EMBRACING INTERNET OF MEDICAL THINGS

A multiple case study of contextual factors' influence on the implementation of IoT healthcare solutions

Camilla Jacobson

Petra Karjalainen

Abstract

With the growing trend of digitalization, new opportunities to disrupt the way value is created, offered and defended have arisen in the healthcare industry. One of the emerging concepts of digitalization is the Internet of Things (IoT), referred to as Internet of Medical things when applied in healthcare. Although these solutions bring a lot of potential opportunities for cost-reduction and improved outcomes, it also includes risks that the operators should take into account. The previous research is lacking comprehensive studies of the contextual factors and how those affect the implementation of IoT solutions in healthcare. This study aims to address this gap by understanding how contextual factors affect the implementation of IoMT solutions. To achieve this aim, a multiple case study is conducted, giving a holistic view of seven contextual factors. The results from the primary and secondary data illustrate that all of the seven studied contextual factors do influence the implementation of the solutions by the studied cases, although in different ways. The results of this study can be used by the managers of IoMT firms for creating implementation strategies, as well as by other players in the ecosystem for analyzing how to utilize the IoMT solutions.

Keywords: Internet of Things, Internet of Medical Things, contextual factors, healthcare, digital health, eHealth, chronic diseases, distant monitoring devices

Acknowledgements

Table of Content

Table of Figures

Table of Tables

Introduction

In the information-intensive economy of today, Information Technology (IT) plays a vital role in enabling firms to change their traditional processes, as well as facilitating strategic competitive advantage (Gastaldi & Corso, 2012). With the growing trend of digitalization, new opportunities to disrupt the way value is created, offered and defended have arisen in all industries (Walker, Craig-Lees, Hecker & Francis, 2002; Porter & Heppelmann, 2014). As the potential of digital transformation has been highlighted, various e-initiatives have been launched during the last two decades, with the aim of transforming the conventional landscape of business and consumerism (Stephanie & Sharma, 2016). In the new era of communication and technology, internet has become entwined with most aspects in our day-to-day life through the explosive growth of electronic devices (Senthilkumar, Manikandan, Devi & Lokesh, 2018). This has opened up for the facilitation of various services through the usage of cloud computing (Narayanan & Gunes, 2011).

Although revolutionizing most aspects of life, the entrenchment of information and communication technologies (ICT) has been rather inconsequential when it comes to healthcare (Hill & Powell, 2009; Kellermann & Jones, 2013; Stephanie & Sharma, 2014). But like most other industries, the transformative powers of IT utilization and new technologies is also being realized within the healthcare sector (Gastaldi & Corso, 2012; Deloitte, 2018). As the global aging population is growing and chronic diseases are rapidly increasing worldwide, this magnifies the burden on the healthcare system, putting more pressure on governments, healthcare providers and doctors to find solutions (Deloitte, 2018). The digitalization of healthcare assets has been predicted to be one of the most effective ways to improve the efficiency and quality, meanwhile reducing the costs (Gastaldi & Corso, 2012). The adoption of ICT within the healthcare sector has led to notions such as electronic health (eHealth) and mobile health (mHealth), as means of including ICT in healthcare to a greater extent (Solanas et al. 2014; Michalakis & Caridakis, 2017).

One of the emerging concepts of ICT gaining more attention lately for its possibilities to alleviate the aforementioned problems within healthcare is the Internet of Things (IoT). As Internet of Things covers many areas, ranging from enabling technologies to mechanisms integrating the lower level components, the definition still remains broad. In an attempt to create a sound definition of the concept, Minerva, Biro and Rotondi (2015) propose that IoT entails "an application domain that integrates different technological and social fields" (p.6). With the increase of connected devices, combined with advance in systems to capture and transmit the data, this has created the possibility to intelligentize medical services. As the smart sensing technology collects information in real time, this allows for valuable investigation and forecasting of medical elements (Challoner & Popescu, 2019). When applied to the healthcare systems, IoT has been termed the Internet of Medical Things (IoMT) (Chang & Oyama, 2018). IoMT is a connected infrastructure of medical devices, healthcare systems and services and software applications (Chang & Oyama, 2018), and provides great opportunities for decreasing the costs of healthcare while improving efficiency.

While much has been written about IoMT from a technical perspective, highlighting the infrastructure and the architecture of the IoT systems (Yin, Zeng, Chen & Fan, 2016; Chang & Oyama, 2018; Irfan & Ahmad, 2018), less has been written about the indirect influencing factors, which could be argued to be equally important when reviewing the success of implementation (Coles et al. 2017). With researchers emphasizing the need for more exploration of the application of IoMT within healthcare, and to

investigate requirements from the healthcare side (Sun et al. 2018), we would like to add to the literature stream by applying another theoretical lens. With the raise of new applications of digital technologies within the healthcare, this also challenges the traditional models by providing new models for value creation within the health ecosystems (Iyawa, Herselman & Botha, 2016). As many actors interact within these ecosystems, it is of value to conduct further research examining what contextual factors influence the implementation of new technologies, aimed at alleviating the traditional healthcare model (Gjestsen, Wiig & Testad, 2017).

Despite the potential that such technologies could have in terms of primary healthcare improvement, the implementation rate has been rather low, with the healthcare failing to catch up with the medical industries rapid progress (Meskó, Drobni, Bényei, Gergely & Győrffy, 2017; Waters et al. 2011). Drawing parallels to similar implementation but of assistive living technologies, Gjestsen et al. (2017) explain this by pointing towards previous research lack of considering critical issues when using the technologies. They continue by emphasizing the need for research considering the wider social frameworks in which the new technologies are implemented within. As healthcare systems have a high level of complexity, the necessity to understand the context of the implementation is even more crucial.

The purpose of this study is to explore how contextual factors affect the operations of IoMT solution providers within the healthcare industry. More specifically, we aim to induce a greater understanding for in what ways the contextual factors affect the implementation of IoMT solutions and if the contexts are either enabling or hindering the implementation process. To fulfill this purpose, this study will utilize an adopted version of the framework of Context and Implementation of Complex Interventions (CICI), which is developed to understand the role of contextual factors in healthcare implementations, by conducting a qualitative multiple case study. Subsequently, as previous studies have failed to capture the context and implementation in appropriate ways, more research exploring how different contextual factors interact and influence the implementation process has been called for (McDonald, 2013; Pfadenhauer et al. 2017). Based on this notion, we pose the following research question:

How do contextual factors influence the implementation of IoMT solutions within health care?

Although IoMT has been praised for its potentially transformational capacity, there is still little guidance for practitioners in terms of contextual factors and implementation of complex technologies to consider when participating in health ecosystems. As Pfadenhauer et al. state (2017), the understanding of context and implementation is insufficient and forms a critical gap between research and practice. By addressing this area which remains unexplored, we want to contribute by exploring the enabling and hindering contextual factors that medtech firms needs to consider when providing IoMT solutions. Therefore the study is of explorative nature where three real world cases will be investigated. The use of specific cases aid in the understanding of the influence of contextual factors and simultaneously become a mean to increase the transferability and applicability of our findings. In all cases the companies have implemented similar IoMT solutions focused on distant monitoring for chronic diseases. The focus on chronic diseases is due to its prevalence and cost for society. As the number of patients with chronic diseases is rising, combined with an increased life expectancy, this has led WHO to estimate that there will be a shortage of 4.3 million health workers around the world (Aluttis, Bishaw & Frank, 2014). Further, chronic diseases are a field where a lot of research has been done, both in terms of the disease but also when it comes to treatment and how technologies can address the growing need for care (Hamine, Gerth-Guyette, Faulx, Green & Ginsburg, 2015). In order to explore the contextual factors, a research model based on an adoption of the Context and Implementation of Complex Interventions (CICI) framework is utilized.

Regarding the outline of this thesis, it is structured in the following manner. Firstly, the introduction part presents the topic, purpose and the research question of this study. Subsequently, relevant research and theoretical background is presented aiming to describe the previous studies of Internet of Medical Things and Contextual Factors, and the research gap is identified based on the literature. Following the related research and theoretical background a description of the chosen the methodology and research design is explained. Thereafter, the empirical findings are introduced and further analysed in connection to the previous literature and chosen theories. Finally, a conclusion is drawn and the stated research question is answered.

Related research

This section presents previous research within the field of Internet of Things and healthcare, providing a foundation for the extended focus on IoMT solutions. First the development of the research area is explained, thereafter the need for more exploration is highlighted.

Internet of Things

For more than a decade Internet of Things (IoT) has gained a lot of interest and is recognized as one of the most important upcoming technologies (Lee & Lee, 2015). Although the term is commonly used and the technology is being implemented, there is no universal definition or understanding of what IoT actually contains of (Wortmann & Flüchter, 2015; Saarikko & Lindman, 2018). IoT was first introduced by Ashton and Brock who founded an Auto-ID Centre at Massachusetts Institute of Technology, describing how Auto-ID represents any type of identification technologies for various technologies that can track object while they are moving between different places (Yin et al. 2016). Since then, the concept has developed and various definitions have been proposed by researchers. Lee and Lee (2015) elaborate how IoT, sometimes even referred to as Internet of Everything, is a global network of devices and machines that are capable of interacting with one another. Similarly, Yin et al. (2016) state how IoT consists of a set of technologies supporting the interaction and communication within a range of networked devices and appliances. Bouhai and Saleh (2017) define Internet of Things as a network that is constantly spreading out and connecting traditional material objects to internet. More recently, Farahani et al. (2018) develop this further as they highlight the ecosystem aspect around IoT by defining it as a constantly growing ecosystem integrating hardware, physical objects, computing devices, software, people and animals over a network which allows them to communicate and collect and share data.

The transformative power of Internet of Things has been stated to bring opportunities for companies to completely convert their business models, having the possibility to introduce new product and solutions using IoT technologies (Porter & Heppelmann, 2014). As explained previously, IoT reflects smart, connected products that have extended capabilities of generating data (Porter & Heppelmann, 2014). Further, it is consisting of physical components such as the mechanical and electric parts of a product, smart components such as sensors, controls and data storage and connectivity components referring to ports, antennas and wired or wireless connections. Connectivity of IoT products can take three different forms: one-to-one, where an individual product connects to a user, one-to-many where a central system is simultaneously connected to many products, or many-to-many where multiple products are connected with each other and often to external data sources as well (Porter & Heppelmann, 2014).

Companies are broadly adopting IoT to increase revenues through enhanced services and to gain competitive advantage in the market (Lee & Lee, 2015). By providing IoT solutions, many traditional manufacturing firms have transferred their business models from traditional to subscription-based models. As Porter and Heppelmann (2014) elaborate, many companies are forced to rethink what industry they are operating in when transforming from traditional manufacturing firms to platform providers. Despite the advantages, adopting IoT solutions requires major investments and resources, whilst assessing the benefits and outcomes of these investments is challenging (Lee & Lee, 2015). Hence, firms need to assess carefully the costs and benefits of each IoT opportunity and challenge to assure careful use of resources.

Digitalization of Healthcare

The increase of healthcare technologies in administering patients' health is referred to as digital health, which refers to when a patient's health is enhanced by the usage of such technologies (Iyawa et al. 2016). Iyawa et al. (2016) define digital health as an improvement in the way how healthcare is delivered by healthcare providers through the use of ICT in order to monitor and improve the wellbeing of patients and to empower them in the management of their own health. Digital health, being a term commonly used among practitioners encompasses a wide range of different concepts such as eHealth, mHealth, connected health and Internet of Medical Things (Lupton, 2014). Whereas eHealth refers to the utilization of internet and web technologies in healthcare delivery services, mHealth regards the use of mobile application in healthcare services (Iyawa et al. 2016).

With the rise of digital health, a vast range of technologies has been made available for healthcare (Meskó et al. 2017). Mobile applications, devices, platforms and websites offer new ways of monitoring, measuring and visualizing the human body for healthcare (Lupton, 2014). Further, technologies such as smartphone connected ECG, genome sequencing, telemedicine and health sensors are now becoming disruptive (Meskó et al. 2017). Further, these innovations are awaited as they have the potential to contribute to a more value-based healthcare, aiding in the clinical judgement and making the patients the point of care. Technologies in which the healthcare is becoming more personalized, thus empowering the patient, is stated to lead to better outcomes and improvement in satisfaction (Kulkarni & Sathe, 2014). Among these technologies are IoT-leveraged solutions for healthcare, as it has the possibility to improve the access to care and increase the quality while reducing the costs.

Internet of Medical Things

Healthcare is one of the industries where IoT applications have gained presence during the recent years. IoT-based healthcare system connects the healthcare resources to operate different healthcare activities like distant monitoring, diagnosing or surgeries over the internet (Yin et al. 2016), and these systems collect data by monitoring and tracking patients, equipment and supplies (Laplante & Laplante, 2016). This cross-sectional application of IoT within healthcare has paved the way for an IoT derivative called the Internet of Medical Things (IoMT) (Chang & Oyama, 2018). As stated, Internet of Medical Things refers to IoT applications within healthcare and is defined by Basatneh, Najafi and Armstrong (2018) as "medical device connectivity to a health care system through an online network, such as a cloud, often involving machine to machine communication" (p.578-579). IoMT encapsulates the connected infrastructure of software applications, healthcare services, systems and medical devices (Chang & Oyama, 2018).

IoMT connects the users, i.e. patients and healthcare professionals, data, processes and enablers such as connected devices and mobile applications together to create more effective healthcare solutions (Deloitte, 2018). The IoMT paradigm consists of three parts: master, server and things (Yin et al. 2016). In this definition master refers to the users, such as the doctors, nurses and the patients, whereas server is the central part of the entire IoMT system and is responsible for prescription generation, database management, data analysis, knowledge base management and subsystem construction. Things on the other hand refer to the physical objects, including humans, that are connected through WAN, multimedia technology or SMS service. Another, similar way to describe the IoMT system is through three main tiers, namely sensors, gateway and medical centre server (Albahri et al. 2018). By this division, the sensors include the gathering of individual health measurements through devices. The collected data is subsequently sent to the gateway, which aggregates the data and transmits it to the

remote server. The last stop, being the medical centre server, is a remote computer in the medical facility which enables real-time monitoring of the data by medical professionals.

