", while Respondent 6 points out that a joint road map would have been beneficial to organize all parties involved.

Furthermore, Respondent 3 mentions that various stakeholders, including researchers and companies involved in innovation that seem to be waiting for the process to simplify before they take active roles. This stance of waiting is confirmed by Respondent 5, who perceive a lot of passive behavior. Meanwhile, Respondent 7 argues for the inclusion of a more diverse group of participants to enrich the preparation process. They also say that:

"*I think that more would benefit from, as an example, creating a pilot study like us. I think that there's some that would've needed to go over the regulation [the EHDS] in order to be in a position where you can work accordingly, now that it [the EHDS] has been approved*" (Appendix 7, #142).

Regarding collaboration between Swedish healthcare and the industry, Respondent 5 states that there is no collaboration at the moment. Respondent 4, who advocates for a more extensive collaboration, emphasizes the need for teamwork: "*a wider involvement of actors is needed in the preparation work for EHDS as a team together*". This statement is repeated by respondent 6 who suggests that "*everyone has their piece of the cake to contribute, thus the pieces must be put together,*" highlighting the importance of collective effort. Furthermore, respondent 6 continues to stress the benefits of collaboration, stating, "*I believe we need to make these joint networks even clearer, where we actually try to figure out a way forward together*" (Appendix 6, #91)..

On the topic of taking initiative, there's a call for action from the government as highlighted by respondent 4, who mentions the expectation for decisive actions now that the EHDS framework is clearer: "*The Swedish state, perhaps under the last two governments, has waited to see where the EHDS regulation or proposal will head. Now that we likely know its structure, it is time to make firm decisions, which we expect, for example, from Mats Nilsson's investigation*." (Appendix 4, #73).

These statements highlight the need for better coordination, overcoming stakeholder passivity, fostering diverse participation and pilot projects, and bridging the collaboration gap between healthcare and industry. There's also a gap in collaboration between healthcare and industry that needs to be fixed by the government to take decisive actions now that the EHDS framework is established. By addressing these areas, it can be concluded that Sweden can enhance its preparation for EHDS and improve the overall efficiency and effectiveness of its healthcare sector.

4.6.2 New organizations entering the TIS

Similarly, Respondents 4 and 6 point out the difficulty in taking action without definitive regulations, which slows down progress. Respondent 7 views adapting to the EHDS as a "*land of opportunities*," emphasizing that while there is great potential, the market requires additional information and support to fully capitalize on these opportunities.

Respondents 4, 6, and 7 all stress the need to begin collaborative preparation once the regulation is finalized and highlight the importance of involving more stakeholders in this process. Respondent 7 expresses the need to more actors being involved by doing things like pilot studies. Respondent 4 puts this bluntly by saying:

"*We need to broaden and involve others in this effort, there's no doubt about that*" (Appendix 4, #75).

Respondent 2 sees significant research potential in using data from EHDS, although they also note structural challenges such as the lack of collaborative models for innovation. This issue is particularly acute at large hospitals and healthcare providers, which struggles to keep up with technological advances and might hinder them, like others, to enter the market in time.

Respondent 7 mentions that the state has made efforts to improve the groundwork for EHDS, though these have not included direct financial incentives. In contrast, Respondent 6 believes that enough authorities and interest organizations are well-prepared and proactive. However, Respondent 6 further argues that regions and municipalities need to be more involved across all levels to make this work. Stating that the regions are the ones who actually holds and owns the health data. Respondent 7 further states the importance of the fact that everyone holds data and must understand and take responsibility for this.

To summarize, the statements reveal several key points about the challenges and opportunities related to the EHDS. Clear regulations are needed to facilitate action and progress. There is a strong potential for the EHDS to transform healthcare, but more information, support, and further stakeholder involvement are essential. Collaborative preparation and a coordinated approach are crucial once the regulations are finalized. Research potential is significant, but structural challenges and a lack of collaborative models hinder progress. Finally, while there

are efforts to lay the groundwork for EHDS, financial incentives, and regional involvement are necessary to fully leverage its benefits.

4.7 Development of Positive Externalities

4.7.1 Forming of formal networks

Respondent 3 explains Institutions like Karolinska Institute, Lund University, Umeå University, and Charité in Germany are keen to advance with EHDS to access data for their research. They support the initiative as much as they can but recognize that progress will take time, stating:

"*They are following this and supporting as much as they can, but they also know it will take time*" (Appendix 3, #68, 78).