Even though the implementation of IoMT within healthcare is still in its infancy (Basatneh et al. 2018), the interest towards distant monitoring devices, such as wearables, has increased during the recent years, and the number of devices on the market is constantly growing (Hassanalieragh et al. 2015). Within IoMT, networked sensors that are either embedded on patient's living environment or worn on the body to enable the capturing of data, indicating information of one's state of wellbeing. The sensors can measure signs and other biometric information enabling diagnosing health issues in an earlier state (Laplante & Laplante, 2016). Furthermore, wearable sensors enable the users to get up-to-date information about their wellbeing, whilst providing real-time information to the healthcare professionals as well (Dimitrov, 2016). As distant monitoring solutions provide the empirical unit for analysis within this research, **Figure 1** provides a visualization of such a solution for further clarification. Although the solutions come in different shapes, they usually contain the components displayed, namely the device with sensors, storage of data, centralized repository and diagnostic applications (Albahri et al. 2018).
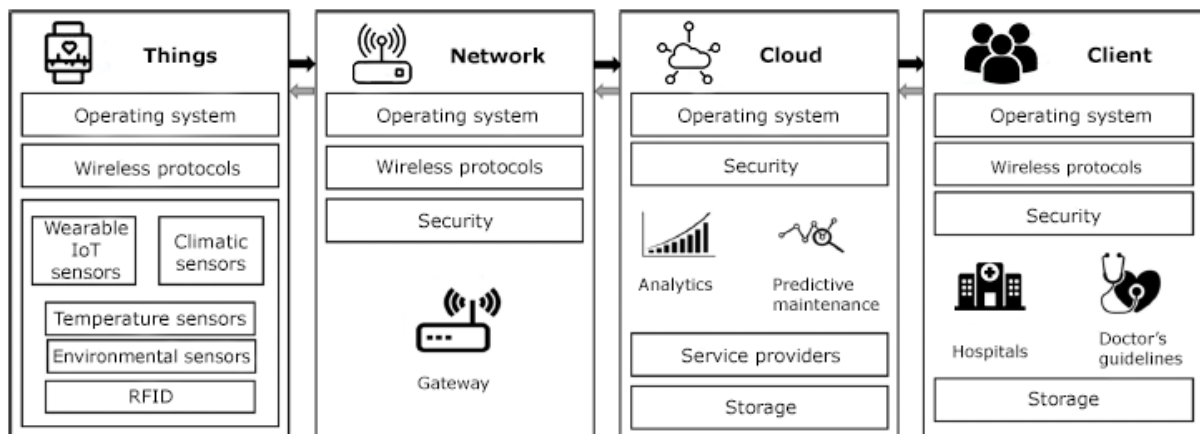
Figure 1: Example of IoMT monitoring architecture; adapted from Jagadeeswari, Subramaniyaswamy, Logesh and Vijayakumar (2018)

Research has pointed to how IoT applications can improve the healthcare provider's efficiency and patient's well-being simultaneously and significantly (Laplante & Laplante, 2016; Turcu & Turcu, 2013). Reviewing the research on IoMT, it has been approached from mainly three perspectives, defining the technology itself (Jagadeeswari et al. 2018; Debbarma, Mitra & Nath, 2018), opportunities and how it can be an enabler (Basatneh et al. 2018; Turcu & Turcu, 2013) and lastly there has been extensive research regarding the challenges connected to security and privacy concerns (Sun et al. 2018; Gulraiz, Rao, Aftab & Saad, 2017). As part of the research body on IoMT, opportunities and challenges have been emphasized (Jagadeeswari et al. 2018; Challoner & Popescu, 2019; Laplante & Laplante, 2016). These will subsequently be explored in the following sections.

Opportunities with Internet of Medical Things

Internet of Medical Things improves and intensifies healthcare services in various ways. Farahani et al. (2017) state how IoMT provides an all-encompassing solution for everyone's needs. IoMT can integrate and fusion different technologies to work seamlessly together and provides the possibility for personalization of the content or service for the user's needs (Farahani et al. 2017). With IoMT, patients

can be monitored throughout their lifetime and hence receive comprehensive long-term visualization of their healthcare data (Irfan & Ahmad, 2018). IoMT can reduce the costs of healthcare as the patients can monitor their own health status, making them to consult doctors only when the status is below the recommendation (Farahani et al. 2017). As Gulraiz et al. (2017) similarly state, IoMT improves the simplicity, affordability and ease of use of devices while increasing the efficiency of healthcare and cutting the costs. Furthermore, the doctors can be more involved as they receive real-time information of patient's health status and can thus monitor a higher number of patients by relying on IT healthcare systems. IoMT increases the availability and accessibility as patients and healthcare professionals can reach the data of health status anytime and is not dependent on the location (Farahani et al. 2017). A report by Deloitte (2018) further highlights the opportunities for decreasing the costs with IoMT, and how it can improve drug management and diagnosis and treatment, enhance patient experience and enables distant monitoring of chronic diseases, leading to improved patient outcomes. Lindman and Saarikko (2018) elaborate how connected healthcare solutions can improve patient security by informing healthcare professionals when a patient needs help. In summary, IoMT brings out the possibility to provide healthcare of better quality to a lower cost (Irfan & Ahmad, 2018), ultimately providing the benefit of longer lives (Gulraiz et al. 2017)

Challenges with Internet of Medical Things

Besides the benefits, IoMT devices possess multiple interconnected risks and challenges. The most prominent ones discussed in research includes security and privacy concerns, lack of standards, limited interoperability, the regulatory environment as well as internal healthcare concerns such as lack of trust, mismanagement and technical debt. These different areas will be further explained below.

As IoMT is expected to witness rapid growth during the upcoming years, the IoT healthcare domain becomes an attractive target for attackers, and the security threats are increasing as IoT devices have more surfaces that are potential surfaces for attacks (Farahani et al. 2017; Lee & Lee, 2015). Lindman and Saarikko (2018) highlight how security threats for IoT can stay unnoticed for relatively long periods of time since IoT devices operate more independently than desktop computers and smartphones, as they run with little involvement from people or fully independently. Michalakis and Caridakis (2017) state how security and privacy are of even higher importance for the users when the IoT solution is provided within healthcare. More IoMT devices are being connected to global information networks, hence designing highly scalable security schemes without compromising the security devices is challenging (Farahani et al. 2017). As IoMT devices are collecting and generating enormous amounts of data, the increasing number of connected devices creates risks for violations of data security (Deloitte, 2018) as the data collection, mining and provision are performed over the internet (Yin et al. 2016). According to Yin et al. (2016) the higher the autonomy and intelligence of things, the harder the protection of personal identities and privacy is. Further research in the field of security and privacy management as well as dynamic trust is called for by Yin et al. (2016).

Lindman and Saarikko (2018) elaborate how the lack of standardization is a potential threat for IoT due to many different suppliers but no clear interface that is used to communicate with different equipment. As a consequence, manufacturers develop their own communication protocols that often possess weak protection against unauthorized access (Lindman & Saarikko, 2018). Farahani et al. (2017) highlight how a dedicated group could be focusing on standardizing healthcare technologies, and how a wide range of topics such as communications layers, device interfaces, data aggregation interfaces and gateway interfaces should be considered. Further, lack of standards can create interoperability issues (Farahani et al., 2017). Deloitte (2018) suggests moving towards open platforms based on open

standards for interoperability to work effectively, as it will enable the providers, payers and technology vendors to make data more available to one another.

Besides standards, IoMT providers need to take regulations into consideration as IoT is regulated by a diverse group of regulatory agencies (Firouzi, Farahani, Ibrahim & Chakrabarty, 2018). The regulatory environment which governs traditional medical devices has made it a difficult task to adopt new models focusing on constant data generation, especially considering the timeline from production to implementation and use (Basatneh et al. 2018). Firouzi et al. (2018) present how IoT is even more regulated within healthcare as the medical field is regulated particularly strictly. As an example, IoMT providers in the US are regulated by three different agencies, all of which need to be considered when entering the market.

Lastly, Laplante and Laplante (2016) elaborate how the lack of trust is an existing issue within IoMT, as the devices create information that seems to be correct and is used as a basis for critical decisions. As the information used could be somehow corrupted or modified, the truthfulness of the information should be ensured when the information is used for decision making (Laplante & Laplante, 2016). To gain the user's trust, IoMT providers should ensure that security and other aspects presented earlier are considered carefully. Moreover, the potential of mismanagement of healthcare sensors or privacy issues with the patient's medical records, may also cause individuals to refrain from adopting IoMT (Challoner & Popescu, 2019). Adding to this, the lack of skilled workers has been highlighted as an issue as well (Williams & McCauley, 2016). Apart from these social concerns, technical ones have been stressed as well. The technical debt and liability of current technologies and systems within healthcare has been emphasized as a prominent challenge (Williams & McCauley, 2016).

Need for Further Research on Internet of Medical Things

To conclude, IoMT can have great benefits such as cost reduction and improved efficiency that can help to tackle obstacles within the healthcare industry. However, there are still challenges in regard to the technology and the adoption of it. Based on the reviewed literature, we can conclude that previous research has covered the aspect of opportunities and challenges connected to IoMT to some extent but most of them do so from a narrow viewpoint and does not account for the potential influence of the context. As previously pointed out, when the setting for the implementation is complex, such as within healthcare, the need to consider the context is even more crucial. Although being praised for its potential, there is still little research exploring real-life cases of IoMT implementations. The ones that do, often focus solely on one contextual dimension such as the technical (Yin et al. 2016) or socio-cultural aspect (Meskó et al. 2017). As previous research has failed to encompass a more holistic view of how the context influence the IoMT solution being provided, this research will subsequently apply such a contextual lens.

Theoretical background

This section includes a descriptive background to the theory of contextual factors, as well as explains the theoretical construct of Context and Implementation of Complex Interventions (CICI) and its applicability for this case. The dimensions of the framework are further elucidated and summarized to build a foundation for the research model.

Contextual Factors

Although the general idea of contextual factors has been known for decades, a precise definition has been lacking within the academia. Edwards and Steins (1999, p.207) define contextual factors as "dynamic forces constituted in the user groups' social, cultural, economic, political, technological and institutional environment". This is further developed by Rosemann, Recker and Flender (2008, p.3), emphasizing it as "the combination of all implicit and explicit circumstances that impact the situation of a process can be termed the context in which a business process is embedded." As contextual factors have many facets in terms of characteristics and can originate from both the internal and external environment (Papadakis, Lioukas, & Chambers, 1998), the need to operationalize when conducting an analysis becomes clear (Banker & Natarajan, 2008). As it might be difficult for companies to identify all of the contextual factors, certain frameworks have been initiated in order to categorize the contextual factors to understand their nature and to increase the applicability of the concept (Dey, 2001; Kronsbein, Meiser & Leyer, 2014).

Within healthcare, contextual factors as a research domain has been increasing lately with various studies trying to conceptualize it (Kitson et al. 2008; McCormack, McCarthy, Wright, Slater & Coffey, 2009; Damschroder et al. 2009; Kaplan, Froehle, Provost, Cassedy & Margolis, 2013; Pfadenhauer et al. 2016). Gjestsen et al. (2017) stress the need of understanding contextual factors as it can enhance the transferability of the knowledge and findings produced. As the phenomenon of health care is a complex system, when integrating a new technology, one needs to consider the wider social framework as the results will be fundamentally context-dependent (Wells, Williams, Treweek, Coyle & Taylor, 2012). In their report, the Agency for Healthcare Research and Quality (2013) emphasizes that by paying attention to the context when designing, conducting and reporting research on health care, it can increase the potential of advancing the understanding of previously inconsistent results. Thus, focusing the research on key features of the environment in which the intervention is immersed in, is indeed an appropriate fit. However, when reviewing the contextual factors one needs to be aware that context is not solely a backdrop to the implementation as it interacts, facilitates or constrains the intervention and its effectiveness (Dopson & Fitzgerald, 2005; Pfadenhauer et al. 2016).

Due to the potential of the research domain, the interest in context has increased in the recent years, with a growing number of studies trying to construct frameworks and models for analyzing its complex nature and influence on healthcare implementation efforts (Øvreveit, 2014; Robert & Fulop, 2014). In their literature review on contextual factors, Coles et al. (2017) provide a summary of the published frameworks, a list comprising of Promoting Action on Research Implementation in Health Services (PARiHS) (Kitson et al. 2008), Context Assessment Index (CAI) (McCormack et al. 2009), Consolidated Framework for Implementation Research (CFIR) (Damschroder et al. 2009), The Model for Understanding Success in Quality (MUSIQ) (Kaplan et al. 2012) and Context and Implementation of Complex Interventions (CICI) (Pfadenhauer et al. 2016). The frameworks propose different instruments for assessing the contextual influence and have been applied in various settings for analyzing different measures of healthcare implementation, interventions and quality improvements. In

a recent research paper the key contextual factors when implementing assistive living technology in the Norwegian healthcare is investigated using the MUSIQ framework (Gjestsen et al. 2017). Although the case does not formulate a solution for how to actually implement assistive living technologies, it provides insights by generating empirical knowledge about the contextual factors that influence the implementation at various levels. Due to its apparent usefulness, the MUSIQ framework was considered in the light of this study, however as it focuses on quality improvement projects (Coles et al. 2017), the framework of CICI was deemed more applicable. As the CICI framework facilitates a way to assess the context when implementing interventions, integrating three dimensions, it was considered a good fit as this research concerns IoMT interventions and their implementation within healthcare.

Regarding the limitations of contextual factors, Coles et al. (2017) state that despite the recent methods addressing the influence of context, research of how to assess or measure contextual factors is still in a rather immature state. Due to this the definitions of context in the literature vary. Moreover, although research on contextual factors is emphasized as valuable, it can likewise be time and labor intensive, depending on the analytical level (Agency for Healthcare Research and Quality, 2013). Further, the same study mentions difficulties in identifying which of the possible contextual factors to track, as a potential concern. Additional critique is given to quantitative assessments as they cannot explore and articulate *how* and *why* contextual factors influence (Coles et al. 2017). However, these potential limitations are limited in this study, as it is of qualitative nature and as the application of the CICI framework provides clear guidelines in terms of contexts to research.

Context and Implementation of Complex Interventions (CICI) framework

When introducing the CICI framework, Pfadenhauer et al.'s (2017) objective was to address the lack of a framework encompassing both contextual elements and the implementation aspect for analysis. Consequently, as a part of a EU funded project, INTEGRATEHTA, they developed a model to facilitate a comprehensive conceptualization for assessment of context and implementation of health interventions. By conducting a systematic literature review, examining the conceptual maturity of both concepts as well as interviews with experts, the first version of the framework was established. The framework was subsequently tested by applying it to an exemplary intervention, to later be iterated and revised. An addition was the inclusion of setting, which although sometimes used interchangeably with context, has a different connotation. This extension provided a clearer conceptual difference and a more precise definition of the characteristics included in the domains. The final version of the framework was then applied to different interventions, meanwhile using various methodological approaches such as applicability assessment, qualitative and quantitative reviews. As it showed coherence, completeness and ease of applicability, it was decided to be the final version.

The CICI framework ultimately encapsulates three dimensions which interact, namely context, implementation and setting (Rohwer et al. 2017). The first dimension, context, includes seven domains; socio-economic, epidemiological, legal, political, ethical, geographical and socio-cultural. The second dimension of implementation concerns implementation domains of theory, process, strategy, agents and outcomes. Lastly, the setting refers to the actual physical location of where the intervention is applied (Pfadenhauer et al. 2017). Additionally, their utilization of the term *intervention* is defined by Pfadenhauer et al. (2016) as referring to the specific object considered, which can be the technology, intervention, innovation, evidence-based practice or the quality improvement.

Context

As previously mentioned, context refers to the characteristics of active and unique factors that surround the implementation. It is not static, but interacts, modifies and either facilitates or hinders the intervention and the implementation of it (Pfadenhauer et al. 2015). The contextual dimension of the CICI framework consists of seven domains; *socio-economic, epidemiological, legal, political, ethical, geographical and socio-cultural*. The *socio-economic* domain incorporates the social and economic resources of a community and the populational access and use of those (Damschroder et al. 2009). The *epidemiological* domain includes the allocation of diseases, the burden of the conditions of the diseases as well as the needs of the population (Rychetnik et al. 2002). Due to this, it also includes the demographic aspect (Hage et al. 2013). The *legal* domain concerns the rules and regulations, initiated and enforced to protect the population's wellbeing and rights (European Network for Health Technology Assessment, 2011). The legal context and its norms are different from the ethical and social ones, as they are imposed by a legislative body, such as the government (Lysdahl et al. 2016). The *political* domain comprises of the distribution of power, resources and the interest of the population. Whereas it does not cover the legislative work mentioned in the previous domain, it does cover the interests and the formal and informal rules of organizations involved in the interaction (Nash et al. 2006). This domain also encompasses the health care system and the procuring of its services. The *ethical* domain includes reflections upon morality, reviewing the principles that guide the behaviour of individuals and institutions. The domain also touches upon subjects such as beliefs and codes of conduct, as it is mainly concerned with the moral norms and values in connection to the intervention of study, and its usage (European Network for Health Technology Assessment, 2014). The *geographical* domain refers to physical environment, mainly the available landscapes and resources, both natural and transformed by humans that are available in the setting examined. Lastly, the *socio-cultural* domain encompasses both explicit and implicit behaviour patterns, their embodiment in symbols and the culture and social norms shared among members of a group (Sabatier, 2007). Hence, this domain covers constructs like conceptions, customs, community and institutions.