Moreover, Respondent 4 mentions that Nordic cooperation under the Nordic Council of Ministers relevant to EHDS, describing it as "*an example of such a network that is not only established but also actively engaged in specific projects*". Respondent 2 is unfamiliar with any network operations and note that they are planning to work closely with the E-Health Authority and the National Board of Health and Welfare to explore areas for joint projects, saying,

"*We will begin work relatively close with the E-Health Authority and the National Board of Health and Welfare with a workshop next week to look at areas where we can undertake joint projects for the government assignment where we will be helpful with our regions*" (Appendix 2, #27).

Respondents 6 underscore the importance of existing networks, which are currently used to manage issues related to EHDS. However, there is a need to further improve and develop these networks, stating "*We think that it might be like this. We believe that more clearly defined official networks will need to be formed*"(Appendix 6: #91).

Regarding collaboration between Swedish healthcare and the industry, Respondent 5 states that there are no collaborations at the moment. Building upon this opinion, Respondent 3 expresses that Sweden has a well-established system and national network, with a specific focus, stating:

"*In Sweden, we have an excellent system with national collaboration groups for pharmaceuticals from medical technology for certain treatment areas. We also have a regional cancer center represented by all regions, creating a framework where stakeholders meet, collaborate, and make decisions regarding patient care.*" (Appendix 3: #122).

However, Respondent 3 further maintains that, regarding collaboration between the industry and healthcare specifically, they actually don't know.

The need for a joint roadmap that coordinates various initiatives from healthcare and industry is highlighted, according to respondents 4 & 6. In this regard, Respondent 4, advocates for

more extensive collaboration, emphasizing the need for teamwork: "*a wider involvement of actors is needed in the preparation work for EHDS as a team together*". This is repeated by respondent 6 who suggests that "*everyone has their piece of the cake to contribute, thus the pieces must be put together*". Furthermore, respondent 6 continues to stress the benefits of collaboration, stating, "*I believe we need to make these joint networks even clearer, where we actually try to figure out a way forward together*" (Appendix 6, #91).

Overall, key institutions and existing networks are eager and supportive of moving forward with the EHDS, but the progress is expected to be slow. There is a clear need for better-defined networks and stronger collaboration between healthcare and industry. Establishing a joint roadmap and encouraging broader stakeholder involvement are crucial steps. By doing so, Sweden can enhance its readiness for EHDS and improve collaboration across the healthcare sector.

4.7.2 Potential barriers hindering efficient networks

Respondent 4 addresses the challenges presented by legal uncertainties, explaining that these often hinder cooperation; it's not the technology but the legal framework that poses barriers. This issue is marked by uncertainty about what is legally permissible, necessitating further clarification to enable effective action, but overall they don't identified any laws in general.

Respondent 4 further stated "*From the government's side, we are encouraged to explore possibilities for regulatory consultation or a regulatory 'sandbox', but it turns out there are legal limitations to this based on current legislation."* (Appendix 4, #65). A similar statement by respondent 5, saying that the problem being the regions acting according to their regional lawyers, and the regional lawyers are often generalists.

Respondent 5 identifies GDPR as a law that limits the EHDS act, stating:

"*I believe the main reasons are that people cannot really handle GDPR. They are worried about sharing data.*".

Respondent 7 discusses another barrier: current legislation, including the Patient Data Act (PDL) and the Health and Medical Services Act (HSA), which does not facilitate data sharing. The surrounding uncertainty and regulations impede the development of integrated systems and networks that could enhance collaboration in preparation for EHDS.

From another angle, Respondent 2 shares a perspective on regional autonomy in handling issues, suggesting that bureaucratic processes often delay effective problem-solving and that regions sometimes feel they do not have ownership of their issues. This respondent's observation reflects a frustration with the administrative hurdles and a desire for more direct control at the regional level, as expressed:

"*It took quite a long time before we had a handle on it, and I think that it can be experienced as very bureaucratic and somewhat like you cannot own your question in the region*" (Appendix 2, #53).

In summary, the respondents' statements illustrate various legal and administrative barriers within the healthcare sector. Legal uncertainties and limitations in current laws, particularly GDPR, are major barriers to effective data sharing and cooperation. Government initiatives

often clash with practical legal constraints, while the regions' reliance on generalist legal advisors leads to careful interpretation of laws. The frustration over bureaucratic processes and lack of ownership within the regions also indicates a need to improve administrative structures for quicker and more efficient solutions. Overall, these statements point to the need for both legal and administrative improvements to facilitate better cooperation and innovation within the healthcare sector.

5 Discussion

The discussion will draw from literature gathered in Chapter 2, as well as empirical data presented in the Results chapter. It will explore correlations between the two in addition to differences, and thus serve as the foundation for which conclusions will be drawn in the next chapter.