Implementation

Due to that implementation as a term used to be rather vaguely defined, Pfadenhauer et al. (2015) conceptualize it as a result of their analysis, stating that implementation emerges as an "actively planned and deliberately initiated effort with the intention to bring a given object into policy and/or practice" (p.110). This is usually done through a process based on a strategy, where the intervention is put on use and promotional efforts are undertaken by agents to increase the adoption and use of the technology (Damschroder et al. 2009; Nilsen, 2015). Thus, implementation is something active and dynamic, deliberately initiated, complex and multi-faceted (May, 2013; Kitson et al. 2013). The implementation process refers to the methods and means to ensure adoption and sustainment of the intervention (Pfadenhauer et al. 2015). Usually these methods include a range of activities tailored to the specifics of the context (Aarons et al. 2014; Damschroder & Hagedorn, 2011). Regarding implementation agents, this covers all individuals and organizations, both internal and external, engaged with the decision to implement the intervention, the ones actually implementing it and the ones being affected by it (Pfadenhauer et al. 2015). Hence, it covers everything from funders, administrators, providers, nurses to patients and their families.

Setting

The domain of setting encompasses the physical and organizational environment in which the intervention is implemented and delivered in (Pfadenhauer et al. 2017). It is the immediate physical

environment, the organizational structure in which the provider and recipient interact, incorporating how the various stakeholders are affected (Pfadenhauer et al. 2016).

Limitations of CICI framework

In terms of limitations, some aspects are mentioned. Although leveraging a systematic research approach in the identification of existing frameworks, theories and models on context and implementation, there is a lack of database searches within management and organizational research (Pfadenhauer et al. 2017). Further, it should also be noted that the dimension of setting is less conceptualized, as it was added in the last iteration. However, this was not deemed a problem since the main focus within this study lies on the seven contexts.

Research model

This chapter proposes the modified research model, based on the Context and Implementation of Complex Interventions framework. The model is subsequently used as a foundation and a guiding tool when collecting the empirical data.

As context is known to have a considerable impact on the uptake, reach and effectiveness of an intervention, but is rarely considered (Pfadenhauer et al. 2017), it provides a case for applying the CICI framework as a research model. With its strong theoretical base and systematic review of empirical application across several health interventions, the Context and Implementation of Complex Interventions framework has proven its value as a research tool (Pfadenhauer et al. 2017). The framework can be applied to health interventions that operate across multiple settings and engage several implementation agents across various sectors. Additionally, it can be adapted for different purposes to match the health technology assessment at hand. Finally, it can also serve as both a determinant framework seeking to conceptualize influences on implementation, or rather as an explorative tool, evaluating and clarifying the context, setting and implementation aspects that have an influence.

Adaptation of the CICI framework

Nonetheless, although being flexible it is not intended as a straitjacket. In order to facilitate a pragmatic application of the framework, one needs to modify the generic suggested checklist in accordance to the intervention being assessed. The generic checklist provides questions regarding how the factors of the respective dimension exert their influence, and how it ultimately affects the implementation of the intervention (Pfadenhauer et al. 2016).

Based on the purpose of this study, to explore how contextual factors affect the operations of IoMT solution providers within the healthcare industry, the CICI framework has been adopted accordingly. As the research focus for this study lies within how the different contextual factors exert their influence on the implementation and provision of IoMT solutions, implementation consequently needs to be defined. Implementation, being a rather broad term as stated previously, is in this study referring to the initiated efforts of bringing a solution into practice. Thus, a certain time frame of the implementation is not given, but it is seen as rather a continuous process of providing the service. Further, in this research the intervention of study concerns IoMT solutions, and more specifically distant monitoring technologies. As previously described, distant monitoring solutions refer to technologies enabling monitoring of patients outside of the conventional clinical setting, providing real-time information to both the patient and the healthcare professionals. Based on these delimitations, the study commenced using the framework provided in **Figure 2** as a guiding tool.
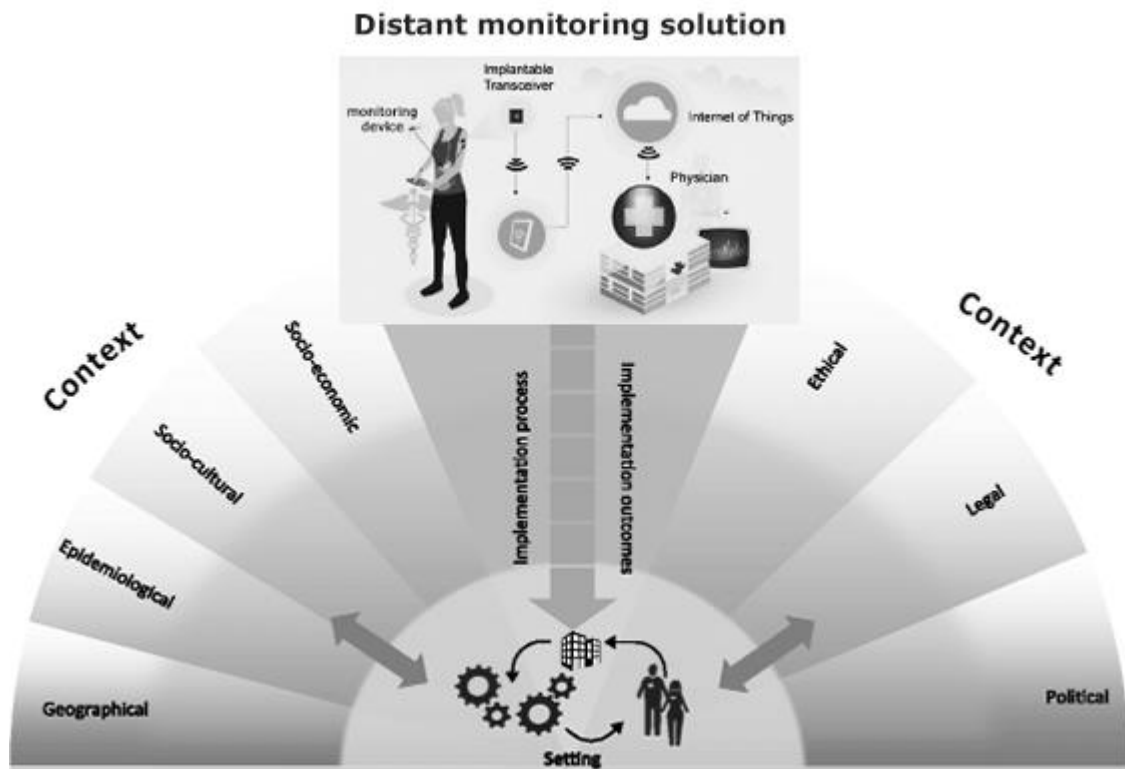
Figure 2: Research model; created by authors; adapted from the CICI framework (Pfadenhauer et al. 2017)

As the purpose of this study is to explore the effects of the contextual factors, naturally the contexts are the main research focus. Therefore, the contextual factors are given priority over elaborating on all the aspects included in the dimension of implementation. Hence, the CICI framework was adopted accordingly, in which the other aspects were limited in the model. The implementation context merely provides a frame for reviewing the current status of providing their solutions among the companies. Further, the setting will still be considered, but not to the same extent as the original model proposes. Although the research model is thorough, one needs to remember that it is impossible to discover everything (Peters, Harmsen, Laurant, Wensing, 2002). However, it provides a structured way for advancing our understanding of the influence of contextual factors on IoMT solutions. Based on the findings, potential modifications to the framework will be explored in our discussion.

Research design

This chapter introduces the methodological approach which has been applied for this study. Further, it includes the research approach, empirical data collection, case sampling and respondents and method for analysis. To conclude the chapter, we elaborate on the qualitative assurance and ethical considerations.

As the aim of this thesis was to provide a better understanding of the role of contextual factors when implementing IoMT solutions within healthcare, a social science approach, allowing for investigation and interpretation of the influence of the various contexts, was needed (Bryman & Bell, 2015). In order to answer the research question, the study was designed as an exploratory qualitative multiple case study. The qualitative approach was chosen due to the aim of facilitating exploration of the influence of the contextual factors, thus the need to focus on words and text is greater than the need for quantitative data (Bryman & Bell, 2015). The qualitative approach is suitable when the interviewer needs a deeper understanding of a problem, as it allows for the opportunity to identify details, which in this case is favourable to grasp the complexity of the problem area. Moreover, due to the aim of this research, the collection of in-depth data from various perspectives was needed, thereby a multiple case study design was applied (Eisenhardt, 1989). By applying a case study design, selected empirical cases where IoMT solutions and connected services in the form of distant monitoring solutions have been implemented, could be explored. Based on the ambition to gain multiple perspectives, the choice was made to include three cases. This in order to gain a deeper understanding of the contextual factors by examining different companies, their solutions and implementations. This further provided the opportunity to contrast the cases, to explore potential similarities and differences (Yin, 2016).

In order to explore the field of IoT solutions within healthcare, the collection and review of previous literature within the field was essential to enquire the right knowledge before the interviews were conducted (Patel & Davidsson, 2014). The collection was based on several keywords, including: Internet of Things + Healthcare and Internet of Medical Things. As some initial journals were found on the topic, additional keywords were introduced, such as: Digital Health, Contextual Factors and Contextual Factors + Healthcare. Further, as the decision was made to focus on the contextual factors affecting the implementation of IoT solutions within healthcare, the literature collection was subsequently expanded to include searching for contextual frameworks. The frameworks encountered were then reviewed and scrutinized to assess the applicability for this case. The main search tools utilized for the literature collection of journals, articles and e-books were Google Scholar, Web of Science and ub.gu.se.

Data Collection

There are various ways in which data can be collected for a qualitative research, including observations, focus groups and in-depth interviews (Patel & Davidsson, 2014). For this study, the data was collected primarily using semi-structured interviews, with an interview guide as a basis. Besides the flexibility of applying semi-structured interviews, it was also used due to the nature of the research question and the previous choice of adopting a hermeneutic perspective, as it is consequently commonly applied (Bryman & Bell, 2015). Further, semi-structured interviews provide the researcher with rich contextual information regarding the respondent's experience as it allows for the interviewer to get a good understanding of the research area without influencing the interviewee with any preconceived notions (Bryman & Bell, 2015). Additionally, it is a collection technique widely adopted in information system research (Schultze & Avital, 2011).

The interview guide mentioned earlier was developed by iterating the suggested guiding questions provided by Pfadenhauer et al. (2017). The final semi-structured interview guide included questions framed around all contextual factors included in the framework, as well as general questions regarding the solution and the service, its implementation and nature. The questions were broad and open-ended to allow respondents to freely discuss what they considered important when answering (Bryman & Bell, 2015). Moreover, by utilizing this type of interview technique, it provided the ability to ask follow-up questions to add ancillary interesting considerations.

The interviews were carried out both through physical meetings and through Skype, with both authors participating. This was mainly due to geographical restrictions, but also done to accommodate the respondents and their busy schedules. In an ideal situation, all of the interviews would have been conducted in-person, however the quality of the physical and Skype interviews were still deemed to be on an even level, thus not affecting the outcome. Before each interview began, the interviewees were made aware of the essence of the research and asked to consent of the recording of the interview (Walsham, 2006). As all of the respondents accepted this, it allowed for the possibility to thoroughly listen and interpret their answer after, as all interviews were transcribed. The participants were also assured of their anonymity in the thesis.

Further, when conducting qualitative interviews one needs to be aware of the level of data saturation, related to the degree to which new data repeat what has already been expressed previously (Saunders et al. 2018). In terms of the number of interviews needed, this depends from case to case. This study resulted in six conducted interviews, although additional ones could be perceived as beneficial, a lot of empirical evidence had been repeated by the sixth interview, pointing to a clear indication. All the interviews had a duration of approximately 60 minutes, and were performed in English, except one interview that was conducted in Finnish and later translated into English. Before this decision was made, the authors made sure the interviewees were comfortable with the choice of language and felt that they could still express themselves in the best possible way.

Sampling of Cases and Respondents

The case study approach is a widely used research strategy, focusing on understanding the dynamics of the case setting (Eisenhardt, 1989; Eisenhardt & Graebner, 2007). Case studies can include the selection of single or multiple cases, analyzed at various levels (Yin, 2012). Moreover, when utilizing multiple cases, they are usually undertaken to jointly explore a phenomenon (Stake, 1995). As the study is of explorative nature, the sampling was done based on the need to find cases that could provide a foundation for better understanding the influence of contextual factors and what needs to be considered when providing similar solutions within the healthcare sector. As stated previously, the criteria were that the companies offered an IoMT service in the form of a distant monitoring solution for chronic diseases within any or several of the Nordic countries. Therefore, several potential case companies were explored and subsequently evaluated against the set criteria. As there is an evident demand for new solutions to alleviate the traditional healthcare, various IT-related projects and initiatives have been initiated and tested (eHälsa2025, 2018). Chronic diseases seem to be one of the main areas prioritized due to its costs and burden on the traditional care (Socialdepartementet, 2014; McKinsey, 2016).

The final cases were strategically selected to meet the requirements and represent the characteristics needed, thus a purposive sampling technique was utilized (Bryman & Bell, 2015). This ensured that the three cases were chosen based on their relevance to answering the research question. Further as they all

met the criteria the findings from the cases could be compared to contrast the derived findings from each case. This meant that some contact details given to digital caregivers were disregarded as they did not offer a service matching the criteria. Furthermore, the participating companies and employees interviewed will be held anonymous due to the competitive nature of the solutions they are offering and developing. Hence, the companies will be referred to as Case 1, Case 2 and Case 3, and the interviewees as Respondent 1, Respondent 2, Respondent 3, Respondent 4, Respondent 5 and Respondent 6. These titles will henceforth be used in the following sections of the thesis. Below, an extended description of the case companies is provided.

Case 1

Case 1 is offering digital health services and ICT solutions in Finland and internationally. The company is based in Finland and is a large-scale player, employing over 4000 people in their different departments. Currently the company offers distant monitoring services for chronic diseases such as high blood pressure (hypertension), asthma and INR. As stated by Yin et al. (2016), IoMT consists of master, server and things. The *master* refers to the user, which in this case is the patients using the distant monitoring solution at the location of their choice. Case 1 provides the *server* which Yin et al. (2016) describe to be responsible for the prescription generation, data analysis and knowledge base management. *Things* refers to the other physical objects, in this case the healthcare professionals as well as the monitoring device, provided by a partnering firm to Case 1, that the patients use for conducting the self-tests. Then the results are automatically transferred to their smartphones from the monitoring devices and sent further to the healthcare professionals interface. Currently Case 1 offers its distant monitoring health solution in Finland, but pilots have been conducted in Sweden and Norway and the company is exploring further internationalization opportunities.