5.1 Knowledge development and diffusion

Knowledge development and diffusion is characterized by broadening and deepening the knowledge base of a TIS (Bergek, 2019), which in our paper is measured by the extent experts perceive general knowledge and awareness. However, all respondents, except respondent 3, explicitly agree to different extents with the thesis on which our knowledge gap is based, e.g., that there isn't enough knowledge about the EHDS in Swedish healthcare. Respondents 1, 4, 5, and 6 attribute this lack of information of how to move forward with the EHDS to the EU along with the Swedish governing agencies, which correlates with He (2023), who states that specifications are still missing from the EHDS protocols. This isn't all too strange though, as Respondent 7 explains that they've been waiting for information to be released once the legislation was passed in April of this year. Meaning that, while information has been short, it's also something that was expected and is logical. Furthermore, as the Swedish Government Offices only just this year appointed Mats Nilsson to investigate the efforts made in the matter of the EHDS (Swedish Government Offices, 2024), it is not surprising that many feel uninformed, which was also pointed out by Respondent 7.

Knowledge diffusion is characterized as the exchange of information in networks, "learning by interacting" for example (Hekkert et al. 2007, n.p.). Respondents 3 and 6 cited the road map released by the Swedish eHealth Agency (Swedish eHealth Agency, 2024) as an example of good efforts of informing and sharing information across the country. However, all respondents stated in some form that a lack of knowledge sharing is a recognized need, thus pointing out a somewhat weak knowledge diffusion, and that efforts like reports by the eHealth Agency and Socialstyrelsen (Socialstyrelsen, 2023a) are good examples of trying to mitigate this. As the eHealth Agency created their road map in order to provide guidance and knowledge about the EHDS, as Socialstyrelsen also did, it can be assumed that there's been a general lack of knowledge that inspired them to write the road maps.

Although, in regard to the lack of information provided by the EU, Guthmuller, Paruolo and Verzillo (2021) summarized that the EU tends to be a good source of information and guidance, functioning through providing regulations rather than providing monetary help, which doesn't correlate with our findings. However, this might be because the EHDS was just recently approved, and thus they haven't had time to inform the public about specifications.

5.2 Legitimation

Legitimation refers to if the TIS is perceived to be legitimate, e.i. it complies with laws and regulations, societal norms (morally acceptable), and expected behavior (Apell & Eriksson, 2023; Bergek, 2019). Our findings regarding legitimation strongly correlates with literature presented in Chapter 2, specifically section *2.2.1 Demand*. As Sweden's population is rapidly aging (AI Sweden, 2024a; Apell & Eriksson, 2023; Rye & Göransson, 2021) and our healthcare systems suffer from a lack of talent in general Apell & Eriksson, 2023; Dagens Medicin, 2023; Socialstyrelsen, 2023b), all respondents state that a generally positive attitude towards the EHDS exists in Sweden, as the EHDS can help alleviate some of the burden this puts on our healthcare system. Furthermore, innovation in Swedish healthcare is highly reliant on the private sector, yet innovation is stifled by a lack of incentives for private companies (Tucker, 2023). This is partly attributed to a lack of access to health data (Burden et al., 2023; Neher et al., 2023; Tucker, 2023; Österberg & Lindsköld, 2020), something that the EHDS is designed to change (Horgan et al. 2022; Molnár-Gábor, 2022). Respondents 4, 5 and 6 cite the perceived benefits for innovation as a major reason for the positive attitudes of the EHDS, which also correlates with the work of Bergek (2019), who says that perceived benefits of a TIS will strongly influence its acceptance.

5.3 Resource mobilization

Resource mobilization refers to the acquisition of funding, human capital and infrastructure (Apell & Eriksson, 2023; Bergek, 2019; Hekkert et al. 2007). The road map by the Swedish eHealth Agency is in part an estimate of costs for the implementation of the EHDS in Swedish healthcare (Swedish eHealth Agency, 2024), and Mats Nilsson's investigation into these efforts are in part meant to determine if these calculations are feasible (Swedish Government Offices, 2024). The latter is yet to release his report, which correlates to our findings as all respondents say that there's an ambiguity to where monetary resources will come from, in what volumes, and when. Furthermore, according to Respondents 3, 4, 5, 6 and 7, there's also currently a lack of funding in the efforts to prepare for the EHDS, which correlates with Tucker (2023) who concludes that the public healthcare sector suffers from a general lack of resources in regard to tech innovation. Although, Respondent 7 makes a valid point of this being because the EHDS was just recently approved in april, and thus the real work has just begun. However, the research by the Swedish eHealth Agency and the Swedish Government Offices could be viewed as a commencement of R&D programs, which is a part of resource mobilization (Hekkert et al. 2007).

Interestingly, according to Respondents 5 and 7 the current external funding that is coming is in part from the EU, which contradicts statements by Guthmuller, Paruolo and Verzillo (2021) who says that this is not typical of the EU. Respondent 7 further states that several organizations are spending money internally on this effort to prepare.

In line with our literature review (Apell & Eriksson, 2023; Dagens Medicin, 2023; Socialstyrelsen, 2023b), Respondents 2, 4, 5, 6, and 7 believe that Sweden is currently missing domestic talent (or competence) in relation to the implementation of the EHDS. Respondent 3 does, however, not fully agree with this but does recognize it in some aspects. Furthermore, while respondent 6 do agree with there being a shortage of people with the

necessary expertise, they also emphasize that those who do work with this matter are highly competent, but due to their somewhat small numbers efforts will have to be well guided. Although, in regard to human capital the research by the Swedish eHealth Agency and the Swedish Government Offices could be viewed as an attempt to structure competence, in accordance with (Bergek, 2019; Hekkert et al. 2007).

Sweden has a problem of transmitting health data across regions, as it's sometimes easier to transmit it across nation borders (European Commission, Directorate-General for Health and Food Safety, 2022b; Federation of European Academies of Medicine, 2023; Österberg & Lindsköld, 2020) which is further supported by Respondent 4. However, Sweden is currently transitioning to a more homogeneous set of EHR systems (Cederberg, 2023) which respondents 5, 6 and 7 says is in line with preparation for the EHDS. In correlation with the interoperability issues (European Commission, Directorate-General for Health and Food Safety, 2022b; Federation of European Academies of Medicine, 2023; Österberg & Lindsköld, 2020), Respondent 6 explains that due to our high level of digital maturity, we have numerous IT systems to support our healthcare, and they don't always integrate well with each other. While Respondents 5, 6 and 7 think that transitioning into new EHR systems is a step in the right direction, Respondent 5 also says that it isn't enough in regards to technical infrastructure. This is supported by Respondent 7 who thinks that they need to ramp up the pace in order to finish in time. As Horgan et al. (2022) stresses the importance of the readiness of each member states' technical infrastructure, the pace of this transition could be considered as crucially important. Hence, it can be argued that a sufficient amount of infrastructure exists across the country (Bergek, 2019; Hekkert et al. 2007), just not quite the right one yet.

Furthermore, the eHealth Agency mentioned that Snomed CT, which has a certain coding standards of medical terms, as being a part of the EHDS specifications, and Respondent 3 mentions that these are partly being implemented but aren't in place yet.

5.4 Guidance of search

As Hekkert et al. (2007) explain, Guidance of Search refers to mechanisms that guide the selection of strategic and technological directions that best address the specific needs and preferences of users with focus on development. The results identified a current lack of a common and unified plan for the implementation of the EHDS, as shown in the data in section *4.4 Guidance of search*, but also in *4.1 Knowledge development and diffusion* to a certain extent. Respondents 6 pointed out that this leads to different regions, municipalities, and organizations creating their own plans and roadmaps, causing fragmentation. Respondent 6 mentioned that despite an overall plan, specific sub-goals to measure progress are lacking, emphasizing the need for a unified plan. As mentioned in a report by the EU Commission, varying stakeholder engagement may present a challenge (European Commission, Directorate-General for Health and Food Safety, 2022a), and Deloitte pointed out that fragmented efforts may complicate the implementation (Deloitte, 2024).

However, a critical point is the perceived lack of strategy and leadership, despite Respondents 2, 3, 4, 6 and 7 expressing that Sweden is *generally* heading in the right direction. Respondent 6 further stated that there are no clear sub-goals and end goals. This indicates that one of the blocking mechanisms for the implementation of the EHDS in Swedish healthcare is the lack

of specificity in goal setting. Without clear sub-goals and a defined end goal, it becomes difficult to measure progress and ensure that efforts are directed appropriately, creating uncertainty and inefficiency in the implementation process. This can be traced back to Respondents 1, 4, 5, 6 and 7 attributing a lack of guidance and information provided by the EU and Swedish governing agencies. This is not to say that it is strange that information hasn't been released since the legislation was just recently passed, information is however still perceived to be short in stock, which Respondent 7 states is only logical due to the timeframe. Hekkert et al. 's (2007) view of guidance of search refers to the strategic and technological choice of path, which according to our results is unclear at this moment.