Case 2

Case 2 is based in Sweden and offers a complete medical service for high blood pressure, based on a distant monitoring solution. The company was founded in 2017 and is a small-scale player, consisting of roughly 15 employees as of today. In terms of IoMT element, the *master* in this case is also the user or the patient using the solution provided. The next element of the IoMT is the *server* which for Case 2 handles the data analysis, providing medical prescription guidelines and health results. *Things* in this case is also the physical objects, referring to the monitoring device with sensors for transmitting of the blood pressure results by the patients, as well as the healthcare professionals connected in the ecosystem. The patients do the self-tests at home after initially being on-boarded through a triage system, in which they are asked to fill in several health-related questions and to take a test in one of the affiliated external laboratories. This diagnosis is done to determine that the right patients are on-boarded, namely patients that can be helped by the preventative measures and have not yet suffered by stroke, kidney failure or cardiovascular disease, as those should be treated by specialists in the traditional care. Subsequently, when matching the criteria for treatment, the patients are asked to download the app provided by Case 2 and are sent the monitoring device. The device is CE-labelled and produced by an external partner. In the app, videos are provided on how to use the technology and how to measure correctly in a standardized way. Apart from being able to see their transmitted results (which also are transmitted to Case 2's systems), the patients are additionally given guidance in terms of lifestyle advice or have the possibility to speak to a doctor through the chat function. The service is currently provided in Sweden, but the company is in the midst of exploring the possibility of an international launch.

Case 3

Case 3 is based in Sweden and provides a digital health ecosystem by offering a scalable platform, in which the individual gets personalized health service. The solution enables the patients to monitor themselves at home and have real-time contact with healthcare professionals when needed. The company was founded in 2016 with the aim of developing solutions for a connected healthcare for the patients they deemed need it the most, the elderly and patients with multiple chronic diseases. Like Case 2, the company is a small-scale player as well, consisting of approximately 10 employees. As Case 3 is providing an integrated platform-like solution, part of its offerings is based on IoMT technology. Similar to the two previous cases, the *master* in this case is also the one using the solution provided. The next element of the IoMT is the *server*, which for Case 2 handles the data analysis and the connected personal health records. *Things* in this case is also the physical objects, referring to the monitoring health wearables and sensors, enabling the patients to take their daily vital measurements. The sensors are thus responsible for collecting and transmitting the data. Further, things also refer to the health care providers connected through the platform ecosystem. The solution includes functions for managing personal needs regarding health monitoring, medication, training and food. Further, monitoring devices and the sensors are provided by partners to the firm. The cloud service of the company provides analysis and cognitive services. The patient has control of the personal data, which is safely stored, and decide whom to share it with. For the caregiver, the real-time patient data that is gathered is processed and analyzed to help the doctors and nurses prioritize in their work. Several pilots have been conducted in Sweden, and the company is in the midst of rolling out another pilot focusing on the chronic disease of heart failure and obstructive lung disease (COPD). Currently Case 3 is offering their service in Sweden but is aiming to go international eventually.

Sampling of Respondents

After the cases had been chosen, a snowball sampling technique was used to identify whom to initially contact (Bryman & Bell, 2015). This person was asked based on adequacy in answering the interview questions, or due to their network and possibility to refer to other potential respondents relevant for the research question (Walsham, 2006). The person contacted agreed to an interview in all cases, as well as helped with referrals to other suitable people. Due to this, people with different backgrounds and positions were contacted and interviewed, allowing for a more comprehensive and holistic view of the impact and influence of the different contextual factors.

The initial idea was to include three interviews per case, although in the end this was not feasible due to external circumstances. In case 2, two additional people with the roles of respectively CEO and product manager were initially set out to be interviewed, but unfortunately had to cancel due to time constraints. However, as a solution they were sent the questions and were asked to add their thoughts. Additional secondary material in the form of consultancy reports were provided to induce a more complete foundation. For case 3 two interviews were made, due to a current expansion and time constraints likewise. However, additional secondary material was provided in this case as well.

As the analytical perspective of the study is from the IoMT providers' viewpoint, a decision was made to only include interviews with employees of the companies. Although interviewing patients of the services as well as people within the traditional healthcare system could have added an additional layer, this was deemed outside of the scope for this study, making the focus too broad. As the service providers are the ones facing the contextual factors when implementing the service, their perspective was chosen as the main focus for this study, instead of taking the viewpoint of all actors within the ecosystem. Below in **Table 1** the respondents are presented, given pseudonyms, but still their real titles.

Table 1: Interviewees

Company	Respondent	Title	Date
Case 1	Respondent 1	Director of International Healthcare	2019-04-12
Case 1	Respondent 2	Service Manager	2019-03-28
Case 1	Respondent 3	Director of Medical Marketing	2019-03-22
Case 2	Respondent 4	Chief Medical Officer & Consultant	2019-04-02
Case 3	Respondent 5	CEO & Founder	2019-04-25
Case 3	Respondent 6	Tech Lead & Head of Design	2019-04-25

Data Analysis

As previously mentioned, the interviews for this thesis were recorded and later transcribed. In order to aid in the answering of the research question, a thematic analysis was used to analyze the collected qualitative data in a structured and systematic manner (Bryman & Bell, 2015). Braun and Clarke (2006, p.79) describe a thematic analysis as "a qualitative analytic method for identifying, analyzing and reporting patterns or themes within data". Regarding thematic analysis, it can either be theory-driven or data-driven, where the analysis either starts with theory or raw data (Braun & Clarke, 2006). This study employed both approaches, using mainly a theory-driven approach was utilized in the beginning, where indications in the findings were structured around the research model. This was however, followed by a more empirical approach, exploring the raw data to identify additional trends and indications within the contexts not identified by prior literature. The coding was done using the data analysis software NVivo. Initially axial coding was used to scan for similarities, differences and variations, whereas check-coding was mainly employed as both of the authors coded the same transcripts and later discussed any disagreements (Miles & Huberman, 1994). This provides a way to address the potential subjectivity of the coding as well as a way to strengthen clarity and reliability (Walsham, 2006). Furthermore, the analytical process included the comparison of the derived findings with the outcomes of prior research and theory. The final material was consequently read through several times to secure its alignment with what was said during the interviews.

Based on the results, the level of influence for each contextual factor was identified as either low, moderate or significant. This was done based on the respondents' answers, for instance based on statements such as "*This affects us very much*" or "*We haven't thought of this that much*". Further, as the data was categorized with NVivo, we identified how often the different categories appeared in the results.

Quality Assurance

The relevance and applicability of quality criteria in qualitative research have been contested, as its constructs are not as well defined as within quantitative research, where one elaborates on internal and external validity and reliability (Bryman & Bell, 2015; Fejes & Thornberg, 2015; Creswell, 2007). Nevertheless, there is still a need to assess whether the results a valid, and several researchers have addressed this, providing alternative measure for qualitative research. By using the concepts from

quantitative research, Yin (2018) presents an adapted approach for qualitative discussions in case study research. Bryman and Bell (2015) further highlight the importance of trustworthiness, which is divided into subcriteria of credibility, transferability and dependability (Lincoln & Guba, 1985). By utilizing these approaches, several measures have been undertaken to increase the quality of the study.

To achieve credibility in the research findings, methodological rigour is suggested. Thus, initially previous literature was used for defining concepts and the CICI framework to provide consistency and a logical model for analysis (Yin, 2018). Further, we made thorough measures to consider the transparency throughout the process of collecting and analyzing the empirical data. We ensured that we understood the information we inquired from the research participants so nothing was wrongly interpreted, thus achieving respondent validation (Bryman & Bell, 2015). In terms of the research transferability, for qualitative research it regards in which context the research findings can be valid within. A key decision to improve the analytical generalizability was to pursue a multiple-case study design over a single-case design (Yin, 2018). This allowed for cross-case comparisons, providing rich data regarding the influence of the contextual factors. However, the findings within this study are still limited to the context of the providers perspective. Regarding dependability, a systematic approach with highly transparent procedures are essential for providing the chain of evidence needed (Yin, 2018). Thus, the aim has been to be as clear and transparent throughout the research process as possible, providing descriptive explanations for the methodological choices made and how the conclusions drawn were derived.

Ethical Considerations

As healthcare is a sensitive sector in terms of ethical considerations, this aspect was considered during the study. Mainly, this was reviewed in connection to the information and respondents needed for the purpose of the study. As the sector is strictly guarded in terms of laws protecting the information of patients, this was avoided by purposely only interviewing respondents from the providers perspective. Additionally, no specific patient data were discussed during the interviews or disclosed within the document material provided by the companies. Additionally, ethical considerations regarding the companies and their provided solutions have been further considered and elaborated on when asking them about the ethical context. Further, due to their anonymity the respondents were very open regarding both success factors and obstacles regarding the implementation of their service. The anonymity of the companies, the respondents' names, the name of the solutions offered a means to increase the integrity and confidentiality of the respondents.

Results

*This chapter presents the findings from the three cases, providing informative descriptions on the influence of the seven contextual factors on the implementation of the technology and the service provided. For the ease of following the results, a summary of the contexts' descriptions is provided in **Table 2** below.*

Table 2: Description of the Contextual Factors

Contextual factor	Description
Socio-economic	The social and economic resources of a community and the populational access and use of those.
Epidemiological	The allocation of diseases, burden of the conditions of the diseases as well as the needs of the population.
Legal	The rules and regulations, initiated and enforced to protect the population's wellbeing and rights.
Political	The distribution of power, resources and the interest of the population. Formal and informal rules of organizations involved in the interaction.
Ethical	The principles that guide the behaviour of individuals and institutions. Beliefs and codes of conduct, moral norms and values in connection to the intervention.
Geographical	The physical environment, available landscapes and resources, both natural and transformed by humans that are available in the setting examined.
Socio-cultural	The explicit and implicit behaviour patterns, their embodiment in symbols and the culture and social norms shared among members of a group.

Case 1

Case 1 is currently providing their distant monitoring solutions to a large number of healthcare centres around Finland. Both technical and clinical pilots have been conducted. Some of the solutions for different therapy areas have already been commercialized and are implemented and used in healthcare centres around Finland. Case 1 is currently in the process of starting a pilot in Sweden soon, and is searching for partnering opportunities in Norway. Further internationalization opportunities are currently being explored.

Socio-economic

The socio-economic factors were stated to have an impact on the operations of Case 1. The respondents highlighted the importance of proving the socio-economic value of the solution. Before entering the market with any solution, Case 1 performs extensive clinical trials to prove the value of the solution, mainly to showcase its ability to provide more health. As explained by Respondent 2, the process is initiated when a high unmet clinical need is discovered. Consequently, a case is commenced to determine if the company can provide a solution to create better health through additional living years against a lower cost. As highlighted by respondent 3, the evaluation concludes with a *go or no-go* decision:

> *"We have learned that a service that has been scientifically proven to have positive effects to the society has a much higher success rate in the market. If we cannot provide better health with smarter cost structures for the society, then we will not produce the service".*

Regarding the cost of the service, the patient's economic situation does not have an effect, as Case 1 is providing the solutions directly to the healthcare centres. However, when conducting the clinical trials, a process is also initiated to define the price society is willing to pay. As the institutions in the OECD top 50 countries are carrying most of the costs of healthcare, this makes the solution more available for everyone. As a result, technologies which can provide more efficient healthcare are encouraged. Respondent 3 explained how a recent study conducted by them proved how the society can save up to 20 million euros by using their solution, and further elaborated how proving the value and cost effectiveness pushes the solution forward. All respondents highlighted that once the health economic effects are proven to be positive, thus providing more health with smarter cost structures, proving the value of using their solution for the healthcare centres is easier.

Epidemiological

The epidemiological factors were found to have some impact. Respondent 1 stated how the epidemiological factors affect the service design, as chronic diseases are mainly prevalent amongst the older population Hence, this must be taken into account in the service design. Respondent 3 mentioned that although the average age of the patients is relatively high, the patients mostly enjoy using their solution and find it easy to use due to the design. The respondents stated that the high number of patients does not affect what diseases they decide to provide their distant monitoring solutions for, as this decision is done based on where they can solve the high unmet clinical needs.

Legal

The importance of national and EU regulations, as well as data protection regulations was highlighted when asked about the role of legal factors. Case 1 is affected by national laws and EU-wide regulations. Respondent 1 highlighted the importance of data protection regulations, which need to be taken into account especially when internationalizing services. Although EU has regulated this, there is still country specific-data protection practices within EU meaning that Case 1 needs to have lawyers and data protection professionals on-board during the internationalization process.

International standards do affect the operations of Case 1. As an example, Case 1 operates in countries where the CE-marking is in place. The respondents stated that the CE-marking provides guidelines for how the system should be designed. As the CE-marking is valid in all EU countries it helps them while expanding to other countries. Besides the CE-marking, Respondent 1 mentioned standards related to transferring data and different international standards, such as HL7. Other standards are related to how to store, back up, delete and log the data in the cloud, and ISO standards were mentioned as well. Respondent 1 explained the following related to standards:

> *"The legal regulations and standards help us incredibly much. Those are helpful also when a professional comes to us and asks if we provide a certain solution that they have in mind, and when we tell them that we follow the internationally recognized standards, everyone is happy. We don't need to start explaining it further."*

The legal factors were stated to both slow down the implementation and increase complexity, but at the same time also provide guidelines which help during the implementation and internationalization processes. The respondents highlighted how the increasingly coordinated regulatory environment enables the implementation process as it makes the planning process much clearer and gives them better guidance and a roadmap of where to go.

On the other hand, regulations can disturb and slow down the innovation processes. Respondent 3 elaborated how EU has introduced a new medical device regulation, which has been referred to as an "innovation killer" as it slows down the innovation and implementation processes especially for start-ups. Respondent 2 further explained the downsides of the regulatory factors by stating:

> *"Standards and regulations are making things slower, instead of coming up with something and bringing it to market in six months it will wake two or three years instead. On the other hand, this is definitely needed because as a taxpayer, we shouldn't allow anybody coming and promising something while taking taxpayers money."*

Ethical

Based on the results, ethical factors do have a moderate impact on the operations of Case 1. The role of data protection, risk mitigation, system security and responsibilities were brought up in the interviews. Respondent 3 highlighted the following:

> *"The ethical aspects such as risk mitigation and security are something we always consider in meetings. When we are implementing something new we always have a risk mitigation workshop where we consider the potential risks and how those can be mitigated. The two big questions are the data protection aspects and how big responsibility we as a company want to take."*

The ethical factors were found to be in favour of Case 1, as having a good reputation being an ethical operator can improve the success rate of their solution. As Case 1 has handled big amounts of data for many years already, it was deemed to be one of the reasons why they have been able to succeed with distant patient monitoring. Their status as a secure company has been beneficial. Thus, the ethical factors were not seen as specifically limiting, but rather as something that should be followed as it decreases the likelihood of facing ethical issues. Respondent 2 mentioned how the discussion of whether it is ethical to use patient data should be turned around:

> *"Should we reframe the question and ask if it's ethical not to use the data as it can bring so much more insight into the care and provide so much better treatment for the patient?"*

Political

The political factors were found to have some impact on Case 1. Respondent 3 elaborated how they always have a dialogue with key opinion leaders, who have done a lot of research and publications within certain therapy areas to get their approval. This helps them to form partnerships and gain acknowledgment in the industry. Based on their opinion on the value of the solution, a decision to proceed or not is made. Respondent 3 and 2 elaborated how digital health solution providers should not identify themselves only as IT companies, as they might be viewed negatively as healthcare solution providers, which can hinder their potential operations in the healthcare industry. National politics does not have a big impact on the operations. Respondent 3 stated the following:

> *"All the politics are facing the same problem of ageing population so in that sense this is an easy one, as if we can provide something that's bringing more health and maybe even decreasing the costs, then politically these are easy ones. I haven't heard of a country that would be saying that we are definitely not going to digitalize anything."*

In terms of how to enable the solution, having good relationships with key opinion leaders was explained as beneficial by Respondent 3, as they have broad networks which could be leveraged for future partnerships. The main political factors limiting the implementation of the technology were told to be the complexity of the healthcare industry and its internal politics, as well as the reputation of IT companies in the healthcare industry.