Respondent 7 expressed that there is no clear plan, and that the government has only recently appointed an investigator for the EHDS, which is true (Swedish Government Offices, 2024). They do, however, state that Sweden's heading in the general right direction. Respondent 6 also emphasizes the need for a common roadmap, as current efforts are somewhat scattered and fragmented. The fragmented approach can create obstacles for a unified implementation of the EHDS, highlighting the need for better cooperation.

In summary, Swedish experts in the health IT industry identify fragmentation and lack of coordination, lack of strategy and leadership, and the need for a common roadmap as prominent barriers. Although, it is important to reiterate that Respondents 2, 3, 4, 6 and 7 still assessed that Sweden is *generally* on the right track. Alluding to that, the guidance of search, as described by Hekkert et al. (2007), is *generally* heading in the right direction, but lacks concrete goals and therefore sub-goals.

5.5 Entrepreneurial experimentation

Entrepreneurial experimentation is crucial for driving innovation and development within a TIS (Hekkert et al., 2007). Currently, the level of entrepreneurial experimentation within Swedish healthcare is clearly low and fragmented, according to Respondents 2, 3, 4, 5, and 7. But some of them also state that *there is* experimentation going on. Respondent 7 claims that Sweden has reached farther than other countries, but the perception is still that more can be done considering the beneficial circumstances of Swedish digital infrastructure. This limitation presents a barrier to the implementation of the EHDS Act, as Bergek et al. (2008) name entrepreneurial experimentation as a main driver in reducing uncertainty within a TIS by creating knowledge. This can again be connected back to the current lack of guidance and information provided by the EU and Swedish governing bodies.

Furthermore, strict GDPR interpretations, mentioned by Respondent 5, align with findings from Burden et al. (2023), Neher et al. (2023), Tucker (2023), and Österberg & Lindsköld (2020), who argue that Sweden's stringent GDPR interpretations hinder innovation. The lack of access to health data is holding back the development of innovation in healthcare. This constraint is seen as an obstacle to Sweden's engagement in preparations for the EHDS, thereby limiting market formation, as the literature emphasizes the importance of creating protected spaces and regulations to promote the use and development of technology (Bergek, 2019). Interestingly, the EHDS was partly designed as a complement to the GDPR to allow for greater innovation within healthcare by increasing access to health data, however the current GDPR legislation is holding back experimentation that would ease the implementation of the EHDS. Thus, creating a paradox of sorts.

Respondents 3, 5, 6 and 7 mentioned the regions' current transition into new EHR systems as experimentation in line with the EHDS. However, this might be more applicable to creating sufficient IT infrastructure and thus falls under the function *resource mobilization*. Although, as this does allow for creating general knowledge about implementation of the EHDS within the TIS through trial-and-error activities, it is in line with what Bergek et al. (2008) describes as entrepreneurial activities as well and is therefore applicable to both.

In summary, the current barriers to the implementation of the EHDS Act within Swedish healthcare include a low level of entrepreneurial experimentation, strict GDPR interpretations that limit market formation, and a lack of preparation for implementing international standards. To overcome these barriers, Sweden needs to increase its coordinated efforts for experimentation, create more flexible regulatory environments, and ensure that the technical standards supporting the EHDS are fully implemented. These measures will promote innovation and efficient data sharing, which are crucial for achieving the goals of the EHDS Act.

5.6 Market formation

Bergek (2019) and Hekkert et al. (2007) refers to market formation as a protected space in which goods and services can flow, if public policies have been put in place for the TIS. We've chosen to assess market formation on the national policies Sweden chooses to adopt to enhance the TIS for the purposes of implementation of the EHDS, but as the EHDS is yet to go into effect it will also be assessed on the number of organizations entering the space (Bergek et al. 2008). Respondents 4 and 5 believe that Sweden would benefit from more organizations working towards preparing for the implementation of the EHDS, and Respondents 7 perceives a lack of incentives for organizations to enter the TIS which correlates with the findings of Tucker (2023).

Respondent 3 argues that organizations are acting passive in relation to the EHDS, as they wait for guidance on processes, which is confirmed by Respondent 5 who also perceives a lot of passive behavior. Respondents 4 and 6 themselves feel that it's difficult to take action without clear goals and objectives, which strengthens the reason for passive behavior by organizations currently external to the TIS, as explained by Respondents 3 and 5. To mitigate this, Respondent 4 calls for more definitive action when the investigative report by the Swedish Government Offices is released (Swedish Government Offices, 2024). And Respondent 7 says that Sweden would benefit from more people doing research of their own, thus creating more knowledge within the TIS. Again, tying back to the perceived lack of knowledge and guidance provided, as explained in *5.1 Knowledge development and diffusion*. This call for action by Respondent 4 is in line with what Bergek (2019) considers to be policy engagement for the TIS.

Respondent 6 expresses that enough organizations are working on the preparation for the EHDS, however they do insist that the regions will have to be further involved and collaboration is key. Further collaboration and exchange of services between actors would serve the function *market formation* to be considered as stronger, according to Bergek (2019). Respondents 4 and 7 agree with the need for more extensive collaboration to foster networks within the TIS, while Respondent 5 argues that there is no collaboration at this time. This was

also pointed out as a potential challenge by the European Commission and Deloitte (Deloitte, 2024; European Commission Directorate-General for Health and Food Safety, 2022a).

Respondents 2, 5, and 7 emphasize the potential for market innovation in relation to the EHDS, which correlates with Horgan et al. (2022) who expresses a similar optimism for European healthcare innovation pending a successful implementation. However, Respondent 2 believes that there's a need for more collaborative models in order for innovation to thrive, noting that large hospitals and healthcare providers in general stand no chance of keeping up with the latest tech innovations by themselves and therefore need private sector help, which is supported by Tucker (2023).

5.7 Development of positive externalities

Bergek (2019) explains that development of positive externalities can be assessed on the diffusion of best practices as well as coordinating other actors. Apell and Eriksson (2023) expands further and explain that it can be assessed by the establishment of formal networks between actors, which is what this thesis will mainly focus on. Respondents 2, 3, 4, and 6 all speak of existing networks coordinating, formal and informal, to implement the EHDS. Moreover, they all speak to the need for and importance of expanding, improving, formalizing and adding additional networks in order to foster sufficient collaboration. So, while there are some networks dealing with issues regarding the EHDS in healthcare, there’s also a recognized need to further this effort in line with what Apell and Eriksson (2023) and Bergek (2019) describes.

Respondents 4, 5 and 6 also recognize legislation as a barrier to establishing networks, but also in general as they try to prepare for the EHDS, most notably GDPR as mentioned before. This correlates with earlier studies (Burden et al., 2023; Neher et al., 2023; Tucker, 2023; Österberg & Lindsköld, 2020), specifically Österberg and Lindsköld (2020) who explain that Sweden’s interpretation to the GDPR might be the hardest in the EU. Which also correlates with Respondent 5 who states that Sweden’s handling of the GDPR has put it on a certain list with undesirable countries to work with in this regard, leaving Sweden out of a beta testing version of the EHDS.

Moreover, Respondent 2 mentioned that the current bureaucratic climate affects regional autonomy leaving some regions to feel like they don’t have much power. This somewhat correlates with results from respondent 5 who says the regulatory uncertainty leaves regions to act alone and thereby acting according to the opinion of regional lawyers. Further complicating inter-regional cooperation, and subsequently inter-regional networks. This also correlates with the findings of (European Commission, Directorate-General for Health and Food Safety, 2022b)

6 Conclusions

The purpose of this qualitative study was to explore possible blocking mechanisms in Sweden for the implementation of the EHDS, as perceived by Swedish experts. This was done by assessing strengths and weaknesses in the functions of the TIS framework. In order to facilitate our aim, the following research question was posed:

What do Swedish experts in the healthcare IT industry consider to be blocking mechanisms for the implementation of the EHDS in Swedish healthcare?

The functions *knowledge development and diffusion, resource mobilization, guidance of search* and *entrepreneurial experimentation* were assessed as *current* blocking mechanisms.

As functions overlap and influence each other, interventions can be made in a specific function and strengthen others through a ripple effect. This ripple effect goes both ways, as the main blocking mechanisms identified was knowledge development and diffusion, i.e. how much the sector knows and shares their knowledge in reference to the EHDS' implementation, and one recurring theme stood out that affected the other functions. Namely the lack of official guidance by governing authorities on the matter. Many cited the upcoming release of the report by the Swedish Government Offices as a good jumping off point on this matter. Additionally, it isn't illogical that more information has been flowing from the EU and Swedish governing authorities since the legislation was just recently passed. That, however, does not negate the *current* perception of lack of information and guidance, i.e. knowledge development. Moreover, as this still presents itself as a *current* issue, it serves as a blocking mechanism. It's worth mentioning that knowledge diffusion, i.e. sharing of knowledge, was also recognized as insufficient, but efforts are being made to resolve this.