Geographical

The geographical factors do not significantly affect the operations of Case 1. Respondent 1 brought up the infrastructural aspects in terms of how the accessibility and integrity of networks can affect the usability of their system:

> *"If you don't have a functioning network or you are in an area where the internet connection is not that strong, it affects the service design. We need to design the services so that they work under weak connections. We now have a system that a user can do the self-monitoring and training themselves in self-treatments without internet connection. But when the internet connection activates, the healthcare professional will see the monitoring results."*

Respondent 3 explained that as their solution is providing distant monitoring, the patients who are living far from healthcare centres can do the tests at home instead of driving to the centres, so in that sense the geographical factors are enabling factors. Respondents 2 and 3 brought up how the geographical factors could be looked from an environmental perspective, as their solution can decrease the need to drive back and forth to the healthcare centres, thus saving fuel.

Socio-cultural

Respondent 1 explained how they need to ensure that healthcare professionals are actively and continuously trained to use different smartphone models and healthcare technologies, as some of the professionals do not have sufficient digital capabilities yet. Respondent 3 elaborated further on this by explaining how the nurses have sometimes been slightly resistant during the early phases of the implementation, which is mostly due to their busy schedules. This can be solved by having continuous feedback sessions with the healthcare professionals in all levels throughout the implementation process.

> "*Currently there are so many digital initiatives and many hospitals are also trying to become paper free, so you can imagine how many digital solutions the nurses have to take in all the time. So, for them it's a new solution after a new solution so you really have to make it valuable and show them the value to make them believe in it.*"

Respondent 2 elaborated how the socio-cultural factors might hinder the digitalization of the healthcare industry, as the healthcare professionals might have monetary incentives to meet the patients physically instead of having more communication through the digital channels, making the adaptation to new technologies slower. Other socio-cultural hinderers brought up by Respondent 1 were restricting health conditions, such as memory disorders, that might be present amongst the elderly population.

Case 2

The roll-out and implementation of Case 2's IoMT-based service was made in December 2018, after several pilots with user tests had been conducted and evaluated. Moving forward the company is set on

an international launch later this year. Moreover, additional health services are aimed to be developed, especially when a sufficient amount of data has been acquired and machine learning can be applied. Currently, Case 2 has a collaboration with a primary health care facility in one of the largest regions, which makes their distant monitoring solution and service available for all citizens due to the free choice of clinic (Fria Vårdvalet). Throughout the implementation phase a network of lab partners close to the two largest cities has been established, with the future aim of including laboratories all over the country. Currently the company has their own contracted doctors, but as the company expands, the goal is to team up with insurance companies and establish a closer collaboration with the traditional health care and other digital health care providers.

Socio-economic

The socio-economic factors were stated to greatly impact Case 2 operations. The current Swedish system aims to give everyone equal access to health care, subsidizing the cost of healthcare. Subsequently, in order for the health care to be cheap for the patients, the provider of the service, whether traditional or digital, needs to have an agreement with the government. Hence, as of today the patients pay zero, which becomes an important basis for providing the service. However, the Swedish Association of Local Authorities and Regions (SKL) have recently decided that patients will have to pay 100 SEK nationally for every digital care visit. Although, still being cheaper compared to the 250-300 SEK usually paid for a visit to the doctor, this decision is highlighted by Respondent 4 as a factor which could potentially influence the continuous implementation and operations of the company:

> "*Well one thing that could really make things difficult, is if SKL decides that what the patient should pay suddenly increases. If they push up the price for the patients to pay, then the patient will be more hesitant, as they might not want to pay that much. The second is if they decide to lower the compensation, then that will affect us as there will be almost no profit, as we are giving away the monitors to the patients for free. [...] Those things could affect our service of course, but it is not in line with the 2025 vision for Sweden to become the leading digital health care provider in the world, so I doubt it will happen but you never know.*"

Connected to the market structure, the health care model provided by the company is emphasized as one of the major benefits by Respondent 4. The strong belief in the model as a better way to treat patients affected by chronic diseases, providing better access to healthcare while reducing the burden of the traditional care, seems to be a strong socio-economic driver. However, due to the stated need of these solutions in society, the competition and growing interest is stressed as a potential future concern.

Epidemiological

The epidemiological factors were found to impact Case 2, as it provides a demand for their service. The frequency of hypertension in combination with the healthcare system being unable to cater to their needs, were stated as two big influencers. Of the two million people in Sweden who have high blood pressure, only 15-20 percent reach their targets. Due to this failure, many patients are suffering complications such as stroke, which subsequently is costing the society a vast amount of money. Additionally, the older people get, the more prevalent it becomes. Due to the aging population and the spread and prevalence of the disease, the global need is huge, creating favouring conditions for the solution.

Legal

There are several rules and regulations guarding how healthcare should be provided, which consequently has an influence on Case 2 operations. When elaborating on the legal aspect, several laws which Case 2 has to abide by were mentioned by Respondent 4. Initially one has to register as a caregiver at The Swedish Medical Products Agency (MPA). Then when providing the service the company has to follow the Health and Medical Care Act (HSL), which is the uniform healthcare regulation for Sweden. Then there is the Patient Safety Law and the Management System for Systematic Quality Work, aiding in how medical technical devices should be used. Regarding the data, the General Data Protection Regulation (GDPR) applies to the storage of the data. Apart from these, the device itself and the whole concept are CE-marked as well. Although all these legal aspects are imposed to protect the societal interests, the amount of laws could be seen as a barrier when it comes to being a provider. However, the positive aspect of safety the regulations induce was highlighted by Respondent 4 as well:

> *"Then not everyone can go up and say we're going to provide a blood pressure treatment. [...] In one or another way you have to work with these aspects already when you start building the system. If you don't follow these regulation from start, you're not doing anything correctly. Basically they're not hindering but giving us guidance in how we should provide our services in a correct way even though we're doing it digitally. So actually it is helping us.*

Although the legal environment creates an initial entry barrier to the sector, it also fends off some competition due to the difficulties of navigating the legal context. Nonetheless, the dimension was stated as complex to manage, but yet very important as all issues concerns the safety of the patient.

Ethical

Respondent 4 highlighted several aspects that influence how the service is delivered. First and foremost, several ethical principles are given by the Society for Doctors (Läkarsällskapet) and Association for Physicians (Läkarförbundet), which the company follows. Similar to the regulatory aspects, Case 2 has a strong belief that these guidelines provide support in how to deliver the service and thus will make it better. Further, as the solution includes a vast amount of data being stored, the aspect of data protection was brought up when reflecting upon the ethical context. However, respondent 4 compared it to the traditional healthcare system, in which a server could potentially be hacked likewise. With iCloud being used for data storage, a lot of protective measures have been taken in order to secure the patients data and avoid any leakage of personal information. In accordance with the regulations for medical journals, the patient's data is stored for at least ten years. However, if a patient decides to leave the service, the file is closed and the doctors can no longer see or access the information in the patient's file. This is emphasized as something which makes the system potentially even more secure in terms of patient's privacy:

> *"I think that in a way, it's even better than the medical journal system in the hospitals, because there I can still access patients that aren't mine, even though they have left the primary care. You can still go in and read if you want to. It's not legally right, but it's possible."*

As ethical issues can occur in conflict, the issue of responsibility was brought up during the interview as well. Risk assessments are a natural part of the whole process of providing the service, and several measures have been made to reduce the risks involved. As the main risk would be to get the blood pressure wrong, and thus potentially the inaccurate medical advice or dosing, this has been addressed by the service design of the monitoring device and the software. Furthermore, additional video tutorials

are provided and doctors are available through the chat function. Moreover, in terms of responsibility if something would potentially go awry, every patient is assigned a certain doctor when on-boarding the service. Hence, the doctor becomes responsible for the patient in the event of a mistake. Further, the risk of miscommunication was highlighted as a result of the communication being chat-based, as it could potentially lead to missing information and the delay of treatment. However, such a risk was deemed minimal, as follow-ups are made.

Political

Regarding the political domain, there seems to be a clear vision of trying to leverage digital technology within healthcare to a greater extent. The 2025 eHealth Vision proclaimed by the government, stating that Sweden should become the leading digital healthcare provider, is highlighted by Respondent 4 as a direction which is in favour of their service. However, at the same time decision made by SKL regarding the cost structure and subsidizing of digital care, makes the current political situation more complex to navigate and assess. As resources are scarce and there is an ongoing debate in society concerning digital health care and the cost for society, the political dimension is highlighted as amongst the ones with largest impact on the service. Consequently, Case 2 is working in every possible way to provide evidence in how they can offload the traditional health care by offering a more precise care, involving the patients. However, the internal politics of the healthcare industry is an evident factor as well, as the mindset of the current healthcare professionals were discussed. Even though there are doctors and nurses who do not want to see a change in the old traditional ways of treating patients, there are doctors who believe in the inclusion of digital technologies likewise.

> *"I don't think we can avoid digital care, it's really an effective way of treating patients. We just need to find harmony with the old traditional healthcare system."*

Geographical

As stated previously everyone can get access to the digital health service provided by Case 2 through the ability to choose your own clinic. However, with the current infrastructure of lab partners, this becomes to some extent one of the main challenging factors. But as the network of lab units is growing, the aim is to offer the service with the same convenience for all citizens of Sweden. Further, as some or the more rural areas in the north of Sweden do not have the same close access to health care, this is deemed as something working in favour of Case 2 services. Patients in geographically remote places are stated to be one of the main beneficiaries.

Socio-cultural

Being a rather broad dimension, respondent 4 initiated the discussion by commenting on the high level of willingness to use digital technology among the Swedish population. As the entrenchment of smartphones has enabled the usage of health applications, there is a lot of existing knowledge among the patients when it comes to tech-based health care. With a current patient base consisting of people over the age of 75 years, using the monitoring technology successfully, the age should not solely be considered a disadvantage. Further, as stated previously, on a societal level there is an ongoing debate regarding digital health care and the cost for society. This influences the citizens as well and whether they feel like digital health care is safe and a convenient way of getting treatment. Adding to this, Respondent 4 pointed to the potential of digital health care making the patients feel less exposed. Because of this it might be easier for patients to communicate with their doctor when they do not have

to see each other. Lastly, the adaptability from the healthcare side and doctors' willingness to use and recommend the service was once again brought up, with the respondent stating that:

> *"They don't want to see change of the old traditional ways of treating patients, even though we know they are not the most effective ones. I'm not sure, if you put all the majority of doctors together, if the majority of thinkers are on our side or on the other side. But I think with time, time is in our favour."*

Case 3

After parts of Case 3's solution was tested in an European project for generating user-feedback in 2017, a pilot project was initiated in 2018. The project was conducted in collaboration with a health care centre and a municipality providing healthcare in the home. During the spring of 2018, 20 patients with previous heart failure were included to use the service and technology provided by Case 3. All patients were given a tablet with appurtenant technical solutions of monitor instruments. After three months the pilot concluded and was evaluated, however several of the patients decided to continue using the solution and an additional 128 patients were added. Even eight months since the pilot commenced, there has been no acute hospital visits due to heart failure. Since the initial implementation, several other municipalities have been interested, and subsequently three more pilots have been initiated as well. Case 3 is currently in dialogue with health care providers aiming to offer the solution on a greater scale.

Socio-economic

Taking the socio-economic aspects into account, there are major improvements that could be fulfilled by digital health technologies according to Respondent 5. Both in terms of savings for the hospitals, but also the access to care among the people that need it the most. This is why Case 3 was initially founded, as explained by Respondent 6. The company was initiated due to them encountering an unmet need. Even though the transformation within healthcare was stated to be slow by the respondents, the vast amount of cost savings that could be realized for the society is emphasized as an enabling dimension. Only the pilot project conducted was calculated to have saved the county council approximately 350 000 SEK. By scaling nationally, the estimated savings could reach numbers such as 13 billion SEK. This due to a causality of less acute hospital visits, ambulance and transportations needed.

Another dimension highlighted as important in the light of the future potential, is where to put the responsibility for individual patients. As Case 3's solution reduces hospital visits due to limiting readmissions into acute care, 60-75 percent of the savings happen in the hospitals and not the primary care. However, with the current financing structure, it is the primary care which has to make the investment of buying the solution. This subsequently becomes a problem as their resources are highly restrained. Respondent 5 stresses that the cost structure evidently needs to be altered, as it becomes a liability for providers of digital health care. The limited monetary resources also tie in with other constrained resources, such as available nurses. Estimations have predicted that there will be a lack of 164 000 nurses by 2023, which calls for the need of change within healthcare.

> *"For anything that's done today within healthcare, it's a problem to meet with the (nurses working) hours. We can clearly see that the hours are really hard to find. It's not only about the budget any longer, it's even to find the hours for implementing it, because nurses don't want to be nurses. It's a staffing problem."*

Connected to the cost of implementing the service is the cost of using it. Currently none of the patients using Case 3's solutions have paid anything as it is all covered by the health care institutions. Thus, the cost becomes something that is negotiated between Case 3 and the health care. So far Case 3 has received some funding from various institutions to develop and evaluate their service. The need for developing a network of partners was stated during the interview with Respondent 6. Because of the external funding, Case 3 is currently in the midst of expanding their services to include treatment for more diseases.

Epidemiological

The epidemiological factors were found to influence the service, as it becomes a prerequisite for Case 3's existence. As the company currently is focusing on the people with the greatest need of care, elderly with multiple diseases are especially prone within this group. To explore and evaluate the need of this group, the pilot was conducted in one of the cities with the largest share of elderly people. A decision that was made, according to Respondent 6, based on the demographic trends and the likelihood of it reflecting the Swedish population in ten years. Respondent 5 elaborated further on the future situation, by stating:

> *"The opportunity is that the market will grow rapidly. We will have 50% more people above 80 years old and have 164 000 less nurses in 2023, which is dramatic. So the gap is there! If you look at the demographics on a country level, you get one picture, but if you look at it from a county council level only the three big ones will have a positive numeration of how many people that will be working. The other ones with a growing share of elderly people will have a flat or even declining working population."*

The epidemiological context and its future development was stated be an enabler for any provider of services targeting the group of elderly or people with chronic diseases. Connected to the main age group of the solution is the design and functionality of the technology provided. The service design has been accounted for, as Case 3 has worked a lot to make the technology and interface as intuitive as possible.

Legal

The importance of regulations was highlighted when asked about the role of legal factors. Similar to the laws mentioned by Case 2 in the legal section, Case 3 follows the regulation of HSL, GDPR, the Patient Data Law and additionally the Social Services Act (SOL). Further, the legal structure was stated to be partially enabling for Case 3's operations. This as they are collecting data on a patient level and not on a system level connected to the municipalities or county councils, which provides them with the ability to share the data. Although, at the same time the current law system was questioned by Respondent 5. As regulations in regards of HSL or SOL rarely have been tried in court, lawyers working for the municipalities make their own interpretations. Due to this, municipalities and county councils may operate under different conditions, which affects the companies having them as customers. The need for clearer legislations was stressed by Respondent 5:

> *"If you don't know the rules before you start the game, it's gonna be impossible. So of course we would like to see clearer rules and guidance. I mean we, as a small company, started by doing a 120 page legal report based on how the legislation looks today. It took us three weeks with a lawyer just to go through all regulations. For a start-up company who is funded with our own means, should we do that? It's crazy, somebody should have done that and created a transparency, guiding - 'you should do this and this' and 'you shouldn't do that'."*

In line with this, Respondent 5 stressed that more could be done legally to favour the development of digital health care. If the government were to decide that everybody should have the right to a digital tool, much like they decided that everybody should wear a bike helmet, that would be a huge enabler for Case 3's services. At the same time it is also stated that the government has been aware for a long time that regulatory changes are needed, but that the adaptation is slow.