While Sweden does possess a national digital infrastructure, our results along with literature indicate that it is currently not compatible with the EHDS. As Sweden suffers from a less-than-optimal number of competent individuals in this regard, which correlates with previous studies, efforts will have to be put in the right places which requires good guidance. Good and concrete guidance is something Sweden does not possess at this moment. Although efforts to prepare the Swedish digital infrastructure for the EHDS are ongoing, it's far from done, and this alone will not be enough. Furthermore, this study finds that current funding is insufficient in the efforts of implementing the EHDS, which correlates to literature explaining that public sector healthcare lacks monetary resources. Moreover, an uncertainty in relation to future funding exists, i.e. where it will go, when, and how much. This is again attributed to the lack of official texts on the matter, i.e knowledge development. Thus, resource mobilization is considered a current blocking mechanism.

Guidance of search was identified as a blocking mechanism despite our results showing that many believe that Sweden is heading in the general right direction. We assessed it as a blocking mechanism due to our empirical data showing a lack of clear strategy, goal and subgoals. This, again, ties back to the lack of guidance, or knowledge development and diffusion, by Swedish governing authorities as well as the EU. It should be noted that many organizations are working to create knowledge and road maps, albeit fragmented and not coordinated. It should also be reiterated that this isn't unexpected to some as the legislation

was just recently passed, but again, that does not negate the current situation as it is still the perceptive reality found in our data.

Entrepreneurial experimentation was identified as a blocking mechanism due to our results depicting the low level and fragmented nature of current endeavors. Our findings also correlate with literature discussing Sweden's relatively limited level of healthcare innovation in part due a harsh interpretation of the GDPR.

In conclusion, these are current blocking mechanisms for the implementation of the EHDS in Swedish healthcare, as shown from our analysis of data gathered from experts on the matter. That is not to say that Sweden won't successfully implement the EHDS in time, however, these are the obstacles that need to be overcome in order to do so. Understanding that and mitigating these blocking mechanisms might make all the difference. The EHDS presents great opportunities for both Sweden and the EU in relation to optimizing healthcare operations and promoting healthcare innovation. Let's not waste it.

6.1 Future Research

Future research should be conducted once the report often referred to by our respondents by the Swedish Government Offices is released in order to assess then-ongoing work to comply with specifications of said report. Moreover, as little information is available on private sector involvement and readiness for the EHDS, a knowledge contribution could be made by assessing their readiness to make use of the then-available data for the purposes of innovation. A mixed-methods approach could be incorporated to do this, as to gather data from more numerous respondents, such as every region, as well as get insight from industry leaders.

Furthermore, a knowledge contribution could be made by future research by studying EHR systems integration with the EHDS with a specific focus on what technological adjustments are being made to do this. This could also be complemented with studies focusing on the human aspects of change management in regard to potential new best practices to comply and accept the EHDS.

As regions in Sweden differ in the healthcare operations in various ways and with different needs, it would be interesting to contribute knowledge on how specific regions tackle the implementation of the EHDS. This could also be segmented into focusing on regions working with the same EHR systems, as they also differ from region to region. Lastly, studies on how to overcome the blocking mechanisms identified in this study would benefit not only Sweden, but the entire EU.

Appendix 1 - Interview Outline

Introduktion	Vi undersöker hur redo Sveriges sjukvård och relevanta stakeholders är för den kommande EU-lagen ”European Health Data Space (EHDS)”. Detta berör en rad områden, men inte minst hur redo man är för de tekniska kraven som kommer att ställas. Frågorna vi kommer ställa är i stor utsträckning utformade efter ramverket Technological Innovation Systems. Innan vi börjar, har du några frågor till oss?
Start frågor	1. Kan du berätta lite om dig själv, din arbetsplats och era dagliga sysslor?
	2. Skulle du säga att Sverige ligger i fas för att tackla de kraven som EHDS ställer?
Stakeholder Analysis	3. Vilka forskningsorganisationer är huvudspelare i dagens utveckling av AI för sjukvården?
	4. Vilka forskningsorganisationer är huvudspelare i dagens utveckling av system som ska stödja EHDS?
	5. Vilka organisationer är huvudspelare när det gäller implementeringen och utvecklingen av dessa teknologier?
	6. Vilka regioner eller statliga initiativ är drivande i denna fråga när det gäller?
Knowledge development and diffusion (Refers to the scientific, technological and market knowledge base)	1. Var skulle du säga att kunskapsläget ligger kring EHDS i Sverige och svensk sjukvård? Kan vara bland forskare och experter, men även andra människor som berörs av EHDS.
	2. Hur bra är man i dagsläget på att dela med sig om information för förhållningssätt angående EHDS?
	3. Hur bra anser du att forskningsbasen, alltså mängden forskning, gällande EHDS i Sverige är?
	4. Hur kunniga är både privata- och offentliga aktörer att integrera sina system med EHDS’ pseudonymiserade data?
	5. Vem eller vilka är de största kunskapsbidragarna i Sverige när det kommer till hanteringen av EHDS och utvecklingen av teknologin som de kräver?
	6. På vilket sätt blir folk informerade om EHDS och dess konsekvenser och följder?
Legitimization (Relates to the social acceptance and compliance of the technology.)	7. Hur anser du att acceptansen kring EHDS i sjukvården?
	8. Hur ser ni på slutprodukten av EDHS, mer positivt eller negativt?
	9. Vad är de största invändningarna folk har mot EHDS?
Resource mobilization (Mobilization of infrastructure and human and financial resources.)	10. Vilka typer av resurser investeras i teknologi för att hantera EHDS krav?
	11. Vilka resurser och investeringar finns idag för att tackla EHDS krav, är de tillräckligt?
	12. Var kommer de största investeringarna i EHDS ifrån? Vilka investerar mest i EHDS-teknologier?
Guidance of search (Influence on the direction of development.)	13. Anser du att man i dagsläget lägger fokus på rätt delmål? Att man går i rätt spår helt enkelt med rätt prioriteringar
	14. Sätter olika auktoriteter, alltså politiker, industriledare eller utnämnda experter, ut sunda mål i förberedelsen för EHDS?
	15. Vad har ni för mål när det kommer till förberedelser för EHDS?
Entrepreneurial experimentation (Refers to experimentation and testing of new applications.)	16. Kan du berätta om några initiativ bedrivna av organisationer, institutioner eller företag som syftar på att arbeta med teknologi och processer specifikt för EHDS?
	17. Anser du att man i dagsläget börjat experimentera med teknologi som stödjer EHDS regleringar för datahantering till en rimlig mängd?
	18. Hur har svenska organisationer reagerat överlag till de tekniska krav som EHDS ställer?
	19. Hur viktigt tror du att entreprenörskap och innovation från den privata sektorn kommer att vara framöver i förberedelsen för EHDS?
Market formation (When innovations are widely available on the market.)	20. Anser du att Sverige främjar förberedelsen inför EHDS med säg incitament eller nya regleringar?
	21. Anser du att tillräckligt med organisationer arbetar med förberedelsen för EHDS? a. Till exempel privata aktörer som kommer kunna nyttja datan eller myndigheter som ska bygga infrastrukturen.
	22. Vilka marknadsmöjligheter och barriärer anser du att det finns idag för svenska organisationer vid utvecklandet av teknologier för EHDS?
	23. Hur förbereder sig marknaden för dessa möjligheter och barriärer?
Development of positive externality (Reinforcing system where all functions are fulfilled and spread positive effects)	24. Tycker du att det finns etablerade nätverk mellan olika aktörer som jobbar med detta (förberedelsen för EHDS) och hur väl fungerar de?
	25. Hur fungerar samarbetet mellan sjukvården och industrin i förberedelsen?
	26. Finns det lagar eller andra regler som idag förhindrar ett väl fungerande samarbete och/eller nätverk mellan relevanta aktörer när det kommer till förberedelser inför EHDS?
Slutfrågor	27. Hur redo är organisationer som jobbar med sjukvården att hantera data på det sättet som EHDS avser?
	28. Hur långt ifrån skulle du säga att Sverige är från att på ett gediget sätt kunna dela och använda data på det sättet som EHDS avser?

Appendix 8 - Review and Approval of transcript

Hej ***Respondent Name***,

Hoppas att allt är bra med er. Bifogat finner ni en transkribering och de använda resultaten av vår intervju som kommer att vara med som appendix i vårt arbete, vilket ska lämnas in den 20 maj. Transkriberingen kommer att tas bort inför uppladdning av arbetet efter godkännande från den ansvariga läraren via Lund University Publications (LUP).

Hör gärna av er om ni inte är bekväma med någon punkt eller om vi har missuppfattat något som sagts.

Appendix 9 - AI Contribution Statement

This study initially used OpenAI's ChatGPT 3.5/4 in order to brainstorm ideas and then troubleshoot said ideas. We also used AI, Whisper & Klang.ai, to transcribe the interviews. However, some audio files had poor quality, making them unsuitable for transcription. Therefore, all text was reviewed again by the authors. Furthermore, ChatGPT was used in chapter 3 to improve the grammatical structure and language of some paragraphs, however, this was proofread, and no additional information was added in the text ChatGPT generated. It was purely done to improve readability. No AIs were used to analyze the data we generated, as we felt that we'd lose insight into what we'd actually studied.

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