Ethical

During the interviews, the ethical context was found to impact the operation and implementation of the service. Data protection and responsibility were two of the main things that the respondents accentuated. As mentioned during the legal context, Case 3 is controlled by a vast amount of regulations. Due to this, the service provided is considered in line with ethical conduct. Furthermore, the aspect of data protection was brought up by Respondent 5, pointing to it as a vital aspect for the operations and something that has been extensively considered during the implementation. Additionally, the respondent points to cases of security breaches which have been debated in society:

> *"Handling data is a sensitive thing. We have seen, at least in Sweden, too many examples where government organizations or municipalities have not been handling data in the right fashion. I mean we have 1177, Transportstyrelsen and so on, which is of course embarrassing for the whole system."*

Even though people are getting more aware of the extensive amount of data gathered about the users in general, and thus asking questions regarding privacy, this has not been a major issue for Case 3. All of the patients are aware of how the service works and have chosen to opt in for the digitized care. The data, which is seen as secondary journal data, is collected in the back-end and stored safely. No data is stored out in the development as it is transferred in real time. Moreover, a two-factor authentication is used to provide a secure communication. Although all of these measures are in place to maximize the security, data protection is said to be a continuous concern since they will continue to handle sensitive data. However, Case 3's digital ecosystem is emphasized to be a solution to some problems when it comes to how many entities that should have access to someone's data. By allowing for secondary services to screen the data without giving it away, this enables the development of better services. By providing an intermediary and reducing the number of suppliers handling the data, this was stated to work as an enabling factor.

In terms of the ethical aspects of putting more responsibility on the patients, this was stated to not be a problem, rather the contrary. The increased feeling of safety due to the daily monitoring has been highlighted as something positive among several patients. The transparency is stated to induce a greater control over their situation and values.

Political

The political dimension was found to have a big impact on Case 3. Respondent 5 stressed problems with the national politics and the discussions regarding the current healthcare system. One of the key restraints concern how the budget is divided and the money allocated, as it is divided on a higher level which does not incentivize caregivers. As the primary care providers are financed based on their patient stock, it becomes a problem as most of the savings are enabled on a hospital level. Further, the political ignorance and lack of envision of how to handle the increasing costs of healthcare was stressed as worrisome by Respondent 5. SKL has stated that the Swedish society is missing between 30-50 billion

SEK to be able to provide the same level of healthcare in the future as of today. However, it was also emphasized that it does not necessarily requires an increase in the needed financing, but rather clear and distinct changes in the structure of how healthcare is delivered.

> *"We will not solve this by feeding more money into the system, because the system is wrong. The healthcare system needs to be healed first, rather than just providing more money into it."*

Additionally, changes in leadership, both on the political side but also within healthcare, was pointed out as a key. Even though the Swedish society has set an eHealth vision to be reached by 2025, a lot of discussions Case 3 has had with the traditional healthcare remains around the question of '*how?*'. Although the healthcare providers are aware of the need of new solutions, questions are often raised regarding how to make it fit within the current budget and how to implement it within the organization. The reluctance, stating that the organization is not ready, is hindering according to Respondent 5.

> *"I think it's very strange that you can formulate it that way. Of course it's good that they have pointed out the direction, but again I don't think we have enough sense of urgency in our acting right now. 2025 is very soon. We know that for one innovation in Sweden it takes 17 years from when it's ready until it has reached the floor in health care. So, on one hand I feel that 'yes, things start to move faster'. But at the same time it definitely doesn't. Because, when we talk with the big county councils they are still starting small pilots here and there, when they should be scaling now. Otherwise they don't have a chance of meeting the targets."*

Geographical

The geographical factors were stated to have a moderate impact on Case 3. The infrastructural aspects in terms of accessibility to broadband or telecommunications was brought up by Respondent 5 as having an influence. However, as it is a factor outside the scope of their control, it was expressed to not be a major concern. As the distant monitoring technology is beneficial for patients who have difficulties getting to the hospital, this was seen as an aspect in their favour.

Socio-cultural

Respondent 5 mentioned several aspects of the socio-cultural context which influence the implementation in various ways. Even though Sweden could be considered as one of the more advanced countries in terms of digitalization, 1.1 million of the population is not using internet on a daily basis. Nonetheless, the willingness to learn still remains high, and many patients who did not have a smartphone have learnt to use the digital health technology and distant monitoring solutions provided by Case 3. However, more challenges are stated to come from the health care professional's side rather than the patient side, as their willingness to believe in the patient's capability is deemed to be a much bigger problem than the actual capability of the patient. Healthcare professionals often question the ease of using the technology, however as stressed by Respondent 5, the whole ecosystem and solution are built around the capabilities of the patients as it needs to be designed for the patient's needs. The challenge is not the actual usage, but the perception and trust among the doctors and nurses, to believe that the patient can manoeuvre this type of service.

> *"The major issue we have is the reduction from 'can the patient do that?'. Every pilot we start, someone calls us and says, 'I had video meeting and it worked!'. And we say 'Well yeah, so we have done 250 000 of those video meetings already, we know that it works'. But it quite clearly shows what the state of level the users are today."*

Respondent 5 stressed that the lack of trust towards the patient's capabilities is a problem connected to change mentality and leadership, as many leaders hide behind legislations and says that the laws need to be changed first, rather than actually trying to investigate how these new digital tools can be used to alleviate the healthcare.

> *"Many people say that we need to change the law, and I agree, I think that we need to do that. But we have also proven it's all about leadership. What we did in the [pilot project] was thanks to one leader within the health care that said 'we should, and we can do so much better for the patients. If we can do something better for my patient let's do it!'. We did that without any changes of the law or changes in the current health care structures. Leadership and change management is a great thing in organizations. Unfortunately, municipalities and county councils are not organizations which have great change management. It's big rigid structures."*

It is evident that the lack of coordination and the slow process of digitalization is posing challenges for Case 3 moving forward with the implementation of their service.

Analysis & Discussion

In this chapter the analysis of the empirical findings in conjunction with the theoretical background is presented. As this study investigates how contextual factors influence the implementation of IoMT solutions within three cases, an analysis centred around the contextual factors is provided. Further, this chapter concludes by summarizing the findings, meanwhile also providing an extended discussion regarding the empirical findings and what implications they have in terms of research.

Socio-economic

As stated earlier, the socio-economic context includes the social and economic resources of a community and how the population can use and access them (Damschroder et al. 2009). Based on the empirical findings, the socio-economic context has a significant impact on all studied cases. The findings support what previous research has identified as opportunities of IoMT. Farahani et al. (2017) stated how IoMT offers opportunities for reducing the costs of healthcare as the patients can monitor their own health status which makes them consult the doctors less. This could be seen as one of the core reasons for why the cases are providing the distant monitoring solutions, as the solutions provide more cost-efficient ways to treat the patients. The respondents highlighted how their solutions can bring more health with better cost-structures, which supports the statements by Gulraiz et al. (2017) of how IoMT can improve simplicity and affordability while increasing the efficiency of healthcare and cutting the costs. The socio-economic factors were seen as strong enablers, as proving the socio-economic value pushes the solutions forward and can help to solve the challenges coming from the ageing populations and lack of healthcare resources. As highlighted for example by all respondents of Case 1, once the socio-economic value is scientifically proven and shown, the success rates are significantly higher. Potential hinderers brought up during the interviews include scenarios where the society would decide to cut down the monetary investments whilst making the patients pay more for the distant monitoring solutions. To conclude, from the socio-economic perspective IoMT works mainly as an enablers and companies planning to provide distant monitoring or IoMT solutions within healthcare should be able to prove the socio-economic value of their solutions to increase their solution's success rates.

Epidemiological

The epidemiological context refers to the allocation of diseases, needs of the population, the burden of diseases conditions and the demographic factors (Rychetnik et al. 2002; Hage et al. 2013). The findings show that the epidemiological factors were having a moderate impact on all cases, however Case 2 and Case 3 highlighted greater impact than Case 1. Case 2 and Case 3 explained how the demographic distribution of the population provides a demand for their service as chronic diseases are prevalent amongst the elderly people. This was also highlighted by the previous research, as IoMT systems enable doctors to monitor a higher number of patients (Gulraiz et al. 2017). On the contrary Case 1 stated that the high number of potential patients amongst the elderly people does not work as the only driver behind their solution, as they base their decisions on where they identify high unmet clinical needs. The epidemiological factors were found to have an effect on the service design, as the solutions need to be designed to cater to the needs of the users within the target group. This meanwhile considering the restrictions that some of the users might have such things as memory disorders or a low level of digital skills. The epidemiological factors were not found to be specifically enabling or hindering. The growing elderly population could be seen as an enabler as the number of patients is increasing, and the distant monitoring solutions can improve the efficiency of healthcare. Potential hindering factors were told to

be related to the restrictions coming from the age limitations as explained above. However, as addressed by Case 1, this can mostly be solved with good service design. However, as explained earlier in relation to the socio-cultural context, most of the patients were able to use the solutions despite their age. Moreover, we can assume that the epidemiological context will have a great impact and thus create a larger need for digital solutions in the future, as the number of nurses is significantly decreasing, while the amount of elderly people is increasing. To conclude, the epidemiological context helps to justify the need for digital health solutions, as the population is ageing in the Nordic countries and the healthcare is lacking professionals. However, the decision to offer services should not only be based on these factors but also the viability and clinical need of the solution.

Legal

The legal context refers to the initiated rules, regulations, norms and laws established to protect the population's health and promote its wellbeing (EUNETHTA, 2011). The legal context widely affects the studied organizations. As presented earlier, IoT is regulated by a diverse group of regulatory agencies (Firouzi et al. 2018). This is the case for the studied organizations as they are regulated under national and EU-wide regulations. Case 1 had experienced how national regulations can differ even between the Nordic countries to some extent, as it was described as a small hinderer. However, it can be solved with the help of legal professionals but takes extra time during the internationalization process. Furthermore, the regulatory environment was considered to hinder the implementation process as understanding the regulatory environment can take a lot of time. As an example, Case 3 had spent three weeks before the implementation with a lawyer going through all aspects of the legal environment they are regulated under. All studied cases agreed that the regulations slow down the implementation process. Nevertheless, interestingly enough all cases saw the regulatory environment being more of an enabler than hinderer, as it provides guidance and direction for their operations.

Lack of standards was one of the challenges of IoMT presented by theory, as it can create interoperability issues. The results did not support this statement of lacking standardization, as most of the IoMT solutions fall under the CE-marking in the EU and the cases are affected by other standards as well such as ISO and HL7. Hence, at least the healthcare industry seems to have regulated IoT systems quite well. The CE-marking was described as an enabler. Although the process for getting the marking takes time, having the marking makes the operations way easier. As Case 1 described, once they have the CE-marking, they can expand to all other European countries as they all follow the same standard.

Ethical

The ethical domain consists of factors reflecting upon morality, beliefs and code of conduct, and is concerned with the prevailing moral norms and values. Furthermore, aspects such as privacy concerns, system security and the aspect of responsibilities are considered under the ethical domain (EUNETHTA, 2014). The studied cases are significantly affected by the ethical factors, closely related to the legal factors explained above, as the role of data protection, security aspects, risk mitigation and the level of responsibilities were discussed during the interviews. Case 1 and 2 brought up the role of responsibility in a case if something would go wrong with their solutions and systems, with Respondent 3 further mentioning that the company should consider what level of responsibility they should take if something goes wrong. The previous research extensively emphasized the security risks associated to IoMT (Michalakis & Caridakis, 2017; Farahani et al. 2017; Deloitte, 2018; Yin et al. 2016). However,

our results do not support this statement as strongly, as the respondents expressed that they are considering this, but by following the regulations the risk of security breaches are deemed low.

The data protection aspect was highlighted as a very significant factor, as the regulations are affecting all of the cases. Case 1 explained how the regulations differ on a country level even though all countries would be a part of the EU and regulated under GDPR. Hence this has required them to include lawyers during the internationalization process. The previous research highlighted the risks related to data protection within IoMT (Yin et al. 2016; Deloitte, 2018). Based on the results this aspect was playing a significant role in the implementation. However, the data protection regulations were seen as enablers, as by following these strict regulations the likelihood of data security violations is smaller. Furthermore, Respondent 2 turned the question of if it is ethically right to use patient's healthcare data around, by asking if it is rather unethical to not use utilize the patient data, as it can be used for gaining more insights and the possibility to provide entirely new ways of monitoring the patients and treating them better. The ethical context can further work as an enabler for companies, as having a reputation of being an ethical company that handles data protection well can bring competitive advantage for the companies.

Political

As previously stated, the political context includes distribution of power, resources and the interest of the population. As regulatory work is included in the legal context, the political one is more concerned with the governing power and the internal politics of the institutions involved in the interaction (Nash et al. 2006). Based on the empirical findings, the political context is deemed to have a moderate to a great impact on the studied cases. Further, it was found to be both enabling and hindering in various ways. Case 1 stressed more favouring factors and elaborated on how having good relationships with external partners and opinion leaders work enabling for them. Further, if clinical results can prove the benefits of more health and reduced costs, it should be an easy political decision as the need is massive.

Whereas national politics were stated to not have a big impact on the operations in the Finnish market, the political situation in Sweden was stressed as part of the problem both by Case 2 and Case 3. Even though the direction of the 2025 eHealth vision in Sweden was stated to be an enabling factor, as it potentially will lead to more favouring legislations, the lack of urgency was stressed as a key problem. There is a lot of discussions of how digitalization will be harnessed to bring more health but very few examples. Furthermore, the budget and allocation of money within the current healthcare system in Sweden was highlighted as a hindering factor. The current structures are not incentivizing caregivers to buy digital solutions. Moreover, many healthcare centres have problems to fit such an upfront investment within its budget.

Further, the complexity of the healthcare industry and its internal politics was partly stated to be hindering, due to the reputation of IT companies within the industry. This finding is in line with the statements by Laplante and Laplante (2016), which highlighted the lack of trust as a challenge when it comes to IoMT solutions. To change the mindset of the current healthcare professionals, IoMT providers need to ensure that the security and other aspects, such as the interoperability, are considered carefully. Although stated to be mostly hindering, Case 1 also hinted about a shift within the internal politics. As medical firms provide frameworks and operating models that should be followed, this enables a greater utilization of digital technologies within healthcare, thus also changing the view on such solutions.

Geographical

The geographical context concerns the physical environment, mainly the available landscapes and resources, both natural and transformed by humans that are available in the setting examined (Pfadenhauer et al. 2016). The findings show that the geographical factors did not significantly affect the cases. However, in all cases it was seen as an enabling factor because of the distant monitoring technology being beneficial for all the patients with no proximity to the healthcare facilities. In addition to this, as the patients do not have to travel to the healthcare centers to take their tests, the flexibility aspect was highlighted by Case 1 as a major benefit. This is in accordance with what Farahani et al. (2017) found, stating that IoMT increases availability and accessibility as patients and healthcare professionals can reach the data of health status anytime and is not dependent on the location. Further, as the trips to the hospital becomes less, the potential environmental benefits were briefly touched upon as well. However, regarding hindering aspects, the infrastructural aspects in terms of how the accessibility and integrity of networks can affect the usability was mentioned by Case 1 and Case 3. Although mentioned, this was not perceived as a major concern. Case 2 expressed more impact from the geographical context than the other two cases. This was largely due to issues they have had in initiating a national network of lab partners. Although hindering them to some extent, a more ubiquitous network is in the pipeline.

Socio-cultural

As stated earlier, the socio-cultural context encompasses cultural and social norms and how they are enacted in both explicit and implicit behaviours (Sabatier, 2007). Based on the empirical data, the context can be deemed to have a large impact on all three cases, both with an enabling and hindering influence. The findings especially highlighted the ease for patients as an enabling factor, as the solutions provides convenience by reducing physical visits to healthcare facilities. Further, as the solutions allow for patients to be more involved in their own care, this patient empowerment was seen as something appreciated and beneficial. This is in line with the opportunities stated by Farahani et al. (2017) as well as in the report from Deloitte (2018). Moreover, the willingness to use the technologies was stated to be high. As there is high level of digital awareness among the Nordic population in general, all companies confirmed that they are leveraging the existing knowledge when delivering their services. Interestingly, even the elderly people, which one could assume does not have the same digital competences, was expressed to be eager to use the solutions. With high net promoter scores, there is a clear demand and pull from the patient side. Although, especially Case 1 stressed the need for intuitive service design and having a dialogue with both patients and healthcare professionals from the beginning of the development. Otherwise, this can quickly turn to a hindering factor.

Regarding the hindering aspects, although some things were highlighted in connection to the patients, such as potential difficulties when measuring and risk of miscommunication, most of the things emphasized concerned the healthcare side. The preconceived notions of the patients' digital competence seem to be one of the major hinderers. Further, the trust issue was highlighted, explained by Laplante and Laplante (2016), as there is a certain reluctance from the healthcare side to let external entities handle patient data. Thus, ensuring data security becomes a crucial aspect to succeed. Moreover, the digital capabilities within healthcare was pointed to as a potential hindering factor. This is in line with the concerns mentioned by Williams and McCauley (2016), however according to Case 1, this can be overcome by getting continuous feedback from the doctors and nurses during the implementation. Overall, the main hindering factor seems to be the lack of capabilities and leadership within healthcare.

Case 3 emphasized the need for leadership and change mentality within healthcare. This as healthcare comprises of rigid structures, where change needs to happen to address the current mindset.

Setting

The domain of setting encompasses the physical and organizational environment, in which the intervention is implemented and delivered in (Pfadenhauer et al. 2017). Based on the findings from the empirical material, setting was not deemed to have a large impact due to the interventions digital nature. In terms of setting, Case 2 mentioned that they would like to establish a closer collaboration with the traditional health care system, however stating that it is difficult as the structure of systems is very complex. Where the cases' offices are located was stated to not have any impact at all, and neither the type of healthcare site such as local healthcare centres or hospitals. Due to the technology being scalable, it is more about local market adaptations in terms of sales and marketing. The only factor slowing down the entry process into a new setting, a new region or country in this case, is related to the national regulations, as the firms need a thorough understanding of the local regulatory environment before entering the market. However, when entering and being part of a new setting, local knowledge and networks were said to be enablers.

Implementation

As implementation is stated to emerge as an "actively planned and deliberately initiated effort with the intention to bring a given object into policy and/or practice" (Pfadenhauer et al. 2015, p. 110), this was touched upon in the empirical findings as all the questions regarded influence on their implementations. Case 1 talked about different implementation phases, covering everything from the technical and clinical pilots to when one is commercializing the intervention. When pursuing an implementation, several aspects of the contextual factors need to be considered during the different stages. As it is about digital transformation, the implementation strategy need to cover a vast amount of issues connected to legal aspects, proof of financial viability, responsibility and data protection, networks, change management and training. By reviewing these various dimensions, it can help the implementation process as well as the final result because in the end, a lot of responsibility is going to be put on the providing companies.

Discussion of the Findings

All seven studied contexts impacted cases. Socio-economic, legal, ethical, political and socio-cultural domains were found to have a significant impact. None of these contexts was solely enabling or hindering, as all had some enabling and hindering aspects. However, especially the socio-economic and legal contexts were interestingly found to be mainly enabling contexts, whereas ethical and political contexts were characterised as both enabling or hindering. The epidemiological and geographical contexts had a low impact on the studied cases and were not clearly enabling or hindering. A summary of the findings is provided in **Table 2**.

These seven contexts provide a holistic view of contextual factors affecting the implementation of distant monitoring solutions. However, the CICI framework leaves out the technical aspects of the implementation, which is not necessarily a contextual factor but should be considered anyhow. We recommend that the technical factors should be reviewed continuously throughout the implementation process besides the setting, implementation and contextual domains. Based on this multiple-case study utilizing the CICI framework, we can conclude that the CICI Framework provides a good and

comprehensive tool for analyzing the contextual factors' influence on the implementation IoMT solutions. The respondents felt that the contexts do cover most of the things they have been considering during the implementation process, besides the technical aspect previously mentioned. Companies can utilize the CICI Framework by looking at the questionnaires and detailed explanations of each domain for reviewing their operations. Further, the different contexts can be analyzed when creating implementation strategies.

Some additional challenges and opportunities were identified during the interviews which were not addressed by the previous literature. The lack of incentives and reluctance from the healthcare side to go through this cultural transformation will potentially make patients a driving force in initiating these changes. Similar to this, the respondents highlighted how the patient's digital capabilities are on a fairly good level, however the healthcare professionals are lacking trust in the patient's capabilities. Another fact highlighted especially by the start-up firms studied, mainly Case 2 and Case 3, was the lack of capability and capacity of the regulatory agencies to integrate innovations into health care fast enough. As practical implications, the IoMT providers should concentrate highly on the service design, as this helps to tackle a lot of potential hinderers. Moreover, IoMT providers should be involved in building the digital capabilities of the patients as well as the healthcare professionals. The collaboration between the different parties, the IoMT providers and the traditional healthcare providers, as well as regulatory parties and governmental decision makers, were highlighted as important during the interviews, and should be further enhanced and elevated.

Table 3: Summary of the Findings

Context	Level of influence	Enablers	Hinderers
Socio-economic	Significant	• Cost reduction • Improved cost-effectiveness • Higher success rates once the socio-economic value is proven	• If institutions decide to cut down monetary support by making the individuals to pay more
Epidemiological	Moderate	• Growing elderly population • Prevalence of chronic diseases	• Potentially restrictions due to the age, e.g. memory disorders
Legal	Significant	• Provides guidance • Standards ease the internationalization process	• Time consuming • Costly
Ethical	Significant	• Data protection regulations reduces risk of security breaches • Reputational advantage as an ethical provider	• Time consuming
Political	Moderate to significant	• Having good relationships with external partners and opinion leaders • Swedish eHealth vision of 2025	• Budget and allocation of money within Swedish healthcare system • Complexity of the industry and internal politics • Reputation of IT companies
Geographical	Low	• Patients far away from healthcare centers can do the tests at home • Time savings and environmental benefits as patient's do not need to drive far to the healthcare centers	• Poor network connections in rural areas
Socio-cultural	Significant	• Higher patient involvement • High willingness to use the technologies	• Healthcare professionals' assumptions of the patient's digital capabilities • Lack of digital capabilities among healthcare professionals • Lack of change mentality and leadership within healthcare

Conclusion

This study aimed to understand how the contextual factors affect the implementation of IoMT services. More precisely, a multiple case study was conducted utilizing an adopted version of the Context and Implementation of Complex Interventions framework (CICI) to analyze seven contextual factors and setting. Thus, by researching cases using the framework to review the impact and influence of the contextual factors, this study contributes with insights in terms of how they enable and hinder the implementation of such solutions. By collecting empirical data through interviews with three different IoMT providers, the influence was subsequently assessed and analyzed, in order to answer the following research question:

"How do contextual factors influence the implementation of IoMT solutions within health care?"

This study gained an insight into the effects of contextual factors and their influence in the implementation of IoMT solutions within healthcare. Based on the real-life case studies, we can conclude that the implementation of IoMT solutions is highly influenced by contextual factors. All of the studied contexts were found to have both enabling and hindering aspects influencing the implementation of IoMT solutions. When weighing the evidence, socio-economical, legal, ethical and socio-cultural contexts were found to have the most significant impact. Further, the political and epidemiological contexts were deemed to have a more moderate impact and lastly the geographical context was stated to have a low level of influence.

Theoretical contribution

It is evident that there is a gap between the two academic streams of Internet of Medical Things and Contextual Factors in healthcare. We believe that positive results could be achieved by bridging them together to a greater extent. By conducting research with a greater socio-technical approach, more applicable and transferable findings could potentially occur. Hence, this thesis provides the first stepping stone in the aim of bridging these literature streams and an initial attempt in addressing the encountered gap. As previous theory is lacking a more comprehensive view on contextual factors influence on Internet of Things solutions within healthcare, due to prior studies mainly focusing on solely one or two aspects, this study contributes to this gap by testing and validating the CICI framework in this setting and by providing a holistic view. Thus, this study contributes to the existing literature of Internet of Medical Things and Contextual factors.

Practical implications

This study gives managerial implications for IoMT providers, as it can be used by the managers for making implementation strategies and analyzing the impact of contextual factors. The CICI framework gives a good holistic view of the environment and contextual factors, however one should be aware that the framework itself is rather broad and mainly ignores the technical factors. This study can further be used by other players in the ecosystem, such as the healthcare professionals or regulatory agencies, as the results touches upon potential enablers or hinderers coming from the collaboration with the them. This could help the ecosystem to think how to ease the processes and communication to ease the operations of IoMT providers. The CICI framework as a managerial tool provides a good sense for creating implementation strategies and reviewing the contexts.

Limitations

This research has some limitations that needs consideration. Firstly, the cases are based in different countries. Although this was not seen as large issue as the differences between the Nordic countries are relatively small, this aspect could have potentially been studied further, as some contextual factors might be affected by this. Secondly, although all studied cases provide distant monitoring solutions, Case 1 is significantly larger in size, than Case 2 and Case 3 which are still in a start-up phase. This gives Case 1 some advantage in terms of the amount of available resources and their already existing installed base. Thirdly, the studied framework is rather broad as a lot of information can be categorized under the seven studied contexts. As an alternative, we could have focused solely on one or two contexts. However, as the previous research is lacking a holistic view of the implementation and challenges and opportunities of IoMT, we wanted to address this gap by exploring the influence of all seven contextual factors. Lastly, in terms of methodological choices there are some limitations. Whereas most of the limitations already have been addressed in the *Quality Assurance* section in the method part, something that could also be reflected upon is the nature of qualitative studies and how the findings are based on the researchers own interpretations. Hence, future research is encouraged to further validate the findings.

Future Research

This study contributes to the existing body of literature within Internet of Medical Things, Contextual factors and Digital Health. Other scholars and students interested in the topic can use it for their own studies by building upon this research. Future studies could investigate this topic by taking the perspective of another player in the ecosystem, or by including more entities in the study. Especially contrasting our findings against a similar study from the healthcare professionals' perspective would presumably provide valuable insights. The future research could further include more firms from different geographical locations, or firms providing other types of IoMT services. Although this study touched upon the domains of implementation and setting, the main focus of this study was on the role of the contextual factors, hence this leaves room for further research gaining a deeper understanding on these aspects.

References

Aarons, G.A., Fettes, D.L., Hurlburt, M.S., Palinkas, L.A., Gunderson, L., Willging, C.E., & Chaffin, M.J. (2014). Collaboration, Negotiation, and Coalescence for Interagency Collaborative Teams to Scale-up Evidence-based Practice, *Journal of Clinical Child & Adolescent Psychology*, vol. 43, pp.915–928

Agency for Healthcare Research and Quality. (2013). Contextual Factors: The importance of considering and reporting on context in research on the patient-centered medical home, Available online: https://pcmh.ahrq.gov/sites/default/files/attachments/ContextualFactors.pdf [Accessed 20 February 2019]

Albahri, O.S., Zaidan, A.A., Zaidan, B.B., Hashim, M., Albarhi. A.S., & Alsalem, M.A. (2018). Real-Time Remote Health-Monitoring Systems in a Medical Centre: A review of the provision of healthcare services-based body sensor information, pen challenges and methodological aspects, *Journal of Medical Systems*, vol. 42, pp.164

Aluttis, C., Bishaw, T., & Frank, M.W. (2014). The Workforce for Health in a Globalized Context: Global shortages and international migration, *Global Health Action*, vol. 7, no. 1, pp.23611

Banker, R.D. & Natarajan, R. (2008). Evaluating Contextual Variables Affecting Productivity Using Data Envelopment Analysis. *Operations Research*, vol. 56, no. 1, pp. 48-58

Basatneh, R., Najafi, B., & Armstrong, D.G. (2018). Health Sensors, Smart Home Devices, and the Internet of Medical Things: An opportunity for dramatic improvement in care for the lower extremity complications of diabetes, *Journal of Diabetes Science and Technology*, vol. 12, no. 3, pp.577–586

Bouhaï, N. & Saleh, I. (Eds.). (2017). *Internet of things: evolutions and innovations*. John Wiley & Sons

Braun, V. & Clarke, V. (2006). Using thematic analysis in psychology, *Qualitative Research in Psychology*, vol. 3, no. 2, pp.77-101

Bryman, A. & Bell, E. (2015). Business Research Methods (4th edition). Oxford: University Press

Challoner, A. & Popescu, G.H. (2019). Intelligent Sensing Technology, Smart Healthcare Services, and Internet of Medical Things-based Diagnosis, *American Journal of Medical Research*, vol. 6, no. 1, pp.13–18

Chang, C.K., & Oyama, K. (2018). Guest Editorial: A Roadmap for Mobile and Cloud Services for Digital Health. IEEE Transactions on Services Computing, vol. 11, no. 2

Coles, E., Wells, M. Maxwell, M., Harris, F.M., Andersson, J., Gray, N.M., Milner, G., & MacGillivray, S. (2017). The Influence of Contextual Factors on Healthcare Quality Improvement Initiatives: What works, for whom and in what setting? Protocol for a realist

review. *Systematic Reviews*, vol. 6, no. 168, pp.1-10

Creswell, J.W. (2007). Qualitative Inquiry and Research Design: Choosing among five approaches (2nd edition). Thousand Oaks, London: Sage

Damschroder, L.J., Aron, D.C., Keith, R.E., Kirsh, S.R., Alexander, J.A., & Lowery, J.C. (2009). Fostering Implementation of Health Services Research Findings into Practice: A consolidated framework for advancing implementation science, *Implementation Science*, vol. 50, pp.1–15

Damschroder, L.J. & Hagedorn, H.J. (2011). A Guiding Framework and Approach for Implementation Research in Substance Use Disorders Treatment, *Psychology of Addictive Behaviors*, vol. 25, pp.194–205

Debbarma, J., Mitra, S., & Nath, S. (2018). An Investigative Evaluation of the Developments of the Internet of Things based Health Care Systems, P*roceedings of International Conference on Computational Intelligence & IOT (ICCIIoT) 2018*

Deloitte. (2018). Medtech and the Internet of Medical Things: How connected medical devices are transforming health care, Available online: https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-medtech-iomt-brochure.pdf [Accessed 07 February 2019]

Dey, A.K. (2001). Understanding and using context. Personal and Ubiquitous Computing, vol. 5, no. 1, pp.4-7

Dimitrov, D.V. (2016). Medical Internet of Things and Big Data in Healthcare, *Healthcare Information Research*, vol. 22, no. 3, pp.156–163

Dopson, S. & Fitzgerald, L.A. (2005). The active role of context. In: Dopson, S., & Fitzgerald, L.A, editors. Knowledge to action? Evidence-based health care in context. Oxford: Oxford University Press, pp.79-102

Eisenhardt, K. M. (1989). Building Theories from Case Study Research, *Academy of Management Review*, vol. 14, no. 4, pp.532-550

Eisenhardt, K. M. & Graebner, M. E. (2007). Theory Building from Cases: Opportunities and Challenges, *Academy of Management Journal*, vol. 50, no. 1, pp.25–32

eHälsa2025. (2018). Uppföljningsrapport 2018: Vision e-hälsa 2025, Available online: https://ehalsa2025.se/wp-content/uploads/2019/03/Uppföljningsrapport-2018-Vision-e-hälsa-2025-1.pdf [Accessed 23 April 2019]

European Network for Health Technology Assessment (EUNETHTA). (2011). HTA Core Model for screening technologies, Work Package 4 Core HTA EUnetHTA Joint Action 2010 - 2012, Available online: https://www.eunethta.eu/wp-content/uploads/2018/01/EUnetHTA-Core-Model-for-screening-technologies_first-draft-2011-sep..pdf [Accessed 20 February 2019]

European Network for Health Technology Assessment (EUNETHTA). (2014). Joint Action 2 Work Package 8. European network for health technology assessment (EUnetHTA), Available online: https://www.eunethta.eu/ja2-archive/ja2-wp8-maintenance-of-hta-core-model-infrastructure-to-support-shared-production-and-sharing-of-hta-information/ [Accessed 20 February 2019]

Farahani, B., Firouzi, F., Chang, V., Badaroglu, M., Constant, N., & Mankodiya, K. (2017). Towards Fog-driven IoT eHealth: Promises and challenges of IoT in medicine and healthcare, *Future Generation Computer Systems*, vol. 78, no. 2., pp.659-676

Fejes, A. & Thornberg, R. (2015). Handbok i kvalitativ analys [Guide in Qualitative Analysis] (2nd edition), Stockholm: Liber

Firouzi, F., Farahani, B., Ibrahim, M., & Chakrabarty, K. (2018). Keynote Paper: From EDA to IoT eHealth: Promises, Challenges, and Solutions. *IEEE Transactions on Computer-Aided Design of Integrated Circuits and Systems,* vol. 37, no. 12, pp.2965-2978

Gastaldi, L. & Corso, M. (2012). Smart Healthcare Digitalization: Using ICT to effectively balance exploration and exploitation within hospitals, *International Journal of Engineering Business Management*, vol. 4, no. 9

Gjestsen, M.T., Wiig, S., & Testad, I. (2017). What Are the Key Contextual Factors When Preparing for Successful Implementation of Assistive Living Technology in Primary Elderly Care? A case study from Norway, *BMJ Open*, vol. 7:e015455

Gulraiz, J.J., Rao, M.L., Aftab, F., & Saad, R. (2017). Internet of Medical Things (IOMT): Applications, benefits and future challenges in healthcare domain, *Journal of Communications*, vol. 12, No. 4

Hage, E., Roo, J.P., Van Offenbeek, M.A.G., & Boonstra, A. (2013). Implementation Factors and Their Effect on e-Health Service Adoption in Rural Communities: A systematic literature review, *BMC Health Services Research*, vol. 13

Hamine, S., Gerth-Guyette, E., Faulx, D., Green, B., & Ginsburg, A. (2015). Impact of mHealth chronic disease management on treatment adherence and patient outcomes: A systematic review, *Journal of Medical Internet Research*, vol. 17, no. 2, pp.52

Hassanalieragh, M., Page, A., Soyata, T., Sharma, G., Aktas, M., Mateos, G., Kantarci, B., & Andreescu, S. (2015). Health Monitoring and Management Using Internet-of-Things (IoT) Sensing with Cloud-based Processing: Opportunities and challenges, *In Services Computing (SCC), 2015 IEEE International Conference*, pp.285-292

Hill J.W. & Powell, P. (2009). The national healthcare crisis: Is eHealth a key solution? *Business Horizons*, vol. 52, no. 3, pp.265-277

Irfan, M. & Ahmad, Naim. (2018). Internet of medical things: Architectural model, motivational factors and impediments. *IEEE 2018 15th Learning and Technology Conference (L&T)*

Iyawa, G.E., Herselman, M. & Botha, A. (2016). Digital health innovation ecosystems: From systematic literature review to conceptual framework. *Conference on Enterprise Information Systems / International Conference on Project Management / Conference on Health and Social Care Information Systems and Technologies*, CENTERIS /Projman / HCist 2016, 5-7 October 2016, Porto, Portugal. In: Proceida Computer Science, vol. 100, pp. 244-252

Jagadeeswari, V., Subramaniyaswamy, V., Logesh R., & Vijayakumar V. (2018). A Study on Medical Internet of Things and Big Data in Personalized Healthcare System, *Health Information Science and Systems*, vol. 6, no. 14, pp.1-20

Kaplan HC, Froehle CM, Provost LP, Cassedy A, & Margolis PA. (2013). An Exploratory Analysis of the Model for Understanding Success in Quality, *Health Care Management Review*, vol. 38, pp.325–338

Kellermann, A.L. & Jones, S.S. (2013). What It Will Take To Achieve The As-Yet-Unfulfilled Promises Of Health Information Technology, *Health Affairs*, vol. 32, no. 1, pp.63-8

Kitson A, Rycroft-Malone J, Harvey G, McCormack B, Seers K, & Titchen A. (2008) Evaluating the Successful Implementation of Evidence into Practice Using the PARIHS Framework: Theoretical and practical challenges, *Implement Science,* vol. 3, no. 1

Kitson, A., Powell, K., Hoon, E., Newbury, J., Wilson, A., & Beilby, J. (2013). Knowledge Translation Within a Population Health Study: How do you do it?, *Implementation Science*, vol. 8

Kronsbein, D., Meiser, D., & Leyer. M. (2014). Conceptualisation of Contextual Factors for Business Process Performance. *Proceedings of the International MultiConference of Engineers and Computer Scientists 2014*, Vol II, IMECS 2014, 2014, Hong Kong

Kulkarni, A. Sathe, S. (2014). Healthcare Applications of the Internet of Things: A review, *International Journal of Computer Science and Information Technologies*, vol. 5, no. 5, pp.6229-6232

Laplante, P. A., & Laplante, N. (2016). The internet of things in healthcare: Potential applications and challenges. *It Professional,* vol. 18, no. 3, pp.2-4

Lee, I. & Lee, K. (2015). The Internet of Things (IoT): Applications, investments, and challenges for enterprises. *Business Horizons*, vol. 58, no. 4, pp.431-440

Lincoln, Y. S. & Guba, E. G. (1985). Naturalistic inquiry, Beverly Hills, California: Sage

Lindman, J. & Saarikko, T. Internet of Things: Threats and opportunities for society, Available online: https://rib.msb.se/Filer/pdf/28468.pdf [Accessed 10 February 2019]

Lupton, D. (2014). Health Promotion in the Digital Era: A critical commentary, *Health Promotion International*, vol. 30, no. 1, pp.174-183

Lysdahl, K.B., Mozygemba, K, Burns, J., Chilcott, J.B., Brönneke, J.B., Hofmann, B (eds.). (2016). Guidance for assessing effectiveness, economic aspects, ethical aspects, socio-cultural aspects and legal aspects in complex technologies, Available online: http://www.integrate-hta.eu/down- loads/

May, C. (2013). Towards a general theory of implementation, *Implementation Science*, vol. 8

McCormack B, McCarthy G, Wright J, Slater P, & Coffey A. (2009). Development and Testing of the Context Assessment Index (CAI), *Worldviews Evid-Based Nurs*, vol. 6, no. 27–5

McDonald KM. (2013). Considering Context in Quality Improvement Interventions and Implementation: Concepts, frameworks, and application, *Acad Pediatr,* vol. 13, no. 6, pp.45–53

McKinsey. (2016). Värdet av digital teknik i den svenska vården, Available online: https://www.mckinsey.com/~/media/McKinsey/Industries/Healthcare%20Systems%20and%20Services/Our%20Insights/Digitizing%20healthcare%20in%20Sweden/Digitizing-healthcare-in-Sweden.ashx [Accessed 23 April 2019]

Meskó, B., Drobni, Z., Bényei, É., Gergely, B., & Győrffy, Z. (2017). Digital Health is a Cultural Transformation of Traditional Healthcare, *Mhealth*, vol. 3, no. 38

Michalakis, K. & Caridakis, G. (2017). IoT Contextual Factors on Healthcare, *Advances in Experimental Medicine and Biology*, pp. 189-200

Miles, M.B. & A.M. Huberman. (1994). Qualitative Data Analysis (2d edition). Thousand Oaks, CA: Sage

Minerva, R., Biru, A., & Rotondi, D. (2015). Towards a Definition of the Internet of Things (IoT), vol. 1, *Torino, Italy: IEEE Internet Initiative*

Narayanan, H.A.J. & Güneş, M.H. (2011). Ensuring Access Control in Cloud Provisioned Healthcare Systems, *Consumer Communications and Networking Conference (CCNC)*; IEEE, pp.247-251

Nash, R., Hudson, A., & Luttrell, C. (2006). Mapping Political Context: A toolkit for civil society organisations overseas development institute—research and policy in development programme

Nilsen, P. (2015). Making Sense of Implementation Theories, Models and Frameworks, *Implementation Science*, vol. 10, no. 53

Papadakis, V.M., Lioukas, S., & Chambers, D. (1998). Strategic Decision Making Processes: The role of management and context, *Strategic Management Journal*, vol. 19, no. 2, pp.115-147

Peters, M., Harmsen, M., Laurant, M., & Wensing, M. (2002). Ruimte voor verandering? Knelpunten en mogelijkheden voor verbeteringen in de patiëntenzorg [Room for improvement? Barriers

to and facilitators for improvement of patient care]. *Nijmegen: Centre for Quality of Care Research (WOK),* Radboud University Nijmegen Medical Centre

Pfadenhauer, L., Rohwer, A., Burns, J., Booth, A., Lysdahl, K.B. Hofmann, B., et al. (2016). Guidance for the assessment of context and implementation in health technology assessment (HTA) and systematic reviews of complex inventions: the context and implementation of complex interventions (CICI) framework. Integrated health technology assessment for evaluating complex technologies (INTEGRATE-HTA), Available online: https://www.integrate-hta.eu/wp-content/uploads/2016/02/Guidance-for-the-Assessment-of-Context-and-Implementation-in-HTA-and-Systematic-Reviews-of-Complex-Interventions-The-Co.pdf [Accessed 28 February 2019]

Pfadenhauer, L.M., Mozygemba, K., Gerhardus, A., Hofmann, B., Booth, A., Lysdahl, K.B., Tummers, M., Burns, J., Rehfuess, E.A. (2015). Context and Implementation: A concept analysis towards conceptual maturity, Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen

Pfadenhauer L, Gerhardus A, Mozygemba K, Lysdahl KB, Booth A, Hofmann B, et al. (2017). Making Sense of Complexity in Context and Implementation: The context and implementation of complex interventions (CICI) framework, Implementation Science, vol. 12, no. 21

Porter, M.E. & Heppelmann, J.E. (2014) How Smart, Connected Products Are Transforming Competition, *Harvard Business Review*, vol. 92, pp.64-88

Robert, G., & Fulop, N. (2014). The Role of Context in Successful Improvement. In: Perspectives on context. London: The Health Foundation, pp. 59-85

Rohwer, A., Pfadenhauer, L.M., Burns, J., Brereton, L., Gerhardus, A., Booth, A., Oortwijn W., & Rehfuess, E.A. (2017). Logic Models Help Make Sense of Complexity in Systematic Reviews and Health Technology Assessments, *Journal of Clinical Epidemiology*, vol. 83, pp.37-47

Rosemann, M., Recker, J.C., & Flender, C. (2008). Contextualization of Business Processes, *International Journal of Business Process Integration and Management*, vol. 3, no. 1, pp.47-60

Rychetnik, L., Frommer, M., Hawe, P., & Shiell, A. (2002). Criteria for Evaluating Evidence on Public Health Interventions, *Journal of Epidemiology and Community Health*, vol. 56, pp.119-127

Sabatier, P.A. (2007). Theories of the Policy Process, Westview Press

Saunders, B., Sim, J., Kingstone, T., Baker, S., Waterfield, J., Bartlam, B., Burroughs, H., & Jinks, C. (2018). Saturation in Qualitative Research: Exploring its conceptualization and operationalization, *Quality & Quantity*, vol. 52, no. 4, pp.1893-1907

Senthilkumar, T., Manikandan, B., Ramya Devi, M., & Lokesh, S. (2018). Technologies Enduring in

Internet of Medical Things (IoMT) for Smart Healthcare System, *International Journal of Scientific Research in Computer Science, Engineering and Information Technology*, vol. 3, no. 5, pp.566-572

Schultze, U. & Avital, M. (2011). Designing Interviews to Generate Rich Data for Information Systems Research, *Information and Organization*, vol. 12, no. 1, pp.1-16

Socialdepartementet. (2014). Nationell Strategi för att förebygga och behandla kroniska sjukdomar, Available online: http://www.regeringen.se/contentassets/642cd2c63546450c8d439fbc1f3e1a76/handlingsplan-2014-till-nationell-strategi-for-att-forebygga-och-behandla-kroniska-sjukdomar-s2014.016 [Accessed 23 April 2019]

Solanas, A., Patsakis, C., Conti, M., Vlachos, I.S., Ramos, C., Falcone, F., Postolache, O., Perez-Martines, P.A., Di Pietro, R., Perrea, D.N., & Martínez-Ballesté, A. (2014). Smart Health: A context-aware health paradigm within smart cities. *IEEE Communications Magazine*, vol. 52, no. 8, pp.74-81

Stake, R. E. (1995). The Art of Case Study Research. Thousand Oaks, CA: Sage

Stephanie, F.L., & Sharma, R.S. (2016). Health on a Cloud: Modeling digital flows in an e-health ecosystem, *Journal of Advances in Management Sciences & Information Systems*, vol. 2, pp.1-20

Sun, W., Cai, Z., Li, Y., Liu F., Fang, S., & Wang, G. (2018). Security and Privacy in the Medical Internet of Things: A review, security and communication networks, vol. 2018, article ID. 5978636, 1-9pp

Turcu, C.E. & Turcu, C.O. (2013). Internet of Things as Key Enabler for Sustainable Healthcare Delivery, *Social and Behavioural Sciences*, vol. 73, pp.251-256

Walker, R. H., Craig-Lees, M., Hecker, R. & Francis, H. (2002). Technology-Enabled Service Delivery: An investigation of reasons affecting customer adoption and rejection. *International Journal of service Industry management*, vol. 13, no. 1, pp.91-106

Walsham, G. (2006). Doing Interpretative Research, *European Journal of Information Systems*, vol. 15, no. 3, pp.320-330

Waters, E., Hall, B.J., Armstrong, R., Doyle, J., Pettman, T.L., & de Silva-Sanigorski, A. (2011). Essential Components of Public Health Evidence Reviews: Capturing intervention complexity, implementation, economics and equity, *Journal of Public Health*, vol. 33, pp.462–5

Wells, M., Williams, B., Treweek, S., Coyle, J., & Taylor, J. (2012). Intervention Description is not Enough: Evidence from an in-depth multiple case study on the untold role and impact of context in randomised controlled trials of seven complex interventions, *Trials*, vol. 13

Williams, P.A.H. & McCauley, V. (2016). Always Connected: The security challenges of the

healthcare Internet of Things, *IEEE 3rd World Forum Internet Things, WF-IoT 2016*, pp.30–35

Wortmann, F. & Flüchter, K. (2015). Internet of things. Business & Information Systems Engineering, 57(3), 221-224

Yin, Y., Zeng, Y., Chen, X., & Fan, Y. (2016). The Internet of Things in Healthcare: An overview, *Journal of Industrial Information Integration*, vol. 1, pp.3–13

Yin, R. K. (2018). Case study research and applications. *Design and methods*. SAGE Publications Ltd

Øvreveit, J. (2014). How Does Context Affect Quality Improvement? In: Perspectives on context. London: The Health Foundation, p.59-85